**`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 in the details in the soft copy, 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 this study

·         Do not leave any questions unanswered

·         Write the 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** | **Roles and responsibility\*** | | **Signature** | |
| Principal Investigator | ` | |  |  |  | |  | |
| Co-Investigator |  | |  |  |  | |  | |
| Co-Investigator |  | |  |  |  | |  | |
| Co-Investigator |  | |  |  |  | |  | |
| Co-Investigator |  | |  |  |  | |  | |
| Co-Investigator |  | |  |  |  | |  | |
| Co-ordinator |  | |  |  |  | |  | |
| Co-ordinator |  | |  |  |  | |  | |
| \* Roles and responsibilities of investigators: choose the appropriate codes (A to R) below and write them against their name in the appropriate column above. | | | | | | | | |
| A.     Concept  B.      Design  C.      Screening of patients  D.     Selection and recruitment of study participants  E.      Informed consent  F.      Selection & Recruitment of patients  G.     Laboratory investigations  H.     Laboratory report interpretation  I.        Treatment decision  J.        Patient evaluation  K.     SAE evaluation and reporting | | | L. Examination of patients on follow-up  M. Data collection and monitoring of data  N. Interpretation of data  O. Statistical analysis & Interpretation  P. Maintaining patients file and master file of project  Q. Drafting final report  R. Submission of final report to funding agency and YEC-1 | | | | | |
| (If additional collaborators attach details and letter of Consent by collaborator(s) on a separate page)  Please attach brief curriculum vitae of  the study team members (principal investigator, co- investigator, study coordinator)  Attached   Non-sponsored (Investigator Initiated) study  Sponsored study | | | | | | | | |
| Does any research team member have any **conflict of interest** in the present study?  (financial/non financial)  If Yes, specify | | | | | Yes | No | | NA |
| Whether the PI is handling other research protocols at present.  If yes,  Number of ongoing protocols handled by the PI at present studies approved by YEC-1 or YEC-2  Describe briefly the details of the status of the protocols | | | | | Yes | No | | NA |
| 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) | | | | | Yes | No | | NA |
| **Training   certificates** of   principal   investigator   and coordinators  (mandatory for drug  and device trials not  for observational studies**)** | | | | | Yes | No | | NA |
|  |  |  |  |  |  |  |  |  |

**PART B: SPONSOR DETAILS:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sponsor Information:** | | | | |
| 1 | **Indian** | State Govt. | Central Govt. | Private |
| 2 | **International** | Govt. | Private | UN Agency |
| 3 | **Industry** | National | Multinational |  |
| 4 | **Yenepoya deemed to be University** | Seed Grant | Institutional support |  |
| 5 | **Contact address** |  | | |
| 6 | **Indian contact address (For international sponsors)** |  | | |
| Budget information | | | | |
| 1 | **Total Budget: Rs.** | | | |
| 2 | **Please give details of allocation of budget in an attachment.** Attached  | | | |
| 3 | **Research Fund will be deposited in:  If other, please specify** | | | |

**PART C: STUDY DETAILS**

|  |  |  |
| --- | --- | --- |
| **Details of the study (Tick whichever applicable)** | | |
| **Type of study** | Epidemiological survey/ study | Observational study |
|  | Basic science (Proteomic/ metobolic/ biomarker/ / biochemical/ histopathological) | Genetic/ genomic study |
|  | Clinical trial | Interventional study |
|  | Surgical intervention | Interview/ Questionnaire based study |
|  | Medical device | Retrospective study |
|  | In vitro studies | Data in public domain |
|  | Any other: Specify |  |
| **Number of centres** | Single centre | Multicentre: |
| **If multi- centric:** | Number of centres In India  Global: | Names and countries of centres: |

**PART D: CLINICAL TRIAL DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Provide details, if it is a Clinical Trials:** | | | |
| 1 | **Nature of trial** | Medicine | Devices |
| Vaccine | Indian system of Medicine |
| Any other:  Specify: | Not applicable |
| 2 | **Approved**  **(Provide reference of approvals)** | Yes | No |
| If Approved: |  |
| In India | InUK/Europe |
| In USA | NA |
| Other countries:  Specify: |  |
| **3** | **Route** | Does it involve change in route of administration | Yes #  No  Not applicable |
| If Yes #,  Whether DCGI/other regulatory authority’s permission obtained | Yes \*  No \*\*  Not applicable |
| If yes \* Date of Permission |  |
| If No \*\*,  Whether applied of permission | Yes/No  Not applicable |
| 4 | **New investigational drug** | Yes  No  Not applicable | If yes,  IND No. |
| a) Investigator’s Brochure submitted | 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 |
| To submit package insert in case test drug is already marketed in India | Attached  Not attached |
|  |  | Are you aware if this study/similar study is being done elsewhere?  **If yes give details** | Yes:  No |
| Whether DCGI’s permission for testing IND obtained?  If yes, Date of permission | Yes  No |
| Whether DCGI’s permission for testing IND is applied for? | Yes  No |
| 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 |
|  | 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  No  Not applicable |

**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. Background and need for the study 3. Objectives 4. Methodology (The methodology must be in great detail): 5. Sample/data collection details 6. Study tool 7. Statistical tests 8. Budget and funding details 9. Utilisation of the results **whether it is of national significance with rationale** |

**PART F: PARTICIPANT DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Provide details about research participants** | | | |
| **Sample Size :**  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): | | | |
| Duration of study  No. of visits for the purpose of screening and research : | | | |
| 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**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 |  |  | |  |
| **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** |  |  |  | |
| **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**: | | | |
| Is the risk reasonable compared to the anticipated benefits to research participants / community / country? | Yes | No | NA |
| Is there physical / social / psychological risk / discomfort?  If Yes,  ·         Minimal or no risk  ·         More than minimum risk  ·         High risk | Yes | No | NA |
| Is there a benefit To the research participants?  ·         Direct  ·         Indirect | Yes | No | NA |
| Benefit to the society | Yes | No | NA |

**PART K: DATA SAFETY**

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

|  |
| --- |
| **Statement of Compliance:**    We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the New Drugs and Clinical Trials Rules 2019 and the current ICMR guidelines and any other recent notification/s from CDSCO (updated as applicable)], and the Indian  GCP Guidelines while conducting the research study.  We also ensure that Principal Investigator / Institution will pay for the expenses for the treatment and / or compensation if research related injury.  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) |