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**Protocol Submission Application Form for Initial Review for Drug Trials and Other Regulatory Studies (Industry and Government sponsored studies)**

***Instructions to the Principal Investigator:***

* *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*

|  |
| --- |
| YUEC Protocol No: *(to be filled in by the YUEC Secretariat after submission of complete package)* |
| Title of the protocol: |
|  | **Name**  | **Designation and qualification** | **Department and Institution** | **Roles and responsibility\*** | **Signature**  |
| Principal Investigator |  |  |  |  |  |
| Co-Investigator  |  |  |  |  |  |
| Co-Investigator |  |  |  |  |  |
| Co-ordinator  |  |  |  |  |  |
| Co-ordinator  |  |  |  |  |  |
| \* Roles and responsibilities of investigators: choose the appropriate codes (A to T) below and write them against their name in the appropriate column above. |
| 1. Concept
2. Design
3. Screening of patients
4. Selection and recruitment of study participants
5. Informed consent
6. Selection & Recruitment of patients
7. Laboratory investigations
8. Laboratory report interpretation
9. Treatment decision
10. Patient evaluation
11. SAE evaluation and reporting
 | 1. Examination of patients on follow-up
2. Data collection and monitoring of data
3. Interpretation of data
4. Statistical analysis & Interpretation
5. Maintaining patients file and master file of project
6. Drafting final report
7. Submission of final report to funding agency and YUEC
8. Publication
9. Any other, please specify
 |
| (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  |
| **Sponsor Information :**  |
| 1 | **Indian** | State Govt. | Central Govt. | Private |
| 2 | **International** | Govt.  | Private | UN Agency |
| 3 | **Industry**  | National | Multinational |  |
| 4 | **Contact address**  |  |
| 5 | **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** |
| **Details of the study** |
| **Type of study** | Epidemiological | Animal study |
|  | Basic Science | Any other:Specify: |
| **Number of centres** | Single centre | Multicentre: |
| **If multi-centric:** | Number of centres In IndiaGlobal: | Names and countries of centres: |
| **Clinical Trials:** |
| 1 | **Nature of trial** | Medicine | Devices |
| Vaccine | Indian system of Medicine |
| Any other: Specify:  | Not applicable |
| 2 | **Approved** | Yes | No |
| If Approved: |  |
| In India | UK/Europe |
| USA | NA |
| Other countries:Specify: |  |
| **3** | **Route**  | Does it involve change in route of administration | Yes #NoNot 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/NoNot applicable |
| 4 | **New investigational drug** | YesNoNot applicable | If yes, IND No.  |
| a) Investigator’s Brochure submitted | YesNoNA |
| b) *In vitro* studies data | YesNoNA |
| c) Preclinical Studies done | Yes NoNA |
| Clinical Study Phase  | IIIIIIIV |
| To submit package insert in case test drug is already marketed in India | AttachedNot 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 | YesNo |
| Whether DCGI’s permission for testing IND is applied for? | YesNo |
| For Ayurvedic or herbal formulations, is a copy of the marketing/ manufacturing license issued by the FDA to the company submitted? | YesNo Not applicable |
|  | **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 :**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 : |
| Will research participants from both genders be recruited | Yes | No | NA |
|  Inclusion / exclusion criteria given | Yes | No | NA |
| Type of research participants: |
| 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 |
| **6** | **Privacy and confidentiality** |
| Direct identifiers | Yes | No | NA |
| Indirect identifiers (coded) | Yes | No | NA |
| Completely anonymized (delinked)  | Yes | No | NA |
| **7** | **Use of biological/hazardous materials** |  |  |  |
| Fetal tissue or abortus | Yes | No | NA |
| Human organs or body fluids  | Yes | No | NA |
| Recombinant /gene therapyIf yes: DBT approval obtained | Yes | No | NA |
| Pre-existing/stored/left over samples | Yes | No | NA |
| Collection of 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? | YesYes | NoNo | NANA |
| Use of Infectious/ bio hazardous specimens | Yes | No | NA |
| Proper disposal of material | Yes | No | NA |
| **8** | **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 institutionOutside institutionIf outside institution, Address: Specify with details of collaborators |
| **9** | 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 |
| **10** | 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 |
|  | Memorandunm of Understanding: If yes, details | Yes | No | NA |
|  | Material Transfer Agreement If yes, details | Yes | No | NA |
| **11** | **Consent form & participation information sheet** | Yes | No | NA |
| Tick which elements are included:Simple language Alternatives to participation Statement that study involves research Confidentiality of records Sponsor of study Contact information Purpose and procedures Statement that consent is voluntaryRisks & Discomforts Right to withdrawBenefitsCompensation for study related injuries Compensation for participationBenefits, if any, on future commercialization Consent for future use of biological material If written consent will not be obtained, give reasons: Whether applied for waiver of Consent: |
| **Who will obtain consent?** PI/Co-PI Nurse/CounselorResearch staff Any other, specify |
| **12** | **Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – if so kindly attach a copy)** | Yes | No | NA |
| **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 |
| **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 YUEC 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 |
| **15** | Is there compensation for participationIf Yes, (tick appropriate) Monetary In kindSpecify amount and type: | Yes | No | NA |
| **16** | Is there compensation for injury? If Yes, (tick appropriate) by Sponsorby Investigator by insurance by any other company  | Yes | No | NA |
| **17** | Do you have any conflict of interest in the present study?(financial/non financial)If Yes, specify | Yes | No | NA |
| **18**  | Number of protocols handled by the PI at present including current Status of ongoing studies approved by IEC and carried out by the Principal Investigator. (Information to be given: whether study is initiated, no. of approved research participants, no. of research participants enrolled, no. of active research participants, no. of research participants who have completed the study and total duration of the study. Describe briefly | Yes | No | NA |
| **19** | 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 |
| **20** | **Training certificates** of principal investigator and coordinators (mandatory only for drug and device trials not for observational studies**)** | Yes | No | NA |
| **21** | **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 | 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 Schedule Y [Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2013, 8th February 2013 and any other recent notification/s from CDSCO (updated as applicable)], Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2006), Indian GCP Guidelines (2001) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (1996) while conducting the research study.

We also ensure that Principal Investigator / Institution will pay for treatment and / or compensation if study related injury occurred due to protocol violation by PI / study team.

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)