**Yenepoya Ethics Committee-1**

**Ann01/SOP 06/v3: Application form for initial review for all protocols**

**(Regulatory, non-regulatory clinical trials, observational and basic science studies)**

**Instructions to fill:**

* *Please fill out the soft copy of this form, print and take signatures, wherever applicable*
* *Incomplete files will not be accepted*
* *Tick √ in the box for the appropriate answer*
* *Write Not Applicable (NA) if question is not applicable for this study*
* *Do not leave any questions unanswered*
* ***Strictly do not edit/delete the content or formatting of this form***
* *Write annexure numbers whenever documents are referred to in the application form*

**PART A: INVESTIGATOR DETAILS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| YEC-1 Protocol No. (to be filled in by the Secretariat when a protocol number is assigned): | | | | |
| Title of the protocol: | | | | |
|  | Name | Designation and qualification | Department and Institution | Email id and phone number |
| Principal Investigator |  |  |  |  |
| Co-Investigator |  |  |  |  |
| Co-Investigator |  |  |  |  |
| Co-Investigator |  |  |  |  |
| Co-ordinator |  |  |  |  |

*(Add additional rows for any category if required)*

|  |  |  |
| --- | --- | --- |
|  | **Please ensure that the following details are accurate and complete** | **Yes/ No** |
|  | Curriculum vitae of each of the investigators and research coordinators attached:   * Mandatory details: Titles of research conducted in the last 5 years, publications in the last 5 years, GCP training in the last 3 years, research methodology training, research ethics training, specialized training as per protocol requirement * CV updated not older than 3 months * CV should not exceed 5 pages * CV should be signed and dated |  |
|  | All relevant training certificates of principal investigator and co-investigators attached (GCP training certificates not older than 3 years) |  |
|  | Declaration of conflict of interest by each of the research team members for the present study (financial and non-financial) attached (YEC-1 SOP03/v3) |  |

**PART B: SPONSOR DETAILS (IF APPLICABLE)**

|  |  |  |  |
| --- | --- | --- | --- |
| **S No** | **Sponsor level** | **Sponsor details** | **Yes/No/NA** |
|  | International | Governmental (NIH, NHRS) |  |
|  |  | Non-governmental organization (non-pharma, non-industry for example WHO, UN, Wellcome Trust, etc) |  |
|  |  | Private organization (pharma/industry) |  |
|  | National | Central Government (ICMR, DBT, DST, etc) |  |
|  |  | State Government (VGST, etc) |  |
|  |  | Private organization (pharma/industry) |  |
|  | Yenepoya University | Institutional support |  |
|  |  | Seed Grant |  |
|  |  | Any other |  |
|  | Status of funding approval | Applied and approved |  |
|  |  | Applied and under review |  |
|  |  | Not applied, likely to apply in future |  |
| *Please attach approval letter from the sponsor, where applicable* | | | |

|  |  |  |
| --- | --- | --- |
| **Budget information** | | |
|  | Total Budget (in INR): | |
|  | Details of allocation of budget in a separate attachment | Yes/ No |
|  | YEC-1 sitting fees (if applicable): provide details of payment | Yes/ No |

**PART C: STUDY DETAILS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Details of the study (Tick whichever applicable)** | | | | |
| Clinical drug trial (regulatory) |  | Interview/Questionnaire-based | |  |
| Clinical drug trial (academic) |  | Observational (cross-sectional or longitudinal) | |  |
| Surgical intervention (new or modified technique) |  | In vitro | |  |
| Medical device, implant or prosthesis |  | Retrospective/Case-control | |  |
| Other interventions |  | Data in public/private domain | |  |
| Genetic/genomic/stem cell |  | Epidemiological survey | |  |
| Basic science (Proteomic/ metabolomic/ biomarker/ biochemical/ histopathological) |  | Any other: Specify | |  |
| Number of centres | Single/Multi centre | | | |
| If multi- centric (Number of centres): | India:  Global: | | Names and countries of centres: | |

**PART D: CLINICAL TRIAL DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Provide details, if it is a Clinical Trial:** | | | |
| 1 | **Nature of trial** | Medicine (new drug, new chemical entity) |  |
| Vaccine |  |
| Devices |  |
| Indian System of Medicine |  |
| Surgical |  |
| Any other: Specify: |  |
| 2 | **Whether the intervention is approved**  **(Provide reference of approvals)** | Yes | No |
| If approved, please specify the country of approval: | Yes/No |
| India |  |
| USA |  |
| UK/Europe |  |
| Other countries: Specify |  |
| **3** | **Route** | Does the study involve an existing drug with a new (unapproved) route of administration? | Yes #  No  Not applicable |
| If Yes #,  Whether DCGI/other regulatory authority’s permission obtained (please furnish a copy) | Yes \*  No \*\*  Not applicable |
| \*If yes, date of permission |  |
| \*\*If No, whether applied for permission (please furnish a copy of application and submit a copy of the approval letter once it is sanctioned) | Yes  No  Not applicable |
| 4 | **Investigational New Drug** | Does the study involve a new drug, not yet approved for marketing (or is in the market for less than 4 years)? | Yes##  No  Not applicable |
| ##If yes, please provide IND No. |  |
| ##If Yes, whether DCGI/other regulatory authority permission obtained (please provide a copy) | Yes+  No++  Not applicable |
| +If yes, date of permission |  |
| ++If No, whether applied for permission (please provide a copy of the application and submit a copy of the approval letter once it is sanctioned) | Yes  No  Not applicable |
| For Ayurvedic or herbal formulations, is a copy of the marketing/ manufacturing license issued by the FDA to the company submitted? | Yes  No  Not applicable |
| Details of storage, dispensation and retrieval of medications | Yes  No  Not applicable |
| a) Investigator’s Brochure submitted (containing details of chemical/pharmaceutical information; marketing information; BA/BE studies) | Yes  No  NA |
| b) *In vitro* studies data | Yes  No  NA |
| c) Preclinical Studies done | Yes  No  NA |
| Clinical Study Phase | I  II  III  IV |
| Please submit package insert in case test drug is already marketed in India | Attached  Not attached |
|  |  | Is this study/similar study being done elsewhere?  **If yes give details** | Yes  No |
|  | Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India(CTRI)/WHO platform registry registration number/any other: | | Yes$  No$$  Not applicable |
|  | $If yes, please provide a copy of the registration | | Yes  No |
|  | $$If no, please state the reason for not registering | |  |

**PART E: PROTOCOL DETAILS**

|  |
| --- |
| **Protocol of proposal: (Submit as attachment)**  ***PI to note that all the protocol and related documents must bear the title of the document, version number, page number, date and signatures wherever applicable*** |
| 1. Title 2. Executive summary (not more than one page) 3. Background and need for the study 4. Objectives 5. Methodology (The methodology must be in great detail): Refer to the section on methodology in SOP06/v3) 6. Sample/data collection details 7. Study tool 8. Statistical tests 9. Budget and funding details 10. Timeline (Gantt chart) 11. Study flowchart/algorithm 12. Utilisation of the results **whether it is of national significance with rationale** |
| Is the PI or the Co-PI or any other research team member concurrently involved in any study with similar (or almost similar) objectives, or similar set of participants? Yes/No  If yes, please provide the details of that study: |

**PART F: PARTICIPANT DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Provide details about research participants** | | | |
| **Sample Size :**  Number of research participants at this centre:  Number of research participants who will receive intervention:  Number of research participants who will receive placebo:  Number of participants who will receive standard-of-care treatment:  Number of research participants at other sites in India :  Number of research participants at other sites outside India:  Total number of research participants at all sites: | | | |
| Duration of study: Less than 6 months / more than 6 months to 1 year / more than 1 year  No. of visits that each participant is anticipated to make for the purpose of screening and research: | | | |
| Is there a plan for management of screen failures? | Yes | No | NA |
| Will participants be recruited in multiple studies concurrently? | Yes | No | NA |
| Is there a plan for randomization of participants?  If yes, please provide details in the methodology section | Yes | No | NA |
| Is there a plan for blinding (and unblinding)?  If yes, provide details in the methodology section | Yes | No | NA |
| Will study subject management include check-in/check-out procedures?  If yes, please provide details in the methodology section | Yes | No | NA |
| Is there a participant number assignment plan?  Please provide details in the methodology section | Yes | No | NA |
| Will  research  participants  from both genders  be recruited | Yes | No | NA |
| Inclusion / exclusion criteria given | Yes | No | NA |
| Type of research participants:  (\* If vulnerable population is included, the PI must submit the appropriate checklist for involvement of vulnerable population in research available in SOP19/v3 and provide attachment number) | | | |
| Volunteers | Yes | No | NA |
| Patients | Yes | No | NA |
| Vulnerable participants | Yes | No | NA |
| Pregnant women\* | Yes | No | NA |
| Elderly | Yes | No | NA |
| Mentally challenged\* | Yes | No | NA |
| Fetus\* | Yes | No | NA |
| Illiterate | Yes | No | NA |
| Handicapped | Yes | No | NA |
| Children\* | Yes | No | NA |
| Captives | Yes | No | NA |
| Terminally ill | Yes | No | NA |
| Seriously ill | Yes | No | NA |
| Economically or socially backward | Yes | No | NA |
| Dependent staff \* | Yes | No | NA |
| Institutionalized students\* | Yes | No | NA |
| Employees \* | Yes | No | NA |
| HIV | Yes | No | NA |
| Any other | Yes | No | NA |
| Will any advertising be done for recruitment of research participants? (posters, flyers, brochures, websites, notices, letters  – if so kindly attach a copy) | Yes | No | NA |
| Is there compensation plan for participation  If Yes, (tick appropriate)  Monetary  In kind  Specify amount and type: | Yes | No | NA |
| Is there compensation plan for injury?  If Yes,  (tick appropriate)  by Sponsor  by Investigator by insurance  by any other company | Yes | No | NA |

**PART G: PRIVACY AND CONFIDENTIALITY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Privacy and confidentiality** | | | |
| Direct identifiers (Name, address, phone numbers, photographs, videographs) | Yes | No | NA |
| Indirect identifiers (coded) | Yes | No | NA |
| Completely anonymized (delinked) | Yes | No | NA |

**PART H: USE OF BIOLOGICAL/ HAZARDOUS MATERIAL**

|  |  |  |  |
| --- | --- | --- | --- |
| **Use of biological/hazardous materials (Tick)** |  |  |  |
| Fetal tissue or abortus | Yes | No | NA |
| Human organs or body fluids | Yes | No | NA |
| Recombinant /gene therapy  If yes: DBT approval obtained | Yes | No | NA |
| Pre-existing/stored/left-over samples | Yes | No | NA |
| Collection from banking/future research | Yes | No | NA |
| Collection for banking/future research | Yes | No | NA |
| Use of ionizing radiation/radioisotopes  If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained? | Yes  Yes | No  No | NA  NA |
| Use of Infectious/ bio hazardous specimens | Yes | No | NA |
| Proper disposal of material | Yes | No | NA |
| **Will any sample collected from the patients be sent abroad?** | Yes | No | NA |
| **If yes**  Sample will be sent abroad because (Tick appropriate option):            Facility not available in India            Facility in India inaccessible            Facility available but not being accessed                 If so, reasons…………………………………..                  Lab. Address: | | | |
| **If no,**  Test on samples will be carried out (tick appropriate option):  In institution  Outside institution  If outside institution, Address:  Specify with details of collaborators | | | |
| Is  the proposal  being submitted  for clearance from  Health Ministry’s Screening Committee (HMSC) for International collaboration? (required  in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution) | Yes | No | NA |
| In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction from the Dean obtained/ applied for? If yes, details: | Yes | No | NA |
| Memorandum of Understanding:  If yes, details | Yes | No | NA |
| Material Transfer Agreement  If yes, details | Yes | No | NA |
|  |  |  |  |

**PART I: INFORMED CONSENT PROCESS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Details of consent form & participation information sheet** | Yes | No | NA |
| Tick which elements are included:  Simple language  Regional language understood by the participant  Alternatives to participation  Statement that this consent is for research and not therapy  Sponsor of study  Contact information  Purpose and procedures in detail  Risks & Discomforts  Benefits  Statement that consent is voluntary  Right to withdraw  Confidentiality of records  Compensation for study related injuries  Compensation for participation  Benefits, if any, on future commercialization  Consent for future use of biological material  Consent for photographs, if applicable  Consent for publication/ conference presentation |  |  |  |
| **Details of informed consent process** | Y | N | NA |
| **Who will obtain consent?**  PI/Co-PI  Nurse/Counselor trained in ICH-GCP guidelines  Research team member  Any other, specify |  |  |  |
| Where will the consent be taken? Specify the room |  | | |
| 1. General ward |  |  |  |
| 1. Private ward |  |  |  |
| 1. OPD |  |  |  |
| 1. Community setting |  |  |  |
| 1. Admission counter of the hospital |  |  |  |
| 1. Procedure room |  |  |  |
| 1. Laboratory |  |  |  |
| 1. Radiology room (X-ray, USG, CT or MRI) |  |  |  |
| 1. Pre-operative holding area |  |  |  |
| 1. Operation theatre |  |  |  |
| 1. Any other (please specify) |  |  |  |
| Whether audio-visual recording of consent will be done? |  |  |  |
| Whether audio recording of consent will be done? |  |  |  |
| Whether surrogate consent will be obtained? |  |  |  |
| Whether written or oral assent will be obtained? |  |  |  |
| Whether electronic consents will be obtained? |  |  |  |
| If written consent will not be obtained, give reasons: |  | | |
| Whether applied for waiver of Consent: |  |  |  |

**PART J: RISK AND BENEFIT**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **13** | **Risks & Benefits**: | | | |
| Will the risk to the participants be reasonable compared to the anticipated benefits to research participants / community / country? | Yes | No | NA |
| Will the research participant experience physical/social / psychological risk/discomfort?  If Yes,  ·         Minimal or no risk  ·         More than minimum risk  ·         High risk | Yes | No | NA |
| Will there be a benefit to the research participants?  ·         Direct  ·         Indirect | Yes | No | NA |
| Will there be a benefit to society? | Yes | No | NA |

**PART K: DATA SAFETY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **14** | **Data Monitoring** | **Yes** | **No** | **NA** |
| Is there a data & safety monitoring committee/ Board (DSMB)? |  |  |  |
| Is there a plan for reporting of adverse events? |  |  |  |
| If yes, reporting is done to :  Sponsor  YEC-1  DSMB |  |  |  |
| Is    there   a plan    for interim    analysis of data? |  |  |  |
| Are there plans for storage and maintenance of all trial databases? |  |  |  |
|  | If yes, for how long? |  | | |

|  |
| --- |
| **Declaration for responsible conduct of research by PI and other Co-PI’s/Co-I’s:**    We hereby declare that the information given above is true and that we will comply with the all the stipulations/recommendations mentioned in the New Drugs and Clinical Trials Rules 2019, the current ICMR guidelines, any other recent notification/s from CDSCO (updated as applicable), the Indian  GCP Guidelines and the Declaration of Helsinki, while conducting the research study.  We hereby declare that neither the PI, nor the Co-PI, nor any other members of the research team are concurrently involved as research team members in a similar study or another study using the same set of participants, as this one.  We also ensure that the Principal Investigator/Institution (for non-funded studies) will pay for the expenses for the treatment and/or compensation of research-related injury, as deemed necessary by Yenepoya Ethics Committee - 1.  Signature of Principal Investigator with date:    Signature/s of Co-investigators with date:  1.  2.    3.    4.    5.  Signature of coordinator:  1.    2. |
| Forwarded by Heads of Department(s)  Signature/s with date of Heads of Department(s):  Stamp/Seal of the Department(s) |