**Yenepoya Ethics Committee - 1**

**Ann01/SOP 06/v4:**

**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 the question is not applicable to this study****Do not leave any questions unanswered; do not delete any portion****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:** |
| **Researcher code** | **Research team member** | **Name** | **Qualification Designation and Department; Institution** | **Phone number****Email ID** |
|  | **Principal Investigator** |  |  |  |
| 2 | Co-Investigator  |  |  |  |
| 3 | Co-Investigator |  |  |  |
| 4 | Co-ordinator  |  |  |  |
| *Add additional rows above to add details of more investigators* |

**Activity log of research team members**

| **No.** | **Activity*****Marking for all rows is mandatory.*** *Any row unmarked will be considered as an incomplete protocol package and returned to PI. Add NA if the activity is not applicable to your study* | **Researcher code/initials**  **(Add more columns, if needed for additional researchers) and tick against the appropriate cell.**  |
| --- | --- | --- |
| **1**  | **2** | **3** | **4** | **5** | **6** |
| 1.
 | Study conceptualization |  |  |  |  |  |  |
|  | Design of the study |  |  |  |  |  |  |
|  | Participant recruitment (flyers, advertisement, medical records, etc) |  |  |  |  |  |  |
|  | Participant screening (selection based on inclusion/ exclusion criteria) |  |  |  |  |  |  |
|  | Informed consent process |  |  |  |  |  |  |
|  | Collection of biological samples (as applicable) |  |  |  |  |  |  |
|  | Laboratory investigations and interpretation |  |  |  |  |  |  |
|  | Storage and disposal of samples/tissues |  |  |  |  |  |  |
|  | Storage and log maintenance of study intervention |  |  |  |  |  |  |
|  | Administering the study intervention/ tool/ questionnaire/ interview |  |  |  |  |  |  |
|  | Purchase, procurement, inventory in-charge |  |  |  |  |  |  |
|  | Ensuring standard of care |  |  |  |  |  |  |
|  | SAE reporting, evaluation and management  |  |  |  |  |  |  |
|  | Participant follow-up visits |  |  |  |  |  |  |
|  | Collection, monitoring and storage of data |  |  |  |  |  |  |
|  | Data analysis & interpretation |  |  |  |  |  |  |
|  | Maintaining participant file and master file of project |  |  |  |  |  |  |
|  | Drafting interim and final report |  |  |  |  |  |  |
|  | Reviewing interim and final report  |  |  |  |  |  |  |
|  | Authorship placements (for publication) (write 1 for first author, 2 for second author, …) |  |  |  |  |  |  |
|  | Communications with YEC-1 |  |  |  |  |  |  |
|  | Any other activity |  |  |  |  |  |  |

| **Sl No.** | **Submission of documents for individual researchers** | **Researcher code (Add more columns, if needed for additional researchers) and write Yes/No against the appropriate cell** |
| --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** | **6** |
|  | Recently updated CV attached\* |  |  |  |  |  |  |
| 1.
 | Conflict of Interest declaration signed\*\* |  |  |  |  |  |  |
|  | Training certificates attached including GCP\*\* |  |  |  |  |  |  |

**\* CV should be updated and signed (within 6 months), brief with relevant and recent research and training related activities**

**\*\*CoI declaration is mandatory for studies involving any product with marketing potential. If none of the researchers has a CoI, submit a commonly signed CoI declaration form. If any researcher has a CoI, then individual CoI forms are to be submitted.**

**\*\*\*Valid (within3 years) GCP training certificate is mandatory for clinical trial**

**PART B: STUDY DETAILS**

| **S. No.** | **Type of study (Please make sure the information provided here accurately reflects the study design)** | **Tick whichever applicable** |
| --- | --- | --- |
| 1.
 | **Prospective studies involving human participants** |
|   | **A.**    **For Interventional study (Please mark the appropriate type)** |
|  | 1. **Regulatory clinical trial**
 |  |
|  | 1. **Investigator-initiated/Academic clinical trial**
 |  |
|  | 1. **Surgical/Invasive procedural intervention trial**
 |  |
|  | 1. **Device study**
 |  |
|  | 1. **Vaccine trial**
 |  |
|  | 1. **Other intervention (Specify)**
 |  |
|  | **B.**    **For observational studies (Please mark the appropriate type)** |
|  | **1.     Clinical** |  |
|  | **2.     Epidemiological** |  |
|  | **3.     Questionnaire-based** |  |
|  | **4.     Qualitative study(in-depth interview, etc)** |  |
|  | **5.     Genomic/ genetic study** |  |
|  | **6.     Proteomic/ metabolomic/ biomarker study** |  |
|  | **7.     Biochemical** |  |
|  | **8.     Histopathological** |  |
|  | **9.     Any other (Specify)** |  |
| 1.
 | **For retrospective study involving human participants (Please mark the appropriate type)** |
|  | 1. **Medical record based**
 |  |
|  | 1. **Imaging**
 |  |
|  | 1. **Left-over biological samples**
 |  |
|  | 1. **Any other (Specify)**
 |  |
| 1.
 | **For studies with no direct involvement of human participants (Please mark the appropriate type)** |
|  | 1. **Data in public domain**
 |  |
|  | 1. **In vitro studies on anonymous samples/ cell cultures**
 |  |
|  | 1. **Any other (Specify)**
 |  |
| 1.
 | **For any other: Please specify** |  |

**Study sites:**

| **S. No.** | **Study sites** | **Number and details of the site** |
| --- | --- | --- |
|  | **For multi-centric global studies provide the following details**  |
|  | 1. **Number of sites globally**
 |  |
|  | 1. **Number of sites in India**
 |  |
|  | **For multicentric Indian studies provide number of sites** |  |
|  | **Single site (Provide specific details of the site: Name of the hospital, laboratory, department, centre, community setting, etc** *(Please note that YEC-1 will provide EC approval only for those studies which are conducting with 50 Km of its radius)* |  |

**PART C: PARTICIPANT DETAILS**

| **Please fill in all the details matching with what is written in the protocol. If there are no participants, please write NA and proceed to the next section** *Please note that YEC-1 will issue approval only for participants enrolled at this centre* |
| --- |
| **Sample size**  |
| 1. Number of research participants at this centre
 |  |
| 1. Number of research participants at other sites in India
 |  |
| 1. Total number of research participants at all sites (globally):
 |  |
| **Duration of study and participation** |
| 1. Duration of study (data collection)
 |  |
| 1. Duration of participation of individual participant
 |  |
| 1. No. of visits the participant has to make for the purpose of screening and research
 |  |
| **Nature of research participants on whom the research is focussed:** *(\*If vulnerable population is included, PI must submit the appropriate checklist for involvement of vulnerable population in research available in SOP19/v4)* |
| **Nature of research participants**  | **Yes/No** |
| 1. Healthy Volunteers
 |  |
| 1. Patients
 |  |
| 1. Pregnant women/Fetuses\*
 |  |
| 1. Children\*
 |  |
| 1. Mentally challenged\*
 |  |
| 1. Physical/other challenges
 |  |
| 1. Illiterate/Economically or socially backward
 |  |
| 1. Elderly
 |  |
| 1. Terminally/seriously ill
 |  |
| 1. Unconscious/those undergoing surgery under GA
 |  |
| 1. Institutionalized students/captives
 |  |
| 1. Transgenders/LGBTQ+ groups
 |  |
| 1. Employees/students\*
 |  |
| 1. HIV/AIDS
 |  |
| 1. Tribal population
 |  |
| 1. Any other
 |  |
| **Recruitment and compensation strategies**  |  |
| 1. Will  research  participants  from  any category be excluded from enrollment without scientific justification?
 |  |
| 1. Have the inclusion/exclusion criteria been clearly given
 |  |
| 1. Will any advertising be done for recruitment of research participants? (posters, flyers, brochures, websites, notices, letters  –  if  so  kindly attach a copy)
 |  |
| 1. Is there a compensation plan for participation (reimbursement for time and trouble taken). If Yes, please specify whether monetary or in kind with details.
 |  |
| 1. Is there a compensation plan for research-related injury? If Yes,  (tick appropriate)
	1. by Sponsor
	2. by Investigator by insurance
	3. by any other company
 |  |
| 1. Is there a plan for access to the interventional treatment after the research is completed (post-trial access)?
 |  |

**PART D: DATA PRIVACY AND CONFIDENTIALITY**

| Provide details of data anonymity | Yes/No/Not applicable  |
| --- | --- |
| 1. Will the data collection form collect direct identifiers (name, address, phone numbers, UHID, photographs, videographs)
 |  |
| 1. Will the data collection form have indirect identifiers (coded) that can be used later to identify persons?
 |  |
| 1. Is the data collection form completely anonymized (delinked)
 |  |

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

| **Does the study involve use of biological/hazardous materials? (Please tick)** | **Yes/No/Not applicable**  |
| --- | --- |
| 1. Fetal tissue or abortus
 |  |
| 1. Human organs or body fluids
 |  |
| 1. Pre-existing/stored/left-over samples
 |  |
| 1. Collection from banking/future research
 |  |
| 1. Recombinant /gene therapy
2. If yes: DBT/GEAC approval obtained?
 |  |
| 1. Use of ionizing radiation/radioisotopes
2. If yes, has BARC approval for radioactive isotopes been obtained?
 |  |
| 1. Use of Infectious/ bio hazardous specimens
 |  |
| 1. Will the samples collected from this study be shared or used for future research? (please include this statement in the PIS/ICF)
 |  |
| 1. Proper disposal of material (please provide details in the protocol)
 |  |
| 1. Will any sample collected from the participants be sent abroad?   If yes,
	1. Reason for sending samples abroad
		1. Facility not available in India / Facility in India inaccessible
		2. Facility available but not being accessed (give reasons)
	2. Lab. Address:
 |  |
| **If no,**Test on samples will be carried out (tick appropriate option): In institution / Outside institutionIf outside institution, Address:     Specify with details of collaborators |
| Is 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) |  |
| 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: |  |
| Memorandum of Understanding:  If yes, details |  |
| Material Transfer Agreement If yes, details |  |

 **PART F: INFORMED CONSENT PROCESS**

| **Consent form & participation information sheet** |  |
| --- | --- |
| **Please make sure all the relevant points are included in the PIS and ICF** |
| Simple languageRegional language understood by the participantAlternatives informed to participation Statement that this consent is for research and not therapy Name of the sponsor of study Contact details of the researchersPurpose and procedures in detail have been informed Risks & discomforts have been explained Benefits spelled out…(whether direct or indirect)Statement that consent is voluntaryRight to withdrawConfidentiality of records and who will have access to the dataCompensation for study related injuriesCompensation for participationBenefits, if any, on future commercializationConsent for future use of biological material  Consent for photographs, if applicableConsent for publication/ conference presentation |  |
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| **Who will obtain consent?**PI/Co-PI     Nurse/Counselor trained in ICH-GCP guidelines Research team memberAny 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 G: RISK AND BENEFIT**

| **Risks & Benefits**: |
| --- |
| Is the risk reasonable compared to the anticipated benefits to research participants / community / country? |  |
| Is there physical / social / psychological risk / discomfort?If Yes, Minimal or no risk· More than minimum risk· High risk |  |

**PART H: PROTOCOL DETAILS**

| **Protocol of proposal: (Submit as attachment; do not fill the various sections here)*****PI to note that all the protocol and related documents must bear a header with the title of the document, version number, and date; a footer with page numbers and signatures of all researchers wherever applicable. Please tick the following if they have been addressed in the protocol*** |
| --- |
| **Main protocol: Should contain all details. Please refer to the template provided.** 1. Title
2. Executive summary
3. Background and need for the study
4. Research question/Aim/Objectives
5. Methodology (In great detail):
6. Sample/data collection details
7. Study tool
8. Statistical tests
9. Budget and funding details
10. Utilisation of the results whether it is of national significance with rationale
11. References (in Vancouver style)

**Annexures:**1. Data collection form (case record form; participant diary; etc)
2. Participant Information Sheet (PIS) in English and local languages (with back translation and certificates of translation in the case of regulatory clinical trial)
3. Informed Consent Form (ICF) in English and local languages (with back translation and certificates of translation in the case of regulatory clinical trial)
4. CVs of all the investigators
5. Conflict of Interest declarations (of all research team members)
6. Permission letters/MoUs/Material Transfer Agreements/SRB approval
7. CTRI registration
8. DCGI approval (wherever deemed necessary)
9. EC approval letters from other sites (if multicentric)
10. Statistician’s certificate/letter on sample size calculation
11. YEC-1 checklists as applicable (vulnerability, consent waiver, etc)
12. In the case of **regulatory clinical trials,** in addition, please provide
	1. Investigator brochure
	2. PI undertaking
	3. Tripartite Clinical Trial Agreement
	4. Insurance policy (and insurance certificate)
 |
| **Data collection form: Attach as annexure**  |
| 1. Required for all studies including prospective interventional or observational studies and retrospective studies.
2. Preferably be anonymised.
3. Data collection form must contain only those parameters which are required to analyse and meet the objectives of the study.
4. May include screening parameters, inclusion and exclusion criteria.
5. Must contain the title of the study, name of the PI and version no and date in the header.
6. Please note- it is not the same as a clinical case proforma used in clinical practice/healthcare.
7. If questionnaire is used, provide details of validation and pre-testing whenever applicable
 |

**PART I: SPONSOR DETAILS:**

**(For sponsored studies only; (If non-sponsored/non-funded study- write not applicable)**

| A.    Name of the Sponsor/funding agency: |  |
| --- | --- |
| B.     Contact details:   |  |
| C.     Status of funding approval (Applied/approved/under process) |  |
| D.    Amount |  |
| E.     Budget details (Attached/Annexure number) |  |
| F.     Nature of the sponsor | **Tick as applicable** |
| 1. International Governmental (NIH, UN, WHO, etc)
 |  |
| 1. International Private (including MNCs with offices in India)
 |  |
| 1. Indian Governmental
 |  |
| 1. Indian Private (Industry)
 |  |
| 1. Yenepoya (deemed to be University)
 |  |

**PART J: CLINICAL TRIAL DETAILS:**

**(FOR SPONSORED/ACADEMIC CLINICAL TRIALS ONL)Y**

| **Details of the trial**  | **Provide specific details**  | **Whether this is approved/Not approved by DCGI (Submit documents)** |
| --- | --- | --- |
| Medicine/ Vaccine//Indian system of Medicine/ Biologicals/ Others (Specify) |  |  |
| Name of the drug/ vaccine/ biological/ AYUSH  |  |  |
| Route of administration |  |  |
| Indication |  |  |
| Dosage  |  |  |
| Formulation |  |  |
| Combination of drugs (if any) |  |  |
| Clinical trial phase (0/I/II/III/IV) |  |
| **Provide the following details for all INDs** | Submitted/Not submitted/ Not applicable |
| Investigator’s Brochure |  |
| *In vitro* studies data/ Pre-clinical studies  |  |
| Package insert in case test drug is already marketed in India |  |
| For Ayurvedic or herbal formulations, is a copy of the marketing/ manufacturing license issued by the FDA to the company submitted? |  |
| Is the trial registered with the Clinical Trial Registry of India? (mandatory for drug trials)If yes, please provide the CTRI provisional registration number here |  |
| **Data safety and monitoring- Please provide the following details**  |
| Is there a data & safety monitoring committee/ Board (DSMB)? Provide details  |  |
| Is there a plan for reporting of adverse events? Provide details of reporting to sponsor, Ethics Committee and DSMB  |  |
| Is    there    a    plan    for    interim    analysis    of data? Provide details  |  |
| Are there plans for storage and maintenance of all trial databases? If Yes, for how long? |  |

**PART K: STATEMENT OF COMPLIANCE**

**(For all studies)**

| 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 hereby comply with all the terms and conditions in the EC approval letter and communications. Signature of Principal Investigator with date:Signature/s of Co-investigators with date:   Signature of coordinator(s):  |
| --- |
| Forwarded by Heads of Department(s)Signature/s with date                                                                        Stamp/Seal of the Department(s) |