





Standard Operating Procedures of Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC)

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The Rajiv Gandhi Centre for Biotechnology (RGCB) had its humble beginning on July 03, 1990, as Centre for Development of Education, Science and Technology (C-DEST), an autonomous society registered under the Travancore Cochin Literary, Scientific and Charitable Society Registration Act of 1955 (Reg.No.418/90) by a group of well-known professionals and social workers for undertaking and promoting research, field studies, action projects, etc. The Government of Kerala took the landmark decision to restructure the institute into a comprehensive biotechnology centre and thus was established the Rajiv Gandhi Centre for Biotechnology (RGCB) on April 18, 1994. RGCB was the first research institute established for research and development in the field of Biotechnology, in India. On August 2, 2007 the Union Cabinet chaired by Honourable Prime Minister announced the decision on taking over of RGCB as a National Institute under Ministry of Science & Technology (Department of Biotechnology) with effect from April 1, 2007.

Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC) (Reg. No. ECR/484/Inst/KL/2013) is constituted by the Director, RGCB under the authority of Department of Biotechnology, Ministry of Science and Technology and registered with Central Drugs Standard Control Organization, and Department of Health Research, Government of India. IHEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and wellbeing of the research subjects/participants. The IHEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IHECs will be to review all research projects involving

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human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency. The RGCB Human Ethics Committee comprises a panel of distinguished luminaries in various professional and social fields.

The complete list of RGCB Human Ethics Committee members are given below:

SI No	RGCB IHEC Members	Role
1	Justice K. Padmanabhan Nair Former High court Justice of Kerala	Chairperson
2	Mr. Raman Srivastava IPS	Vice Chairperson/Lay person
3	Dr. V. Ramankutty	Medical Scientist
4	Dr. K. Ramadas	Medical Scientist
5	Dr. Easwer H.V	Clinician
6	Dr. Nandini K Kumar	Ethicist
7	Dr. S. Remadevi	Social Scientist
8	Adv. Benoy T George	Legal Expert
9	Dr. Priya Srinivas	Basic Scientist
10	Dr. E. Sreekumar	Basic Scientist
11	Dr. Asha S Nair	Basic Scientist
12	Dr. Devasena Anantharaman	Member Secretary
13	Dr. Debasree Dutta	Alternate Member Secretary/Basic Scientist

List of Abbreviations

Acronym	Full Title/Description
ADR	Adverse Drug Reaction
AE	Adverse Event
BA	Bio-availability
BIS	Bureau of Indian Standards
CDC	Centre for Disease Control and Prevention
CDSCO	Central Drugs Standard Control Organization
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
COI	Conflict of Interest
CONSORT	Consolidated standards of reporting trials
CRF	Case Record Form
CRO	Contract Research Organization
CRS	Clinical Research Secretariat
CTA	Clinical Trial Agreement
DBT	Department of Biotechnology
DCGI	Drug Controller General of India
DCR	Drugs and Cosmetic Rules, 1945
DGFT	Directorate General of Foreign Trade
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DSMSC	Data Safety Monitoring Sub Committee
DTAB	Drugs Technical Advisory Board
ELSI	Ethical, Legal and Social Issues
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FERCAP	Forum for Ethical Review Committees in Asia and the Western Pacific Region
GCP	Good Clinical Practice
GMP	Good Manufacturing Practices
IHEC	Institutional Human Ethics Committee
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Committee on Harmonization
ICJME	International Committee of Medical Journal Editors
ICMR	Indian Council of Medical Research
IND	Investigational New Drug
IRB	Institutional Review Board
IRC	Institutional Research Committee
ISI	Indian Standards Institute
MOU	Memorandum of Understanding
NDA	New Drug Application

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NIH	National Institutes of Health
NOC	No-objection Certificate
OHRP	Office for Human Research Protections
PI	Principal Investigator
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
IRC	Institutional Review Committee
WHO	World Health Organization
WMA	World Medical Assembly

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Glossary

Audit:

- I. A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
[http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 23rd Nov 2015]
- II. **Audit of a Trial-** A systematic verification of the study, carried out by persons not directly involved, such as:
 - a. Study related activities to determine consistency with the Protocol
 - b. Study data to ensure that there are no contradictions on Source Documents. The audit should also compare data on the Source Documents with the interim or final report. It should also aim to find out if practices were employed in the development of data that would impair their validity.
 - c. Compliance with the adopted Standard Operating Procedures (SOPs).
[<http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf> accessed on 23rd Nov 2015]

Adverse Event: Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

Amendment protocol: Amended parts and related documents of the protocol, previously approved by the RGCB IHEC. In the course of the study, the PI may decide to make changes in the protocol

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Assent: To agree to participate in research by children from 7 - 18 years of age who are old enough to understand the implications of any proposed research but not legally eligible to give consent. For children from 7-12 years it will be oral assent and from >12 – 18 years it will be written assent. Informed consent of parent/LAR is necessary except in certain circumstances, e.g. risky behaviour of adolescents.

Biomedical and health research: Research including studies on basic, applied and operational research designed primarily to increase the scientific knowledge about diseases and conditions, their detection, cause and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation including clinical research.

Beneficence: To try to do good or an action which weighs the risks against benefits to prevent, reduce or remove harm for the welfare of the research participant(s) in any type of research.

Biobanks: a repository for storing biological samples or data to be used in research. Biobanks usually require investigators or institutions to agree to certain conditions as a condition for sharing samples or data with them.

Clinical trial: A clinical trial is any research/study that prospectively assigns human participants or groups of humans to one or more health-related intervention(s) to evaluate the effects on health outcomes. The intervention could be drugs, vaccines, biosimilars, biologics, phytopharmaceuticals, radiopharmaceuticals, diagnostic agents, public health interventions, socio-behavioural interventions, technologies, devices, surgical techniques or interventions involving traditional systems of medicine, etc. As per amended Schedule Y (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effect with the objectives of determining safety and/or efficacy of a new drug. The academic clinical trial as per GSR 313 (e) dated 16 March 2016 is a clinical trial using intervention falling under the definition of 'New Drug' but intended only for academic purposes and not marketing purposes.

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Compensation: Provision of financial payment given to any participant or research participants or their legal heirs when the injury occurs due to participation in research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care. In biomedical and health research of academic nature it will be as per institutional policy.

Confidentiality: Keeping information confidential, which an individual has disclosed in a relationship of trust and with the expectation that it shall not be divulged to others without permission. Also it means prevention of disclosure of information and documents related to RGCB IHEC to other than authorized individuals.

Datasets: A dataset is an organized collection of data and information maintained in physical and / or electronic /digital form that can be used for biomedical and health research.


Declaration of Helsinki: A set of recommendations or basic principles that guide medical doctors in the conduct of biomedical research involving human subjects. It was originally adopted by the 18th World Medical Assembly (Helsinki, Finland, 1964) and recently revised (52nd WMA General Assembly, Edinburgh, Scotland, October 2000).

Document: Document may be of any form, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

Exemption from review: A research study is said to be exempt from review when the proposals with less than minimal risk with no linked identifiers are submitted and requires only approval of member-secretary. Such proposals are to reported to the full committee during its meeting.

Expedited review/meeting: An expedited review is an accelerated review process for proposals having minimal risk, revised document with minor changes for approval by a sub-committee comprising Chairperson, member-secretary and 1 or 2 designated members of RGCB IHEC. The decision is reported to the full board in the subsequent meeting. .

Full Committee Review: Review of initial, resubmitted, continuing review, amendments of protocols and or PIDs and any other documents, which are tabled in

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the meeting of the full RGCB IHEC committee for detailed discussion and decisions. This has to be on regular basis or in emergency/urgent situations this can be reviewed during unscheduled meeting.

Independent Consultant (IC): An independent consultant is a subject expert in a specified field who gives advice, comments and suggestions upon review of the study protocols. He/she has no affiliation to the investigators proposing the research protocols.

Informed Consent Document: Written signed and dated paper confirming a participant's willingness to voluntarily participate in a particular research, after having been informed of all aspects of the research that are relevant for the participant's decision to participate.

Initial Review: The first-time review of the protocol done during the meeting of the full committee.

Inspection: An official review/ examination conducted by regulatory authority(ies) of the documents, facilities, records and any other resources that are deemed by the authority(ies) to be related to the study. The inspection may be carried out at the site of the trial, at the sponsor's / or CRO's facilities and Ethics Committee in order to verify adherence to Good Clinical Research Practice. [http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 23rd Nov 2015] [<http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf> accessed on 23rd Nov 2015]

Investigational New Drug(s) (IND): IND means a new chemical entity or a product having therapeutic indication but which has never been tested earlier on human beings.

Investigator's brochure: The Investigator's Brochure (IB) is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects.

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Justice: Pertains to fairness in the way people are dealt with, indicating fair selection and distribution of benefits and risks to participants who should be fully apprised about them.

Lay person: A literate person who has not pursued a medical science/health related career in the last 5 years and is aware of the local language, cultural and moral values of the community.

Legal Expert: A person with a basic degree in law from a recognized university (with experience).


Legally Acceptable/Authorized Representative (LAR): A person who will give consent on behalf of prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by RGCB IHEC

Less than minimal risk: Research, in which there is no known physical, emotional, psychological, or economical risk to the study participants. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.)

Maleficence: The act of committing harm or a harmful act.

Master SOP files: A collection of the Standard Operating Procedures (SOP) of RGCB IHEC, accessible to all staff, RGCB IHEC members, auditors and government inspectors as a paper copy and the approval signatures on first page. When a copy of this is provided to members of RGCB IHEC it is termed controlled copy.

Minimal risk: Minimal Risk: It means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy, or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current

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everyday life. Example for minimal risk: A retrospective review of patient case records to determine the incidence of disease/ recurrence of disease]

Non-compliance: Failure or refusal to act in accordance with approved study protocol.

Past SOPs of RGCB IHEC: A collection of previous official versions of SOPs and relevant information regarding the changes and all pre-planned deviations.


Protocol Deviation- A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the RGCB IHEC. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the RGCB IHEC using the standard reporting form. A protocol deviation is a less serious non-compliance with the approved study protocol.

Protocol Violation: The act of doing something that is not as per the approved study protocol, which violates ethical principles and/or human rights. The RGCB IHEC monitors whether investigators conduct the study in compliance with the approved protocol, national regulations or not and/or fail to respond to the RGCB IHEC request for information/action.

Protocol Waiver: A protocol waiver is an intentional deviation from the approved **protocol**, such as the enrolment of a participant in violation of the **protocol's** inclusion/exclusion criteria. Prior approval from RGCB IHEC has to be obtained before implementing necessary departures from the protocol.

Quorum: Minimum number and/or kind of EC members required for decision making during a meeting.

Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC): It is an independent body responsible for ensuring the protection of the rights, safety, dignity and well-being of human participants involved in a clinical research under the aegis of Rajiv Gandhi Centre for Biotechnology and to provide public assurance of their protection.

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Revision with major amendments: The proposed study/protocol/study related documents, requires significant modifications and will be placed before the full committee for reconsideration to get approval.

Revision with minor amendments: The proposed study/protocol/study related documents, requires minor modifications and will be placed before the expedited review to get approval.

RGCB IHEC members: Individuals serving as regular members of the Rajiv Gandhi Centre Biotechnology Institutional Human Ethics Committee.

Serious Adverse Event (SAE): An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanent impairment or damage.

Social Scientist: A person who is an expert on societal and social behaviour with specialization/ experience in the area.


Socio-behavioural research: Refers to the socio-behavioural studies on response of individuals, groups, organizations or societies to external or internal stimuli.

SOP Effective date: The date of implementation of SOPs after acceptance by the Director, RGCB following signed and dated approval of the Chairperson, RGCB IHEC.

SOP Team: A team of members including the Member Secretary and any other member of RGCB IHEC identified by the Chairperson, which prepares or revises SOPs of the designated ethics committee of RGCB.


SOPs (Standard Operating Procedures): A detailed, written instructions, in a certain format, describing activities and actions undertaken by the RGCB IHEC to achieve uniformity in the performance of a specific function. The aim of the SOPs and their accompanying checklists, and forms is to simplify and standardize the functioning, whilst maintaining high standards of Good Clinical Practice.

Study Assessment Form: An official record that documents the protocol review process.

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Study protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization for all types of trial, biomedical and behavioural research.

Vulnerable participants: This category includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

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SOP Prepared by:

Name and Position on the RGCB IHEC	Signature with date
Dr. Abitha Thomas Secretariat, RGCB IHEC	
Ms. Divya Jayalekshmy Secretariat, RGCB IHEC	

Reviewed by:


Name and position on RGCB IHEC	Signature with date
Dr. Devasena Anantharaman, Member Secretary, RGCB IHEC	

Approved by:

Name and Position on the RGCB IHEC	Signature with date
Justice K. Padmanabhan Nair, Chairperson, RGCB IHEC	

Accepted by:

Name and Position on the RGCB IHEC	Signature with date
Professor M. Radhakrishna Pillai Director, Rajiv Gandhi Centre for Biotechnology	

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Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing, Amending, Control of SOPs for the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee

SOP Code: SOP 01/V2

Date: November 30, 2019

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1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC). The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national, and international ethical guidelines.

1.2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the RGCB IHEC.

1.3. Responsibility


It is the responsibility of the Chairperson of the RGCB IHEC to appoint a SOP team to formulate a new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures, format and coding system as per the contents in the checklist provided earlier that is used while drafting or editing any SOP of RGCB IHEC. All members of RGCB IHEC will review the SOPs and approval will be given by Chairperson of RGCB IHEC. The SOPs shall then be accepted by the Director, RGCB.

1.3.1 Secretariat of RGCB IHEC will

- Assist Chairperson to formulate a SOP Team
- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Ensure that all the RGCB IHEC members and involved administrative staff have access to the SOPs
- Ensure that all the RGCB IHEC members and involved staff are working according to current version of SOPs
- Maintain an up-to-date distribution list for each SOP distributed to the EC members.
- Maintain a register to record the names of investigators to whom SOPs are distributed
- Maintain a file of all current SOPs and the list of SOPs
- Maintain a file of all past Master SOPs of the RGCB IHEC.

1.3.2 SOP team will

- Assess the request(s) for SOPs revision in consultation with the Secretariat, Member Secretary and Chairperson
- Propose new/modified SOPs as needed
- Draft the SOPs giving step by step process details in consultation with the designated RGCB IHEC members and involved administrative staff
- Make a list of SOPs with coding reference
- Review the draft SOPs

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- Submit the draft for approval to Chairperson

1.3.3 Chairperson of the RGCB IHEC will

- Appoint one or more SOP Teams
- Approve the SOPs
- Sign and date the approved SOPs

1.3.4 RGCB IHEC members and involved administrative staff (if any) will

- Sign and date the approved SOPs when they receive it
- Maintain a file of all SOPs received

1.4. Detailed instructions

1.4.1 Identify the need for new or amendment of current SOP

Any member of the RGCB IHEC or Secretariat who would feel the requirement of a revision or notices an inconsistency/ discrepancy/ has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by writing to the RGCB IHEC Chairperson either as an email/letter/verbal request in a meeting. The Chairperson will inform all the RGCB IHEC members about this request at a regular full-board RGCB IHEC meeting. If the RGCB IHEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson to proceed with the revision process of the SOP. If the RGCB IHEC members do not agree, no further action will be taken. The Chairperson will inform the member of the RGCB IHEC or Secretariat who made the request for modification of the SOP.

1.4.2 Appoint the SOP Team(s)


- The Chairperson will constitute a SOP Team consisting of the member-secretary and two or more members of the RGCB IHEC who have a thorough understanding of the ethical review process.
- The SOP writing team will carry out the subsequent steps as described in sections **1.4.3-1.4.7**.

1.4.3 List all relevant procedures

- Write down step by step all the procedures of the RGCB IHEC that are to be standardized in the form of a SOP
- Organize, divide and name each process

1.4.4 Write and review a new SOP

- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson.

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- Each SOP should be given a number and a title that is self-explanatory and easily understood. A unique code number with the format SOP xx/Vy will be assigned to each SOP item by the Secretariat. “xx” will be a two-digit number assigned specifically to each activity based SOP. “V” refers to version of the SOP and “y” will be a number identifying the version, e.g. the first SOP of the current version would be SOP 01/V1 i.e. it is SOP number 01 with version 1.
- Each SOP may have annexure(s), which are forms to be filled in by various stakeholders [RGCB IHEC or Principal Investigator (PI)]. Each annexure will be given a unique code number with the format AX pp/SOP xx/Vy. AX refers to annexure form, pp is a two-digit number identifying the number of the annexure, while xx/Vy refers to the SOP number and its version. For example AX 01/SOP 01/V1 means annexure form number 1 belonging to SOP 01/V1.
- Each SOP will be prepared according to the standard template AX 01/SOP 01/V2. Each section of the SOP will have Title name, number of SOP and effective date (aa/bb/cccc) i.e. the date of approval of the SOP by the Chairperson. The header of each page of the SOP will have RGCB logo, title name and number of SOP and effective date, whereas the footer will bear the page number as page p of q (total) pages.
- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team/RGCB IHEC members. After incorporating the suggestions put forth by the SOP team members, a copy of the revised draft SOP will be sent to the Member-Secretary, who will circulate it to all the RGCB IHEC members.

1.4.5 Write and review a revised SOP

- If a SOP supersedes a previous version, the latter will be indicated in the Document History Form (AX 02/SOP 01/V2) along with description of the main changes.
- The rest of the steps are as described in **Section 1.4.4**.

1.4.6 Prepare and submit final draft

- The SOP Team will submit the reviewed SOP to the RGCB IHEC Members who will review it at a meeting.
- The suggestions that are agreed upon by the RGCB IHEC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- The SOP team would stand automatically dissolved once the RGCB IHEC takes final decision regarding the SOP.

1.4.7 Approve the new / revised SOP

- The final version will be presented to the Chairperson for review and approval.

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- The authors (SOP team members), reviewers and the Chairperson will sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from which the SOP will be implemented. The face page may also contain signature of Head of the Institution as having accepted the document as per the institutional policy.

1.4.8 Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date.
- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.
- A copy of the approved SOP (termed controlled copy) will be distributed to the RGCB IHEC members and a log will be maintained as per the annexure - AX 03/SOP 01/V2.
- One complete original set of current SOPs will be filed in the SOP Master file by the RGCB IHEC Secretariat in the RGCB IHEC office.
- Photocopies made from the official paper versions of the SOP can be considered current or official as controlled copies, if stamped and signed by Member Secretary or authorized individual for distribution to RGCB IHEC members.
- SOPs are made available to all Investigators on Institute website.
- When the revised version is distributed, all the RGCB IHEC members will be requested to destroy their copy of earlier version.
- Only one copy of the earlier version will be clearly marked 'Superseded' and filed in the file entitled 'Past SOPs of the RGCB IHEC' by the RGCB IHEC Secretariat in the RGCB IHEC office.
- The process of evolution of previous SOPs of the RGCB IHEC will be documented in defined format as per AX 04/SOP 01/V2.
- The RGCB IHEC members and Secretariat will review the SOPs at least once in every 3 years.

1.5. Flow Chart

No.	Activity	Responsibility
1	Identify the need for new or amendment of current SOP	Any member of RGCB IHEC, secretariat or administrative staff
2	Appoint the SOP Team(s)	Chairperson
3	List all relevant procedures	SOP Team
4	Write a new/ revised SOP	SOP Team

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5	Review a revised SOP	SOP Team and/RGCB IHEC members
6	Prepare and submit final draft	SOP Team
7	Approve the new/revised SOP	Chairperson
8	Acceptance of the new/revised SOP	The Director, RGCB
9	Implement, distribute and file SOPs	RGCB IHEC members and Secretariat

1.6. Annexure

- Annexure 1 AX 01/SOP 01/V2- Template for SOPs
- Annexure 2 AX 02/SOP 01/V2- Documentation of History of the SOPs
- Annexure 3 AX 03/SOP 01/V2- Log of the RGCB IHEC members receiving
- Annexure 4 AX 04/SOP 01/V2- Template for SOP

Annexure 1: AX 01/SOP 01/V2


Main Text:

1. **Purpose:** Summarizes and explains the objectives of the procedure.
2. **Scope:** States the range of activities that the SOP applies to.
3. **Responsibility:** Refers to person(s) assigned to perform the activities involved in the SOP
4. **Detailed instructions:** Describes procedures step by step in short and clear sentences
5. **Annexure:** Forms to capture information pertaining to the SOP instructions
6. **Flow chart:** Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity

Annexure 2: AX 02/SOP01/V2

Documentation of History of the SOPs Details of superseded SOP

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)


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Annexure 3: AX 03/SOP 01/V2
Log of the RGCB IHEC members receiving SOPs

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date

Annexure 4AX 04/SOP01/V2
Template for SOP


Institutional Human Ethics Committee	
Title: Title which is self-explanatory and is easily understood	
SOP No: SOPxx/Vy	Page: a of b
Code : SOP xx/Vy	
Effective date: DD/MM/YYYY	
Authors: xxxxxxxxx Reviewed by: xxxxxxxxx Approved by: xxxxxxxxx Accepted by: xxxxxxxxx	

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Constitution of RGCB IHEC- Selection, Roles and Responsibilities of Members of the IHEC

SOP Code: SOP 02/V2

Date: November 30, 2019

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2.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR) of members, which provide the framework for constitution, selection, roles and responsibilities of the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC) and procedures for maintaining confidentiality of all activities and documents.

2.2. Scope

This SOP applies to the constitution of the RGCB IHEC, selection, roles and responsibilities of members of the RGCB IHEC and maintenance of confidentiality of all activities and documents.

2.3. Responsibility

The selection of Chairperson, Member Secretary and RGCB IHEC members will be done by the Director of Rajiv Gandhi Centre for Biotechnology. It is the responsibility of all the RGCB IHEC members and the Secretariat to read, understand, follow and respect this SOP.

2.4. Detailed Instructions


2.4.1 Composition of the Institutional Ethics Committee

The RGCB IHEC will be established by the Director, RGCB. The Chairperson and RGCB IHEC members can suggest names of potential members but the final decision will remain with the Director, RGCB.

- Its hierarchical position in the organization and authority under which it is established will be clearly indicated (AX 02/SOP 02/V2)
- The RGCB IHEC will be multidisciplinary and multi-sectorial in composition.
- The RGCB IHEC will be composed of at least 13 members and a maximum of 15 members as per the requirement of ICMR Guidelines 2017 for National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

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- The members will
 - Include a combination of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view to promote adequate review of research.
 - Having differing backgrounds to promote complete and adequate review of research.
 - Have the required qualifications as prescribed by applicable regulations and guidelines from time to time
 - Have the expertise, time and commitment to perform all functions
- The RGCB IHEC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community / society.
- The committee should include at least one member whose primary area of expertise is in a non-scientific area, a clinician, legal expert, layperson and at least one member who is independent of the institution/research - social scientist or representative of NGO/voluntary agency/philosopher/ethicist/theologian.
- The RGCB IHEC may invite member(s) of specific patient groups or other special interest groups for an RGCB IHEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (refer to SOP 05/V2) and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have right to vote. (refer to SOP 05/V2)
- The Composition shall be as follows:
 - Chairperson (must not be affiliated to the institution)
 - Co-Chairperson (if appointed, must not be affiliated to the institution)
 - One Member Secretary (must be affiliated to institution)

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- One alternate Member Secretary (if appointed, must be affiliated to institution)
- One or more Basic Medical Scientist having post graduate qualification in medical field (after MBBS) in pharmacology (preferably clinical Pharmacologist for reviewing proposals on drugs, devices, vaccines and others included under the definition of new drug as per D&C Act)/ Pathology/ Microbiology/ Anatomy/ Physiology/ Biochemistry and adequate experience (may or may not be affiliated to institution).
- One or more clinicians from various institutes (at least one should be affiliated to institution)
- One legal expert or retired judge (must not be affiliated to institution)
- One social scientist/ representative of non-governmental agency/ One philosopher, ethicist or theologian, intellect, educationist (must not be affiliated to institution)
- One or more lay person (non-scientific person) from the community and should be literate and aware of local, social and cultural norms of the particular area (must not be affiliated to institution).

2.4.2 Composition of SAE subcommittee under IHEC

The RGCB IHEC Chairperson will delegate SAE review to subcommittee members constituted by some members of IHEC. Primarily clinician, basic medical scientists (preferably pharmacologist), will be part of the subcommittee along with member secretary. Delegation of some responsibility to any other ethics committee member e.g. legal expert (if required) would be done at the discretion of Chairperson or Alternate Chairperson. This subcommittee will review the SAEs submitted by PI (on site) and will report to the IHEC for the purpose of reimbursement and compensation etc. which will further review and forward that information to CLA (Central Licensing Authority).

2.4.3 Agreement regarding Maintenance of Confidentiality

2.4.3.1 It is the responsibility of each RGCB IHEC member to sign the agreement

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contained in the confidentiality Form (AX 02/SOP 03/V2) when accepting to be a member for reviewing research projects.

2.4.3.2 The staff of the secretariat will also sign a confidentiality agreement.(AX 02/SOP 03/V2)

2.4.3.3 The Secretariat will obtain the signature of the RGCB IHEC Chairperson on the Confidentiality form

2.4.3.4 The secretariat will provide RGCB IHEC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and IHEC Chairperson) and acknowledge the receipt of agreement with their signature and date.

2.4.3.5 The Secretariat will keep the original copies of the signed Agreements in the IHEC office in the file entitled 'Confidentiality Agreement' file for members and photocopies of the agreement in the individual members' files.

2.4.4 Tenure of Membership

The tenure of RGCB IHEC will be for a term of 3 years from the date of appointment. Chairperson and all members shall serve on the committee for a maximum of two terms. After serving two terms a member could be re-appointed after a break of a term. Under exceptional circumstances, extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human research. This may be decided as two incremental extensions for two years at a time.

2.4.5 Appointment of New Members

2.4.5.1 The RGCB IHEC members will be appointed by the Head of the Institution in consultation with the Chairperson of IHEC of Rajiv Gandhi Centre for Biotechnology.

2.4.5.2 New members will be appointed under the following circumstances:

- a. When a regular member completes her/his tenure.
- b. If a regular member resigns before the tenure is completed.
- c. If a regular member ceases to be a member for any reason including death

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or disqualification.

2.4.5.3 New members shall be identified by the Chairperson according to the membership requirement as stated in this SOP for fulfilling the conditions of appointment. The RGCB IHEC members may also suggest the names of new members to be appointed. The Chairman, RGCB IHEC will make the final decision regarding the appointment.

2.4.6 Conditions to be fulfilled by a member after appointment

2.4.6.1 Members to be appointed on the RGCB IHEC will need to submit the following:

- a. a recent CV signed and dated
- b. Training certificates in Ethics and/ or GCP and SOP. In case training certificates are not available at the time of induction as member in the RGCB IHEC, the member must submit these within 6 months of appointment.


2.4.6.2 Members must be willing to

- a. Publicize her/his full name, profession and affiliation.
- b. Sign the Confidentiality Agreement and maintain confidentiality regarding meeting, deliberations, applications, information on research participation and related matters.
- c. Read, understand, accept and follow the Conflict of interest policy and sign the Conflict of interest agreement form.
- d. Be committed and understanding to the need for research and for imparting protection to research participants in research.

2.4.7 Resignation and Disqualification of Members

2.4.7.1 **Resignation:** RGCB IHEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.


2.4.7.2 **Disqualification for conduct unsuitable of an RGCB IHEC member:**

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- a. RGCB IHEC Chairperson or Member-secretary will initiate the process on receipt of a written communication provided by EC member or a member of the public alleging misconduct by a member.
- b. The Chairperson will satisfy herself/himself that a *prima facie* case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of RGCB IHEC could be questioned, the Chairperson may suspend the membership of the concerned EC member till the final decision is taken by RGCB IHEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an RGCB IHEC member and will not perform any duties as EC member.
- c. The Chairperson may call for a meeting of the RGCB IHEC specifically to discuss this issue or the matter will be taken up for discussion during full committee review meeting. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the RGCB IHEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend herself/himself.
- d. The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd of the majority of members present in the meeting). The Chairperson will convey the disqualification to the concerned member through a written communication.

2.4.7.3 Disqualification for not attending IEC meetings: A member may be disqualified from RGCB IHEC membership if the member fails to attend more than 3 consecutive EC meetings without prior intimation. The process conducted will be as follows:

- a. The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the RGCB IHEC without prior intimation.
- b. The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next RGCB IHEC

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meeting.

- c. A written communication will be sent to the concerned EC member informing her/him that the issue of disqualification would be discussed at the meeting, inviting the member to be present at the meeting to clarify her/his position. Alternately, the concerned EC member will be allowed to explain her/his uninformed absence in a letter addressed to the Chairperson, which will be read and reviewed at the meeting.
- d. The Chairperson or Member-Secretary will inform the other EC members about the cessation of membership of the member by written communication or during the next meeting of RGCB IHEC.

2.4.8 Hierarchy

- a. Chairperson, Vice Chairperson, Member Secretary and Alternate Member Secretary may be appointed from amongst the members.
- b. The Chairperson will head the committee. Vice Chairperson will head the committee in the absence of chairperson.
- c. The Member Secretary and the Alternate Member Secretary (whenever applicable) will be in-charge of all documents and funds in the possession of the committee.
- d. Other EC members will be regular committee members with equal ranking.

2. 4. 9 Functions of Chairperson

- 2.4.9.1.1 The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals and be accountable for independent and efficient functioning of the committee
- 2.4.9.2 Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations.
- 2.4.9.3 Ratify minutes of the previous meetings
- 2.4.9.4 In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee

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member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.

2.4.9.5 Seek COI declaration from members and ensure quorum and fair decision-making.

2.4.9.6 Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

2.4.10 Functions of Vice Chairperson

To act as Chair in the absence of Chairperson and to perform all functions of Chairperson.

2.4.11 Member secretary

2.4.11.1 Signs documents and communications related to RGCB IHEC functioning.

2.4.11.2 Communicates with the RGCB IHEC members and applicants/ investigators.

2.4.11.3 Notifies the Principal Investigator regarding RGCB IHEC decisions related to the submitted research proposal.

2.4.11.4 Provides necessary administrative support for RGCB IHEC related activities to the Chairperson.


2.4.11.5 Provides updates on relevant and contemporary issues on ethics in health research as well as relevant contemporary literature to the committee members.

2.4.11.6 Receives ethics committee review processing fees and issue official receipts for the same.

2.4.11.7 Delegates various responsibilities to appropriate and authorized individuals.

2.4.11.8 Ensures adherence of EC functioning as per SOPs.

2.4.11.9 Prepares and makes available annual reports/annual financial statements of the RGCB IHEC, if any, for scrutiny by auditors/ inspectors.

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2.4.12 Functions of the Alternate Member Secretary

The Alternate Member Secretary will perform the same functions of Member Secretary in her/his absence

2.4.13 Functions of RGCB IHEC members

- 2.4.13.1 Attend RGCB IHEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- 2.4.13.2 Filling up the review form as primary or secondary reviewer.
- 2.4.13.3 Submit the review form within the dedicated time.
- 2.4.13.4 Review, discuss and consider research Proposals submitted for evaluation.
- 2.4.13.5 Monitor Serious Adverse Event reports and recommend appropriate action(s).
- 2.4.13.6 Review the progress reports and monitor ongoing studies as appropriate.
- 2.4.13.7 Should lead the protocol and Informed consent form discussions as primary or secondary reviewers.
- 2.4.13.8 Do on-site monitoring visits whenever needed.
- 2.4.13.9 Evaluate final reports and outcomes.
- 2.4.13.10 Maintain confidentiality of the documents and deliberations of RGCB IHEC meetings.
- 2.4.13.11 Declare any conflict of interest in writing to the Chairperson, if any, at each meeting.
- 2.4.13.12 Participate in continuing education activities in bioethics related to biomedical and health research and provide the training certificate to the RGCB IHEC secretariat for filing.
- 2.4.13.13 Provide an updated CV when requested for by the RGCB IHEC secretariat.
- 2.4.13.14 Carry out work delegated by Chairperson, Member-secretary/Alternate Member-secretary.
- 2.4.13.15 Assist Chairperson, Member-secretary/Alternate Member-secretary in carrying out RGCB IHEC work as per SOPs.

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2.4.13.16 Be updated on relevant laws and regulations.

2.4.14 Quorum requirements

Any decision taken in the RGCB IHEC meeting either by the Chairperson/Vice Chairperson will not be valid without fulfilment of the quorum requirements given below:

2.4.14.1 As per ICMR Guidelines

- a. Minimum any five members in the meeting room including medical, non-medical or technical and/or non-technical members
- b. Presence of one non-affiliate member preferably lay person

2.4.14.2 As per CDSCO specific requirement

- a. Medical basic scientist (preferably a clinical pharmacologist)
- b. Clinician
- c. legal expert
- d. social scientist or representative of non-governmental voluntary agency/philosopher/ethicist/theologian/a similar person
- e. Lay person.

2.4.15 Secretariat

2.4.15.1 The Secretariat will be composed of the administrative supporting staff


2.4.15.2 The Secretariat will support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions

2.4.15.3 All the staff of the Secretariat will sign a confidentiality agreement which should be filed in the IHEC office.

2.4.15.4 The working rules for the Secretariat are stated in (AX 01/SOP 02/V2)

2.4.16 Types of projects reviewed by IHEC

The RGCB HEC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, Government of India/ NGOs, studies in collaborations with international organizations/universities, all dissertation projects (postgraduate students: MD, MS, MCh, DM, Mch, DNB, PhD, MSc, MPTh, MOTh, Nursing, dental and any other allied

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courses run by recognised Institutions as applicable), research projects of undergraduate students carried out under the guidance of faculty (e.g. Central Council for Research in Ayurvedic Sciences, Indian Council for Medical research studentship or any other) and investigator initiated research studies which are self-funded/ funded by Institutional funding bodies.

2.4.17 Honorarium to the Members

Reimbursement of travelling expenses and /or reasonable honorarium for attending the RGCB IHEC meetings may be given to the EC members.


2.4.18 Preparing an annual activity report of the RGCB IHEC for submission to the Head of the Institute

The Member Secretary will make a yearly activity report for submission to the Head of the Institute, which will include the following elements:

- a. Number and dates of the RGCB IHEC meetings of full committee
- b. Number of SAE subcommittees and any other subcommittee, as applicable
- c. Number and type of proposals (Pharma/Government sponsored/ Dissertations/investigator initiated) reviewed in a year, status of each study proposal whether completed/ ongoing / terminated/deferred.
- d. Number of approvals for full board review/ expedited review with decisions
- e. Brief details about workshops, training programs and other activities undertaken by the RGCB IHEC and those attended by EC members
- f. Any other matter

2.4.19 Training of the IHEC Members in Research Ethics

- An individual selected as a new member of the RGCB IHEC will be required to attend at least one meeting as an 'Observer' before being inducted as a member of the EC.
- Member Secretary or an RGCB IHEC member may provide introductory

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training in Research Ethics and GCP to the new member.

- Other alternative for training certificate in ethics and GCP could be by online method or by attending workshops.
- Training in SOP will have to be in-house by member secretary or an RGCB IHEC member.
- A newly inducted member should submit a certificate of training in 6 months.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/or re-training program related to research ethics, as a delegate, faculty or facilitator, etc.
- The RGCB IHEC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update or assess the EC Members and Institutional faculty members.
- The RGCB IHEC may nominate and/or sponsor the expenses of (as applicable) an EC member or prospective members for attending conference, continuing education session workshop and/or training program etc.

5. Reference to other applicable SOPs

SOP 03/V2 - Conflict of Interest Policy for Institutional Ethics Committee

SOP 08/V2 - Agenda Preparation, Meeting Procedures and Recording of Minutes

6. Annexure

- Annexure 1 AX 01/SOP 02/V2-IEC Administrative Staff: Working rules
- Annexure 2 AX 02/SOP 02/V2-Organizational Chart of the Institution
- Annexure 3 AX 03/SOP 02/V2 - List of Ethics Committee Members
- Annexure 4 AX04/SOP 02/V2 – List of SAE Subcommittee Members
- Annexure 5 AX05/SOP02/V2- CV format for IHEC Members

Annexure 1: AX 01/SOP 02/V2 The IEC Secretariat/ Administrative Staff: Working Rules

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There will be employees in the RGCB IHEC secretariat to assist Member Secretary for smooth functioning of IHEC. Administrative officers/ assistants with support staff of attendants/helpers may be appointed as and when deemed necessary by the RGCB IHEC. This staff will help the IHEC Chairperson and Member-Secretary. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of eligible leaves may be recommended by IHEC members and discussed during regular RGCB IHEC meeting and will be recorded in minutes.

The administrative staff will report to the Chairperson and/or Member Secretary.

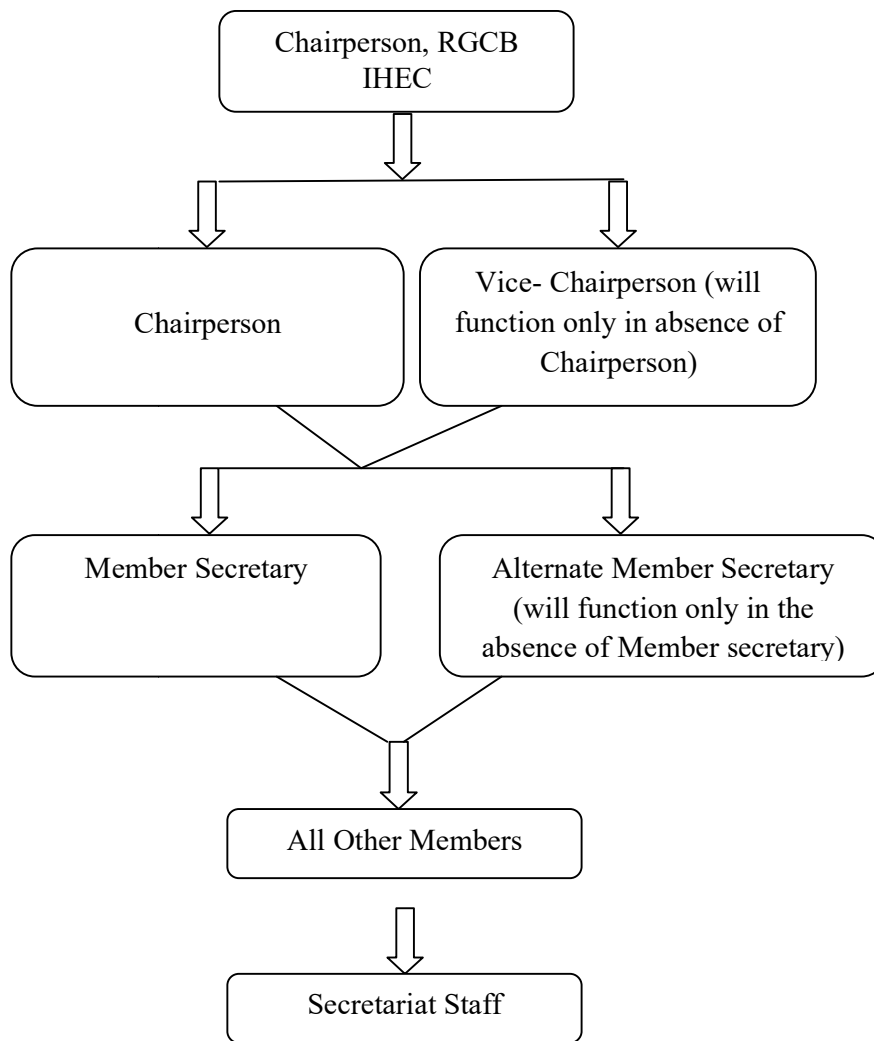
Duties of RGCB IHEC Secretariat


1. Correspondence with RGCB IHEC members and external experts
2. Correspondence with the investigators
3. Preparing agenda and minutes of the RGCB IHEC meetings
4. Answering queries of the investigators
5. Filing study related documents
6. Archiving and maintaining the study files, SOPs, all correspondences
7. Maintaining electronic database of the RGCB IHEC records with access limitation.

Duties of the attendant/s /helper/s

1. Assisting the secretariat in arranging the RGCB IHEC meetings
2. Dispatching sets of study documents to EC members and external experts
3. Receiving the study related documents from and dispatching the EC letters to the investigators
4. Filing study related documents
5. Archiving and maintaining the study files
6. Assisting the Secretariat during the meetings.

Annexure 2: AX 02/SOP 02/V2




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Annexure 03: AX 03/SOP 02/V2

RGCB IHEC Membership List

Name of the Ethics Committee: Institutional Human Ethics Committee CDSCO Reg No. Address: Membership List Dated:						
S. No.	Member Name	Role In Ethics Committee	Highest Degrees Earned	Gender	Primary Scientific or Non-Scientific Specialty	Affiliation With Institution
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						

Note: The Ethics Committee membership list is current date. It gets updated when there is change in membership.


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**Annexure 04: AX 04/SOP 02/V2
SAE Sub-Committee Members List**

S. No.	Member Name	Role In SAE Subcommittee	Highest Degrees Earned	Gender	Specialty	Affiliation with Institution
1						
2						
3						
4						

7. Flowchart

Sl. No.	Activity	Responsibility
1.	Composition of the Institutional Ethics Committee	Head of the Institute
2.	Selection and appointment of Chairperson	Head of the Institute
3.	Appointment and conditions of appointment of new members	Head of the Institute
4.	Initiation of the process of appointment	Secretariat
5.	Tenure of Membership	Head of the Institute
6.	Resignation and disqualification of members	Chairperson and IHEC Members
7.	Quorum requirements	Member Secretary and Secretariat

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Annexure 05: AX05/SOP02/V2
CV format for RGCB IHEC Members


Name			
Current Affiliation (<i>Job Title, department and organization.</i>)			
Address			
Telephone (Landline)	No		Mobile No
Email address			
Qualifications			
Details of any relevant membership/experience or training in the areas of ethics			
Training:			
•			
Membership:			
•			
Experience:			
•			
Signature:		Date:	

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Handling Confidentiality and Conflict of Interest among Ethics Committee Members

SOP Code: SOP 03/V2

Date: November 30, 2019

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3.1. Purpose

The purpose of this SOP is to describe the process to maintain confidentiality and to identify and manage conflict of interest among RGCB IHEC members.

3.2. Scope

This SOP covers the policy applicable to all RGCB IHEC members, which is related to maintaining confidentiality and identification, declaration and management of conflict of interest

3.3. Responsibility

All RGCB IHEC members (regular and alternate) are responsible for understanding definition of conflict of interest (COI) and for self-identifying and disclosing these documents. The Chairperson would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

3.4. Definitions


- Confidentiality is obligation of the members/stakeholders to prevent disclosure of information and documents related to RGCB IHEC to other than authorized individuals.
- Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like financial or non-financial (personal, academic or political) gain.
- Types of COI
 - A personal COI is said to exist when -
 - there is immediate family relationship (spouse, parent or parent of spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent who resides with a RGCB IHEC member or consultant or who receives 50% or more support from a RGCB IHEC member, regardless of age) or other close current personal relationship("step" relationships included) with the investigator, or with co-investigators;
 - RGCB IHEC member or her/his immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff;
 - The proposed research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest, if applicable).
 - A professional COI means the RGCB IHEC member or her/his immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

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- A financial COI for RGCB IHEC members and immediate family exists when the RGCB IHEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

5. Detailed Instructions

- Voluntary disclosure regarding COI by RGCB IHEC member - The RGCB IHEC member should determine whether she/he has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.
- RGCB IHEC members should not participate in discussing, or decision making while reviewing research proposal applications at any level (exempt, expedited, or full-board) if they have conflicts of interest except to provide information requested by the RGCB IHEC.
- At the time of becoming a RGCB IHEC member, she/he should sign a confidentiality and COI agreement.
- If an RGCB IHEC member has a COI with regard to a proposal, she or he should notify the RGCB IHEC Secretariat and return the documents.
 - a) If an RGCB IHEC member has a COI for a study for which she or he has been assigned the task of a primary reviewer, she or he should inform the RGCB IHEC secretariat so that the review is reassigned to other members.
 - b) If an RGCB IHEC member has a COI for review of research study at a meeting, she or he should inform the Chairperson and leave the meeting room while decision about the study is being taken. She/he may stay in the meeting room only to answer questions about the research. This is applicable also for RGCB IHEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.
 - c) Recusal - RGCB IHEC member who declares COI and leaves the meeting does not count as part of the quorum for the decision making process either by consensus/vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence, which should be recorded in the minutes of the meeting.
 - d) If a RGCB IHEC member finds that she/he has a COI during the conduct of a research project approved by RGCB IHEC, he/she

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shall report the conflict to the RGCB IHEC members at the beginning of the meeting or at the next RGCB IHEC meeting.


- At the beginning of each meeting, the RGCB IHEC Chairperson asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, RGCB IHEC member having conflict discloses that just before the review of the relevant item begins.
- If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chair/ Vice-Chair should be appointed for discussion on such a project.
- When determination regarding existence of COI is uncertain, more information is gathered from the respective member/declared related sources and determination is done by RGCB IHEC member with the help of RGCB IHEC, or by RGCB IHEC Chairperson / Member Secretary (as applicable)
- The RGCB IHEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
- The RGCB IHEC shall not approve a research study proposal where a COI is not managed or eliminated
- Management of COI,
 - RGCB IHEC members will disclose the COI as discussed above
 - RGCB IHEC members will not serve as reviewers
 - RGCB IHEC members will not influence the discussion and decision making of the concerned study despite staying away during the RGCB IHEC meeting.
 - Experts/consultants – Proposal will not be sent if COI is declared.
- RGCB IHEC Member Secretary and the Secretariat will record the points related to disclosure and management of COI in the minutes of the meeting of the RGCB IHEC.
- Resolution of COI will be taken up on a case by case basis through detailed discussion among the members.

6. Annexure

Annexure 1 AX 01/SOP 03/V2 – Conflict of Interest Declaration Form for RGCB IHEC Members

Annexure 2 AX 02/SOP 02/V2-Confidentiality Agreement Form for IHEC members

Annexure 3 AX 03/SOP 03/V2- Confidentiality agreement form for IHEC Secretariat

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Annexure 01: AX 01/SOP 03/V2

Conflict of Interest Declaration Form for RGCB IHEC Members

All the IHEC members must disclose any circumstances that could represent a potential conflict of interest (i.e. any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Conflict of Interest (COI) form for any financial, professional or other interest relevant to the subject of the work reviewed at the meeting in which you are a part of or contribute towards and any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgement (e.g. employer, close professional associates, administrative unit or department).

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist to the RGCB IHEC Chairperson. The outcome of which may be to refrain your participation in certain study reviews or discussions or may decide that you be totally recused from the meeting, after consulting with you.

Declaration

In most instances, I am aware that in the event a conflict of interest exists, the reviewer would be required to refrain from participating in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest.

- ☐ I have no conflict of interest to report
- ☐ I have the following conflict of interest to report
 - I. Personal
 - II. Professional
 - III. Financial

Please describe any relationships, transactions, positions you hold (volunteer or otherwise), or circumstances that you could contribute to a conflict of interest.

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this agreement.

Signature of RGCB IHEC Member with date: _____

Signature of Member Secretary with date: _____

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Annexure 02: AX 02 /SOP 03/V2


Confidentiality Agreement Form for RGCB IHEC Members

I _____ (EC Member's name) have been appointed as a member of the RGCB IHEC based on my individual merit and have been asked to assess research involving human participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national guidelines/ regulations (international regulations in addition, if applicable) and institutional policies.

I agree to hold all the information deemed Confidential, Proprietary or privileged in trust or confidence. This information provided to me for research review whether explicit or implied, verbal or documentary, incorporated in computer software or held in electronic storage media/device or otherwise shall be used only for contemplated purposes and not for any other purpose. As written confidential information including any copies and notes thereof, provided for review is sole property of the RGCB IHEC it shall not be copied or retained, and promptly returned or properly handled in the manner required by the EC, including destruction of the same.

I agree to take reasonable measures to protect the information from use by third parties including access to it under Right to Information Act; not to use the Confidential Information for any purpose outside the Committee's mandate or which would result in a benefit to me or any third party; and upon termination of my functions as a Committee member to destroy all Confidential Information including any minutes or notes I may make or keep as reference as a IEC member. Furthermore, I confirm that my performance of this agreement is consistent with the Institution's policies and any contractual obligations they may have with third parties.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

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Signature of RGCB IHEC Member

Date

Signature of Member Secretary

Date

I acknowledge that I have received a copy of this Agreement signed by the RGCB IHEC member secretary and me.

Signature of RGCB IHEC Member

Date

Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the RGCB IHEC. A copy will be given to you for your records.

Note:

Legal compulsion to disclose

In the event that the member becomes legally compelled to disclose any Confidential Information the member shall give prompt notice in writing of such facts to the RGCB IHEC so that EC has an opportunity to seek a protective order or other remedy. In the event that such protective order or other appropriate remedy is not sought by the RGCB IHEC or is sought but is not obtained; the member will, nevertheless, disclose only that portion of the Confidential Information as is necessary to comply with its obligations under law and shall use reasonable endeavours to obtain any appropriate court order or other reliable assurance that Confidential treatment will be accorded to Confidential Information so disclosed.

Governing Law:

This agreement shall be governed and construed in accordance with the application of Indian laws, and that the local courts in Coimbatore shall have exclusive jurisdiction in respect of disputes over subject matter of this Agreement.

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Annexure 03: AX 03 /SOP 03/V2

Confidentiality Agreement Form for Secretarial Staff of RGCB IHEC

I, _____ (Name) secretarial staff and a non-member of RGCB IHEC understand that the documents and information related to EC activity assigned to me as staff of RGCB IHEC office are confidential. I shall use the information only for the indicated purpose as required by the EC and shall not duplicate, give or distribute these documents/ information to any person(s) without permission from the RGCB IHEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information confidential.

Signature of staff with date

Signature of Member Secretary with date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Member Secretary and me.


Signature of the recipient with date

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Selection and Responsibilities of Independent Consultants

SOP Code: SOP 04/V2

Date: November 30, 2019

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4.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging expertise of medical professionals as 'Independent Consultants' (IC) to the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC).

4.2. Scope

This SOP covers the procedures for selecting, appointing ICs and getting their expert opinion during the RGCB IHEC review process. It also defines the responsibilities of IC.

4.3. Responsibility

It is the responsibility of the Chairperson/ Member Secretary/ RGCB IHEC member(s) to nominate the name of one or more IC(s). The Chairperson is responsible for endorsing the choice of IC nominated by RGCB IHEC Member Secretary/ RGCB IHEC member(s). The administrative procedures regarding selection, confidentiality agreement and maintenance of roster of ICs will be carried out by RGCB IHEC secretariat.

4.4. Detailed instructions

4.1 Recommendation of names of ICs and making a roster of ICs for the RGCB IHEC

- Chairperson/ Member Secretary/ RGCB IHEC members will nominate the names of ICs from different disciplines of Medicine.
- Member Secretary in consultation with Chairperson will select a panel of IC(s) for the RGCB IHEC.
- Member Secretary will confirm their willingness through telephonic/ electronic communication. Head of the Institute will issue an appointment letter for the IC(s).
- After receiving written confirmation from ICs, a list of speciality wise ICs will be maintained by the secretariat in the RGCB IHEC records. The details of each IC (Name, designation, affiliation, contact details, and updated curriculum vitae) will be maintained in the RGCB IHEC records.

4.2 Consulting an IC during RGCB IHEC review process

- An RGCB IHEC member/ Member Secretary/ Chairperson may suggest that the opinion be sought from one or more IC(s) and may suggest the name of a particular IC(s) from the roster of ICs maintained by the RGCB IHEC or from outside the roster, if during the review process of any given research study it is felt that the study involves procedures or information that is not within the area of collective expertise of the RGCB IHEC members.

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- The Member Secretary in consultation with Chairperson (or at full board meeting; as deemed necessary) will identify and select the IC(s) outside the roster to be invited based on area of expertise, independence, and availability.
- Member Secretary on behalf of the RGCB IHEC will invite IC(s) in writing to assist in the review of the research study and provide her/his independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through telephonic/ electronic communication.

4.3 Communication with ICs


- The Secretariat may request a copy of the updated curriculum vitae of the IC (those outside roster) for RGCB IHEC records and future reference.
- The Member Secretary will request IC to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the Confidentiality Agreement and Conflict of Interest Agreement form (AX 01/SOP 04/V2) for careful reading, understanding, and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert/ RGCB IHEC members.

4.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality

- **Agreement**

- o The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement.
- o The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- o The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC(s).

4.5 Review of research study proposal

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- The Secretariat will provide study protocol documents along with the Study Assessment Form AX 02/SOP 7A/V2 to the IC(s). The IC(s) may be provided with a copy of 'Guidelines for Reviewers'.
- The IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the IC(s) becomes a permanent part of the study file.
- The assessment report will be reviewed by Member Secretary in the RGCB IHEC meeting when the concerned study is being discussed.
- If deemed necessary, the Chairperson or Member-secretary may seek additional information or clarifications from the IC in writing. Additional Information provided by the IC will be considered as a part of the Assessment Report.
- If deemed necessary, the Chairperson or Member-secretary may invite the IC(s) to attend an RGCB IHEC meeting for providing additional information or clarifications that may be sought by RGCB IHEC members or Chairperson. However, the IC will not participate in the decision making process on the research study.
- IC may be reimbursed for expenses on travel (if invited to attend the meeting), time spent for review or any other incidental expenses, etc.

4.6 Tenure of Services of IC

- The roster of ICs maintained at the RGCB IHEC office will be modify as membership changes occur.
- For IC appointed for a particular study, the services of IC get automatically terminated once the protocol receives RGCB IHEC clearance. The need for an IC will be revisited during each progress report discussion. If required, the same IC (as far as possible) will be re-invited to any or all of the progress report discussions. RGCB IHEC will document the invitation, re-appoint and termination of the services of IC.

4.7 Responsibilities of IC

- If IC agrees to review a research proposal, she/he will comply with RGCB IHEC requirements of signing confidentiality and conflict of interest agreements.

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- IC will review the research study and complete the Assessment Form (duly signed and dated) within a stipulated period or by a stipulated date.
- IC will attend a RGCB IHEC meeting for providing additional information or clarifications, if invited by Member Secretary in consultation with the Chairperson. However, the IC will not participate in the decision making process on the research study.
- IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

5. Flow Chart

No.	Activity	Responsibility
1	Recommendation of a name of one or more IC(s)	RGCB IHEC Member, Member Secretary or Chairperson
2	Selection and Appointment of IC(s)	Member Secretary in consultation with Chairperson
3	Invitation to IC(s) on behalf of RGCB IHEC	Chairperson/ Member-Secretary
4	Co-ordination with IC(s) for fulfilling administrative requirements	RGCB IHEC Secretariat
5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	IC, Chairperson
6	Maintenance of a specialty-wise list/ roster of ICs	RGCB IHEC Secretariat
7	Reviewing documents pertaining to research project	IC

6. Annexure

- Annexure 1 AX 01/SOP 04/V2- Confidentiality Agreement and conflict of interest form for a Reviewer / Independent consultants

Annexure 01-A: AX 01-A/SOP 04/V2 Confidentiality Agreement and Conflict of Interest Form for a Reviewer / Independent Consultants

Agreement on Confidentiality

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I, _____ (Name and Designation)
as a non-member of RGCB IHEC understand that the document(s) sent to me by the RGCB IHEC is/are confidential. I shall use the information only for the indicated purpose described by the RGCB IHEC and shall not duplicate, give, convey or distribute these documents to any person(s) without prior permission from the UEC. I agree to take full responsibility to keep the information confidential.

Agreement on Conflict of Interest

In accordance with the policy of the RGCB IHEC regarding conflict of interest that no reviewer may undertake to review, comment or participate in decision making of any activity in which she/he has actual/potential conflict of interest, I will immediately disclose to the Chairperson of the RGCB IHEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee.

I, _____ (name) have read and accept the
aforementioned terms and conditions as explained in this Agreement.


Signature _____ Date _____
(Incorporate the capacity of the declarant as Reviewer/Consultant)

Member Secretary's Signature _____ Date _____

I acknowledge that I have received a copy of this Declaration signed by the RGCB IHEC Member Secretary and me.

Signature and Date


[The original signed and dated Declaration will be kept in file in RGCB IHEC Office. A copy will be given to Reviewer/IC for records]

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Procedures for allowing Guest/ Observer to visit RGCB IHEC office or attend RGCB IHEC meeting

SOP Code: SOP 05/V2

Date: November 30, 2019

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5.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC) and the Guest/ Observer whenever he/she visits the RGCB IHEC Office or attends an RGCB IHEC full board meeting. The SOP is needed to ensure adequate protection of confidentiality of information related to research studies.

5.2. Scope

This SOP covers the procedures for allowing guest/ observer to visit the RGCB IHEC Office and observe a meeting in progress.

5.3. Responsibility

- It is the responsibility of Member Secretary in consultation with Chairperson to decide whether a guest/ observer may be allowed to visit the RGCB IHEC Office or attend an RGCB IHEC meeting.
- It is the responsibility of the guest/observer(s) intending to attend an RGCB IHEC meeting to read, understand, accept and sign the agreement contained in the Confidentiality form prior to visiting RGCB IHEC/attending an RGCB IHEC meeting.
- The Secretariat will ensure that the Confidentiality Form is duly signed and dated by the guest or observer for RGCB IHEC/RGCB IHEC meeting and will file it in RGCB IHEC records.


5.4. Detailed instructions

5.4.1 Receiving request from guest/observer to visit RGCB IHEC office or attend RGCB IHEC meeting

- On receiving a written or verbal request the RGCB IHEC Member/Member Secretary/ Secretariat will obtain permission from Chairperson.
- The date and time of the visit will be informed to the guest/ observer in writing/email.
- The request letter/email will be filed in RGCB IHEC records by the secretariat.

5.4.2 Filling up of Confidentiality Agreement and Conflict of Interest Form

- Confidentiality Agreement and Conflict of Interest Form (AX 01/SOP 05/V2) will be provided to the guest attendee/ observer on the day of visit/ at the time of meeting.
- The guest/ observer will read the form carefully before visit/or before commencement of the meeting and fill the details in the form.

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5.4.3 Ask questions, if any

- If there are any doubts, the guest/observer will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and / or clarifications.

5.4.4 Signing of Confidentiality Agreement Form

- The guest /observer will sign and date the document before a member of the Secretariat.
- She/he will return the signed form to the Secretariat.
- The Secretariat will obtain the signature of the RGCB IHEC Chairperson on the Confidentiality / Agreement Form.
- The secretariat will provide guest or observer a photocopy of the Confidentiality Agreement Form for their records (duly signed and dated by them and RGCB IHEC Chairperson) and acknowledge the receipt of agreement by their signature.
- The Secretariat will keep the original copy of the signed Agreements at the RGCB IHEC office in the files entitled 'Confidentiality Agreement file for guests/observers, Independent Consultants (IC)'.
- The Secretariat will store the file in a secure cabinet with controlled access.

5.4.5 Keep the Agreement in mind

The guests/observer must implement the clauses of the signed Confidentiality Agreement Form.

5.5. Flow chart

No.	Activity	Responsibility
1.	Receiving request from guest/ observer	RGCB IHEC Secretariat/ Member/Member Secretary
2.	Allowing a guest/ observer	Chairperson
3.	Informing guest/ observer about visit/ meeting date and time	RGCB IHEC Secretariat
4.	Read the text carefully and thoroughly, sign the confidentiality agreement	Guest/observer
5.	Filing of signed confidentiality form in RGCB IHEC records	RGCB IHEC Secretariat

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5.6 Annexure

- Annexure 1 AX 01/SOP 05/V2-Confidentiality Agreement and AX 01/SOP 03/IV COI for Guest/Observer visiting RGCB IHEC office or attending an RGCB IHEC Meeting.

Annexure 1: AX 01/SOP 05/V2

Confidentiality Agreement and Conflict of Interest Form for Observer/Attendees to RGCB IHEC Meetings

I, _____ (name), understand that I am being allowed to visit RGCB IHEC office facility / attend the RGCB IHEC meeting on _____ at _____am/pm as a Guest/Observer at _____ (Venue).. I understand that I may become aware of some confidential information during my visit to RGCB IHEC office/ during the course of the RGCB IHEC meeting. Upon signing this form, I agree to take full responsibility to keep the information strictly confidential unless I am legally compelled to disclose only that portion of the Confidential Information as may be necessary as part of my duty.

I do not have conflict of interest, personal, professional or financial, but in the event of my having it related to my visit/ during the course of RGCB IHEC meeting I will inform EC of the same for it to take appropriate action in the matter accordingly.

Signature of the Guest/ Observer attendee with date

Signature of Chairperson with date

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by Chairperson, RGCB IHEC and me.


Signature of the Observer/attendee and Date

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Management of Submission of Research Study Protocol and Study Related Documents

SOP Code: SOP 06/V2

Date: November 30, 2019

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6.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC) should manage submitted protocol and other documents.

6.2 Scope

The scope of this SOP includes submission of research proposal and related documents for Initial Review;

- Resubmission of research Proposal with corrections and amendments
- Submissions of written communications related to continuing Review of approved protocols.

6.3 Responsibility

It is the responsibility of the RGCB IHEC Secretariat to receive, record and distribute the received protocols and any other documents for review, act on the instructions given by the RGCB IHEC authorities and ensure that the communication reaches the concerned recipient.

6.4 Detailed Instructions

6.4.1 Receive study protocols/ documents

The Principal Investigator (PI) will submit a research proposal to the RGCB IHEC office for review and decision under any of the following sections within the specified time period:

- New Proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols and related documents:
- Documents related to continuing review of approved protocols such as-
 - Protocol progress and final reports
 - Protocol completion/Termination
 - Protocol deviations/violations/non-compliance
 - Serious Adverse Events (SAE) initial/ follow up/ final reports
- All other documents for consideration at the full committee meeting (except those related to participant safety, which may be submitted any time) must be submitted at least 30 days in advance of the meeting to be considered in the next meeting agenda.

6.4.2 Initial Review Application

The Secretariat will check the hard and soft copies to ensure the availability and full compliance of the following items:

1. 15 sets of hard copies of the proposal (One original and 14 sets of Photostat copies) and a soft copy to ihec@rgcb.res.in

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2. A completely filled RGCB IHEC Project Submission Application Form for Initial Review AX 1-A/SOP 06/ V2 and AX 1-B/SOP 06/V2
3. The marked checklist (AX 02/SOP 06/V2)
4. Duty Delegation Log of the Study team (AX 03/SOP 06/V2)
5. Document Receipt Form (AX 04/SOP 06/V2)
6. Verify contents of Submitted Documents: The Secretariat will:
 - a Use the checklist to confirm whether all the ticked documents are there in the application docket/package
 - Project submission application form for initial review
 - Covering letter to Member Secretary/ Chairperson duly signed by PI
 - Protocol as per the requirements of the current guidelines and regulations. (AX01/SOP 06/V1-New Format.....to be added)
 - Protocol Amendments (if any)
 - Informed consent document (ICD) in English (as per sample format page 50 of ICMR's National Guidelines) or Waiver of Consent form as per SOP 15/V2
 - ICD in Regional languages (if applicable)
 - Back translations of ICDs (if applicable)
 - Translation and Back translation certificates (if applicable)
 - Amendments to the ICD (if any)
 - Case Record Form
 - Recruitment procedures: advertisement, notices, letters to investigators (if applicable)
 - Patient instruction card, identity card, diary etc. (if applicable)
 - Investigator's Brochure (as applicable for Drug/Device trials)
 - Applicable Regulatory permissions/approvals DCGI (CLA) approval, FDA marketing/manufacturing license for herbal drugs, Health Ministry Screening Committee (HMSC) approval, Bhabha Atomic Research Centre (BARC) approval) (as applicable).
 - Investigator's Undertaking to DCGI
 - Administrative sanction from the head of the Institution or Memorandum of Understanding in case of studies involving collaboration with other institutions. (if applicable)
 - A copy of Administration sanction from the head of the Institution or Memorandum of Understanding for sending the samples to laboratories outside the Institution. (if applicable)
 - Brief Curriculum Vitae of all the study team members
 - GCP training certificate (within 1 year) of principal investigator, co-investigator/s and study coordinator/s. (if applicable)

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- Research Methodology training certificate (within 5 years) of principal investigator, co-investigator/s and study coordinator/s (if applicable)
 - List of ongoing research studies undertaken by principal investigator
 - Undertaking to comply with national and international ethical guidelines, GCP protocols and relevant regulations
 - Details of Funding agency / Sponsor and fund allocation
 - Clinical Trial Agreement between the sponsors, investigators and the head of the institution(s) if applicable
 - Insurance policy (if applicable) with the insurance certificate for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk
 - Indemnity policy clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk.
 - Ethics Committee clearance of other centres (if applicable)
 - Institutional Stem cell Research Committee approval (if applicable)
 - Documentation of clinical trial registration (if available)
 - Processing fee payment receipt (See Guidelines for investigators)
 - Any additional document(s), as required by RGCB IHEC
- The Secretariat will ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing by the Secretariat).
- **Complete the submission process:**
 - The Secretariat will:
 - Complete the checklist of submission
 - Stamp the receiving date on the first page of the covering letter and initial it.
 - Make a photocopy of the completed document receipt form AX 04/SOP 06/V2 and return the original copy of the document to the applicants for their records.
 - Keep the copies of the submitted documents with original signatures in the protocol “Submission” file.
 - Number the project file as IHEC/ Month (00)/ year (0000)/Number (00)
 - Dispatch and Store the received Documents: The Secretariat will
 - Prepare 2sets of a protocol package containing completed application form AX 1-A/SOP06/V2 and AX 1-B/SOP06/V2,

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protocol related documents along with checklist AX 02/SOP06/V2 and send 1 set to the IHEC members along with a copy of Project Assessment Form for Initial Review AX 02/SOP07A/V2 after the last day of submission is over, ensuring at least 3 weeks for review before the next meeting (if applicable).

- Store the appropriately labelled original protocol documents in the designated storage area in the RGCB IHEC office.
- If the RGCB IHEC members prefer to receive and review soft copies, these are sent via email/CD/pen drive along with a copy of Project Assessment Form for Initial Review AX 02/SOP7A/V2


6.4.3 Resubmission of Protocols with corrections and Amendments of protocol/ related documents

- For resubmitted protocol, the PI will submit one soft copy and required number of hard copy of the amended Protocol and related documents (as per SOP 09/V2) with list of comments and clarifications/changes made at appropriate pages.
- The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier submitted protocol mentioning the justification for the amendment.
- The protocol related documents which do not require to be changed and are already submitted to the RGCB IHEC office during initial review are not required to be submitted again.
- The Secretariat will present the docket to the Member Secretary
- The Member Secretary (MS) will determine whether all steps of the resubmitted protocol as for Initial review are followed.
- If the resubmitted protocol is based on query response, then it will be handled as decided in the meeting.

6.4.4 Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Progress reports Study completion/termination, SAE report, Protocol deviations

- The RGCB IHEC will receive one soft copy and required number of hard copy of the Continuing Review Report, Amended Protocols and related documents, Study completion/termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

7.4.5 Processing Fees for RGCB IHEC Review

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- The fees for reviewing various categories of research study proposals are provided by the host institute. The RGCB IHEC functions as a non-profitable service entity.

6.5 Reference to other applicable SOPs

SOP 7A/V2: Full Review of Research Study Protocols

SOP 09/V2: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

SOP 15/V2: Request for Waiver of Written Informed Consent and Waiver of Consent

6.6 Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages	RGCB IHEC Secretariat
2	Initial Review Application	RGCB IHEC Secretariat
3	Resubmission of Protocols with Corrections	RGCB IHEC Secretariat
4	Protocol Amendments	RGCB IHEC Secretariat
5	Annual Continuing Review of Approved Protocols	RGCB IHEC Secretariat
6	Protocol Completion	RGCB IHEC Secretariat

6.7 Annexure

- Annexure 1-A AX 01-A/SOP 06/V2- Project submission application form for initial review for regulatory clinical trials (Pharma Industry and Government sponsored studies).
- Annexure 1-B AX 01-B/SOP 06/V2- Project submission application form for initial review for academic (non-regulatory) studies.
- Annexure 2 AX 02/SOP 06/V2-Checklist of protocol submission
- Annexure 3 AX 03/SOP 06/V2- Duty Delegation Log of Study team
- Annexure 4 AX 04/SOP 06/V2- Document Receipt Form

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Annexure 1-A: AX 1-A/SOP 06/V2

Project Submission Application Form for Initial Review for Regulatory Clinical trials (Pharma Industry and Government sponsored studies)

- Please fill in the details in legible hand writing
- Tick ✓ in the box for the appropriate answer
- Tick/ Write NA if question is not applicable

RGCB IHEC Protocol No.				
Title of the Proposal				
	Name	Designation	Department & Institution	Signature
Principal Investigator				
Co-Investigator				
Co-Investigator				
Coordinator				
(For additional collaborators attach details and letter of Consent by the collaborator(s) on a separate page.)				
Please attach brief curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) Attached				
Is the study funded? Or non-funded (investigator initiated)				

1. Sponsor Information: ☐ Sponsored ☐ Non Sponsored

(i) **Indian** ☐ Government ☐ Private Agency ☐ NGO/ Non-profit organization

(ii) **International** ☐ Government ☐ UN agencies ☐ NGO/ Non-profit organization

(iii) **Industry** ☐ National ☐ Multinational

If Sponsored, Contact Address of Sponsor:

If sponsor is not from India, contact address in India:

2. Total Budget :Rs. _____ per patient **OR** _____ total project

Please give details of allocation of budget in an attachment.

Type of Study: ☐ Interventional ☐ Observational ☐ Thesis/dissertation

☐ Epidemiological ☐ Other Academic Studies

☐ Other, Please specify _____

Study Recruitment: ☐ Prospective ☐ Retrospective

Study Design: ☐ Open-labeled ☐ Randomized

Blinding: ☐ Triple blinded ☐ Double blinded ☐ Single blinded

Arms: ☐ Cross-over ☐ Parallel

Control: ☐ Treatment controlled ☐ Placebo controlled

Clinical Study Centers: ☐ Single center ☐ Multi-centric (Attach list of centers)

If multicentric, no. of centers: India _____ Globally: _____ (attach list of countries)

3. Clinical Trials:

(Tick the appropriate boxes)

i. What does the study involve use of?

☐ Medicine ☐ Devices ☐ Vaccines ☐ Diagnostic process/kit ☐ Surgical process

☐ Indian Systems of Medicine ☐ Any other ☐ **Specify:** _____

☐ NA

ii. Where Is it approved and marketed?

☐ In India ☐ UK & Europe ☐ USA

☐ Any other country specify: _____ ☐ NA

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4. Protocol of the proposal–Introduction, review of literature, aim(s)& objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale: (Submit as attachment)

5. Research participants

Sample Size:

- i. Number of research participants at this centre: _____
Number of research participants at other sites in India : _____
Total number of research participants at all sites (globally): _____
- ii. Duration of study: _____
No. of visits : _____
- iii. Will research participants from both genders be recruited

☐ Yes ☐ No ☐ NA

- iv. Inclusion / exclusion criteria given

☐ Yes ☐ No ☐ NA

- v. Type of research participants:

☐ Volunteers ☐ Patients ☐ NA

- vi. Vulnerable research participants

☐ Yes ☐ No ☐ NA


If yes, specify:

- ☐ pregnant women ☐ elderly ☐ mentally challenged
☐ illiterate ☐ handicapped ☐ children
☐ elderly ☐ HIV ☐ fetus
☐ economically or socially backward/ institutionalized employees/ students/ dependent staff
☐ seriously/terminally ill ☐ captives
☐ Any other, Specify: _____

Comments about vulnerability

6. Privacy and confidentiality

- i. Study involves: ☐ Direct Identifiers ☐ Indirect Identifiers/coded
☐ Completely anonymized/ delinked
- ii. Confidential handling of data by staff ☐ Yes ☐ No

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(Tick the appropriate box/option)	Yes	No	NA
7. Use of biological/hazardous materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Use of fetal tissue or abortus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. Use of organs or body fluids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. Use of recombinant/gene therapy If yes, has Department of Biotechnology(DBT) approval for DNA products been obtained: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. Use of pre-existing/stored/left over samples	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. Collection for banking/future research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Use of ionizing radiation/radioisotopes If yes, has Bhabha Atomic Research Centre(BARC) approval for radioactive isotopes been obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. Use of Infectious/bio hazardous specimens	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. Proper disposal of material	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Will any sample collected from the patients be sent abroad? If yes, Sample will be sent abroad because(Tick appropriate box): <input type="checkbox"/> Facility not available in India Facility in India inaccessible <input type="checkbox"/> Facility available but not being accessed If so, reasons..... Lab. Address: _____ _____ If no, test on samples be carried out: <input type="checkbox"/> In institution <input type="checkbox"/> Outside institution If outside institution, specify with details of collaborators _____ Address: _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Is the proposal being submitted for clearance from Health Ministry's Screening Committee(HMSC)forInternationalcollaboration?(requiredincaseofstudiesinvolving collaborations with foreign Laboratory/ Clinic/Institution)

☐ Yes ☐ No ☐ NA

11.Incase of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/ Institution has administrative sanction from the Dean obtained/applied for?

☐ Yes ☐ No ☐ NA

Memorandum of Understanding: ☐ Yes ☐ No ☐ NA

Material Transfer Agreement : ☐ Yes ☐ No ☐ NA

12. Consent : ☐ Written ☐ Oral ☐ Audio-visual ☐ NA

If Written,

(Tick the appropriate box/option)

	Yes	No	NA
Sponsor of study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Contact information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Purpose and procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Statement that consent is voluntary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risks &Discomforts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Right to withdraw	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benefits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Compensation for participation (travel, inconvenience, incidental)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Compensation for study related injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benefits, if any, on future commercialization	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consent for future use of biological material and/or data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If written consent will not be obtained, give reasons: _____

Whether applied for waiver of Consent: _____

Who will obtain consent?

☐ PI/Co-PI

☐ Nurse/ Counselor ☐ Research staff

☐ Any other, specify _____

(Tick the appropriate box/option)	Yes	No	NA
13. Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – if so kindly attach a copy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Risks & Benefits:			
i. Is the risk reasonable compared to the anticipated benefits to research participants / community/ country?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. Is there physical / social / psychological risk / discomfort? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, <input type="checkbox"/> Less than minimal risk <input type="checkbox"/> Minimal risk <input type="checkbox"/> More than minimal risk			
iii. Is there a benefit (a) To the research participants? <input type="checkbox"/> Direct <input type="checkbox"/> Indirect (b) Benefit to society <input type="checkbox"/> Direct <input type="checkbox"/> Indirect			
15. Data Monitoring			
i. Is there a data & safety monitoring committee/ Board (DSMB)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA			
ii. Is there a plan for reporting of adverse events? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA If Yes, reporting is done to : <input type="checkbox"/> Sponsor <input type="checkbox"/> IEC <input type="checkbox"/> DSMB			
iii. Is there a plan for interim analysis of data? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA			
iv. Are there plans for storage and maintenance of all trial databases? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA If Yes, for how long? -----			
16. Is there compensation for participation <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA If Yes, <input type="checkbox"/> Monetary <input type="checkbox"/> In kind Specify amount and type: -----			

17. Is there compensation for injury?

☐ Yes ☐ No ☐ NA

If Yes, ☐ by Sponsor ☐ by Investigator ☐ by insurance

By any other company, Specify: _____

18. Do you have any **conflict of interest in the present study? (financial/non financial)**

☐ Yes ☐ No


If Yes, specify:-----

19. Number of DCGI regulated protocols handled by the PI at present: _____

Information to be given on current status of ongoing studies approved by IEC and carried out by the Principal Investigator

Study Name	Approved by EC	Approved by DCGI	Status & No. of Patients	Duration of Project
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Awaiting SIV <input type="checkbox"/> Enrolling; _____ patient <input type="checkbox"/> Follow up; _____ patient <input type="checkbox"/> Awaiting Close out	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Awaiting SIV <input type="checkbox"/> Enrolling; _____ patient <input type="checkbox"/> Follow up; _____ patient <input type="checkbox"/> Awaiting Close out	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Awaiting SIV <input type="checkbox"/> Enrolling; _____ patient <input type="checkbox"/> Follow up; _____ patient <input type="checkbox"/> Awaiting Close out	

Describe briefly in a separate sheet, if required)

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20. Current Brief Curriculum Vitae (signed and dated copy) of the study team members-principal investigator, co-investigator and study coordinator (Information required: age, designation and department, educational qualification, previous research experience in last five years) (Information about GCP training of PI and Co-investigator)	(To be enclosed along with the form)
21. GCP training certificates of principal investigator and coordinators (mandatory only for drug and device trials not for observational studies)	(To be enclosed along with the form)

22. Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India (CTRI)/any other WHO platform registry Registration number: _____ If not registered, state the reason: _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Statement of Compliance: We hereby declare that the information given above is true and that we will comply with the relevant guidelines and regulations mentioned in the Drugs and Cosmetic Act 1940; New Drugs and Clinical Trials Rule, 2019, Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017), Indian GCP Guidelines and the International Council on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (R1 – 1996 and R2 -016) while conducting the research study.			


Signature of Principal Investigator with date: _____

Signature/s of Co-investigators with date:

1. _____ 2. _____ 3. _____

Signature of coordinator: 1. _____ 2. _____

Forwarded by Heads of Department(s)

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Signature/s with date of Heads of Department(s):

_____, _____

Stamp/Seal of the Department(s)

Annexure 1-B: AX 1-B/SOP 06/V2
Project Submission Application Form for Initial Review for Academic
(non-regulatory) Studies

Please fill in the details in legible hand writing

Tick ✓ in the box for the appropriate answer/ Write NA if question is not applicable

RGCB IHEC Protocol no. _____

Title of the project: _____

	Name	Designation	Department and Institution	Signature
Principal Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				

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For additional collaborators attach details and letter of consent by the collaborator (s) on a separate page.

Non-sponsored study	Sponsored study <input type="checkbox"/>
If Non-Sponsored Study: Type of study: Thesis/dissertation _____ ICMR _____ Other Academic <input type="checkbox"/> Duration of study _____ Approx. Completion date (MM/YY) _____	
If sponsored, Total Budget : Rs. _____ From where is the study being funded _____ Research fund is being utilized from in-house funding authority _____ any <input type="checkbox"/> or If any other, please give details _____ Allocation of budget heads (Please attach separate sheet if needed) _____ _____	

	<input type="checkbox"/>	<input type="checkbox"/>
1.Type of Study: <input type="checkbox"/>		
Prospective <input type="checkbox"/>		
Retrospective <input type="checkbox"/>		
Cross sectional <input type="checkbox"/>		
Is the study	Observational/	Interventional?
If interventional, does the study involve testing of a new drug or of care practices? _____		

2. Does the study meant for academic trial involve use of : marketed Drug / Vaccine/ Device/ Traditional/herbal Medicine

New Technique (surgical/PT/OT/ Psychotherapy etc) Diagnostic Kit/ Investigations

If _____ other, _____ please _____ specify _____

i) Is the test drug / device marketed in India Yes No

Please attach copy of package insert/product insert.

ii) Does the test drug involve a change in use, dosage, route of administration? Yes

No If yes, please attaches copy of DCGI permission/medicine insert.

3. Subject selection:

i) Number of subjects at this centre if multicentric, total number of subjects

ii) Vulnerable subjects Yes No (If yes, tick the appropriate)

pregnant women illiterate seriously/terminally ill children

neonates mentally challenged elderly handicapped

economically/socially backward institutional employees / students

Any other

If other, please specify _____

4. Does the study involve use of

i) foetal tissue or abortus

Yes

No

ii) organs or body fluids

Yes

No

iii) Gene therapy

Yes


No

If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.

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v) infectious / bio hazardous specimens	Yes	No
vi) Will pre-existing/stored/left over samples be used?	Yes	No
vii) Will samples be collected for banking/future research	Yes	No

viii) Will any sample collected from patient be sent abroad? If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ix) Is there any collaboration with any foreign lab., clinic or hospital ? If yes, please submit a copy of Health Ministry Screening Committee (HMSC)/ ICMR approval (as applicable for foreign collaborations).	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, please attach a copy for IEC review.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6. Is there compensation for participation (travelling allowance)? If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount / type: _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7. Are there any arrangements for compensation / treatment of trial related injury? If yes , by sponsor <input type="checkbox"/> by investigator <input type="checkbox"/> By insurance company <input type="checkbox"/> by others <input type="checkbox"/> Please submit a copy of the insurance policy if it is available.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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8. Do you have any conflict of interest in the present study?

(Financial / non – financial/ any other)

If _____ yes, _____ specify:

.....

9. Is any other department involved in participant recruitment/investigation, but not co-investigators or collaborators? Yes _____ No _____

If yes, specify

Name _____ and _____ signature _____ of _____ concerned _____ Head _____ of Department.....

We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.

Signature of Principal Investigator: _____

Signatures of Co- investigators:

1. _____ 2. _____

3. _____ 4. _____

Forwarded by _____ Heads of Department(s) _____
_____ Stamp/Seal of the Department(s)

Please fill the form in legible handwriting or type the information.

Write 'Not Applicable' (NA) wherever necessary. Incompletely filled form will not be accepted.

Annexure 2: AX 02/SOP 06/V2 Check List for Protocol Submission

Check List of Documents for Protocol Submission to be filled in by the study team

Protocol submission for initial review

(Tick accordingly; compulsory documents have to be submitted by ticking in the box marked as 'Yes') * Compulsory documents for initial review.


Sr. No.	Document	Yes	No	Date by which it will be submitted, if pending	NA

 RGCB <small>RESEARCH GROUP FOR CLIMATE CHANGE & BIODIVERSITY</small>	RGCB IHEC SOP	SOP Version 2 Date: November 30, 2019
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1	*Project submission application form duly filled				
a.	Covering Letter				
b.	Project proposal – 15 hard copies				
c.	Project proposal – soft copy sent by e-mail/ CD-ROM/pendrive by uploading				
d.	CV of all investigators (including guide)				
e.	Fee for review				
2	Approval of Departmental Review Board (DRB)(for thesis/dissertations proposals)				
3	*Letter to Member Secretary/ Chairperson				
4	*Summary of protocol (in not more than 500 words)				
5	*Protocol				
6	*Informed consent document in English				
7.	*Informed consent documents in Regional languages (Total No:-)				
8.	Back translation of Informed Consent Documents (if available)				
9	Translation and Back translation certificates (if available)				
10	*Case Record Form				
11	*Research participants recruitment procedures: advertisement, notices (If applicable)				

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12	*Patient instruction card, identity card, diary etc.				
13.a	*Research Participants Questionnaire/s (If applicable)				
13.b	Research participants confidentiality statement				
14	*Investigator Brochure				
15	*Insurance certificate and policy				
16	*Investigator's undertaking to DCGI/CLA				
17	DCG(I) approval [if DCGI/CLA approval is awaited, the same should be mentioned in the covering letter to the RGCB IHEC]				
18	*Clinical Trial Agreement for drug trial / Memorandum Of Understanding / Copy of clinical trial protocol Material Transfer Agreement (MTA), as applicable, for collaborator & Govt sponsored trials (draft if final not ready)				
19	FDA marketing/manufacturing license for herbal formulations/ nutraceuticals				
20	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations				
21	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy				
22	a) Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) Or Memorandum of Understanding (as applicable) a) Administrative sanction from the Head of the Institution for the samples to be sent to outside institution (one copy) Or				

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	Material Transfer Agreement (if applicable)				
	b) Administrative sanction from the Head of the Institution for the samples to be sent to outside institution (one copy) Or Material Transfer Agreement (as applicable)				
23	*Budget Sheet for the Proposed Study (Format for budget sheet stated below)				
24	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) (one copy only)				
25	*Ethics Committee clearance of other centres (Total No ____)				
26	*Log of delegation of responsibility of the study team members - Sample Format Enclosed) (AX 03/SOP 06/V2)				
27	*Document Receipt Form (one copy only)				
28	*Current Status of Ongoing Studies approved by RGCB IHEC conducted by principal investigator (information may be submitted separately)				
29	Documentation of clinical trial registration (in Clinical Trial Registry of India) / any other WHO platform registry (whenever applicable)				

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30	*GCP training certificates of principal investigator, co-investigator/s, study coordinator/s for interventional clinical trial sponsored by pharmaceuticals companies of training taken in last 5 years (one copy only)				
31	Any other Documents submitted				

Annexure 3: AX 03/SOP 06/V2
Delegation of Responsibilities of Study team

Study Title _____

Name	Role	No.
	Principal Investigator	1
	Co-Investigator	2
	Co-Investigator	3
	Co-investigator	4
	Co-Investigator	5
	Co-investigator	6
	Study co-ordinator *	7
	Study co-ordinator *	7
	Laboratory Technician	8
		9
		10

* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor)


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(Please place tick marks against assigned duties for each member in the following table)

Code	TASKS	Role Played by Each Study Team Member									
		1	2	3	4	5	6	7	8	9	10
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										

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M	Review & sign of the lab reports										
N	Receive the study drug, document drug dispensing, storage & accountability										
O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										

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**Annexure 4: AX 04/SOP 06/V2
Document Receipt Form for Initial Review**

Protocol Number:	Submitted date:	
Protocol Title:		
Principal Investigator:		
Department		
Communication with the RGCB IHEC :	E-mail address Phone Fax	
For office use only		
Documents submitted:	<input type="checkbox"/> Complete documents <input type="checkbox"/> Incomplete documents <input type="checkbox"/> Resubmission Date	
Documents to be submitted later :	<input type="checkbox"/> final signed clinical trial agreement <input type="checkbox"/> informed consent form (in vernacular language) <input type="checkbox"/> study budget <input type="checkbox"/> DCGI <input type="checkbox"/> CTRI <input type="checkbox"/> GCP Training certificate <input type="checkbox"/> Other sites EC permission <input type="checkbox"/> Others.....	To verify and tick whether documents received. <input type="checkbox"/> final signed clinical trial agreement <input type="checkbox"/> informed consent form (in vernacular language) <input type="checkbox"/> study budget <input type="checkbox"/> DCGI <input type="checkbox"/> CTRI <input type="checkbox"/> GCP Training certificate <input type="checkbox"/> Other sites EC permission <input type="checkbox"/> Others..... <hr/> <input type="checkbox"/> Research methodology
Received by (Name and signature) :		
Date on which documents received:		

Note: Please bring this receipt with you when you visit the office of the Institutional Ethics Committee.

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Categorisation of New Research Study Protocols Received for Initial Review

SOP Code: SOP 07/V2

Date: November 30, 2019

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7.1 Purpose

The purpose of this SOP is to describe the procedure to categorize new research study protocols submitted by investigators for initial review by full committee/ expedited review committee or for exemption from review process.

7.2. Scope

This SOP covers the process of categorization of new research study protocols submitted to Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC) for initial review. It does not cover subsequent submissions.

7.3. Responsibility

It is the responsibility of the Member-Secretary (in consultation with Chairperson if necessary) to categorise the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants: Full board review, expedited review and exemption from review.

7.4. Detailed Instructions

7.4.1 New proposals received for initial review

- New research study proposals received on or before the date specified will be considered for review in the next RGCB IHEC meeting.
- The Secretariat will ensure that application of the research proposal is complete in terms of required documents (if any essential document is not available, an explanation must be sought in writing for the RGCB IHEC to review). (As per SOP 06/V2).

7.4.2 New proposals forwarded to Member Secretary

- The Secretariat will forward the soft copy of the research proposal to the Member Secretary for initial screening within 2 working days of receiving the proposal.
- The Member Secretary will screen the research proposals and categorise the proposals as elaborated in Section 7.4.3 within 2 working days of receipt.

7.4.3 Categorisation of New proposals for review by RGCB IHEC

The Member Secretary in consultation with Chairperson (if required) will categorise the proposals into three types of review processes, which along with the criteria to decide the type of review (www.icmr.nic.in Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, 2017) are explained below:

- **Full Committee Review:** When new research proposals and other related documents are tabled in a formally convened meeting of the Institutional


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Human Ethics Committee for detailed discussion and decision, this is called Full Committee Review.

- All research proposals presenting more than minimal risk that are not covered under exempt, emergency or expedited review should be subjected to full committee review, some examples are;
 - Research involving vulnerable populations, even if the risk is minimal;
 - Research with minor increase over minimal risk (see table 2.1 of ICMR guidelines 2017 for further details);
 - Studies involving deception of participants (see section 5.11 of ICMR guidelines 2017 for further details);
 - Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/ or modify any decision taken by the subcommittee or expedited committee;
 - Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
 - Major deviations and violations in the protocol;
 - Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
 - Research during emergencies and disasters either through an expedited review/scheduled or unscheduled full committee meetings. This may be decided by member secretary depending on the urgency and need; Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.
- **Expedited Review:** When new research proposals and related documents undergo a speedy review process by only two or three designated (by the Chairperson) Institutional Human Ethics Committee members it is called Expedited Review.
 - Expedited review may be sufficient if the research study involves not more than minimal risk as defined in the ICMR guidelines.
 - For example; Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
 - Research involving clinical documentation materials that are non-identifiable (data, documents, records);

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- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
 - Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
 - Minor deviations from originally approved research causing no risk or minimal risk;
 - Progress/annual reports where there is no additional risk, for example activity limited to data analysis.
 - Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and
 - For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local RGCB IHEC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
 - Research during emergencies and disasters covered by section 12 of ICMR guidelines 2017 (The following are examples of documents that will undergo expedited review but are NOT in the category of INITIAL review)
 - Revised proposal with minor modifications previously approved through full review by the RGCB IHEC.
 - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
- **Exemption from review:** When research fulfils the following criteria, the RGCB IHEC may grant an exemption from review:
 - Research does not involve live human participants, is on data in the public domain, or is on anonymised data derived from participants and the research has less than minimal risk to participants, an exemption from RGCB IHEC review may be considered.
 - Examples that may be eligible for exemption from review include:
 - Research conducted on data available in the public domain for systematic reviews or meta-analysis;
 - Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
 - Quality control and quality assurance audits in the institution;
 - Comparison of instructional techniques, curricula, or classroom management methods;
 - Consumer acceptance studies related to taste and food quality; and
 - Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is

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refinement and improvement of the programme or monitoring (where there are no individual identifiers).

7.5 Reference to other applicable SOPs:

- SOP 06/V2: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review
- SOP 7A/V2: Initial Full Board Review of New Research Study Protocols
- SOP 7B/V2: Expedited Review of New Research Study Protocols
- SOP 7C/V2: Exemption from the Ethics Review of Research Study Protocols

7.6. Flow Chart

No.	Activity	Responsibility
1	Receiving new research study proposal and related documents by a fixed date of the month	Secretariat
2	Verifying completeness of submitted research study documents	Secretariat
3	Forwarding of new proposals to Member Secretary RGCB IHEC	Secretariat
4	Categorization of the Protocols into 3 categories: full board, expedited review and exemption from review process	Member-Secretary/Member Secretary in consultation with Chairperson (if applicable)

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Initial Full Committee Review of New Research Study Protocols

SOP Code: SOP 07A/V2

Date: November 30, 2019

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7A1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC) members will perform an Initial full committee review of new research proposals using the Assessment Form.

7A2. Scope

This SOP applies to the initial review and assessment of all research study protocols submitted for review and approval from the RGCB IHEC. All research studies presenting with more than minimal risk and which do not qualify for exemption (See SOP 7C/V2) or expedited review (See SOP 7B/V2), are covered in this SOP.

7A3. Responsibility

7A.3.1. The Member Secretary is responsible, after categorisation of the studies (as per SOP 07/V2), to forward the studies to the Secretariat.

7A.3.2. The RGCB IHEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the RGCB IHEC members for review (If the study is categorised for Full Board review), and communication of the review results to the investigators.

7A.3.3. RGCB IHEC members (including Member Secretary) will be responsible for reviewing the research proposals and related documents within the given time frames.


7A.3.4. It is the responsibility of all the RGCB IHEC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.

7A.3.5. The RGCB IHEC members are responsible for attending and participating actively in the discussion at the full Board Meeting

7A.3.6. The Member Secretary is responsible for setting up the Full Board Meeting (SOP 07A/V2)

7A.3.7. The RGCB IHEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

7A.3.8. The Chairperson is responsible to sign and date the decision in the RGCB IHEC Decision Form AX 03/SOP 7A/V2.

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7A4. Detailed instructions

7A.4.1. Appointment of primary reviewers

The Member Secretary/Chairperson will appoint two or more primary reviewers for each study on the basis of expertise in the related field and experience. They may include one clinician and one non-technical person to the extent possible. More than two may be appointed if necessary.

7A.4.2. Distribute the protocol package

- a. The Secretariat will fill in the required details in the cover letter to the RGCB IHEC Members requesting initial review (AX 01/SOP 7A/V2) and in the study assessment form AX 02/SOP 7A/V2.
- b. The Secretariat will send a packet (hard or soft copy) to the RGCB IHEC members.
 - i. Letter to RGCB IHEC Members requesting Initial Review
 - ii. Study Submission Application Form AX 01/SOP 06/V2
 - iii. Protocol and related documents
 - iv. Study assessment form AX 02/SOP 7A/V2 in case it is to the Primary reviewer.


7A.4.3. Receive the distributed protocol package

- a. The RGCB IHEC members will receive the protocol package with the Study Submission Application Form AX 01/SOP 06/V2, in a CD or pen-drive or as hard copy (if desired so).
- b. Designated primary reviewers will also receive the Study Assessment Form for Initial Review AX 02/SOP 7A/V2

7A4.4. Verify the contents of the package

- a. The RGCB IHEC member will verify all the contents.
- b. The RGCB IHEC member will check the meeting date to see if it is convenient for most of the members to attend the meeting.
- c. The RGCB IHEC member will notify the RGCB IHEC Secretariat if any documents are missing or if the specified date of the RGCB IHEC meeting is not convenient to attend.

7A4.5 Review by the RGCB IHEC members

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7A4.5.1.Review of the protocol

- a. The proposal will be reviewed by each member as per guidelines to review a research proposal described in AX 05/SOP 7A/V2.
- b. The RGCB IHEC member will consider the following criteria when performing the review of the study protocol and the study related documents:
 - i. Scientific design and conduct of the study
 - ii. Risks and potential benefits
 - iii. Selection of study population and recruitment of research participants
 - iv. Inducements, financial benefits and financial costs
 - v. Protection of research participants' privacy and confidentiality
 - vi. Procedures for voluntary, informed consent
 - vii. Risk to participants
 - viii. Needs of dependent persons
 - ix. Community considerations
 - x. Qualifications of Investigators and assess adequacy of study sites
 - xi. Disclosure or declaration of potential conflicts of interest
 - xii. Ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.
 - xiii. Permission for access to participants from other institutions or bodies
- The RGCB IHEC member will consider the following criteria when performing the review of the Informed Consent Document (as per AX 05/SOP 7A/V2)
 - Voluntary, non-coercive recruitment, participation/ withdrawal
 - Procedures for obtaining informed consent

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- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document.
- Translation of the informed consent document in the local languages
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about the research project, participants' rights and injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support
- Treatment and compensation for study related injuries
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent process (investigator/investigator designee and witness (if applicable))
- Provision for audio-visual recording of consent process in case of regulatory clinical trials

7A4.6 Use of study assessment form for reviewers

- The assessment form is designed to standardise the review process.
- All reviewers will fill out the form (AX 01/SOP 7A/V2 - letter to RGCB IHEC members requesting initial review with study assessment form) and write their comments related to review of the research proposal.

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- In addition, primary reviewers will use the study assessment form (AX 02/SOP 7A/V2) to ensure that all elements of research study are reviewed and are accordingly documented during the discussion / meeting.
- The duly filled, signed and dated assessment forms will be returned along with the research proposals to the Secretariat 7 days prior to the meeting.

7A4.7 Gather the assessment reports

The RGCB IHEC Secretariat will collect soft copy and hard copy of the Assessment Forms, comments from each reviewer and file in the original study file. If the comments come as a soft copy, it will be collated for discussion at the meeting.

7A4.8 RGCB IHEC meeting

- At the commencement of the meeting itself members having conflict of interest, if any, on the proposals coming up for discussion shall disclose the same and be absent at the time when the particular proposal is taken up for consideration. Such absentees shall not be considered for the required quorum for the particular proposal. The minutes of the meeting shall also include details of such abstention.
- During the discussion at the meeting, the primary reviewer shall brief the members about summary of the study proposal and read out the comments and evaluation provided on the assessment form.
- The comments of independent consultant (if applicable) will be discussed by the member secretary.
- The other RGCB IHEC members shall give their comments right after the presentation.
- The investigator/sub-investigator may be called in to provide clarifications on the study protocol that she/he has submitted for review to the RGCB IHEC.
- The RGCB IHEC members will discuss and clarify the comments and suggestions.

The Member secretary (assisted by the Secretarial staff) shall record the discussions

- The final decision on the study will be recorded as: Approved/ Approved with recommendations/Revision with minor amendments/Revision with major amendments/Disapproved either by broad consensus or by voting (majority considered as 50%+1). Decision in the meeting shall be made by

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consensus or by majority votes and will be recorded in the RGCB IHEC Decision Form AX 03/SOP 7A/V2 by the Member Secretary.

- The following will not be eligible to participate in decision making or vote -
 - Absentee members who have declared conflict of interest
 - Member(s) of the committee who is/are listed as investigator(s) on a research proposal
 - An investigator or study team member invited for the meeting
 - An independent consultant invited for the meeting to provide opinion
 - Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee.
- In the case of decision to raise any query as a prelude to further consideration of the proposal, the Committee will specify whether the query responses and (if applicable) revised proposal will go only to the Chairman, Member Secretary, a specified subcommittee, to primary reviewers or to Full Committee before final approval. In case the sanction is granted taking into account the response by the Chairman or Secretary the fact will be reported to the RGCB IHEC at the next meeting.
- The response and changes carried out may be considered for discussion at a future RGCB IHEC meeting.
- If the RGCB IHEC decision is 'Disapproved / deferred' or calling for further details, clarifications or documents, the decision shall be communicated by the Secretariat to the Principal Investigator through appropriate letter within 14 days.
- If the study is approved, the Committee may, in appropriate cases, recommend monitoring of a study depending on the degree of risk involved.
- The Secretary shall prepare the minutes of the meetings of the RGCB IHEC with all relevant details including the list of participating members, and get it approved by the Chairman.
- The Secretary shall implement the decisions taken by the RGCB IHEC and maintain all required registers and records.

4.9 Final communication of the RGCB IHEC decision taken on the study to the Principal Investigator

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- When the study is approved by the RGCB IHEC, the Secretariat will prepare an approval letter AX 04/SOP 7A/V2 in the prescribed format which is to be sent to the Principal Investigator within 14 days of the meeting.
- If the Committee disapproves a study, the Secretariat immediately notifies the investigator in writing about the decision and the reason/s for not approving the study within 14 working days.
- A notifying letter to the investigator should state the following:
“If you are aggrieved by this decision, you may address the Chairman pointing out specific reasons if any, for concluding that the decision was erroneous or that it requires re-review. This will be done within four (4) weeks of the receipt of the committee’s decision. ”
- If the Committee has directed modifications to the scheme of research or sought for further documents, the Secretariat will send a written request to the investigator asking for the same. In such cases the Principal Investigator shall provide such additional details within six weeks.

4.10 Storage of Documents

- Records can be maintained in hard copies as well as soft copies.
- All records must be archived for a period of at least 3 years after the completion/ termination of the study.
- Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations.
- Records may be archived for a longer period, if required by the sponsors/regulatory bodies or the subject matter is involved in litigation.

4.11 Annexure

- Annexure 1: AX 01/SOP 7A/V2 Letter to RGCB IHEC Members requesting Initial Review with study assessment form.
- Annexure 2: AX 02/SOP 7A/V2 Study Assessment Form to be used by the Primary Reviewer
- Annexure 3: AX 03/SOP 7A/V2 Institutional Human Ethics Committee Decision Letter
- Annexure 4: AX 04/SOP 7A/V2 Format of Full Committee/Expedited Committee Approval letter
- Annexure 5: AX 05/SOP 7A/V2 Guidelines for reviewing a study protocol

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Annexure 1: AX 01/SOP 7A/V2

Letter to RGCB IHEC Members requesting Initial Review with study assessment form

Dear member,

The next meeting of the RGCB IHEC will be held on at in

You are requested to review the proposals in the package especially the ones marked to you as primary reviewer preferably within 5 working days of receiving the package. Please review the proposal and related documents as per the guidelines attached with Annexure 1 and provide your comments below and fill the study assessment form (for primary reviewers only) provided with the package (AX 02/SOP 7A/V2). Kindly confirm your availability for the meeting.

Name of Member	Date of Receipt	Signature	Attending meeting (Y/N)

Protocol Number : (as per RGCB IHEC records)		Date of receipt at RGCB IHEC office after review by E member (DD/MM/YY):	
Protocol Title :			
Name of the Principal Investigator		Designation	Department
Name of the Reviewer:			

Comments:

 RGCB <small>REGULATORY GUIDANCE FOR A BETTER TOMORROW</small>	RGCB IHEC SOP	SOP Version 2 Date: November 30, 2019
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Signature of RGCB IHEC member reviewing the study:		Date:
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Annexure 2: AX 02/SOP 7A/V2
Study Assessment Form to be used by the Primary Reviewer

Date of RGCB IHEC Meeting									
	D	D	M	M	M	Y	Y	Y	Y

Protocol Number :		Date (DD/MM/YY):	
Protocol Title :			
Principal Investigator:			
Department :			
No. of Participants at the site:		No. of Study site(s):	


Mark and comment on whatever items are applicable to the study.

Items	Comments
1 Objectives of the Study () Clear () Unclear	
2 Need for Human Participants () Yes () No	
3 How many participants? at the site () total including other sites ()	
4 Study design and methodology: () Appropriate and clear () Need changes	
5 Background Information applicable to rationale of objectives () Sufficient () Insufficient	

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<p>6 Risks and Benefits Assessment *</p> <p>Level of risk –</p> <ul style="list-style-type: none"> • Less than minimal • Minimal • Minor increase over minimal risk or low risk • More than minimal risk or high risk <p>Benefit to risk ratio</p> <p>() Acceptable () Unacceptable</p>	
<p>7 Inclusion Criteria:</p> <p>() Appropriate () Inappropriate</p>	
<p>8 Exclusion Criteria</p> <p>() Appropriate () Inappropriate</p>	
<p>9 Discontinuation and Withdrawal Criteria</p> <p>() Appropriate () Inappropriate</p>	
<p>10 Involvement of Vulnerable Participants *</p> <p>() Yes () No</p> <p>If yes, mechanism to protect vulnerable participants</p>	
<p>11 Sufficient number of participants (sample size)?</p> <p>() Yes () No</p>	
<p>12 Control Arms (placebo, if any)</p> <p>() Yes () No</p> <p>If yes, justification for the use of placebo</p>	
<p>13 Are qualification and experience of the Investigators appropriate?</p> <p>() Yes () No</p>	
<p>14 Disclosure or Declaration of Potential conflicts of Interest</p> <p>() Yes () No</p>	
<p>15 Facilities and infrastructure of Participating Site</p> <p>() Appropriate () Inappropriate</p>	
<p>16 Compliance to Regulations</p> <p>() Yes () No</p>	

17 Community Consultation if applicable * () Yes () No	
18 Contribution to Development of Local Capacity for Research and Treatment () Yes () No	
19 Availability of similar studies/Results () Yes () No	
20 Benefit to Local Communities () Yes () No	
21 Are blood/tissue samples being sent abroad? () Yes () No	
22 Need for informed consent/ Assent * () Yes () No	
23 Are procedures for obtaining Informed Consent appropriate? * () Yes () No	
24 Contents of the Informed Consent Document * () Complete () Incomplete	
25 Language of the Informed Consent Document * () Clear () Unclear	
26 Details of contact Person(s) for Participants () Yes () No	
27 Privacy & Confidentiality * () Yes () No	
28 Provision for Medical and or/ Psychosocial Support * () Appropriate () Inappropriate	
29 Provision for Treatment of Study-Related Injuries * () Appropriate () Inappropriate	
30 Provision for Compensation * () Appropriate () Inappropriate	

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31 If applicable, mention of storage of biological materials and/or data * () Appropriate () Inappropriate	
32 Will biological samples and/or data sent abroad? () Yes () No If yes, is I being submitted for HMSC?	
33 Involvement of Researchers and Institution in Publication of Results () Yes () No	

Comments on science, ethics and informed consent documents:

Note: * points for comment by non-scientist/bioethicist reviewer

Recommendation: approval/revision/non-approval of project

Reviewer's Signature with date:

Annexure 3: AX 03/SOP 7A/V2
Institutional Human Ethics Committee Decision Letter
(Re-Reg. No. ECR/484/Inst/KL/2013/RR-16)

Document No: RGCB/IHEC/250/2019/0-

Issue Date:

RGCB IHEC Protocol No:
Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee reviewed and discussed your application entitled, " "on August 20, 2019.
Principal Investigators:

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Review Type:

☒ Full Board review
 ☐ Expedited Review
 ☐ Exempted review

Type of Review:

☐ New
 ☐ Revised
 ☐ Continuing

The following recommendations were made by the RGCB IHEC.

Scientific aspects:

Ethical aspects:

Informed Consent Form(ICF)suggestions:

Upon discussion, the RGCB IHEC arrived at the following decision

☐ Approved
 ☐ Revision with minor amendments
 ☐ Revision with major amendments
 ☐ Deferred

Remarks:

1. For approved proposals: please retain a copy for reference and provide an annual progress report for continuing review.
2. For revision with major amendments: please address the recommendations of RGCB IHEC and provide documents for re-revision within 180days.
3. For revision with minor amendments: please address the recommendations of RGCB IHEC and provide documents for expedited review for approval.
4. Inform IHEC immediately in case of any serious adverse events.
5. Inform IHEC in case of any change of study procedures, site and investigator.
6. Inform IHEC in case of any protocol deviation/violation.


Yours Sincerely,

Member Secretary, RGCB IHEC.

Annexure 4: AX 04/SOP 7A/V2
Format of Full Committee/Expedited Committee Approval letter

Date...../...../.....

To,

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Dr.....,

Dept. of.....

Ref: The study no. IHEC/xxx/20xx entitled, “.....”. Sub: Letter no.

Dear Dr.....,

The meeting of the Ethics Committee (RGCB IHEC) was held on..... at
....., in the.....with..... as Chairperson.

.....number of members attended the meeting held on..... The
list of members who attended the meeting is as follows.

Name of Members	Position on RGCB IHEC	Designation & Affiliation


It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The RGCB IHEC has reviewed and approved the following documents submitted for this clinical study at the meeting.

1. Xxx
2. Xxx
3. xxx

The RGCB IHEC hereby approves the proposal entitled, “.....”.

It is understood that the study will be conducted under your direction, in a total of
..... number of research participants, _____ as per the
submitted protocol.

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This approval is valid for three years.

It is the policy of RGCB IHEC that any onsite serious adverse event or the unexpected adverse event to be reported within 24 hours as per the formats specified in SOP 09/V2 to the RGCB IHEC office or by email if its holiday.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the RGCB IHEC of an appropriate amendment. The RGCB IHEC expects that the investigator should promptly report to the RGCB IHEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies, which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before XXXXXXXXXXXX.

A copy of the final report should be submitted to the RGCB IHEC for review.

The RGCB IHEC functions in compliance with applicable guidelines and regulatory requirements.

Sincerely yours,

Member Secretary,

RGCB IHEC

(Signed and dated by the RGCB IHEC Member Secretary)


Date of approval of the study: XX/XX/20XX

Annexure 5: AX 05/SOP 7A/V2

Guidelines for reviewing a study protocol

Reviewers should make use of the following points while reviewing research studies which relate to scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.


- How will the knowledge, result or outcome of the study contribute to human well-being?
 - Knowledge from the basic research may possibly benefit.

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- ❑ A new choice of method, drug or device that benefits the research participants during the study and others in the future.
- ❑ Provide safety data or more competitive choices.
- ❑ Will the study design be able to give answers to the objectives?
- ❑ The endpoints are appropriately selected.
- ❑ The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
- ❑ The control arm is appropriately selected for best comparison.
- ❑ The placebo is justified.
- ❑ The number of study participants in non-treatment (or placebo) arm is minimized.
- ❑ Unbiased assignment (e.g. randomization, etc.) is in practice.
- ❑ Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
- ❑ The sample group size appropriate with the given statistical assumptions.
- ❑ Predictable risks are minimized.
- ❑ The tests and procedures that are more than minimal risk are cautiously used or could be replaced by those, which have lesser risk without compromising the scientific logic.
- ❑ Deception of Research participants is avoided.
- ❑ Instruction and support systems such as counselling for study participants are included (if needed) when deception is integral to the study design.
- ❑ The study participants are adequately assessed and provided follow-up care, if needed.
- Who will be the participants in the study? Whether
 - ❑ The described population is appropriate for the study.
 - ❑ Predictable vulnerabilities are considered.

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- ❑ It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
 - ❑ There will be secondary participants.
- Do the inclusion and exclusion criteria
 - ❑ Selectively include participants most likely to serve the objective of the study?
 - ❑ Equitably include participants?
 - ❑ Properly exclude participants who can predictably confound the results?
 - ❑ Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?
- Does the study design have adequate built-in safeguards for risks?
 - ❑ Appropriate screening of potential participants?
 - ❑ Analysis of the results after a stepwise dose escalation
 - ❑ Does the frequency of visits and biological samplings reasonably monitor the expected effects?
 - ❑ Are there defined stopping (discontinuation) / withdrawal criteria for participants with worsening condition?
 - ❑ Is there minimized use of medication withdrawal and placebo whenever possible?
 - ❑ Will rescue medications and procedures be allowed when appropriate?
 - ❑ Is there a defined safety committee to perform interim assessments, when appropriate?
 - ❑ Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.
- Is pre-clinical and/or early clinical studies sufficiently performed before this study?
 - ❑ The animal study and *in vitro* testing results?
 - ❑ Previous clinical results, if done?

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- ❑ Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
- ❑ The selected dose based on adequate prior results?
- ❑ Monitoring tests designed to detect expected possible risks and side effects?
- Do the study and the informed consent process include issues of special concern, such as:
 - ❑ Waiver or alteration of consent?
 - ❑ Delayed consent (e.g., emergency treatment, etc.)?
 - ❑ Deception?
 - ❑ Sensitive information of participants that may require a confidentiality statement?

Guidelines to review Informed Consent Document/Patient Information Sheet

The actual process of informed consent should:

- ❑ Give the participants significant information about the study.
- ❑ Make sure the participants have enough time to carefully read and consider all options.
- ❑ Answer all questions of the participants before making decision to participate.
- ❑ Explain risks or concerns to the participants.
- ❑ Make sure that all information about the research and consent process is understood to the satisfaction of the participants.
- ❑ Make sure the participants understand the study and the consent process.
- ❑ Obtain voluntary informed consent to participate.
- ❑ Make sure the participants can freely consent without coercion, pressure or other undue influences.
- ❑ Consent should be verified on a continuing basis especially when changes in design of the research or new information are available.

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- If participant is illiterate than her/his legally authorized/acceptable representative should sign consent on her/his behalf in the presence of impartial witness.
- Permission for access to participants from other institutions or bodies

7. Flow Chart


No.	Activity	Responsibility
1	Receive package or research proposal and research related documents package	Secretariat
2	Verify contents and distribute	Secretariat
3	Appointment of primary reviewers	Member Secretary/Chairperson
4	Initial review of documents, Fill review assessment form	RGCB IHEC members
5	RGCB IHEC board meeting, discussion and decision	RGCB IHEC members, Member Secretary, Chairperson
6	RGCB IHEC decision communicated to PI	Secretariat
7	Storage of study related documents with relevant correspondence	Secretariat

 RGCB <small>DISCOVERIES FOR A BETTER TOMORROW</small>	RGCB IHEC SOP	SOP Version 2 Date: November 30, 2019
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Expedited Review of Research Study Protocols

SOP Code: SOP 07B/V2

Date: November 30, 2019

	RGCB IHEC SOP	SOP Version 2 Date: November 30, 2019
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7B1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC) members will perform an expedited review of new research proposal and revised proposals with minor amendments/administrative corrections using a prescribed procedure.

7B2. Scope

This SOP applies to the review and approval of research proposals and related documents, which qualify for expedited review by the RGCB IHEC as per ICMR's Ethical Guidelines 2017. These should carry not more than minimal risk and should fulfil the criteria for expedited review.

7B3. Responsibility

- The Member Secretary in consultation with the Chairperson if necessary, will determine if the proposals qualify for expedite review and is responsible, to forward them to the Secretariat.
- The RGCB IHEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the designated RGCB IHEC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators.
- Designated RGCB IHEC members (including Member Secretary and/or Chairperson) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of the designated RGCB IHEC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The RGCB IHEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.
- The Chairperson is responsible to sign with date in the decision of the RGCB IHEC.

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7B4. Detailed instructions

7B4.1 Appointment of reviewers

After determining whether the Proposal/ Project qualify for an expedited review, the Member Secretary (in consultation with Chairperson) will nominate two or more RGCB IHEC members to review the amended protocol.

7B4.2 Distribution of the protocol package

- The Secretariat will fill in the required details in the nomination form to the RGCB IHEC Members requesting initial review.
- The Secretariat will send a packet (*hard or soft copy*) to the designated RGCB IHEC members.
 - Nomination letter to RGCB IHEC Members requesting initial review (AX01/SOP 7B/V2)
 - Study assessment form (AX02/SOP 7B/V2)
 - Project Submission Application Form
 - Protocol and related documents

7B4.3 Receive the distributed protocol package:

Designated RGCB IHEC members will receive the protocol package with the Project Application Form, in a soft and/or hard copy.

7B4.4 Verify the contents of the package


- The RGCB IHEC member will verify all the contents and will notify the RGCB IHEC Secretariat if any documents are missing.

7B 4.5 Review by the RGCB IHEC members

- RGCB IHEC members will review the protocol within the seven days of receiving the package.
- The comments of the RGCB IHEC members will be duly recorded.
- If deemed necessary, the proposal may be sent to an expert/independent consultant for review.

7B 4.6 Gather the assessment reports.

The RGCB IHEC Secretariat will collect the Assessment Forms with the comments from each designated reviewer of RGCB IHEC and file in the original study file.

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7B 4.7 Decision and Communication of decision to PI and RGCB IHEC full board

- The Member Secretary will discuss the comments of the members with the Chairperson and a decision about the protocol will be taken.
- If there are queries these will be sent to the PI within one working day after receipt by the Secretariat in consultation with Member Secretary.
- The reply from the PI will be discussed by the Member Secretary with the Chairperson or the designated RGCB IHEC members and a decision will be reached.
- The final decision will be recorded on the Study Assessment Form for expedited review.
- The decision will be informed to the RGCB IHEC members at the full committee meeting.
- If deemed necessary by reviewer(s), Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full committee meeting before final decision. The final decision by the Chairperson is recorded on the Study Assessment Form for expedited review.
- The Secretariat will send the Study approval letter to the PI (AX 04/SOP7A/V2).
- If project is deferred or requires resubmission after certain modifications, this will be informed to the Principal Investigator in writing.
- The reasons for deferrel of a project will be specified in the letter sent to PI.
- The expedited review process should be completed within 14 working days.

7B5. Flow Chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review	Member Secretary
3.	Approve the Secretary's recommendation regarding the protocols for expedited review	Chairperson
4.	Expedited process	RGCB IHEC Members/Chairperson
5.	Decision of RGCB IHEC	Chairperson
6.	Communicate with the RGCB IHEC and the Investigator	Member Secretary/ Secretariat

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7B6. Annexure

- Annexure 1 AX 01/SOP 7B/V9 - Form for nomination of RGCB IHEC members for Review
- Annexure 2 AX 02/SOP 7B /V9 -Study Assessment Form for Expedited Review
- Annexure 3 Format for Full committee/Expedited Committee Approval letter AX04/SOP 7A/V2

Annexure 1 AX 01/SOP 7B/V2 Form for nomination of RGCB IHEC Members for Review

Date:

To,

.....
Member, RGCB IHEC,

Ref: The project no.....entitled.....

Sub: Review of

Dear Dr.

The following document/s has/ have been submitted to the RGCB IHEC for review.

1. _____
2. _____
3. _____
4. _____
5. The following members were present to review/ carry out an expedited review of the abovementioned documents.
 1. _____
 2. _____
 3. _____

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For expedited review, you are requested to fill the study assessment form enclosed and send to the RGCB IHEC office within 7 working days:

Signature of Member Secretary with date

Annexure 2AX 02/SOP 7B/V2

Study Assessment Form for Expedited Review

RGCB IHEC Protocol Number :		Date of receipt at RGCB IHEC office (...../...../.....):
Project Title _____		
Name of the Principal Investigator	Department	Contact number
Total no. of Participants at the site:		
No. of Study sites:		
Sponsor:		

Duration of the Study:	
Reviewer's name :	
Type of the Study :	<input type="checkbox"/> Intervention <input type="checkbox"/> Epidemiology <input type="checkbox"/> Observation <input type="checkbox"/> Document based <input type="checkbox"/> Genetic <input type="checkbox"/> Social Survey <input type="checkbox"/> Others, specify.....
Description of the Study in brief: Mark whatever applied to the study.	
<input type="checkbox"/> Randomized <input type="checkbox"/> Open-labelled	

- ☐ Double blinded ☐ Placebo controlled ☐ Treatment controlled
☐ Cross-over ☐ Parallel ☐ Interim Analysis
☐ Use of Tissue samples ☐ Use of Blood samples ☐ Use of genetic materials

Comments:

(Review the protocol and related documents as per the guidelines)

Provisional Decision: ☐ Approved ☐ Resubmission

☐ Disapproved ☐ Full Board

☐ Approved with modifications

Reason for disapproval

Name of the RGCB IHEC member _____

Signature _____ **Date** _____

Final Decision:

Approved YES NO

If disapproved, reasons for disapproval

Further revision with major or minor amendments for resubmission

Any Other _____


Signature of the Member Secretary: _____ **Date:** _____

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Exemption from Ethics Review of Research Study Protocols

SOP Code: SOP 07C/V2

Date: November 30, 2019

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7C1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for exemption from ethics review and approval of a research protocol.

7C2. Scope

This SOP applies to the review of protocols categorized as suitable for exemption from review by the Member Secretary in consultation with the Chairperson. Any research that carries less than minimal risk and fulfils criteria for exemption from review is covered in this SOP.

7C3. Responsibility

- It is the responsibility of the Member Secretary in consultation with the Chairperson to record the decision in the Exemption Form with reasons.
- The RGCB IHEC Secretariat is responsible for recording and filing the decision including the reasons for that decision.
- The Chairperson must sign and date letter conveying the decision.

7C4. Detailed instructions


7C4.1 Receive the submitted documents.

- The Secretariat will receive the Exemption from review Application Form, Protocol and other documents submitted by the investigators.
- The Secretariat will check that the package is complete and will forward it to the Member Secretary for review

7C4.2 Determine proposals eligible for exemption from review

- The Member Secretary will screen the research proposal and determine whether the study qualifies for exemption from review based on the criteria laid down in the Ethical Guidelines of Indian Council of Medical Research (ICMR) about the type of research that involve less than minimal risk fall under this category.
- In some circumstances, research that appears to meet low risk criteria may need to be reviewed by the RGCB IHEC. This might be because of requirements of the publisher of the research or the organization which is providing funding resources and/or existing data or as a condition for access to participants.

7C4.3 Exemption Process

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- If the protocol and related documents satisfy the above stated criteria, the Member Secretary in consultation with the Chairperson will review the brief summary of the project and the Exemption Form.
- The Member Secretary records the decision on the Exemption Form.
- The Secretariat communicates the decision to the investigator.
- The Member Secretary / Chairperson may place the application for review and decision regarding exemption at the next full committee meeting.

7C4.4 Communication

- The decision regarding request for Exemption from review, signed by the Member Secretary of the RGCB IHEC, will be forwarded by the Secretariat to the Principal Investigator within 14 working days after the decision regarding the exemption is taken.
- The Member Secretary will inform the RGCB IHEC members of the decision at the next regular meeting and minute it.

7C5. Flow Chart

No.	Activity	Responsibility
1	Receive the submitted documents.	RGCB IHEC Secretariat
2	Review of proposal and Exemption Form	Member Secretary
3	Recording the decision on Exemption Form in consultation with the Chairperson	Member Secretary
4	Communicate the decision to the Investigator	RGCB IHEC Secretariat
5	Informing the decision to the members in the forthcoming meeting	Member Secretary
6	Recording and filing the decision	RGCB IHEC Secretariat

7C6. Annexure: Annexure 1 - AX01/SOP 7C/V2

Annexure 1 AX01/SOP 7C/V2 Review Exemption Application Form

1 Principal Investigator's Name:

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2 Department:

3 Title of Project:

4 Names of other participating staff and students:

5 Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants 'description, and procedures/methods to be used in the project:-

6 State reasons why exemption from ethics review is requested?

- ✓ Research conducted on data available in the public domain for systematic reviews or meta-analysis
- ✓ Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person
- ✓ Quality control and quality assurance audits in the institution or audit of educational practices
- ✓ Comparison of instructional techniques, curricula, or classroom management methods
- ✓ Consumer acceptance studies related to taste and food quality
- ✓ Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain

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✓ Any other -
.....

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Principal Investigator's signature: _____ **Date** _____

Forwarded by the Head of the Institute:

Name: _____

Signature: _____ **Date** _____

Recommendations by the RGCB IHEC Member Secretary:

Exemption recommended

Cannot be exempted,

Reasons as discussed in full committee

Signature of the Member Secretary: _____

Date _____

Final Decision at Full Board meeting held on:

Exemption allowed/ cannot be exempted,

Reasons _____

Signature of the Chairperson: _____


Date _____

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Agenda Preparation, Meeting Procedures, and Recording of Minutes

SOP Code: SOP 08/V2

Date: November 30, 2019

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8.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, and minutes.

8.2 Scope

This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all RGCB IHEC meetings.

8.3 Responsibility

- It is the responsibility of the Member Secretary assisted by the Secretariat to prepare the agenda for the RGCB IHEC meeting
- The Chairperson will review and approve the agenda
- It is the responsibility of the Member Secretary to ensure proper recording and dissemination of the minutes after the meeting is over.
- It is the responsibility of all members to read and approve the minutes sent to her/him.
- The Chairperson will review and finally approve the minutes

8.4 Detailed instructions


8.4.1 Committee meeting

- The RGCB IHEC Full Board meeting will be scheduled once in three months or as per requirements whichever is earlier.
- Even if there are no new research proposals for review, the gap between two full committee meetings will not exceed 12 weeks.
- If there is a long gap between two meetings the reason for the gap should be documented

8.4.2 Preparation of meeting agenda of full committee

The Member Secretary assisted by the Secretariat will prepare the meeting agenda with date, time and venue of the meeting and will include following subtopics as given below:


- The Secretariat will collect and verify all forms/documents for completeness and make them available in the meeting.

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- The Secretariat will schedule protocols in the agenda as per date of receipt.
- The agenda for the IHEC meeting is prepared at least 15 days in advance before the date of meeting.
- Answers to the RGCB IHEC queries, amended study related documents (Protocol, ICD, CRF and IB) or matter related to safety of participant received from the investigators in due time (4 days prior to the date of the meeting) and any item in emergent and very exceptional circumstances will be included in the additional agenda. This would be done at the discretion of the Chairperson. Member Secretary in consultation with the Chairperson would prepare this.
- Any study-related document which is not presented in due time will not be considered for the meeting.
- Any exempted protocol approved has to be included for ratification in the agenda.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed sufficiently in advance to the RGCB IHEC members through telephone, SMS/ Whatsapp / e-mail or any other electronic means.
- The Secretariat will normally send the final agenda along with notice of the meeting 10 days before the scheduled meeting.
- The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting.

8.4.3 During the meeting

- Meeting will be held as scheduled provided the required quorum is there.
- The Secretariat will obtain the signatures of all the RGCB IHEC members on the attendance register.
- Experts/independent consultants if invited will sign Confidentiality and COI agreement (AX 01/SOP 04/V1) and also if there are guests/observers (AX 01/SOP 05/V1).
- The meeting will begin with a welcome note by the Member Secretary and remarks by the Chairperson
- The Chairperson will initiate the meeting after ensuring that the quorum has been met. The Chairperson at her/his discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.

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- The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict (AX0 /SOP IV).
- If a member has declared conflict of interest, the Chairperson will ask the member concerned to leave the meeting room when the concerned issue is being discussed and this will be minuted.
- The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict.
- The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes of the previous meeting will be considered as confirmed.
- If applicable, the Member Secretary will also ask the members if there is any issue to be raised regarding the list of proposals exempted and approved through expedited process.
- The Member Secretary will present the agenda of the day's meeting for discussion.
- The meeting shall generally proceed in the order as in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed if required.
- In case of projects submitted for initial review; the detailed instructions given in this SOP will be followed.
- Investigators who have been asked by the RGCB IHEC secretariat to provide additional information or clarifications related to their project may do so and attend the RGCB IHEC meeting if permitted to do so. The discussion amongst RGCB IHEC members will not be done while the investigator is in the meeting room.
- Any other matter will be presented by the Member Secretary for comments by the members which will be noted.
- The Member-Secretary assisted by the secretarial staff will record the list of discussions and decisions arrived at for each item in the agenda and will read it before the decision is taken by the Chairperson.

8.4.4 Decision making

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- The final decision on each proposal/ issue discussed in the meeting shall be by broad consensus. In case there is absence of consensus for any reason the majority view recorded as per vote shall be accepted as the decision of the RGCB IHEC.
- Decisions will include approval, disapproval, revision with minor or major amendments, suspension or termination of an ongoing study
- The following persons shall not have the right to vote at the meeting:
 - Member(s) of the committee who is/are listed as investigator(s) on a research proposal that comes up before the discussion in that meeting.
 - An investigator, special invitee (expert) or study team member invited for the meeting.
 - RGCB IHEC members attending through telecom/Skype or other media.

8.4.5 After the Committee meeting

- The Secretariat will prepare the minutes of the meeting in a concise and easy-to-read style soon after the meeting.
- The Secretariat will make sure to cover all contents in each particular category to include the following:
 - Venue of the meeting.
 - Meeting number, date/duration of the meeting (time of commencement and end)
 - i Names of the Chairperson of the meeting, RGCB IHEC members and invitees attending the meeting.
 - ii Name of the individual serving as Chairperson of the meeting
 - iii Details of the study including name of the Sponsor and Investigator(s).
 - iv Protocol number/date/version of protocol.
 - v Names of the Primary Reviewers who presented their findings, if any.
 - vi Follow-up action, if any.

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- vii Summary of minutes highlighting aspects on science, ethics and informed consent document.
- viii Reference to the investigator approval letter that lists all changes requested by the RGCB IHEC (AX04/SOP7A/V2).
- ix Determination of the date for continuing review, if any.

Requirements for each study or activity requesting Expedited Review:

- o Sponsor's name.
- o Protocol number.
- o Investigator's name
- o Lists of expedited approval requests and outcomes.

Requirements for each Continuing Review Report:

- o Sponsor's name, if applicable.
- o RGCB IHEC Protocol number.
- o Investigator's name.
- o Indications of the Committee's determination to continue, terminate, or amend the study.
- o Lists of recommendations or actions to be taken up with the investigator, if applicable.

Requirements for each Adverse Event notification and Final Report:

- o Sponsor's name, if applicable.
- o RGCB IHEC Protocol number.
- o Investigator's name.
- o Report or summary of report provided by the SAE sub-committee.
- o Actions deemed appropriate by the RGCB IHEC.

Requirements for Termination of Approval:

- o Name of the Sponsor.
- o Protocol's EC number.

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- Investigator's name and reason for termination.

8.4.6 Approval of the minutes


- The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairperson for review and approval within 7 working days of the meeting day.
- The Chairperson indicates approval by signing and dating the minutes.
- On receipt of approval from the Chairman, the Secretariat will email the minutes of the meeting to the RGCB IHEC members.

8.4.7 Filing the minutes

- The Secretariat will place the approved versions of the minutes in the minutes file.
- The Secretariat will file the RGCB IHEC Decision Forms in the project files and place all correspondence in the appropriate files.
- The Secretariat will send a list of the studies approved and rejected by the RGCB IHEC at its IHEC meetings along with the details of the study including name of the Principal Investigator, to the Head of the Institute, within 21 days of the RGCB IHEC meeting.

8.4.8 Calling an Emergency Meeting of RGCB IHEC

- The Member Secretary in consultation with Chairperson may decide to call an emergency meeting for any one or more of the following reasons:
 - Urgent issues which, if not decided upon early, could adversely affect or have adverse impact on patient safety, public safety or national significance etc.
 - Occurrence of unexpected serious adverse event(s).
 - Other reasons, as deemed appropriate by the Member Secretary with concurrence of the Chairperson.
- The Secretariat will endeavour to contact each and every RGCB IHEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting.
- The secretariat will prepare packets for distribution to the members containing the information and documents about the matter(s) for which emergency meeting is scheduled or send the relevant details via email.

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- During the meeting, the Chairperson will determine if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least four members (including one scientific and one non-scientific member) are present, given the urgency of the matter under consideration. The IHEC members will act according to the relevant IHEC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full committee meeting.

8.4.9 Releasing IHEC Decision Letters

- IHEC decision letters will be prepared by the secretariat SOP 7A/V2
- Member Secretary will sign the decision letters & it will be released to the investigators within 14 working days after the meeting day.

8.5 References to other applicable SOPs

SOP 05/V2: Procedures for allowing Guest/ Observer to visit Institutional Human Ethics Committee or attend IHEC meeting

SOP 06/V2: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

SOP 07/V2: Categorization of Submitted Protocols for Ethics Review

SOP 07A/V2: Initial Full Committee Review of New Research Study Protocols

8.6 Flowchart

No.	Activity	Responsibility
1	Preparation of meeting agenda prior to a Committee meeting	Member Secretary in consultation with the Chairperson
2	During the Meeting	Secretariat, Members and Chairperson
3	After the Committee Meeting preparation and submission of the draft Minutes for approval of the Chairman.	Secretariat/ Member Secretary
4	Approval of minutes	IHEC members / Chairperson

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5	Communicating the decision to the investigators	Secretariat
6	Filing the minutes	Secretariat
7	Calling an emergency meeting	Member Secretary in consultation with Chairperson

8.7 Annexure

- Annexure 1 AX 01/SOP 08/V2 - Agenda format
- Annexure 2 AX 02/SOP 08/V2- Conflict of Interest form to be signed by RGCB IHEC member before board meeting

Annexure 1

Agenda for RGCB Institutional Human Ethics Committee- Month/Year

Meeting No: Date : Time:

Venue : Faculty Seminar Room, RGCB

Members list

SI No	Members	Role
1	Justice K Padmanabhan Nair	Chairperson
2	Mr. Raman Srivastava IPS	Vice Chairperson/Lay person
3	Dr. Ramankutty V	Medical Scientist
4	Dr. Ramadas K	Medical Scientist
5	Dr. Easwer H.V	Clinician
6	Dr. Nandini Kumar	Ethicist
7	Dr. Rema Devi S	Social scientist
8	Adv. Benoy George	Legal expert
9	Dr. Devasena Anantharaman	Member Secretary
10	Dr. Debasree Dutta	Alternate Member Secretary/Basic Scientist
11	Dr. Priya Srinivas	Basic Scientist
12	Dr. Sreekumar	Basic Scientist
13	Dr. Asha Nair	Basic Scientist

Independent consultants list

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SI No	Name	Specialisation
1	Dr. Saji George	Pharma based clinical trials
2	Dr. G.B.Nair	Microbiome specialist
3	Dr. E V Soniya	Genomics specialist
4	Dr.T.R.Santhosh Kumar	Drug Development

- Welcome Address- Director/ Member Secretary 10.30 am -10.35 am
- Introductory remarks by the Chairman, RGCB-IHEC 10.35am - 10.40 am
- COI declaration by members, if any 10.40am – 10.45am
- Initial Review of Project Presentations by PI/Co-PI and Discussions 10.45 am - 01.30pm
- Lunch break 01.30pm - 02.00pm
- Re-submission 02.00pm – 03.00pm
- Special Requests/Protocol amendments 03.00 pm - 03.30 pm
- Exempted protocol details 03.30pm – 04.00pm
- Progress reports/ completion report 04.30pm – 05.00pm
- Protocol Violation/Deviation/SAE/Site visit report 05.00pm – 05.30pm

SI.No	IHEC Protocol No	PI of the proposal	Title	Sponsor	Primary Reviewer
-------	------------------	--------------------	-------	---------	------------------

- Summarising the Proceedings of the Meeting and Closing Remarks 05.30pm - 06.00pm

SI No	IHEC Protocol No	PI of the proposal	Primary reviewer	Initial comments of EC	PI comments	EC Comments

Order of presentations for Initial Review

Order of presentations for Re-submission

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Annexure 2

Conflict of Interest form to be signed by RGCB IHEC member before board

Date:

To,
The Chairperson,
RGCB IHEC,

I hereby declare the conflict of interest for the project no. IHEC/ /
Entitled, _____ as
:

1. I am the investigator / co-investigator/Author/member of research team
2. I have the following interest in the subject matter of the study under review

- 1) _____
- 2) _____
- 3) _____

Member, RGCB IHEC


Countersigned
Chairperson, RGCB IHEC

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Review of Resubmitted Amended Protocols and Protocol-related Documents

SOP Code: SOP 09/V2

Date: November 30, 2019

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9.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC) manages resubmitted amended study protocols.

9.2. Scope

This SOP applies to the review of research proposals and related documents that have been resubmitted to the RGCB IHEC as amended ones by the Principal Investigator (PI) with clarifications and modifications sought by the RGCB IHEC in initial review.

9.3. Responsibility

- It is the responsibility of the RGCB IHEC Secretariat to ensure the completeness of the documents submitted to the RGCB IHEC.
- Research proposal and related documents revised with minor amendments will undergo expedited review and if they are revised with major amendments they will undergo a full committee review. Additionally, primary reviewers who had reviewed the initial submission may be asked to review the resubmitted proposal and related documents, if any.

If the amendment(s) is/are of administrative nature an expedited review will be undertaken, while if the amendment/s relate to participant safety or data capture full committee review should be recommended. This information would be recorded (during the meeting) on the RGCB IHEC Decision Form.


9.4. Detailed instructions

9.4.1. Receipt of resubmitted protocol and its distribution

- The Secretariat will verify if the PI has replied to RGCB IHEC queries within 14 days of receipt of the letter of comments by the RGCB IHEC.
- If PI does not submit the revised proposal and/or clarification called for by the RGCB IHEC as above, a reminder will be sent after 30 working days of sending the letter. This will be repeated twice at 10 days interval. In case of continued non response/failure within 30 days despite the reminders, all further action regarding the proposal will be dropped and the file will be closed.
- The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat and verified.

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- The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator (PI).
- The Secretariat will check the resubmitted protocol and related documents (hard and soft copy) for the following items
 - ❖ List of point wise reply to the RGCB IHEC letter of comments
 - ❖ Revised version of protocol and/ or the informed consent document and /or any other related documents such as, case report forms, diary sheets, etc. are submitted with the changes made to the documents either underlined or highlighted.
- The amended proposal and related document will require Full Committee review if any of the following changes:
 - ❖ The Protocol amendment changes the risk-benefit assessment such as
 - i a change in study design
 - ii additional treatments or the deletion of treatments
 - iii Changes in inclusion/exclusion criteria.
 - iv change in method of dosage formulation, such as, oral changed to intravenous
 - v Changes in procedures, number of visits/ follow up period or the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant).
 - vi Major changes in the Informed consent document.
- For expedited review, the Chairperson/ Member Secretary will use prescribed form.
- The Secretariat will refer to the RGCB IHEC Decision Form on the given protocol and distribute the documents containing the reply to the query letter, revised protocol and related documents along with Assessment Form for resubmitted protocol to-
 - ❖ The Member Secretary for summarizing and including it in the agenda for full committee review in the forthcoming meeting if the decision on the protocol was 'to be discussed at full committee meeting'
 - ❖ The designated RGCB IHEC members if the decision on the proposal was 'to be reviewed by primary reviewers/two or more RGCB IHEC members.

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- ❖ The Chairperson/Member Secretary if the decision on the protocol was 'Approved with recommendations subject to review by Chairperson/Member Secretary only' as per RGCB IHEC Decision Form.

9.4.2. Review of revised protocol by RGCB IHEC member/Member Secretary/Chairperson:

- The RGCB IHEC member/ Member Secretary/ Chairperson will refer to the query letter/ comments as guidance for the review and consider whether the recommendations of the RGCB IHEC have been followed or adequately responded to.
- The RGCB IHEC member/ Member Secretary/ Chairperson will make further comments where appropriate, in the Assessment Form for resubmitted protocol.
- The Secretariat will retrieve the Assessment Form for resubmitted protocol from the members/Member Secretary/Chairperson.
- In case the decision is to discuss the revised protocol at the full committee meeting, the Member Secretary will present a brief oral summary of the study design and the comments of the RGCB IHEC members/Chairperson in the RGCB IHEC Full Committee meeting.
- The Chairperson shall invite discussion on the protocol revision from all the RGCB IHEC members.
- The final decision regarding the research project shall be reached by consensus/voting and shall be one of the following:
 - a. Approved
 - b. Further modifications to items noted at the convened meeting and follow-up by the Chairperson/Member Secretary/RGCB IHEC members after receipt of the requested modifications for placing in the next meeting
 - c. Not approved giving reasons for disapproval
 - d. Suspend the study, until further information is obtained
- In case the revised protocol is already approved through expedited review, the decision is informed to the members at the full committee meeting.

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- The primary reviewer/RGCB IHEC members performing the review must sign and date the form and return this to the Secretariat after the review.

9.4.3 Communication of the Decision to the Principal Investigator

- If the RGCB IHEC approves the protocol/ informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 14 working days of the meeting.
- The decision regarding disapproval (stating reasons) or request for specific modifications shall be communicated in writing to the investigator within 14 working days of the meeting.
- The letter of comments sent to the investigator shall state that the reply to the letter is expected within stipulated time (within 14 days) and in the absence of any response to the reminders, the project will be declared closed.
- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full committee meeting.

9.5 Flowchart

No.	Activity	Responsibility
1.	Receive the Protocol amendment / Resubmitted protocol	RGCB IHEC Secretariat
2.	Notify the Member Secretary / Chairperson of the RGCB IHEC	RGCB IHEC Secretariat
3.	Determine whether full committee review / review by designated members is needed	RGCB IHEC Member Secretary/ Chairperson
4.	Nomination of Members for review	RGCB IHEC Chairperson
5.	Distribution to RGCB IHEC members	RGCB IHEC Secretariat
6.	Protocol Amendment/ Revised documents Review	RGCB IHEC Members / Member Secretary / Chairperson
7.	RGCB IHEC Decision	RGCB IHEC Member Secretary / Chairperson

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8.	Communication of the Decision to the Principal Investigator	RGCB IHEC Secretariat
9.	Store documents	RGCB IHEC Secretariat

9.6 Annexure

- Annexure 1: AX 1/SOP 09/V2 Assessment of Resubmitted Protocol
- Annexure 2: AX 2/SOP 09/V2 Proposal and/or related documents Amendment Request and Assessment Form
- Annexure 3: AX 3/ SOP 09/V2 Approval letter for Proposal Amendment/Document Amendment.

Annexure 1: AX 1/SOP 09/V2 Assessment of Resubmitted Protocol

RGCB IHEC Protocol Number Protocol Title:	
Number of review : <input type="checkbox"/> 2 nd Review <input type="checkbox"/> 3 rd Review <input type="checkbox"/> 4 th Review	
Principal Investigator:	Department:
Date of Initial Review by RGCB IHEC:	Date of Last Review:
The RGCB IHEC Decision recorded in the meeting minutes: (meeting held on _____)	
Opinion of the reviewer:	
Approved	<input type="checkbox"/> Yes <input type="checkbox"/> No
If not approved, reasons for that	_____
Further revision or modification required	<input type="checkbox"/> Yes <input type="checkbox"/> No: Explain: _____



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To be discussed at the forthcoming full committee meeting	<hr/> <hr/>
Any Other	<hr/> <hr/> <hr/>

Name of the Reviewer: 1) _____	
Signature: _____	Date: _____
Name of the Reviewer: 2) _____	
Signature: _____	Date: _____
Final Decision: Approved YES NO _____	
If not approved, reasons for that _____ _____	
Further revision or modification required for Resubmission	
Any Other	
Signature of the Member Secretary: _____ Date: _____	

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Annexure 2: AX 2/SOP 09/V2
Proposal and/or related documents Amendment Request and Assessment
Form

RGCB IHEC Protocol Number:	
Protocol Title: <hr/> <hr/> <hr/>	
Principal Investigator and Department: <hr/> <hr/> <hr/>	
Approved date:	No. of amendment:

<ul style="list-style-type: none"> ○ State/describe the amendment :type of document/ part of document amended ○ Reasons for the amendment ○ Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)
Have the changes/ modifications in the amended versions been highlighted/ underlined? Yes <input type="checkbox"/> No <input type="checkbox"/>



Name of Principal Investigator: _____

Signature with Date: _____

Type of review :- (Decision by the Chairperson/ Member Secretary)Review by Member Secretary/ Chairperson ☐ Review by designated RGCB IHEC members ☐Full Committee discussion and review ☐

Comments of the reviewer :-

Decision:

☐ Approved ☐ Suggested Recommendation(s)☐ Deferred ☐ Next full board discussion

Name of RGCB IHEC Member / Member Secretary / Chairperson reviewing the project: _____

Signature with Date: _____

Final Decision: Approved

Yes

No

If not approved, reasons for that _____

Further revision or modification required:

Any Other

Signature of the Chairperson/Member Secretary: _____

Date: _____

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Annexure 3AX 3/ SOP 09/V2

Approval letter for Proposal Amendment/Document Amendment

To

..... (PI)

Department ____

Ref: - RGCB IHEC No.

Project title

Dear Dr. _____

We have received from you the following document(s).

1.

2.

At the RGCB Institutional Human Ethics Committee meeting held on _____ the above mentioned documents were reviewed in the presence of following members:

1.

2.

3.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the RGCB IHEC.

After reviewing, the RGCB IHEC has decided to approve: (a) The aforementioned study-related documents OR (b) the following documents:

1.

2.

After reviewing the documents, the RGCB IHEC has decided to approve the aforementioned study-related documents.

Yours truly,

Signature of RGCB IHEC Member Secretary with Date

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Continuing Review of Study Protocols

SOP Code: SOP 10/V2

Date: November 30, 2019

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10.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how continuing review of previously approved protocols should be managed by the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC). The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants.

10.2 Scope

This SOP applies to conducting any continuing review of already approved study protocols at pre-specified intervals. All the projects approved by the RGCB IHEC will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the RGCB IHEC may choose to review or monitor the protocols more frequently.

10.3 Responsibility

It is the responsibility of the RGCB IHEC Secretariat to remind the PIs and Member Secretary regarding continued review of protocols at the correct interval. All the approved protocols will be reviewed annually. It is the responsibility of the Member Secretary to ensure during the RGCB IHEC meeting in which the project is finally approved, that a decision is taken whether the project needs to be reviewed more frequently or not. This must be recorded in the minutes. A fresh decision to increase frequency of review may be taken if required based on the SAE reports, monitoring reports, or safety concerns. This is the responsibility of the SAE subcommittee and Member Secretary.

The RGCB IHEC is responsible for reviewing the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding RGCB IHEC communication.

10.4. Detailed instructions

10.4.1 Determining the date of continuing review

- The date of the continuing review will always be at least once in the year.
- The RGCB IHEC may recommend more reviews during the approval process depending on the level of risk. This will be documented in the minutes.
- The Secretariat will inspect the minutes of meeting to set a timetable for continuing review.

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- The Secretariat will identify and record the due dates for each project.

10.4.2 Notifying the PI or the study team

The Secretariat will send a reminder to the PI as per the prescribed format at least one month prior (if an annual review) or less as appropriate (if any special additional reviews are required) to the due date of continuing review.

10.4.3 Managing the continuing review package upon receipt

The Secretariat will receive one soft copy and required number of hard copies from the PI for continuing review of each approved protocol by the RGCB IHEC.


10.4.4 Verifying the contents of the package

- The Secretariat will ensure that the contents of the package include the following documents:
 - Continuing Review Application in the prescribed Form
 - The Continuing Review Application Form duly filled with an explanation for any “yes” (ticked on the Continuing Review Application in the prescribed form), answers on the application form and a discussion of scientific developments, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. must be discussed in the attached narrative.

The Secretariat will confirm that complete information is appended and signed by the Principal Investigator in the Continuing Review Application form.

10.4.5 Review process

- The Continuing review submission may undergo expedited review or full committee review as deemed appropriate by the RGCB IHEC Chairperson/ Member Secretary.
- The Secretariat will send the Continuing Review Application Form to the designated RGCB IHEC members.
- The RGCB IHEC Chairperson/ Member Secretary/ Member/s will use the Continuing Review Application Form to guide the review and deliberation process to reach one of the following decisions after review:

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1. Noted - The RGCB IHEC approves the continuation of the project without any modifications.
 2. Modifications recommended: Unless the modifications suggested/ recommended by the RGCB IHEC for the protocol have been met the study cannot continue. The amendments and the required documents should be appended and submitted to the RGCB IHEC within one month for re-review.
 3. The project cannot be continued: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the Principal Investigator. Member Secretary shall record this decision.
- The RGCB IHEC Member Secretary will sign and date the final RGCB IHEC decision on Continuing Review Report after a decision has been reached.
 - The decision on continuing review taken by the Chairperson/ Member Secretary/ Member/s will be informed to all RGCB IHEC members at the next full committee meeting.
 - The continuing review report may be discussed at full committee meeting by Member Secretary/PI.
 - The RGCB IHEC Secretariat will maintain and keep the RGCB IHEC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process in the project file.

10.4.6 Communicating RGCB IHEC Decision to the PI

- The Secretariat will notify the PI of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the Chairperson/ Member Secretary/ RGCB IHEC Member/s.

10.4.7 Non-submission of continuing review report by principal investigator before due date.

- If a PI fails to submit the continuing review report within two months of the due date (i.e. 10 months from the date of approval, or earlier on the dates as specified), the Secretariat will send a telephonic and /or email reminder at least 15days prior to the meeting. If there is no response, the RGCB IHEC secretariat will put up the matter for discussion at the forthcoming full committee meeting for appropriate action. This may consist of but not limited to sending:
 - a) A letter asking explanation for non-submission

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b) A letter asking the PI to put recruitment of new participants on hold till report is submitted

c) Any other action as deemed appropriate by RGCB IHEC

5. Annexure

- Annexure 1– AX 01/SOP 10/V2 Reminder letter from the RGCB IHEC to the principal investigator
- Annexure 2 - AX 02/SOP 10/V2 Continuing Review Application Form
- Annexure 3 – AX 03/SOP10/V2 Continuing Review Decision letter

Annexure 1AX1/SOP 10/V2 Reminder letter by the RGCB IHEC to principal investigator

Date:-

Name of Principal Investigator:-

Department:-

Ref: - Project no.

Title:

The above referenced project was approved by the RGCB IHEC on -----
-and is due for Continuing Annual/ Periodic Review by the RGCB IHEC. You are requested to submit an Annual/ Periodic status report in the prescribed format which is enclosed on or before ----- (1 month period)

Signature with date _____
Member Secretary _____

Annexure 2 AX 02/SOP 10/V2 Continuing Review Application Form

Project no. _____ Date of RGCB IHEC approval _____

**Summary of protocol participants:**

No. of participants screened _____

No. of participants approved by RGCB IHEC _____

No. of recruited participants _____

No. of ongoing participants _____

No. of completed participants _____

No. of participants who refused to consent _____

Have any participants been withdrawn from this study? Yes _____ No _____

If no, (state the number and reasons for drop-outs for each participant, attach separate sheet if needed) _____

Have there been any amendments in protocol/ Informed Consent Document since the last review? _____

Yes _____ No _____

Were these protocol/ Informed Consent Document (ICD) amendments approved by RGCB IHEC? _____

Yes _____ No _____

If no, mention the amendments not approved _____

Which protocol amendment (version) is being followed at the site at present _____

Which ICD amendment (version) is being followed at the site at present _____

Has any information appeared in the literature, or evolved from this or similar research that might affect the RGCB IHEC/RGCB IHEC's evaluation of the risk/benefit analysis of participants involved in this protocol? _____

Yes _____ No _____

If Yes (attach separate sheet if needed) _____

No. of SAEs _____

Causality determined by RGCB IHEC: _____

Related and not related _____

Compensation given _____

Whether reports of SAEs so far have been reviewed by the RGCB IHEC- _____

Whether reports of SAEs at other sites have been submitted to the RGCB IHEC- _____

Have any ethics issues encountered? _____

Yes _____ No _____

If yes, write the remedial action taken. _____

Have any participating investigators been added or withdrawn since last review? _____

Yes _____ No _____

If Yes (Identify all changes in the attached narrative) _____


Is report of interim data analysis available? _____

Yes (submit as an attachment) No _____

Is report of the data safety and monitoring board available? _____

Yes (submit as an attachment) No _____

Have any investigators developed COI _____

 RGCB <small>RESEARCH GRANT REVIEW BOARD</small>	RGCB IHEC SOP	SOP Version 2 Date: November 30, 2019
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	related to this protocol? Yes (Append a statement of disclosure) No <input type="checkbox"/>
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Signature of the Principal Investigator with Date:

Assessment of Continuing Review Report by the RGCB IHEC to be reviewed by

- Chairperson /Member Secretary only and inform to the RGCB IHEC members at Full Committee meeting
- Full Committee meeting
- Any 2 RGCB IHEC members and inform RGCB IHEC members at Full Committee

Names of RGCB IHEC members:

1. _____
2. _____


RGCB IHEC decision on continue review report

Approved for continuation without further modifications with effect from.....
Revision incorporating modifications to be re-submitted (State modifications)
To be Discontinued (State reasons)

Date of Full Committee meeting:

Signature of reviewer/s with date:

Signature of Member Secretary with date

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Annexure 3 AX 03/SOP10/V2

Institutional Human Ethics Committee Decision Letter

(Re-Reg.No. ECR/484/Inst/KL/2013/RR-16)


Document No:	RGCB/IHEC/250/2019/00	Issue Date:	
RGCB IHEC Protocol No: IHEC/1/			
Title of the proposal:			
Principal Investigators:			
Reviewed by:			
<input checked="" type="checkbox"/> Full Board review <input type="checkbox"/> Expedited Review <input type="checkbox"/> Exempted review			
Type of Review:			
<input type="checkbox"/> New <input type="checkbox"/> Revised <input checked="" type="checkbox"/> Continuing			
Reason for continuing review:			
<input type="checkbox"/> Progress report <input type="checkbox"/> Addition of collaborator <input type="checkbox"/> Change in Collaborator <input checked="" type="checkbox"/> Title change <input type="checkbox"/> Completion report <input type="checkbox"/> Others, specify _____			
Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee reviewed your application and your protocol IHEC/1/ will henceforth be referred to as “”. RGCB IHEC made the following recommendations: • The protocol can be continued as presented.			
RGCB IHEC decision			
<input checked="" type="checkbox"/> Approved <input type="checkbox"/> Modification recommended <input type="checkbox"/> Deferred			
Reason for deferral, _____			

Remarks:

7. If approved: please retain a copy for reference and project can be continued as presented to the RGCB IHEC.
8. Inform IHEC in case of any change of study procedures, site and investigator.
9. Inform IHEC immediately in case of any serious adverse events.

Yours Sincerely,

Member Secretary, RGCB IHEC.

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6. Flow chart

No.	Activity	Responsibility
1.	Determine the date of continuing review	Administrative officer/ RGCB IHEC Secretariat
2.	Notify the Principal Investigator or study team	RGCB IHEC Secretariat
3.	Manage continuing review package upon receipt and verifying its contents	RGCB IHEC Secretariat
4.	Notify the members of the RGCB IHEC	RGCB IHEC Secretariat
5.	Review of Continuing review report	RGCB IHEC Secretariat, Members and Chairperson
6.	Preparing meeting agenda	RGCB IHEC Secretariat
7.	Communicate the RGCB IHEC decision to the Principal Investigator	RGCB IHEC Secretariat

 RGCB <small>DISCOVERIES FOR A BETTER TOMORROW</small>	RGCB IHEC SOP	SOP Version 2 Date: November 30, 2019
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Review of Protocol Deviations / Violations/ Non-compliance

SOP Code: SOP 11/V2

Date: November 30, 2019

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11.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe action(s) to be taken by the RGCB IHEC when investigator(s)/ trial site(s) fail(s) to:

- follow the procedures written in the approved protocol,
- comply with national and/ or international guidelines, statutory provisions, institutional guidelines or rules or procedures mandated by the Ethics Committee (RGCB IHEC) for the conduct of human research,
- respond to the RGCB IHEC requests regarding statutory, ethical, scientific or administrative matters.

11.2 Scope

This SOP applies to all RGCB IHEC approved research protocols involving human research participants.

11.3 Responsibility

The RGCB IHEC Secretariat is responsible for receiving deviation/ violation reports as per request submitted by the Principal Investigator (PI) /others and placing it on the agenda of the meeting. Reporting of deviation/ violation in any other reporting format will not be accepted.

The RGCB IHEC members should review and take action on such reports.


11.4 Definitions

[National Institute of Health IRB Professional Administrators Committee Regulatory Process Workgroup Version 5.1, 11/18/2005 Available from https://www.genome.gov/Pages/Research/Intramural/IRB/Deviation_Violation_examples8-07.pdf Accessed on 3rd June 2015]

Protocol Violation:

A protocol violation is a deviation from the RGCB IHEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data. If the deviation meets any of the following criteria, it is considered a protocol violation. Example list is not exhaustive.

- I. The deviation has harmed or posed a significant or substantive risk of harm to the research participant. For example,
 - a. Receiving the wrong treatment or incorrect dose.
 - b. Withdrawal criteria met during the study but was not withdrawn.

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- c. Receiving an excluded concomitant medication.
- II. The deviation compromises the scientific integrity of the data collected for the study. For example,
 - a. A research participant who was enrolled does not meet the protocol's eligibility criteria.
 - b. Failure to treat research participants as per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)
 - c. Changing the protocol without prior RGCB IHEC approval.
 - d. Inadvertent loss of samples or data.
- III. The deviation is a wilful breach of human participant protection regulations, policies, or procedures on the part of the investigator(s). For example,
 - a. Failure to obtain informed consent prior to initiation of study-related procedures
 - b. Falsifying research or medical records.
 - c. Performing tests or procedures beyond the individual's professional scope or privilege status (credentials)
- IV. The deviation involves a serious or continuing noncompliance with central, state, local, or institutional human participant protection regulations, policies, or procedures. For example,
 - a. Working under an expired professional license or certification
 - b. Failure to follow central and/or local regulations, and intramural research or CC policies
 - c. Repeated minor deviations.
- V. The deviation is inconsistent with the Human Research Protection requirements in research ethics principles. For example,
 - a. A breach of confidentiality.
 - b. Inadequate or improper informed consent procedure.

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11.5. Detailed instructions

11.5.1 Detection of Protocol deviation/ violation

Protocol deviation/ violation may be detected in one the following ways (but not limited to those listed below):

- a. Protocol deviation/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the RGCB IHEC.
- b. The RGCB IHEC members performing monitoring of the project at trial site may detect protocol deviation/violation if the project has not been conducted as per protocol/ national/ international regulations.
- c. The Secretariat may detect protocol deviation/ violation from failure to comply with statutory requirements/ failure to respond to requests from RGCB IHEC within reasonable time limit/ failure to respond to communication made by RGCB IHEC.
- d. The RGCB IHEC members may detect protocol deviation/ violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization.
- e. The RGCB IHEC Secretariat and/ or RGCB IHEC members may become aware of a protocol deviation/ violation while reviewing study-related documents including reports filed in by the Principal Investigator (PI).
- f. Communication/ complaint/ information received from a research participant who has been enrolled or any individual who has been approached for enrolment.
- g. Any report/ communication brought to the notice of Member, Secretary/ Chairperson of RGCB IHEC by an independent person.
- h. Communication received from the Head of the Institution informing RGCB IHEC about an alleged protocol violation/ protocol deviation.

11.5.2 Receipt of protocol deviation / violation report by the Secretariat

1. The PI will report the protocol deviation/violation in the prescribed form.
2. In case protocol deviation/violation is detected by any other person (See Section 5.1) and reported to the RGCB IHEC (there is no format for this), the Member Secretary will write to the PI to submit a protocol deviation/violation in the prescribed form.
3. The Secretariat will notify the Member Secretary of any protocol deviation/violation report received from the PI/ from any source within 2 working days of receipt of the notification.

11.5.3 Actions to be taken


1. The action of the RGCB IHEC will be based on:
 - The nature and seriousness of the deviation / violation.
 - Frequency of deviation/ violation in the study in the past.

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- Frequency of deviation/ violation in previous studies conducted by the same PI/ Co-PI or in the same department.
2. Member Secretary will decide on the impact of the protocol deviation / violation and act accordingly. Depending upon the seriousness, the RGCB IHEC shall do the following (not limited to these actions):
 - Ask PI for written clarification as soon as the deviation is received
 - If the impact is serious, this report will be shared with the Chairperson and two or more RGCB IHEC members designated by the Chairperson.
 - If the impact of the protocol deviation is serious enough, the Member Secretary will instruct the Secretariat to call for and schedule a full-board meeting specifically to discuss the issue within 7 working days of the initial scrutiny
 - The Secretariat will put up the information and communication at the next full committee meeting for discussion.
 3. The Member Secretary in consultation with RGCB IHEC members will review the information available and deliberate on it.
 4. The Chairperson will take a final decision depending on the seriousness of the violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by voting if there is no consensus.

The decision taken by RGCB IHEC could include one or more of the following:

- Determine that no further action is required, or take other actions as appropriate.
- Inform the PI that the RGCB IHEC has noted the violation / deviation, and instruct the PI to ensure that deviations/ violations do not occur in future and to follow RGCB IHEC recommendations.
- Enlist measures that the PI would undertake to ensure that such deviations/ violations do not occur in future.
- Observe the research or consent process (depending on the nature and frequency of the deviation).
- Suggest modifications to the protocol.
- Alter the interval for submission of the continuing review/ annual project status.
- Ask for additional training of the investigator and study team
- Reprimand the PI.
- Seek additional information from the PI.
- Conduct audit of trial by the RGCB IHEC.
- Suspend the study till additional information is made available and scrutinized.
- Suspend the study till recommendations made by the RGCB IHEC are implemented by the PI and found to be satisfactory by the RGCB IHEC.

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- Suspend the study for a fixed duration of time.
 - Suspension or termination of the study.
 - Revoke approval of the current study.
 - Inform DCGI/ other relevant regulatory authorities.
 - Keep other research proposals from the PI/ Co-PI under abeyance.
- Review and/ or inspect other studies undertaken by PI/Co-PI.

This final decision will be recorded by the Member Secretary.

11.5.4 Procedure for notifying the PI and other concerned authorities

The Member Secretary will draft a notification letter.

- The signed letter by Member Secretary will be sent to the PI and Department Head(s) (if required on case to case basis) and Institutional Officials (if required on case to case basis).
- The RGCB IHEC secretariat will send a copy of the notification to the relevant national authorities (if required on case to case basis) and institutes (if required on case to case basis in case of multi-centric trials).

11.5.5 Records and follow up to be kept by RGCB IHEC secretariat

- The Secretariat will keep a copy of the notification letter in the respective project file.

11.6. Flow Chart

No.	Activity	Responsibility
1	Detection and reporting of Protocol deviation/ violation	RGCB IHEC members/ Secretariat/ principal investigator
2	Receipt of protocol deviation / violation report	Secretariat
3	Review, board discussion, decision and action	RGCB IHEC Members, Member Secretary and Chairperson
4	Notify the Principal Investigator/ concerned authorities of RGCB IHEC action	Secretariat
5	Maintain records	Secretariat

11.7. Annexure

- Annexure - Deviation/ Violation Record

Provisional Decision by the Reviewer (Member Secretary and/or Chairperson and/or IEC Member/s)

- ☐ Noted
- ☐ Request the PI not to perform such deviations/ non compliances/ violations in future
- ☐ Specific recommendations stated below to be followed

-
- ☐ Suspend the study till the IEC recommendations are implemented
- ☐ Suspend the study till information available
- ☐ Terminate approval of the current study

Reasons for termination

-
- ☐ Refuse subsequent applications from PI
- ☐ To discuss at the full Board meeting
- ☐ Any other _____

Reviewed by

Name/s:

Signature/s with date:

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Discussion of the protocol deviation/violation at the

Emergency meeting on _____

Next Scheduled full board meeting on _____

Final decision at the full board meeting held on

Signature with date RGCB IHEC Member Secretary

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Review of Serious Adverse Events (SAE) Reports

SOP Code: SOP 12/V2

Date: November 30, 2019

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12.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) reported to the RGCB IHEC for any study and as part of the oversight of the Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC).

12.2. Scope

This SOP applies to the review of SAE reports (Adverse events/ SAE onsite as well as SAEs of the multicentre studies occurring at other sites (offsite) submitted to the RGCB IHEC.

12.3. Responsibility

The principal investigator is responsible for submitting all the serious adverse event occurring to the clinical trial subjects recruited at the site within 24 hours of occurrence or first information on occurrence of SAE (whichever is earlier) in the format provided by EC. It is the responsibility of the RGCB IHEC to receive all safety reports and get them reviewed by SAE subcommittee and RGCB IHEC in a timely manner.


12.5. Detailed instructions

12.5.1 SAE Subcommittee

- The Serious Adverse Event (SAE) Subcommittee of the RGCB IHEC will review all serious adverse events (SAE) at the site / other sites involving human participants approved by RGCB IHEC.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

12.5.2 Composition of the SAE Subcommittee

- The SAE Subcommittee will be appointed by the Chairperson of RGCB IHEC
- The SAE Subcommittee will be multidisciplinary and multi-sectoral in composition.
- The SAE Subcommittee will be composed of members of the RGCB IHEC.
- The composition shall be as follows:

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- ✓ Chairperson of the SAE Subcommittee
 - ✓ One Member Secretary
 - ✓ At least one member with post graduate qualification in the discipline of Clinician, Clinical Pharmacology
 - ✓ Any other relevant clinical specialties in the institution.
 - ✓ One or two members of RGCB IHEC including non-scientist of RGCB IHEC preferably legal person
 - ✓ RGCB IHEC Secretary will be Ex-Officio member of the SAE Subcommittee.
- The Head of the SAE Subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.
 - The Head of the SAE Subcommittee/ Executive Secretary will sign minutes of the SAE Subcommittee meeting.
 - In case of anticipated absence, the Head of SAE subcommittee will nominate a SAE subcommittee member as acting head. The acting Head will have all the powers of the Head of SAE subcommittee for that meeting.
 - For the SAE Subcommittee meeting, a quorum will consist of at least 4 members as follows- one member (preferably pharmacologist), one member (preferably clinician), member secretary and Head/ Acting head of the SAE subcommittee.
 - The SAE subcommittee will meet as often as required.

12.5.3 Membership requirements

- RGCB IHEC Members will be appointed to the SAE Subcommittee if they show willingness and commitment in terms of time to perform the role and responsibility as SAE Subcommittee member.
- The Chairman of the RGCB IHEC is responsible for appointing the SAE Subcommittee members.
- The tenure of SAE Subcommittee will be for a continuous period of two (2) years from the date of appointment.
- The retiring member will be eligible to be appointed for the new tenure consecutively four times.

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- SAE Subcommittee member may resign from membership by submitting a letter of resignation to the Member Secretary of the SAE Subcommittee. The member may or may not assign reasons for resignation.
- SAE Subcommittee member may be disqualified from SAE Subcommittee membership if the member fails to attend consecutively more than 5 SAE Subcommittee meetings without prior intimation. The Head of SAE Subcommittee will inform Chairperson of RGCB IHEC, in writing, if a member has not attended more than five consecutive meetings of the SAE Subcommittee. The Chairperson will discuss the issue of disqualification at the full committee meeting and allow the concerned SAE Subcommittee member to state reasons for unauthorized absence.


12.5.4 Functions of the Executive Secretary of the SAE Subcommittee

- To schedule and organize the SAE Subcommittee meetings.
- To prepare and maintain meeting agenda and minutes.
- To convene SAE subcommittee meetings
- To prepare the communication letters related to the adverse event reports.
- To communicate with the RGCB IHEC members, regulatory authorities and investigators in timely manner.
- To provide necessary administrative support for SAE Subcommittee related activities.
- To ensure adherence of the SAE Subcommittee functioning as per SOPs

12.6 Onsite SAE

12.6.1 Receipt of SAE report

- The RGCB IHEC Secretariat will receive the following documents within the specified time frame if a SAE is experienced by any research participant:
 - i. Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence as per the format specified in *AX 01/SOP 12/V2*.
 - ii. Due analysis should be submitted by the PI within 14 days from the occurrence of the SAE along with the format specified in *AX 02A/SOP 12/V2*.
 - iii. Due analysis will also be submitted by the sponsor within 14 days in the format specified in *AX 02B/SOP 12/V2*.


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- iv. The follow up reports of all on-site SAE till the event is resolved.
- The RGCB IHEC Secretariat will verify that the report is complete in all respects and that it has been received at the RGCB IHEC office within the specified timelines.
- If the report has been received beyond the specified time, it will be considered as a protocol violation and action should be taken as described in SOP.
- The RGCB IHEC Secretariat will sign and write the date on which the report is received.
- The Secretariat will forward these reports to the RGCB IHEC Member Secretary or Member Secretary of the SAE Subcommittee (if constituted) within two working days.

12.6.2 Review and Decision on SAE Reports and Communication to PI and

Regulatory Authority by RGCB IHEC

- Member Secretary of the SAE committee will review the SAE report and present to the SAE subcommittee (as applicable) for review and opinion.
- At the meeting of RGCB IHEC or SAE subcommittee, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management, and financial compensation to be given to the research participants. The applicable formulae and guidelines as per regulation will be used for discussion.
- If deemed necessary, a decision to hold emergency RGCB IHEC meeting may be taken to discuss about financial compensation. An emergency RGCB IHEC meeting will be scheduled within 7 days for the same.
- The Member Secretary of the SAE subcommittee may refer the SAE report to full committee for review if deemed necessary
- The minutes of the SAE Subcommittee/ RGCB IHEC meeting will include the information on SAE at the site along with the opinion on the above points on the onsite SAE.

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Participant ID	Letter no./and date of reporting	Type of Report (I/FU)	Date of onset	whether study drug with held	SAE Outcome	Causality in the opinion of PI	Recommendation(s) by the SAE Sub-committee

I-initial, FU- Follow-Up

The minutes will be circulated to the RGCB IHEC members *via* email and approval/objection will be sought from the members in a period of 5 working days.

- The RGCB IHEC secretariat will draft a formal letter to the concerned PI and inform him/ her about the RGCB IHEC decision. This letter will be signed and dated by the Member-Secretary or Chairperson (RGCB IHEC) and will be sent to the PI within a period of 7 days from the date of the SAE subcommittee meeting.
- The PI will be requested to reply to the query letter on the SAE report within 7 working days.
- The opinion regarding relatedness, medical management and compensation for research related injury will be communicated to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE in case of regulatory clinical trials.
- The Secretariat will file a copy of these letters in the study file.

12.6.3 Reports of SAE Occurring at other Sites

The investigator will need to submit the SAEs occurring at other sites (CIOMS and SUSARS) in the form of soft copies only (CD) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:.

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Sr. No.	Country	Type of Report (I/FU)	SAE event	Date of onset	Date of report	Out come	Causality	
							Investigator	Sponsor

I-initial, FU- Follow-Up

- For every SAE term, a separate row of the above table is to be used (the SAE terms should not be combined).
- Causality to be stated as related (R) or not related (NR)
- The SAEs occurring at other sites will be reviewed by the Secretary of the SAE Subcommittee, informed to other members and discussed in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites.


12.7 Onsite AE

The RGCB IHEC Secretariat will receive the following documents pertaining to AE occurrence related to research proposals approved by the RGCB IHEC:

1. On site AE reports should be submitted by the PI annually in the continuing review report.
2. In view of the risk assessment of a given research proposal the RGCB IHEC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.

The RGCB IHEC Secretariat will verify that the report is complete in all respects and signed and dated by the PI and that it has been received at the RGCB IHEC office within the specified timelines. If the report has been received beyond the specified time, it will be considered as deviation.

- For all the onsite AE reports received at the RGCB IHEC office, the Administrative Officer of the institution will forward these reports to the Member Secretary of RGCB IHEC for review.
- Member Secretary of RGCB IHEC may put the AE reports for discussion at full board if deemed necessary

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- Queries, if any on the report will be communicated to the PI by the Member

Secretary of RGCB IHEC following full board meeting

- The Administrative Officer/PI will file a copy of these letters in the study file.

12.7.1 Review during the Full board RGCB IHEC meeting

- The RGCB IHEC Member Secretary will read out the minutes of all the SAE subcommittee meetings including the recommendations/ decisions of the SAE subcommittee.
- In case of the SAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.
- The decision can be arrived at by consensus. If not agreed by consensus, the issue would be put for voting. (a majority vote for a decision is 2/3rd majority of the members present and voting)


12.7.2 Decision of RGCB IHEC on SAE review

The SAE Subcommittee/RGCB IHEC may take one or more of the following decisions on review of the SAE reports.

12.7.3 Type of Actions Taken by RGCB IHEC/ SAE Subcommittee on Review of SAE Report:

Following detailed review of the SAE reports and related documents, the RGCB IHEC/ SAE Subcommittee (if constituted) can suggest one of the following actions:

- Note the information about the SAE in records for future reference.
- Request further follow up information and/ or additional details.
- Ask for periodic follow-up of the research participant till SAE is resolved
- Depending on complexities of issue, RGCB IHEC/ SAE Subcommittee may decide to seek opinion of outside expert consultant who is requested to respond within 14 working days.

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- Provide recommendations regarding/ raise queries related to compensation for study related injury and death

12.7.4 Type of Actions Taken by RGCB IHEC following full board review

- Suggest changes/ amendments in protocol, Patient Information Sheet/

12.8 Informed Consent Document/ Investigators' Brochure/ any other study related documents.

- Suspend the study till additional information is available.
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).
- Suspend the study till amendments requested for by the RGCB IHEC are carried out.
- Suspend enrolment of new participants.
- Suspend certain activities under the protocol.
- Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.
- Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional
- Procedures, additional investigations, etc. as prescribed in the amendment.
- Terminate the study.
- Any other appropriate action.
- The decision shall be recorded in the minutes of the full board RGCB IHEC meeting.
- If the recommendation from the RGCB IHEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding

Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the PI through telephone, fax or email within 24 hours. Such a communication will be documented by the RGCB IHEC Member-Secretary in the

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study file. A formal letter to the PI informing about the RGCB IHEC recommendations in such situations will be sent within 5 working days of the RGCB IHEC meeting having taken place.

12.9 References to other applicable SOPs


- SOP 07A/V2 - Initial Full-Board Review of Research Study Protocols
- SOP 08/V2 - Agenda Preparation, Meeting Procedures and Recording of Minutes
- SOP 10/V2 - Continuing Review of Study Protocols

12.10 Flowchart

No.	Activity	Responsibility
1	Receipt of SAE report	RGCB IHEC Secretariat
2.	Submission of SAE report to the SAE Subcommittee	RGCB IHEC Secretariat
3	Agenda and Minutes of the Subcommittee (if constituted)	Executive Secretary of the SAE Subcommittee (<u>if constituted</u>)
4.	Review and discussion of SAE report at the Subcommittee meeting (if constituted)	SAE Subcommittee members (<u>if constituted</u>)
5.	Review and discussion of SAE report at the full Board meeting	Member Secretary
6.	Communication of the RGCB IHEC decision about SAE review to the Licensing authority	Executive Secretary of the SAE Sub-committee (if constituted)/ Member Secretary
7.	Communication of the RGCB IHEC decision about SAE review to the principal investigator	Executive Secretary of the SAE Subcommittee (if constituted)/Member Secretary, RGCB IHEC Secretariat

12.11 Annexure

- Annexure 1: AX 01/SOP 12/V2 – As per Schedule Y Appendix XI: Data Elements for Reporting serious adverse events occurring in a clinical trial (Schedule Y http://dbtbiosafety.nic.in/act/schedule_y.pdf)
- Annexure 2A AX 02A/SOP 12/V2 - Checklist for Onsite Serious Adverse Event submission
- Annexure 2BAX02B/SOP 12/V2 – Onsite Serious Adverse Event Analysis Report

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Annexure 1: AX 01/SOP 12/V2

Data Elements for reporting serious adverse events occurring in a clinical trial

(Schedule Y http://dbtbiosafety.nic.in/act/schedule_y.pdf)

1. Patient Details

- Initials & other relevant identifier (hospital/OPD record number etc.)*
- Gender
- Age and/ or date of birth
- Weight
- Height

2. Suspected Drug(s)

- Generic name of the drug *
- Indication(s) for which suspect drug was prescribed or tested
- Dosage form and strength
- Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
- Route of administration or Starting date and time of day
- Stopping date and time, or duration of treatment

3. Other Treatment(s)


- Provide the same information for concomitant drugs (including non-prescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)

- Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*
- Start date (and time) of onset of reaction or Stop date (and time) or duration of reaction.
- Dechallenge and rechallenge information.
- Setting (e.g. hospital, out-patient clinic, home, nursing home).

5. Outcome

- Information on recovery and any sequelae; results of specific tests and / or treatment that may have been conducted.

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- For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post mortem findings.
- Other Information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history, findings from special investigations etc.

6. Details about the Investigator*


- Name
- Address
- Telephone number
- Profession (speciality)
- Date of reporting the event to Licensing Authority:
- Date of reporting the event to Ethics Committee overseeing the site:
- Signature of the Investigator

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Annexure 2A: AX 02A/SOP 12/V2

Checklist for Serious Adverse Event (SAE) submission (For Onsite SAE)

Sr. No.	Details		
1.	Country (Name of the country should be specified)		
2.	SAE report of death or other than death, Please tick (✓)	Death	Other than Death <input type="checkbox"/>
		Yes / No	Page No.
3.	In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor(Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial / Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	Patient Details		

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a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
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b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13.	Suspected Drug(s)		
a)	Generic name of the drug		
b)	Indication(s) for which suspect drug was prescribed or tested		
c)	Dosage form and strength		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)		
e)	Route of administration		
f)	Starting date and time of day		
g)	Stopping date and time, or duration of treatment		
14.	Other Treatment(s)		
	Provide the same information for concomitant drugs (including non-prescription/OTC Drugs) and nondrug therapies, as for the suspected drug(s).		
15.	Details of the events		
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		

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b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	Dechallenge and rechallenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		

16.	Outcome		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	Details about the Investigator		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		

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18.	Details about the Ethics Committee		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term/ Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by		
	Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23.a)	Duly filled SAE Form as per Appendix XI of Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		


Note: Information not relevant to a particular SAE should be marked with NA

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Annexure 2B: AX 02B/SOP 12/V2 Serious Adverse Event (SAE) Analysis Report
(For Onsite SAE)

Sr. No.	Details		
1.	Country (Name of the country should be specified)		
2.	SAE report of death or other than death, Please tick (✓)	Death	Other than Death <input type="checkbox"/>
		Yes / No	Page No.
3.	In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from		

CDSCO			
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor(Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial / Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		


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12.	Patient Details		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13.	Suspected Drug(s)		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength.		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
e)	Route of administration.		
f)	Starting date and time of day.		
g)	Stopping date and time, or duration of treatment		
14.	Other Treatment(s)		
	Provide the same information for concomitant drugs (including non-prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).		
15.	Details of the events		
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		

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b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	De challenge and re challenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	Outcome		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	Details about the Investigator		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee		

overseeing the site:			
h)	Signature of the Investigator		

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18.	Details about the Ethics Committee		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23.	Duly filled SAE Form as per Appendix XI of		
a)	Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		

Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with evidence of the same)

What is the investigator's assessment for the amount of compensation to be paid?

What is the sponsor's assessment for the amount of compensation to be paid?


Has the participant made a claim? Yes No



If yes, for how much amount _____

If no, please ensure that the participant / nominee have been made aware of his/her' rights regarding compensation. Please submit documentation regarding the same

Signature of the Principal Investigator : Date: _____

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Review of Study Completion Reports

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SOP Code: SOP 13/V2

Date: November 30, 2019

13.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report submitted for studies approved by the Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC).

13.2. Scope

This SOP applies to the review of the Study Completion Report which is a written report of every completed study submitted by the Principal Investigator (PI).

13.3. Responsibility

It is the responsibility of the RGCB IHEC Chairperson/ Member Secretary/ Member/s to review the study report and act on it.

13.4. Detailed instructions

13.4.1. Receipt of Study Completion Report

- The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format (AX 01/SOP 13/V2)) from the PI. The study completion report is expected from the investigator within 1 month of completion of the study at the site.
- In case of multicentric studies, site specific final report to be submitted along with the completion report.
- The Secretariat will follow instructions (Management of Protocol Submission) for receiving and checking the report package.
- It is the responsibility of the RGCB IHEC Secretariat to review the report for completeness.
- The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form and forward it to the Member Secretary within 7 working days of receipt.
- The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full committee meeting.
- If there is a need felt (e.g. a deviation/ violation is noted), the Member Secretary will handle it.

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- The Secretariat shall include the Study Completion Report Form in the agenda for RGCB IHEC members for discussion at the full board meeting.

13.4.2. During the Board meeting

- The Member Secretary will present the report and members can discuss as needed.
- Following the discussion, the Chairperson may take one of the following decision:

a) Noted and accepted

b) Request for additional information / clarification

- The Secretariat will note the decision in the meeting minutes
- The Member Secretary will draft a letter to the PI conveying decision on the study completion report.
- The study shall be considered as closed if the decision by RGCB IHEC is “Noted and accepted”.
- The Secretariat will accept and file the Report and get the Study Completion Report Form (AX 01/SOP 13/V2) signed by the Chairperson.
- The final report will be placed in the master file and kept in the archival area.
- The Administrative Officer will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

13.5. Reference to other applicable SOPs

- SOP 06/V2 - Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review
- SOP 08/V2 - Agenda Preparation, Meeting Procedures and Recording of Minutes
- SOP 11/V3 - Review of Protocol Deviations / Violations

13.6. Flow chart

No.	Activity	Responsibility
1	Receipt of the study completion report	RGCB IHEC Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	RGCB IHEC Secretariat

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3	Verification of the study completion report, preparation of the study completion statement and sending them to the Member Secretary	RGCB IHEC Secretariat
4	Review of the Study completion report for completeness and informing members at full-board meeting	Member-Secretary
5	Inclusion of the report/ review at full-board meeting	RGCB IHEC Secretariat
6	Discussion and decision at the full board meeting	Chairperson
7	Noting the decision in the minutes of the Meeting	RGCB IHEC Secretariat
8	Conveying decision to the Principal Investigator	RGCB IHEC Secretariat
9	Archiving all the study-related documents along with the Study completion report	Administrative Officer

13.7. Annexure

- AX 01/SOP 13/V2Study Completion Report

Annexure 1: AX 1/SOP 13/V2 Study Completion Report Form

(Filled by principal Investigator)


RGCB IHEC Project No:	
Project Title:	
Principal Investigator	
Department	
Total no. of study participants recruited	

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Total no. of study participants approved by the RGCB IHEC for recruitment		
Duration of the study		
*Results (summary) with Conclusion: (use extra blank paper, if more space is required). <hr/> <hr/>		
*Note: If the final report is not available from sponsor, it may be submitted later to the RGCB IHEC once it is ready.		
Number of SAEs at our centre:		
Whether all SAEs intimated to the RGCB IHEC	Yes <input type="checkbox"/> No <input type="checkbox"/>	
No. of patients withdrawn: Reasons for Withdrawal of Patients: <hr/> <hr/>		
Any ethical issues encountered? Action taken:		
Include the list of publications/presentations/patents, if any: 		
Signature of Principal Investigator:	Date :	

**Action taken:**☐ ☐ **Noted and accepted**☐ ☐ **Requires more information/ action as follows:**

_____**RGCB IHEC Meeting date (If reviewed in the meeting)** _____**Final Decision:** _____**Signature of Member Secretary with date:**

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Management of Premature Termination / Suspension / Discontinuation of the study

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SOP Code: SOP 14/V2

Date: November 30, 2019

14.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC) manages premature termination/suspension/discontinuation of a research study.

14.2. Scope

This SOP applies to any study previously approved by the RGCB IHEC that has been recommended for termination/suspension/discontinuation before its scheduled completion.

14.3. Responsibility

It is the responsibility of the RGCB IHEC to manage the termination/suspension/discontinuation of any study recommended for termination by the Data Safety and Monitoring Board, Principal Investigator, Sponsor or other authorized bodies or by the RGCB IHEC that was previously approved by RGCB IHEC. The Secretariat is responsible for management of the process.

14.4. Recommendation for Termination/ Suspension/ Discontinuation


14.4.1 By PI / Sponsor

An investigator/ Sponsor may put on hold a previously approved research when in the judgment of the investigator/ Sponsor this is appropriate to protect the rights or welfare of participants or when new safety information has appeared in the literature, or evolved from this or similar research.

14.4.2 By RGCB IHEC

RGCB IHEC can prematurely terminate/ suspend/ discontinue the study in the following situations:

- Protocol non-compliance/violation following which RGCB IHEC decides in full committee meeting to terminate/ suspend/ discontinue the study.
- SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients.

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- When research is not conducted in accordance with RGCB IHEC policies, is not in compliance with the local regulations or it has been associated with unexpected serious harm to participants.
- Zero accrual or low accrual for 1-2 years.
- Suspended protocols remain open and require continuing review.
 - The RGCB IHEC may revoke approval and terminate previously approved research protocol which will now be considered closed no longer requiring continuing review.

14.5. Detailed instructions

14.5.1. Receipt of Recommendation for Study Termination.

The Secretariat will receive the study protocol termination/suspension/discontinuation report and verify the contents of the report for completeness and/or other documents like letter from PI/ sponsor.

14.5.2. Review by the RGCB IHEC

- The Secretariat will inform the Chairperson and Member Secretary regarding the recommendation for premature termination/ suspension/ discontinuation of study protocol and submit the report within 3 working days of receipt of the same.
- The Chairperson shall review the report and either call for an emergency meeting or discuss the report at the regular full committee meeting and the Secretariat will make arrangement accordingly.
- The Member Secretary in the meeting will inform members the reasons for the premature termination/ suspension/ discontinuation of the project.
- If the report is unclear or more information is required from the PI, the Chairperson shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- The Chairperson/Member Secretary shall acknowledge by signing with date the study termination/ suspension/ discontinuation report.
- If the RGCB IHEC has revoked approval/suspended the study, regulatory authorities and Head of the institution must be informed within 14 working days after the full committee meeting.

14.5.3 Notifying the Principal Investigator

- The Secretariat will prepare a notification letter and send to the PI within 14 working days after the meeting acknowledging the approval of termination/ letter seeking clarifications/information regarding the premature termination.

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- In case a letter is sent seeking clarifications/information regarding the premature termination/ suspension/ discontinuation, the PI shall send a written response within 30 days of receiving the letter.
- If the PI does not comply, the matter will be put to the full committee meeting for discussion.
- The investigator may appeal or respond to the convened RGCB IHEC in writing.

14.5.4 Store the Protocol Documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file for archival.
- The protocol documents will be stored for a period of 3 years for biomedical and health research from the date of project Termination.

14.6. Flowchart

No.	Activity	Responsibility
1	Receive recommendation for study termination/ suspension / discontinuation	RGCB IHEC Secretariat
2	Review and Discuss the Termination/ suspension/ discontinuation report	RGCB IHEC members, Member Secretary and Chairperson
3	Notify the Principal Investigator	RGCB IHEC Secretariat
4	Store the Protocol Documents	RGCB IHEC Secretariat

14.7. Annexure

- Annexure 1 AX 01/SOP 14/V2 - Premature Termination Report.

Annexure 1: AX 01/SOP 14/V2 Premature Termination Report

RGCB IHEC Protocol no.:	
Protocol title:	
Principal Investigator:	
Department:	

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RGCB IHEC approval date:		Date of last Annual/ Periodic status report submitted to RGCB IHEC:	
Date of initiation of Study:		Termination/suspension /discontinuation date:	
No. of participants enrolled:		No. of participants completed:	
No. of ongoing participants:		No. of drop outs: Reason for each drop-out:	
SAEs (total no.): _____	Whether SAEs were reported to the RGCB IHEC? Yes No		
Brief summary of results: (use extra blank paper, if more space is required) _____ _____			
Reason/s for termination/suspension/discontinuation: _____ _____			
Signature of Principal Investigator with date: _____			

Discussed at the RGCB IHEC meeting held on _____

Action taken:

Approval of the Premature Termination/ suspension /discontinuation of the project

Requires more information/ action as follows: _____


Signature of Member Secretary, RGCB IHEC with date

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Waiver of Written / Verbal Informed Consent

SOP Code: SOP 15/V2

Date: November 30, 2019

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15.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC) may grant waiver of written or verbal informed consent.

15.2 Scope

This SOP applies to the all protocols submitted for review by the RGCB IHEC that ask for consent waiver.

15.3 Responsibility

It is the responsibility of the RGCB IHEC to review and approve a request for verbal/written consent waiver. The Member Secretary will record the decision in the minutes and in the Application Form. The Chairperson will sign and date letter conveying the decision.

15.4 Detailed instructions

- The Application Form (AX 01/SOP 15/V2) is designed to standardize the process of applying for waiver of written/verbal consent.
- When a request for waiver of consent is received from the Principal Investigator (PI) to the RGCB IHEC in the given format, the following steps are taken:
 - The RGCB IHEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.
 - The RGCB IHEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- The RGCB IHEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.
- The final decision whether to grant the waiver is taken at a full committee meeting unless the project is considered under expedited review.
- The decision regarding approval/ disapproval of waiver is informed to the PI in writing. If the waiver is not granted, the RGCB IHEC will provide reasons for the same.

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15.5 Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents	RGCB IHEC Secretariat
2	Review of protocol and application for waiver of consent	RGCB IHEC Members
3	Decision regarding waiver of consent	RGCB IHEC Members during Full committee meeting
4	Communicate the decision to the Investigator	RGCB IHEC Secretariat
5	Recording and filing the decision	RGCB IHEC Secretariat

15.6 Annexure

- Annexure 1 Application form for requesting waiver of consent


Annexure 1: AX 01/SOP15/V2 Application form for requesting waiver of consent

1. Principal Investigator's name: _____

2. Department: _____

3. Title of project:

4. Names of co-investigators and Department/s:

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5. Request for waiver of informed consent:

Please tick the reason(s) for requesting waiver

- a Research involves ‘not more than minimal risk’**
- b There is no direct contact between the researcher and participant**
- c Emergency situations as described in ICMR Guidelines**
- d Any other (please specify)**

Statement assuring that the rights of the participants are not violated

State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

Principal Investigator’s signature with date: _____

Final decision at full committee meeting held on: _____

Waiver granted Yes No

If not granted, reasons

Signature of the Member Secretary with Date: _____

Type of research projects which may qualify for consent waiver:


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A request to waive written informed consent must be accompanied by a detailed explanation justifying waiver. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants and maintenance of confidentiality about the data of the research participants. The following criteria (ICMR 2006 guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. e.g. a retrospective review of patient case records to determine the incidence of disease / recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].
2. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. e.g. conducting interviews with citizens about their religious beliefs / people with HIV and AIDS / conducting phone interviews with homosexuals. The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IEC.

[In case of telephonic interviews, waiver of written informed consent may be requested but verbal consent is mandatory].

- a. The following documents need to be submitted for the IEC review for verbal
 - ✓ A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
 - ✓ The interview schedule (questions to be asked) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.
- b. Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart indicating the participants as


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participant 1, participant 2, etc and a column indicating that verbal consent was given along with the date. 3.

3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
4. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc.
5. In emergency situations when no surrogate consent can be taken. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he / she gains consciousness or to relative / legal guardian when available later.

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Site Monitoring and Post-approval Monitoring Activities

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16.1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for monitoring and oversight of a RGCB IHEC approved protocol.

16.2. Scope

This SOP applies to all RGCB IHEC approved studies for which off-site and a routine or for-cause on-site monitoring may be undertaken by the RGCB IHEC.

16.3. Responsibility

It is the responsibility of the RGCB IHEC or Chairperson and Member Secretary to decide to conduct off-site and on-site monitoring. If further required it is the responsibility of the designated RGCB IHEC member(s) to perform on-site monitoring of selected study site(s).

16.4. Detailed instructions

The monitoring process involves two major oversight activities as given below:

- Off-site monitoring/oversight- Review done by Ethics Committee during full Committee meetings on quarterly, half yearly and annual progress report basis depending on the risk involved and duration of the study.
- On-site monitoring/oversight - Review at random done by member secretary in consultation with the Chairperson and assessed by RGCB IHEC designated members for on-site routine or 'for-cause' monitoring.

16.4.1. Off-sight Monitoring

This will be done on 3 monthly basis for protocols of 6 months duration and on 6 monthly basis for those of longer duration. The selection of files for review will be at random.

- RGCB IHEC requirements
 - Compliance with approved protocol and conditions if any
 - Maintenance and confidentiality of records
 - Progress reports and completion report
 - Publications if any during period of study
 - Whether information is submitted for -
 - Any proposed changes in protocol

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- Any unforeseen events that might ethically be unacceptable for continuing the project and would require amendments
- Any new information positive or negative from related studies
- A report will be prepared addressing any shortcomings and nonconformities observed by suggesting corrective and preventive action. The report will be sent to PI for clarification and correction, and submitted to RGCB IHEC for review and appropriate course of action as continuation/discontinuation/suspension/termination.
- The report has to be filed for Record.

16.4.2. On site monitoring

16.4.2.1 Selection of study sites

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Committee, which is recorded in the RGCB IHEC decision form AX 03/SOP 7A/V2) and in the RGCB IHEC minutes.
- “*For-cause monitoring*” will be performed at sites for reasons identified by any member of the RGCB IHEC, after approval by the Chairperson.
- The reasons for identifying a particular site for “*for-cause monitoring*” could include any one or more of the following:
 - Large number of Protocol deviations,
 - Protocol violations even after initial warning,
 - Large number of studies carried out at the study site or by the investigator,
 - Large number of Serious Adverse Events (SAE) reports,
 - High recruitment rate,
 - Complaints received from participants or any other person,
 - Frequent failure to submit the required documents,
 - Any other cause as decided by RGCB IHEC.

16.4.2.2 Before the visit

- Irrespective of the cause for conducting monitoring the following procedure will be followed :

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- The Chairperson will identify and select one or more RGCB IHEC members (henceforth referred to as monitors) to conduct monitoring of a site.
- The selected members will be given an appointment letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson.
- The Secretariat will decide the date of the monitoring in consultation with the monitors and the PI.
- The final date will be communicated to the PI and monitors (with a request to be available).
- The monitor will receive from secretariat the relevant reference material and/or project documents, review them and make appropriate notes/ changes.
- Monitors will carry with them Site Monitoring Visit Report Forms (if applicable) collected from the Secretariat.

16.4.2.3 During the visit

- The Monitor will follow the check list and:
 - check the log of delegation of the team, responsibilities of study team,
 - check if the site is using latest RGCB IHEC approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
 - observe the informed consent process, if possible,
 - review randomly selected participants' files to ensure that participants are signing the correct informed consent,
 - check if the investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study), storage times, conditions and acceptability of expiry dates and if sufficient supplies are available, wherever applicable,
 - verify that the investigator follows the approved protocol and all approved amendment(s), if any,

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- ensure that for clinical trials the investigator and the investigator's trial staff are adequately informed about the trial,
- verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals,
- verify that the investigator is enrolling only eligible subjects,
- determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events,
- review the project files of the study to ensure that documentation is filed appropriately,
- review the source documents for their completeness, and
- collect views of the study participants, if possible,
- The Monitor will fill the Site Monitoring Visit Report Forms (if applicable), sign with date.

16.4.2.3 After the Visit

- The Monitor will submit the completed Site Monitoring Visit Report Forms (if applicable) to the RGCB IHEC secretariat within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).
- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next full board RGCB IHEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The RGCB IHEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
 - Continuation of the project with or without changes,
 - Restrictions on enrolment,
 - Recommendations for additional training,

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- Recruiting additional members in the study team,
- Revising/ providing qualifications/ experience criteria for members of the study team,
- Termination of the study,
- Suspension of the study, etc.
- If the Monitor has findings that impact on safety of the participant, the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.
- The final decision taken at the full board RGCB IHEC meeting will be recorded in the Site Monitoring Visit Report Form.
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

16.5. Annexure

- Annexure 1 - AX 01/SOP 16/V2 Site Monitoring Visit Report
- Annexure 2 – AX 01/SOP 16/V2 Monitoring of Audiovisual recording of AV consent Process

Annexure 1: AX 01/SOP 16/V2

Site Monitoring Visit Report


(Please tick the box corresponding to the answer)

RGCB IHEC Project no.	Date of Visit:
Study Title:	
Principal Investigator and Department:	

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Type of study:	<input type="checkbox"/> Investigator initiated	<input type="checkbox"/> Pharma	<input type="checkbox"/> Thesis
Government agency	<input type="checkbox"/>	Others	<input type="checkbox"/>

Date of RGCB IHEC approval: Date of Initiation of the study: Duration of study:
Reason for monitoring: <input type="checkbox"/> Routine <input type="checkbox"/> For-cause (State reason/s) <input type="checkbox"/> Protocol Violations/Deviations <input type="checkbox"/> SAE reporting <input type="checkbox"/> Recruitment rate <input type="checkbox"/> Other _____
Last monitoring done, if any, <input type="checkbox"/> Yes Date of last monitoring _____ No <input type="checkbox"/>
Project Status: 1. Ongoing <input type="checkbox"/> 2. Completed <input type="checkbox"/> 3. Recruitment Completed <input type="checkbox"/> 4. Follow-up, extension study <input type="checkbox"/> 5. Suspended <input type="checkbox"/> 6. Terminated <input type="checkbox"/> In case of the response to the above question is option 5 or 6, kindly provide reason/s: _____ _____

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Recruitment Status: ☐ Total patients to be recruited : _____

☐ Screened: _____ ☐ Screen failures: _____ ☐ Enrolled: _____

☐ Withdrawn: _____

Reason: _____

☐ Discontinued: _____ Reason: _____

☐ Completed: _____


☐ Active: _____

<p>Are the present study team members as per the list approved by the RGCB IHEC</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Are site facilities appropriate?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Is the recent version of Informed Consent Document (ICD), after RGCB IHEC approval, used?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Whether appropriate vernacular consent has been taken from all patients?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Any other findings noted about the ICDs?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:

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<p>Is recent RGCB IHEC approved version of protocol used?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Have the eligibility, inclusion exclusion criteria been adhered to? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Was informed consent process witnessed?</p>	Comment
<p>Were participants interviewed?</p>	Comment
<p>Any adverse events found?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:

<p>Any SAEs found?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Were the SAEs informed to RGCB IHEC within timelines specified by CDSCO?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:

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<p>No. of deaths reported:</p> <p><input type="checkbox"/> Deaths unrelated to participation in the trial:</p> <p><input type="checkbox"/> Deaths possibly related to participation in the trial:</p> <p><input type="checkbox"/> Deaths related to participation in the trial</p> <p>Any other non-death study related injury</p>	<p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>Comments (If Any)</p> <p>_____</p> <p>_____</p> <p>_____</p>
Compensation paid for study related injury or death	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA</p> <p>Comments (If Any)</p>
<p>Are there any protocol non-compliance deviations/violations?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Have the protocol non-compliance deviations/violations been informed to RGCB IHEC?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
<p>Are all Case Record Forms up to date?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:


<p>Are storage of data and investigating products locked?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	Comment:
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How well are the participants protected? <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Not good	Comment:
Any other remarks <input type="checkbox"/> Yes <input type="checkbox"/> No	Give details:
Duration of visit: _____ hours	Starting from: Finish:
Name of the study team member/s present: Signature _____	Date:
Name of RGCB IHEC members and representatives who attended monitoring visit:	
Completed by: Signature: _____	Date:

Final Decision at the RGCB IHEC meeting held on

Signature of Chairperson, RGCB IHEC with date

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Annexure 2: AX 02/SOP 16/V2

Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured):
 - Yes _____ No _____
 - Remarks: _____
2. The consent is taken in language the participant/LAR understands best and is literate in.
 - Yes _____ No _____
 - Remarks: _____
3. Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process and information about necessity for audiovisual recording
 - Yes _____ No _____
 - Remarks: _____
4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.
 - Yes _____ No _____
 - Remarks: _____
5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
 - Yes _____ No _____
 - Remarks: _____

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6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the RGCB IHEC.

- Yes _____ No _____
- Remarks: _____

7. Explanation or narration by the person conducting the informed consent discussion.

- Yes _____ No _____
- Remarks: _____

8. Questions asked by the potential participant/LAR are answered satisfactorily.

- Yes _____ No _____
- Remarks: _____

9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.

- Yes _____ No _____
- Remarks: _____

10. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.


- Yes _____ No _____
- Remarks: _____

11. Documentation of signatures of all those involved in the Informed Consent Process.

- Yes _____ No _____
- Remarks: _____

12. Clarity and completeness of AV recording

- Yes _____ No _____
- Remarks: _____

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13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.

- Yes _____ No _____
- Remarks: _____

16.6. Flow chart


No.	Activity	Responsibility
1	Selection of study sites	RGCB IHEC Member Secretary/ Chairperson
2	Identification of RGCB IHEC members for monitoring during meeting	Chairperson
2	Inform Principal Investigator in writing	Secretariat
3	Review of RGCB IHEC protocol file prior to visit and collect Site Monitoring visit report from RGCB IHEC office	RGCB IHEC member
4	Review or monitoring of site	RGCB IHEC member
5.	Complete the monitoring report and present in RGCB IHEC meeting	RGCB IHEC member
6.	Communication of RGCB IHEC decision to PI	Secretariat

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Dealing with Participants' Requests and/or Complaints Coming to Ethics Committee

SOP Code: SOP 17/V2

Date: November 30, 2019

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17.1. Purpose

The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint/s that is/are related to their participation in research approved by the Rajiv Gandhi Centre for Biotechnology Institutional Ethics Committee (RGCB IHEC).

17.2. Scope

This SOP applies to handling of requests for information/ complaints made by participants concerning the rights and well-being of the research participants participating in research studies by the RGCB IHEC.

17.3. Responsibility

It is the responsibility of the RGCB IHEC Secretariat and Chairperson/ Member Secretary to initiate the process of giving information asked by research participants or to address any injustice that has occurred, if any complaints are received.

17.4 Detailed instructions

- A request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the RGCB IHEC Member Secretary after entering into the request record form.
- The Member Secretary may receive a request, complaint or query directly from the participant. She/he will record it in the request record form and notify the Secretariat.
- The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant if necessary. If required, the Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).
- The Secretariat will inform the Chairperson about the request, query or complaint received from the research participant.
- In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairperson will provide the information herself/himself or will designate one or more RGCB IHEC member(s) to provide such information.
- In case of a complaint received from a research participant:
 - ❖ The Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson will direct the Member Secretary to:

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- ✓ Appoint a subcommittee of two or more RGCB IHEC members for enquiry in order to resolve the matter.
- ✓ Call an emergency meeting of two or more RGCB IHEC members for discussion or
- ✓ Consider the matter for discussion at the next full committee meeting
- ❖ The Chairperson/ Member Secretary/ designated RGCB IHEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- ❖ The RGCB IHEC will insist on factual details to determine gap, if any, between truth and individual perception.
- ❖ Opportunity will be given to complainant and the accused to make submissions
- ❖ If the matter is serious it will be brought to the attention of the Director who in consultation with the Chairperson will make a decision. For this the Chairperson will provide the following:
 - ✓ the complaint;
 - ✓ material reviewed in the Chairperson's investigation;
 - ✓ the results of the Chairperson's investigation; and
 - ✓ any other relevant documentation.
- ❖ If the Director feels that the matter needs further investigation she/he could set up a panel for that purpose. The possible procedures include the following:
 - ✓ Noting on the file about the occurrence of the matter;
 - ✓ Requirement for amendments to the project, including increased monitoring by the RGCB IHEC;
 - ✓ Suspension of the project;
 - ✓ Termination of the project; or

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✓ Other action to resolve the complaint.

- If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Dean or his/her nominee, or request that the Chairperson do so. The final decision will be taken based on the recommendation of any one of the above by the Member Secretary in consultation with the Chairperson and it will be informed to the research participant and the PI by the Secretariat.
- The information including any action taken or follow-up and final decision will be recorded in the form and signed with date.
- The RGCB IHEC members will be informed about the action taken and the outcomes in the forthcoming RGCB IHEC meeting and minuted.
- The Secretariat will place all documents in the relevant study file.

17.5 Flowchart

No.	Activity	Responsibility
1.	Receiving the request/ query/complaint from research participant	RGCB IHEC Member Secretary/ Member
3.	Initiating process to identify the problem	RGCB IHEC Chairperson/ Member Secretary
4.	Deliberations to arrive at solution	RGCB IHEC Chairperson/ Member Secretary/ Members
5.	Communication with the research participant	RGCB IHEC Secretariat
6.	File the request document	RGCB IHEC Secretariat

17.6 Annexure


- Annexure 1 -Request/ Complaint Form

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Annexure 1: AX 01/SOP 17/V2

Request / Complaint Form

Date:	
Received by :	
Request/ Complaint received through:	<input type="checkbox"/> Telephone No. <hr/> <input type="checkbox"/> Fax No. <hr/> <input type="checkbox"/> Letter / Date <hr/> <input type="checkbox"/> E-mail / Date <hr/> <input type="checkbox"/> Walk-in / Date / Time <hr/> <input type="checkbox"/> Other, specify <hr/>
Participant's Name:	
Contact details Address & Phone:	
RGCB IHEC Project no.	
Title of the Project	

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Starting date of participation :	
Information requested/ complaint/query	
Action taken:	
Reviewed by	
Final Decision	
Date of RGCB IHEC meeting (if applicable)	

Name & Signature of Member Secretary


Date

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Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents

SOP Code: SOP 18/V2

Date: November 30, 2019

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18.1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the Rajiv Gandhi Centre for Biotechnology Institutional Human Ethics Committee (RGCB IHEC), RGCB IHEC administrative documents, archival of closed files and retrieval of documents.

18.2. Scope

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and RGCB IHEC administrative documents by the RGCB IHEC Secretariat.

18.3. Responsibility

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and RGCB IHEC records are prepared, maintained during the study period and kept securely for a period of five years after the closure/ termination of the project.

18.4. Detailed instructions

18.4.1. Maintenance of the Active Study Files

- A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the RGCB IHEC office.
- All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of
 - ✓ All original research proposals reviewed and approved
 - ✓ Reviewer's assessment forms
 - ✓ Study approval letter
 - ✓ Reviewed and approved consent documents
 - ✓ Amendments and any other correspondence
 - ✓ Study progress reports and interim reports
 - ✓ Serious adverse event report forms submitted by investigators
 - ✓ Any other reports
 - ✓ RGCB IHEC correspondence


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- Strict confidentiality will be maintained for the contents of the files
- All active files will be kept secured in a file cabinet with controlled access
- A log book for accessing the files by authorized staff & members will be maintained.

18.4.2. Maintenance of the RGCB IHEC Administrative Records

The RGCB IHEC records will include the following:

1. RGCB IHEC members' records
 - i. Appointment and acceptance letters of each member
 - ii. Signed and dated confidentiality agreements
 - iii. Updated Curriculum vitae (hard copy or soft copy)
 - iv. Training records for each RGCB IHEC member (GCP, SOP)
 - v. Documentation of resignations / terminations
2. RGCB IHEC membership roster - An RGCB IHEC roster will be maintained which will contain:
 - i. Names of RGCB IHEC members
 - ii. Age
 - iii. Gender
 - iv. Evidence of qualifications
 - v. Role on the RGCB IHEC
 - vi. Status of affiliation to institution (e.g., unaffiliated or affiliated)
 - vii. Regular/ Alternate member to the RGCB IHEC (if applicable)
3. RGCB IHEC mandate
4. Correspondence related to changes in RGCB IHEC membership with DCGI, OHRP or any other concerned authority
5. RGCB IHEC attendance roster
6. Agenda and Minutes of RGCB IHEC meetings
7. Standard operating procedures (SOPs)
8. Annual reports

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9. Documents related to Workshops & conferences organized by RGCB IHEC
(Continuing education for members & staff)

10. SOP training and distribution logs

18.4.3. Maintenance of Closed Study Files

- Once the study file is closed (following completion/ premature termination), the related study files will be shifted to the RGCB IHEC Archival shelf.
- All closed study files will be archived in the RGCB IHEC archival shelf for a period of five years from the date of closure of the study.
- A log book for archival of study documents will be maintained

18.4.4. Accessibility / Retrieval

- Study files and administrative records will be made available for audit, making photocopies (if requested by investigator) or any other purpose (e.g., research on SAEs) on request (AX 01/ SOP 18/V2) if authorized by Member Secretary/ Chairperson.
- Representatives of regulatory authorities may have access at all times.
- A log book of retrieval of documents will be maintained.

18.4.5. Disposal of Closed Files and Copies of Protocols and Documents Submitted for RGCB IHEC Review

- At the end of the archival period, the closed files will be shredded and disposed by authorized RGCB IHEC personnel.
- Extra copies of protocols and documents submitted for RGCB IHEC review and any other extra copies will be shredded by authorized RGCB IHEC personnel after the RGCB IHEC meeting without any notification to PI.
- A formal disposal log will be maintained, providing details of documents that will be disposed. (AX 02/ SOP 18/V2)

18.5. Flow Chart

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No.	Activity	Responsibility
1	Organize the contents of the active study files	Secretariat
2	Maintain the active study files and Administrative documents	Secretariat
3	Archival of study files	Secretariat
4	Authorising retrieval of archived documents	Member Secretary
5	Disposing closed study files and maintaining Document disposal log	Secretariat

18.6. Annexure

- Annexure 1 AX 01/ SOP 18/V2 Document Request Form
- Annexure 2 AX 02/ SOP 18/V2 Log for disposal of study documents

Annexure 1: AX 01/ SOP 18/V2 Document Request Form

Project No.:	
Project Title:	
Name of Principal Investigator (PI) :	

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Requested by:	
Documents requested:	
Purpose of the Request:	
Signature of Requesting person:	
Signature of PI:	
Signature of Member Secretary with date:	

Annexure 2: AX 02/ SOP 18/V2
Log for disposal of study document

Project No.	Title	Name of Principal Investigator	No. of files	Date of EC Approval	Date of Study Initiation	Date of Study Closure	Disposed by (Name & Sign) of Authorized Individual

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Reviewing Proposals Involving Vulnerable Populations

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19.1 Purpose

This Standard Operating Procedure (SOP) describes the requirements and process of review of research that involves vulnerable participants.

19.2 Scope

This SOP covers the policies and procedures applied to all research dealing with vulnerable participants submitted to the RGCB IHEC.

19.3 Responsibility

It is the responsibility of the Member Secretary with Secretariat to maintain up-to-date tools, like checklists, for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines.

RGCB IHEC Chairperson / Member Secretary are responsible for ensuring that RGCB IHEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programmes.

The Member Secretary/ Chairperson is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research and for securing consulting expertise as and when required for selected reviews.

RGCB IHEC member is responsible for conducting review of research planned for vulnerable populations, including an assessment of potential for coercion.

19.4 Mandate

- Gazette notification dated 31st July 2015, [G.S.R. 611(E)] has mandated audio-visual recording of informed consent process in case of vulnerable participants in clinical trials of new chemical entity/ new molecular entity. [<http://www.ferci.org/wpcontent/uploads/2014/07/Gazette-Notification-31-July-2015-AV-consent.pdf>]
- Regulatory requirements of Central Drugs Standard Control Organization Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, 2015 for new drugs.
- World Medical Association Declaration of Helsinki- Ethical Principles for Medical Research Involving Human Subjects, 2013.
- National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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19.5 Detailed instructions

19.5.1. Reviewing protocols with vulnerable participants

- The protocol should be reviewed as per SOP 7A/V2. Additionally, the protocol should be reviewed to assess if the following points are addressed:
 - Can the research be performed in any other non-vulnerable participants?
 - Is there justification to use vulnerable population
 - Do the benefits justify the risks o Are the participants selected equitably
 - Have the measures to protect Autonomy of the vulnerable population been described
- RGCB IHEC members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study.
- The review must address all points in the checklists for different vulnerable populations (Annexure 1 to 5- SOP 19/01).

19.5.2. Appointing Reviewers


The Member Secretary/Chairperson will appoint two or more members of the RGCB IHEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols.

19.5.3. Duties of Secretariat

- Provide a suitable checklist to the investigator depending on the type of participants to be recruited for the study.
- Provide appropriate reference material or help reviewer locate the material relevant to vulnerable populations when specifically requested for, by a reviewing member.

19.5.4. Responsibilities of Reviewers

- RGCB IHEC Members will review the protocol and the informed consent document or assent form as per this SOP and SOP 07A/V2.
- The RGCB IHEC members will discuss the comments in the RGCB IHEC meeting and letter regarding approval/modification/ disapproval will be sent to the principal investigator.
- The discussion will be documented in the minutes.

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- The Member Secretary will ensure that the RGCB IHEC recommendations have been incorporated in the revised protocol and protocol related documents.

19.5.5 Approval of the protocol

- The final version of the protocol will be approved at a full board meeting.
- Wherever necessary the RGCB IHEC approval should state that if in future the vulnerability status of the participant's changes, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant will be re-consented.

19.6 Flowchart

No.	Activity	Responsibility
1	Appoint reviewers	Chairperson/ Member Secretary
2	Review the protocol	RGCB IHEC members
3	Discussion at RGCB IHEC meeting	RGCB IHEC members
4	Communicating the decisions to principal investigator	RGCB IHEC Secretariat

19.7 Annexure

NOTE: The following Annexure apply to some sections of vulnerable participants. These checklists should be filled in by principal investigator and should be reviewed by RGCB IHEC members. Appropriate modifications should be made as per individual RGCB IHEC requirement

- Annexure 1 AX 01/SOP 19/V2 – Checklist: Requirements for Research Involving Children
- Annexure 2 AX 02/SOP 19/V2 - Checklist: Requirements for Research Involving Pregnant Women & Fetuses
- Annexure 3 AX 03/SOP 19/V2- Checklist: Research Involving Cognitively Impaired Adults
- Annexure 4 AX 04/SOP 19/V2- Checklist-Research Involving Students, Employees or Residents
- Annexure 5 AX 05/SOP 19/V2 – Checklist: Considerations for Genetic Research
[Adapted from <http://www.kem.edu/wp-content/uploads/2014/04/SOP-24.pdf>,

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Reviewing proposals involving vulnerable Populations
<http://www.kem.edu/wpcontent/uploads/2014/04/SOP-24.pdf>

Annexure 1: AX 01/SOP 19/V2

Checklist: Requirements for Research Involving Children

Name of Principal Investigator:


Study Title:

For the principal investigator		RGCB IHEC Office
RISK DETERMINATION	BENEFIT ASSESSMENT	RGCB IHEC ACTION
<input type="checkbox"/> Minimal*	<input type="checkbox"/> Direct benefit Approvable	Approvable
	<input type="checkbox"/> No direct benefit	
<input type="checkbox"/> Greater than minimal risk	<input type="checkbox"/> Potential benefit to child	Approvable
<input type="checkbox"/> Greater than minimal risk	No direct benefit, offer knowledge about child's condition/disorder	Approvable on case –by-case basis**

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests

** Consent of both parents may be needed as applicable.

	YES	NO	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			

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Does the study involve healthy children?			
a) If yes: Is the inclusion of healthy children justified?			
Are the studies conducted on animals and adults appropriate and justified?			
a) If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
a) If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
b) If Yes: Are the conditions acceptable?			
Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
Are there special problems that call for the presence of a monitor or RGCB IHEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis C)			
If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)			

Signature of Principal Investigator with date _____

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RGCB IHEC Office use only	
Comments of Primary Reviewer:	
Primary Reviewer's Signature and Date	


Annexure 2: AX 02/SOP 19/V2

Checklist: Requirements for Research Involving Pregnant Women and Fetuses

Name of Principal Investigator:

Study Title: When Research involves pregnant women and fetuses

	YES	NO	NA
Where scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses?			
Is the risk to the fetus not greater than minimal, or any risk to the fetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?			
Any risk that is the least possible for achieving the objectives of the research.			
Is the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived?			
Is the woman or her legally authorized representative, as appropriate, fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child?			
Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?			
Do individuals engaged in the research have a part in determining the viability of a fetus?			

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If the response to any of the above is NO, the research should not be approved by the IEC.

When research involves neonate after delivery

	YES	NO	NA
1. Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?			
2. Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?			
3. Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
4. Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?			
5. Do individuals engaged in the research have a part in determining the viability of a fetus?			
A. Fetuses of uncertain viability			
1. Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and is any risk least possible for achieving the objectives of the research?			
OR			
The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means. Will there be a risk to the fetus from the research?			
2. Is the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative obtained?			
B. Nonviable fetuses			
1. Will vital functions of the neonate be artificially maintained?			
2. Is there any risk to the neonate resulting from the research?			
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
4. The legally effective informed consent of both parents of the neonate will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. (The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this			

 RGCB <small>RECOVERED FOR A BETTER TOMORROW</small>	RGCB IHEC SOP	SOP Version 2 Date: November 30, 2019
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paragraph.)			
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If the response to any of above is NO, the research should not be approved by the IEC.

This type of research can be conducted only after The IEC finds that

(a) The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women and/or fetuses.

(b) The research will be conducted in accordance with applicable regulatory and ethical guidelines.

Signature of Principal Investigator: _____ Date _____

RGCB IHEC Office use only	
Comments of Primary Reviewer	
Primary Reviewer Signature and Date	

Annexure 3: AX 03/SOP 19/V2

Checklist- Research Involving Cognitively Impaired Adults

Name of Principal Investigator:

Study Title:

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant (All items must be "Yes")	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the recruitment of participants justified considering the rationale and objectives of the study?
<input type="checkbox"/> Yes <input type="checkbox"/> No	The risk is justified by the anticipated benefit to the participants
<input type="checkbox"/> Yes <input type="checkbox"/> No	The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Will the participants be withdrawn if they appear to

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		be unduly distressed?
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The proposed plan for the assessment of the capacity to consent is adequate
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Consent will be taken from participants capable of being consulted.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?
2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be "Yes")		
Yes	No	Is the recruitment of participants justified considering the rationale and objectives of the study?
Yes	No	Are the foreseeable risks to the participants low?
Yes	No	Is the negative impact on the participant's well-being minimized and low?
Yes	No	Will the participants be particularly closely monitored?
Yes	No	Will the participants be withdrawn if they appear to be unduly distressed?
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate
Yes	No	Consent will be taken from participants capable of being consulted.
Yes	No	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?

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Signature of Principal Investigator: _____ **Date** _____

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Comments of Primary Reviewer	
Primary Reviewer Signature and Date	

Annexure 4: AX 04/SOP 19/V2

Checklist: Research Involving Students, Employees or Residents

Name of Principal Investigator:

Study Title:


Participants who are students, employees or residents require special considerations.

Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?	No	Yes
Have the risks to participants been minimized?	No	Yes
Have participants been assured that participation is voluntary (no signs of coercion)?	No	Yes
Have participants been assured that privacy and confidentiality will be protected?	No	Yes

Answers to all the above points should be YES for approval

Signature of Principal Investigator: _____ **Date** _____

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Comments of Primary Reviewer	
Primary Reviewer Signature and Date	

Annexure 5: AX 05/ 19/V2

Checklist: Considerations for Genetic Research

	Yes	No
1. Will the samples be made anonymous to maintain confidentiality? If yes, then the following checklist points are not applicable		
2. Will the results be disclosed? a) If yes, has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result? b) Will the results be used in management of current condition of patient?		
3. Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
4. Does the proposed study population comprise family members?		
5. Will family members be implicated in the studies without consent?		
6. Will the samples be destroyed in the future?		
7. Will the samples be used for future research		
8. Is genetic counseling being offered?		

Signature of Principal Investigator: _____ **Date** _____


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Comments of Primary Reviewer	
Primary Reviewer Signature and Date	

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Preparing for Ethics Committee Audit/ Inspection

SOP Code: SOP 20/V2

Date: November 30, 2019

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20.1 Purpose

The purpose of this SOP is to guide an Institutional Ethics Committee (RGCB IHEC) to prepare for an audit or inspection of the RGCB IHEC.

20.2 Scope

The SOP applies to all the RGCB IHEC members and the Secretariat.

20.3 Responsibility

It is the responsibility of the Member Secretary, Chairperson, RGCB IHEC Members and the RGCB IHEC Secretariat to keep RGCB IHEC documents ready for audit and to be available to answer questions during audit or inspection by administrative and regulatory authorities.

20.4 Mandate

The Drugs Controller General India (DCGI) in its gazette notification GSR 72E, dated 08th February 2013, 122DD states, 'The Ethics Committee shall allow inspectors of officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of the trial.'

20.5 Detailed instructions

20.5.1 Receipt of notification of an Audit / Inspection

On receipt of written/ mailed communication regarding audit/ inspection visit, the Member Secretary will inform the Chairperson, RGCB IHEC members and the Head of Institution, if applicable about the date and purpose of the audit/inspection.

20.5.2 Preparing for the audit

- On receiving information about the audit /inspection, RGCB IHEC Member Secretary and/ or RGCB IHEC member/s are given the responsibility by the Chairperson to prepare for the visit with assistance of the Secretariat.
- The Member Secretary and / or designated RGCB IHEC member/s will make arrangements in accordance with the steps mentioned in the checklist.(AX 01/SOP20/V2)
- The studies with incomplete / missing documents will be dealt with separately and actions taken will be documented.
- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

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20.5.3 On the day/s of Visit

- Chairperson / Member Secretary / designated RGCB IHEC Member/s should welcome and accompany the auditors/inspectors to the reserved meeting room. Designated team members must be present in the meeting room.
- The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information is needed.
- The RGCB IHEC Chairperson / Member Secretary / RGCB IHEC Members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.
- The information and files requested by the auditors/inspectors should be made available by the Secretariat.
- The Member Secretary/ designated RGCB IHEC member/ Secretariat will make note of the comments, recommendation of the auditors/inspectors.

20.5.4 Correction of deficiencies observed at audit/ inspection

- Member Secretary/ designated RGCB IHEC member/ Secretariat will review comments and recommendations of the auditor/inspector.
- On receipt of Audit/ Inspection Report the Chairperson should implement corrective and preventive measures and set the timeline for implementation of corrections as stated by the auditor/inspector.
- Action plan should be communicated by the Member Secretary/ designated RGCB IHEC member to the auditor/inspector after seeking approval of the Chairperson.
- A review date for an internal follow-up audit will be decided by the Chairperson (if applicable).
- The Member Secretary/ designated RGCB IHEC member should report the outcome of the internal follow-up audit to the Chairperson.

20.5.5 Recording the Audit/Inspection Visit

- The Member Secretary/ designated RGCB IHEC member/ Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.
- The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.

20.5.6 . Flow Chart

No.	Activity	Responsibility
1	Receipt of Audit/ Inspection notification	RGCB IHEC Member Secretary

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2	Preparing for the audit	RGCB IHEC Member Secretary/ designated RGCB IHEC member/ Secretariat
3	Presenting information and files to auditor/ inspector	RGCB IHEC Member Secretary/ designated RGCB IHEC member/ Secretariat
4	Review comments/ recommendation of auditor/ inspector	RGCB IHEC Member Secretary/ designated RGCB IHEC member/ Secretariat
5	Receipt of audit/ inspection report	RGCB IHEC Member Secretary/ designated RGCB IHEC member
6	Planning corrective/preventive actions and setting timeline for their implementation	setting timeline for their implementation RGCB IHEC Chairperson
7	Conducting internal follow-up audit	RGCB IHEC Member Secretary/ designated RGCB IHEC member
8	Recording the Audit/Inspection Visit	RGCB IHEC Member Secretary/ Secretariat

20.5.7 Annexure

- Annexure 1: AX 01/SOP 20/V2- Audit and Inspection Checklist

Annexure 1: AX 01/SOP 20/V2

Audit and Inspection Checklist

1. Date of letter of communication regarding audit/inspection:
2. Date(s) on which the audit/inspection has been agreed on:
3. To ensure the RGCB IHEC members and staff have been informed about the date/s and time.
4. To ensure availability of RGCB IHEC related information – mandate, terms of reference, organization chart (in the print form) in the RGCB IHEC office.

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5. To make sure of availability of latest copy /copies of signed SOPs in print form in the office and/ or in electronic form on the RGCB IHEC computer/s.
6. To review the SOPs and note details of any omissions or deviations, with reasons.
7. To ascertain availability of all national and international ethics guidelines and regulations in print form and / or in electronic form in the RGCB IHEC office. FERCI MODEL SOPs Preparing for Ethics Committee Audit/ Inspection SOP 20/V2: Effective Date: aa/bb/cccc Page 6 of 7
8. To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/ incomplete documentation and actions taken.
 - a. Records regarding applications of research studies for review including protocols and related documents
 - b. Protocol Assessment Records – Comments of RGCB IHEC members, Meeting Agenda, Minutes (documented in individual study file or separately in meeting records file)
 - c. Communication records with investigator (documented in individual study file)
 - d. Amendment Approvals (documented in individual study file) o SAE reports and SAE related communications with investigator and regulators
 - e. Protocol deviation/violation/exception reports(documented in individual study file)
 - f. Continuing and final completion/termination reports (documented in individual study file)
9. To ensure availability of documents regarding list of members, tenure, appointment details, CVs, baseline and periodic training of RGCB IHEC members.
10. To ensure availability of documents regarding appointment, CVs and training of staff of secretariat.
11. To ensure measures for maintaining security of electronic database and office records.
12. To make sure that maintenance, retrieval, storage, archival and tracking of the study files are done as per the respective SOPs.
13. To ascertain proper labelling and indexing of study files and storage cabinets.
14. To decide which members will communicate with auditors/ inspectors, be available for audit/inspection, prepare action plan and conduct follow-up audit(if applicable)
15. To report about findings and report received regarding audit/inspection to RGCB IHEC members at the full board RGCB IHEC meeting.
16. To make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable.

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Training and Assessment of Ethics Committee Members

SOP Code: SOP 21/V2

Date: November 30, 2019

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21.1 Purpose

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the Institutional Ethics Committee (RGCB IHEC) members and the Secretariat. 2.

21.2 Scope

The SOP applies to all the RGCB IHEC members and the Secretariat.

21.3 Responsibility

It is the responsibility of the RGCB IHEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the RGCB IHEC members and the Secretariat. The Chairperson is responsible for assessment of all RGCB IHEC members and complete a self-assessment exercise at prescribed intervals.

21.3 Detailed instructions

21.3.1 Topics for training

RGCB IHEC members should have knowledge of the following:

- ✓ Relevant research ethics and regulatory guidelines
- ✓ Roles and Responsibilities of RGCB IHEC members
- ✓ Review of protocol and related documents, including concepts of Risk
- ✓ Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- ✓ Recent Developments in relevant health science specialties
- ✓ SOPs of the RGCB IHEC

Secretariat should have knowledge and relevant skills for conducting the following activities:

- ✓ Competency in working on Microsoft word, Excel, RGCB IHEC office software
- ✓ Maintenance of RGCB IHEC Database
- ✓ Communication skills- written and verbal
- ✓ Knowledge about the SOPs

21.3.2 Training of new RGCB IHEC Members

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- ✓ Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.
- ✓ An individual selected as a new member of the RGCB IHEC will be required to attend two meetings as an 'Observer' before being inducted as a member of the RGCB IHEC. Member Secretary or an RGCB IHEC member will provide an introductory training to the new member. The new RGCB IHEC members would be encouraged to undergo online EC training programme too.
- ✓ The RGCB IHEC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- ✓ The RGCB IHEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the RGCB IHEC Members to the Institutional faculty members.
- ✓ The RGCB IHEC may sponsor or reimburse the expenses of an RGCB IHEC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).

21.3.3 Training of the Secretariat

The RGCB IHEC Member Secretary along with other members will train the Secretariat on SOPs. There will be initial training and at least one training session per year on SOPs. The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

21.3.4 Assessment of RGCB IHEC members

- The RGCB IHEC members' performance should be evaluated once a year using an assessment form (AX 01/SOP 21/V2) by the Chairperson.
- The Chairperson should do self-assessment once a year

21.3.5 Maintenance of training records of the RGCB IHEC Members and the Administrative Staff

The Secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual RGCB IHEC members. The copies will be filed in the individual members' files. The records

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regarding training copies of the Secretariat will also be maintained in their respective files.

21.4 Flow Chart No.


No.	Activity	Responsibility
1	Ensuring Training of RGCB IHEC members	RGCB IHEC Member Secretary/ Chairperson
2	Training of Secretariat RGCB IHEC Member Secretary/ Members	RGCB IHEC Member Secretary/ Members
3	Assessment of performance of members	RGCB IHEC Chairperson
4	Assessment of performance of Chairperson	RGCB IHEC Chairperson (self evaluation)

21.5 Annexure

- Annexure 1: AX 01/SOP 21/V2- Self Assessment Form for RGCB IHEC Member Secretary/ Member
- Annexure 2: AX 02/SOP 21/V2- Self Assessment Form for RGCB IHEC Chairperson

Annexure 1: AX 01/SOP 21/V2 Assessment Form for Ethics Committee Members

1. Current tenure
2. Terms served
3. Training received
4. Type of training received
5. No of meetings attended
6. No of projects reviewed per meeting as primary reviewer
7. No of projects reviewed per meeting as secondary reviewer
8. Participation in SAE report review process- yes/no
9. Participation in site monitoring visits - yes/no
10. Number and type of continuing training workshops organized for RGCB IHEC members (applicable to Member Secretary)
11. Number and type of continuing training workshops organized for staff of the RGCB IHEC secretariat (applicable to Member Secretary)
12. Any other significant contribution to the field of research ethics
13. Remarks by the Chairperson on the self-assessment

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Annexure 2: AX 02/SOP 21/V2
Self Assessment Form for RGCB IHEC Chairperson

1. Current tenure
 2. Terms served –
 3. Training received –
 4. Type of training received –
 5. No. of meetings held in current year –
 6. No of meetings attended
 7. Whether quorum requirement fulfillment ensured as per schedule Y in RGCB IHEC meetings
 8. Whether considerations related to conflict of interest considered
 9. Any significant contribution to the field of research ethics
 10. Any other comments
-

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Appendix 01/V2

Guidelines for Research Protocols which require Collection and Storage of Genetics Materials

For the purpose of these guidelines, “Genetic Materials” are defined as human tissue samples (blood, serum, tumor, etc.) on which genetic related research, such as biochemical studies of inherited human traits or identification of DNA mutations, may be performed.

A. Previously acquired samples

- i. Previously acquired genetic material may be used if identifiers are stripped irrevocably from samples.
- ii. If identifiers are present, experiments not described in present protocols must be submitted for IEC review.


B. Prospectively acquired samples

1. Anonymous samples (further identification made impossible)

- i. Ownership of genetic material will generally remain with the institution. This must be stated in the consent form.
- ii. The general scope of the investigations must be explained in the consent form, but new avenues of investigation in the future are permissible if this possibility is explained in the consent form.
- iii. Whether the genetic material will be shared by other investigators should be explicit in the consent form.
- iv. The consent form should make clear that no specific information relative to the individual donor will be forthcoming; however, information that accrues from the study that is valuable to society may be shared with the individual.

2. Identified samples

- i. If genetic material is linked to the donor by specific identifiers, ownership of the material will generally remain with the institution. If a commercial use is anticipated for the genetic material, the individual must be notified. The general policy of ownership should be stated in the consent form using the following wording:
“I understand that additional or “leftover” (blood, serum, tumor, etc.) tissue may be

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used for future research which may result in financial gain for RGCB and the researchers. I also understand that my donated tissue will be one of many that are used in the research and it will be virtually impossible to attribute findings to any one sample. I understand, however, that I am not otherwise waiving any of my legal rights by participating in this study.”

- ii. If identifiers are present, new experiments must be reviewed by the EC and new consent obtained from the research participant regardless of the details of ownership.
- iii. The investigator may include a provision in the consent form for new experiments not requiring new consent if identifiers are irrevocably removed from the samples. If the investigator anticipates future experiments without identifiers, this possibility should be present in the original consent form. The methods for removal of identifiers must be approved by the EC. Removal of identifiers must not be employed as a method of avoiding ownership issues.
- iv. A satisfactory method for sharing or withholding information gained by the research must be in the research protocol and clearly indicated in the consent form.
- v. Details for sharing or not sharing the genetic material with other investigators must be present in the protocol and clearly indicated in the consent form.
- vi. The length of time the genetic material will be maintained must be indicated in the consent form.

C. Donation of genetic material as a requirement for participation in a research protocol.

- i. Donation of genetic material may be required for participation in a protocol only if the presence of the genetic material is necessary to satisfy the central question of the research.
- ii. The investigator will be required to make a clear case in the research protocol for the necessity of the genetic material, if donation of genetic material is mandatory.
- iii. This policy applies to genetic material with or without identifiers. APP02/V1

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Appendice 02/V1

Guidelines for Submission and IEC review of Gene Therapy /Gene Transfer Protocols

As of October 10, 2000 the ICMR formulated Ethical Guidelines for Biomedical Research on Human Subjects. ICMRs goal is to insure that no research participant is enrolled in a human gene therapy/gene transfer research protocol before the local IEC have the benefit of the broad perspective and experience in protocol review and risk assessment.

In November 2001, the Department of Biotechnology also finalized the Ethical Policies on the Human Genome, Genetic Research and Services.

Guidelines are available at the Office of Biotechnology Activities Internet site <http://dbtindia.nic.in/ethical.html>

The following items are required to be addressed in the protocol to provide the necessary information for IEC review:

A. Background and justification

- i. Why is this disease a good candidate for gene transfer or gene therapy?
- ii. What previous work has been done, including studies of animals and cultured cell models?
- iii. Does the work demonstrate effective gene delivery? How does the proposed study relate to previous work?
- iv. Is the disease course sufficiently predictable to allow for meaningful assessment of the results of the treatment proposed?
- v. What level of gene expression is presumed to be required to achieve the desired effect?
- vi. Given responses to the above questions, is there a sufficient justification for the investigator to proceed at this point to a clinical trial?

B. Research design

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- i. What are the objectives of the proposed study (e.g., establishing feasibility or relative safety of the gene transfer, determining therapeutic effectiveness, establishing a safe dose range, demonstrating proof of principle, etc.)?
- ii. Is the goal of the study to ameliorate or cure disease or to enhance healthy individuals?
- iii. What is the target tissue for gene transfer (e.g., bone marrow cells, skeletal muscle cells, respiratory epithelial cells, central nervous system tissue, etc.)?
- iv. What method(s) (e.g., direct injection, inhalation, ex vivo genetic modification with injection of modified cells) and reagent(s) (e.g., vectors based on retroviruses, adenoviruses, adeno associated viruses, herpes viruses) will be employed for gene delivery? What is the rationale for their use? Are other methods or reagents known that are more appropriate with regard to efficacy, safety, and stability?
- v. How will the investigator determine the proportion of cells that acquires and expresses the added DNA?
- vi. How will the investigator determine if the product is biologically active?
- vii. Is the planned statistical treatment appropriate: i.e., is it likely to provide valid answers to the study question?
- viii. Is it reasonable to expect that the research design proposed will meet the investigator's objectives?

B. Procedures

- i. What research-specific procedures and research-specific investigations are required by the study over and above those that would be required for patients receiving standard clinical care (e.g., physical examinations, venous or arterial blood tests, collection of target cells, imaging procedures, irradiation, chemotherapy, direct injection of vector, re-injection of genetically modified cells, organ or tissue transplantation, surgery, tissue/tumor donation, questionnaires, interviews)?
- ii. Is long term follow-up appropriate or essential for this protocol? If long term follow-up is proposed, is there justification for the number of visits and the length of time required? Is such follow-up feasible in the case of this protocol (e.g., have provisions been made for subjects who move? Is adequate funding available for such follow-up?)?
- iii. What are the procedures for obtaining or maintaining information in a data/DNA bank (e.g., use of identifiers, limitation on access, need for consent, sharing with other investigators, duration of storage, future subject contact)?

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- iv. Are all of the research-specific procedures necessary? In combination with data collected in the course of clinical care, is it reasonable to expect that the information produced by this study will be sufficient to answer the research question?

C. Confidentiality


- i. Are the practical steps for maintaining confidentiality of data/records/database information clearly specified and adequate (e.g., encryption, use of unique identifiers, sequestering of records, security measures)?

E. Participant selection

- i. How has the study population been defined?
- ii. Has an adequate rationale been provided for each eligibility criterion (e.g., safety considerations, definition of disease, avoidance of additional concurrent therapies, administrative considerations)? Do they strike a defensible balance between scientific validity and generalizability (i.e., is the study population sufficiently, but not unduly, restricted so as to yield interpretable results)?
- iii. How will participants be recruited? If a cohort of eligible patients exists, how will selection be made amongst them? If several trials exist for which the same patients are eligible, how will this be presented to prospective subjects?
- iv. Does the definition of the research population reflect appropriate scientific, clinical, and ethical norms? In recruiting and negotiating with potential participants, have the norms of non discrimination been respected?

F. Risks, discomforts, and benefits

- i. What risks and discomforts are associated with the research-specific procedures and investigations (e.g., surgery, chemotherapy, radiation, bone marrow transplantation)? Have they been minimized?
- ii. If a virus-mediated gene transfer is proposed, what is the potential for the presence of a replication-competent or pathological virus or other form of contaminants? How sensitive are the tests to detect such viruses or contaminants? What level of viral presence or other form of contamination would be tolerable in this protocol?
- iii. Has the possibility of vertical transmission (i.e., gene insertion into germ cells or a fetus) or horizontal transmission (e.g., to family members or health care staff)

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been considered? What measures have been taken to minimize the risks of transmission? Are other measures possible? If transmission were to occur, what would be the consequences?

- iv. What are the risks for the vector to activate an oncogene or inactivate a tumor suppressor gene leading to vector-related malignancy?
- v. Are the risks and discomforts of the study justified given the potential benefit to participants and the scientific importance of the research?

G. Information to participants

- Have prospective participants been adequately informed of the following:
 1. What is being studied and why, giving details about study procedures, known or potential risks, discomforts and benefits, and alternatives to participation;
 2. Their rights: (a) to information on an ongoing basis, confidentiality with regard to their participation and handling of their data, and the right to consult with others before making a decision whether to participate; and (b) to withdraw from the study without penalty or loss of benefits, as well as of any health consequences of withdrawal for themselves or their immediate contacts, or limitations on withdrawal, if any;
 3. Any special issues related to this gene therapy trial, such as uncertainty associated with short and long term risks and benefits or the possibility of media attention; and
 4. Any commercial or financial interests in the research.
- Have prospective participants been provided this information in simple language, using translation where necessary, with answers to their questions, referral to other sources of information, and adequate time to make up their minds whether to participate?
- If there is no individual benefit from participation in the research, has this been appropriately disclosed?
- Will the general study results be made available to participants?
- Do all of the elements of the consent process combine to allow participants a full opportunity to make an informed choice?

Reference:

- ***Ethical Guidelines for Biomedical Research on Human Subjects ICMR 2000***
- ***National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR 2017***