|  |  |
| --- | --- |
|  | **(Annexure 1B)**  **Application Form for Initial Review – Clinical Trial**  Rajiv Gandhi Centre for Biotechnology  **EC Ref. No*.(****for office use):* |

|  |
| --- |
| **General Instructions: a) Tick one or more as applicable. Mark NA if not applicable** |
| **b) Attach additional sheets if required** |

**SECTION A - BASIC INFORMATION**

1. **ADMINISTRATIVE DETAILS**

(a) Name of Principal Investigator:

(b) Designation:       (c) Division:

1. Date of Submission: Click here to enter a date.
2. Title of the study:
3. Acronym/ Short title, (If any):

(g) Details of Investigators:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | Designation and Qualification | | Department and Institution | | Address for communication**[[1]](#footnote-1)** |
| Principal Investigator/Guide | | | | | |
|  | |  |  |  | |
| Co-investigator/student/fellow | | | | | |
|  |  | |  | |  |

(h) Duration of the study:

1. **FUNDING DETAILS AND BUDGET**
2. Total estimated budget for site:
3. Duration of the budget:
4. Indian Sponsor:

Central government funding  State government funding  Institutional funding  Private

Specify

1. International Sponsor:

Government  Private  UN agencies

1. Industry:

National  Multinational

1. Contact address of the sponsor:

|  |
| --- |
| **SECTION B - RESEARCH RELATED INFORMATION** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **OVERVIEW OF RESEARCH** | | | | | | | |
| (a) | | 1. Type of clinical trial  |  |  | | --- | --- | | Regulatory trial | Academic trial |   CTRI registration number:       NABH accreditation number       EC registration number: | | | | | |
| (b) | | Single center  Multi-centric | | | | | |
| (c)  (d)  (e)    (f)  (g)  (h)  (i)  (j)  (k)  (l)  (m)  (n)  (o)  (p)  q)  (r)  (s)  (t)      (u)  (v) | | If regulatory trial, provide status of CDSCO permission letter   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Tick all categories that apply to your trial   |  |  |  |  | | --- | --- | --- | --- | | Phase - I |  | Phase II |  | | Phase III |  | Phase IV or Post Marketing Surveillance |  | | Investigational medicinal products |  | Investigational New drug |  | | Medical devices |  | New innovative procedure |  | | Drug/device combination |  | Bioavailability/Bioequivalence studies |  | | Non-drug intervention |  | Repurposing an existing intervention |  | | Indian system of medicine (AYUSH) |  | Stem cells |  | | Phytopharmaceutical drug |  | Approved drug for any new indication or new route of administration |  | | Others (specify) | | | | | | Trial design of the study (May choose more than one)   |  |  |  |  | | --- | --- | --- | --- | | Randomized |  | Factorial |  | | Non randomized |  | Stratified |  | | Parallel |  | Adaptive |  | | Cross-over |  | Comparison trial |  | | Cluster |  | Superiority trial |  | | Matched-pair |  | Non-inferiority trial |  | | Others (specify) |  | Equivalence trial |  |   If there is randomization, how will the participants be allocated to the control and study group(s)?    Describe the method of allocation concealment (blinding / masking), if applicable | | List the primary / secondary outcomes of the trial. | | Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any Other Agency such as public relation/Human resource? Yes  No  If yes, Name and Contact details:  State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)   |  |  |  |  | | --- | --- | --- | --- | | Project management |  | Clinical and medical monitoring |  | | Regulatory affairs |  | Data management |  | | Statistical support |  | Medical writing |  | | Site management |  | Audits, quality control, quality assurance |  | | Finance management |  | Recruitment and training |  | | Administrative support |  | Others (specify) |  | |  | | | | | | Please provide the following details about the intervention being used in the protocol | | I. Drug/s, device/s and/or biologics; If yes, provide regulatory approval details  Yes  No  NA | | II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details Yes  No  NA | | III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics | | IV. Provide details of patent of the drug/s, device/s and biologics. | | Describe in brief any preparatory work or site preparedness for the protocol? Yes  No NA  If yes, (100words) | | Is there an initial screening/ use of existing database for participant selection? Yes  No  NA  If Yes, provide details*1* | | Are there any anticipated incidence, frequency and duration of adverse events related to the intervention? If yes, provide details of arrangements made to address them. Yes No NA | | Does the study use a placebo?  If yes, justify the use of the placebo and risks entailed to participants. Yes  No  NA | | Will current standard of care be provided to the control arm in the study? Yes No  NA  If no, please justify. | | Are there any plans to withdraw standard therapy during the study ?If yes, please justify.  Yes No  NA | | Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes No  NA | | Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes No | | Participant Information Sheet(PIS) and Informed Consent Form (ICF)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | English |  | Local language  (Certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants) |  | Other*(Specify)* |  |   List the languages in which translations were done  Justify if translation not done  1In order to select participants for your protocol does the protocol requires you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same | | Involvement/consultation of statistician in the study design Yes  No  NA | | Is there any insurance coverage of the trial? If yes, provide details. Yes  No | | i. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? Please provide details. Yes  No    ii. Is the PI trained in GCP in last 3 years?. If yes, Please enclose certificate Yes  No | | | | | | |
| 1. **METHODOLOGY** | | | | | | | |
| (a) | | Is there an external laboratory involved for investigations?**[[2]](#footnote-2)**Yes No NA | | | | | |
| |  | | --- | | **SECTION C - PARTICIPANT RELATED INFORMATION** | | | | | | | | | |
| 1. **RECRUITMENT AND RESEARCH PARTICIPANTS** | | | | | | | | |
| (a) | | | Type of participants in the study: (If no, skip to 6)   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Healthy volunteer |  | Patient |  | Vulnerable person/ Special groups |  | Others *(Specify)* |  |   Who will do the recruitment?  Participant recruitment methods used:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Posters/ leaflets/Letters |  | TV/Radio ads/Social media/Institution website |  | Patients / Family/Friends visiting hospitals |  | Telephone |  | | Others*(Specify)* | | |  | |  | | |  | | | | | | |
| (b) | | | |  |  |  |  | | --- | --- | --- | --- | | Children under 18 yrs |  | Pregnant or lactating women |  | | Differently abled (Mental/Physical) |  | Employees/Students/Nurses/  Staff |  | | Elderly |  | Institutionalized |  | | Economically and socially disadvantaged |  | Refugees/Migrants/Homeless |  | | Terminally Ill (stigmatized or rare diseases) |  | | Any other *(Specify)*: |  | | | | |  | | | | |  1. Will there be vulnerable person/special groups involved? Yes No NA  1. If yes, type of vulnerable person /special groups | | | | | |
|  | | | 1. Provide justification for inclusion/exclusion criteria      1. Are there any additional safeguards to protect research participants? | | | | | |
| 1. **BENEFITS AND RISKS** | | | | | | | | |
| (a) | | 1. Are there any anticipated physical/social/psychological discomforts/ risk to participants?   Yes No  If yes, categorize the level of risk**[[3]](#footnote-3)**:   |  |  |  |  | | --- | --- | --- | --- | | Less than Minimal risk |  | Minimal risk |  | | Minor increase over minimal risk or Low Risk |  | More than Minimal Risk or High Risk |  | | | | | | | |
| 1. Describe the risk management strategy: (if applicable) | | | | | | |
| (b) | | What are the potential benefits from the study? | | Yes | No | If yes, | Direct | Indirect |
| For the participant | |  |  |  |  |  |
| For the society/community | |  |  |  |  |  |
| For improvement in science | |  |  |  |  |  |
| Please describe how the benefits justify the risks : (If minimal / high risk) | | | | | | |
| (c) | | Are Adverse Events expected in the study**[[4]](#footnote-4)**? Yes No NA  Are reporting procedures and management strategies described in the study? Yes No  If Yes, Specify | | | | | | |
| 1. **INFORMED CONSENT** | | | | | | | | |
| (a) | | Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8. Yes No | | | | | | |
| (b) | | Type of consent planned for :   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Signed consent |  | Verbal/ oral consent |  | Witnessed consent |  | Audio-Video (A/V) consent |  | | Consent from LAR (If so, specify from whom) |  | For children<7 yrs parental/LAR consent |  | Verbal assent from minor (7-12 yrs) along with parental consent |  | Written Assent from Minor (13-18 yrs) along with parental consent |  | | Other *(specify)* | | | | | | | | | | | | |
| (c) | | Who will obtain the informed consent?   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | PI/Co-I |  | Nurse/Counselor |  | Research Staff |  | Other*(Specify)* |  |   Any tools to be used | | | | | | |
| (d) | | Participant Information Sheet(PIS) and Informed Consent Form (ICF)  English Local language other (*specify*)    List the languages in which translations were done | | | | | | |
| (e) | | Provide details of Consent if the study uses previously stored samples5 | | | | | | |

|  |  |  |
| --- | --- | --- |
| 1. **STORAGE AND CONFIDENTIALITY** | | |
| (a) | Identifying Information: Study Involves samples/data. If Yes, SpecifyYes No NA   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Anonymous/unidentified |  | Anonymized: reversibly coded | irreversibly coded | Identifiable |  |   If identifiers must be retained, what additional precautions will be taken to ensure that access is limited / data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) | |
| (b) | Who will be maintaining the data pertaining to the study? | |
| (c) | Where will the data be analyzed6 and by whom? | |
| (d) | For how long will the data be stored? | |
| (e) | Do you propose to use stored samples/data in future studies? Yes No Maybe | |
| **SECTION D: OTHER ISSUES** |

|  |  |
| --- | --- |
| **10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES** | |
| (a) | Will the results of the study be reported and disseminated? If yes, specify. Yes No NA |
| (b) | Will you inform participants about the results of the study? Yes No NA |
| (c) | Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details  Yes No NA |
| (d) | If commercial product is developed, is there any plan for post research benefit sharing with participants? If yes, specify  Yes No NA |
| (e) | Do you have any additional information to add in support of theapplication, which is not included elsewhere in the form? If yes, provide the details. Yes No |

*5Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017,Page 54 in Section 5.8*

*6For example, a data entry room, a protected computer etc.*

|  |
| --- |
| **SECTION E: DECLARATION AND CHECKLIST7** |

|  |  |
| --- | --- |
| **11. DECLARATION (Please tick as applicable)** | |
|  | I/We certify that the information provided in this application is complete and correct. |
|  | I/We confirm that all investigators have approved the submitted version of proposal/related documents. |
|  | I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible. |
|  | I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines. |
|  | I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted. |
|  | I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol. |
|  | I/We declare that the expenditure in case of injury related to the study will be taken care of. |
|  | If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable. |
|  | I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed. |
|  | I/We confirm that we will maintain accurate and complete records of all aspects of the study. |
|  | I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples. |
|  | I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study. |
|  | I/We have the following conflict of interest (PI/Co-PI): |
|  | I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable. |
| Name of PI:       Signature: Click here to enter a date. | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **12. CHECKLIST** | | | | | | | | | | |
| **Sl.No** | **Items** | | | | **Yes** | **No** | **NA** | | **Enclosure No.** | **EC Remarks(If applicable)** |
| **ADMINISTRATIVE REQUIREMENTS** | | | | | | | | | | |
|  | Cover letter | | | |  |  |  | |  |  |
|  | Brief CV of all Investigators | | | |  |  |  | |  |  |
|  | EC clearance of other centers**\*** | | | |  |  |  | |  |  |
|  | Agreement between collaborating partners**\*** | | | |  |  |  | |  |  |
|  | MTA between collaborating partners**\*(OTV reference Number)** | | | |  |  |  | |  |  |
|  | Insurance policy/certificate | | | |  |  |  | |  |  |
|  | Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification | | | |  |  |  | |  |  |
|  | Sanction letter from the Head of the Institution | | | |  |  |  | |  |  |
|  | Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol | | | |  |  |  | |  |  |
| **PROPOSAL RELATED** | | | | | | | | | | |
|  | Copy of the detailed protocol8 | | | |  |  |  | |  |  |
|  | Investigators Brochure (If applicable for drug/biologicals/device trials) | | | |  |  |  | |  |  |
|  | Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated) | | | |  |  |  | |  |  |
|  | Assent form for minors (12-18 years) (English and Translated) | | | |  |  |  | |  |  |
|  | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated) | | | |  |  |  | |  |  |
|  | Advertisement/material to recruit participants (fliers, posters etc.) | | | |  |  |  | |  |  |
| **PERMISSION FROM GOVERNING AUTHORITIES** | | | | | | | | | | |
|  | **Other Registration/ permissions** | **Required** | **Not required** | **Received** | | **Applied dd/mm/yy** | | | **EC Remarks** | |
|  | CTRI |  |  |  | | Enter date | | |  | |
|  | DCGI |  |  |  | | Enter date | | |  | |
|  | HMSC |  |  |  | | Enter date | | |  | |
|  | NAC-SCRT |  |  |  | | Enter date | | |  | |
|  | ICSCR |  |  |  | | Enter date | | |  | |
|  | RCGM |  |  |  | | Enter date | | |  | |
|  | GEAC |  |  |  | | Enter date | | |  | |
|  | BARC |  |  |  | | Enter date | | |  | |
|  | Tribal Board |  |  |  | | Enter date | | |  | |
|  | Others (Specify) |  |  |  | | Enter date | | |  | |
| **ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY** | | | | | | | | | | |
|  | **Item** | | **YES** | **NO** | **NA** | **Enclosure no.** | | **EC remarks** | | |
|  |  | |  |  |  |  | |  | | |
|  |  | |  |  |  |  | |  | | |

*7These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements Acknowledgement for Receipt of Application (Copy to be provided to PI)*

**\****For multicentric research. MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre*

*8Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 page no. 35Box 4.4(b)*

1. *Include telephone/mobile, fax numbers and email id* [↑](#footnote-ref-1)
2. *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.* [↑](#footnote-ref-2)
3. *For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1* [↑](#footnote-ref-3)
4. *The term adverse events in this regard encompass both serious and non-serious adverse events.* [↑](#footnote-ref-4)