31. Research Protocol Proforma for Biomedical Project only

INSTITUTIONAL ETHICS REVIEW BOARD
Jawaharlal Nehru University
New Delhi-110067

1. TITLE OF THE STUDY:
2. BACKGROUND OF STUDY:
3. SCIENTIFIC JUSTIFICATION OF THE STUDY:
4. AIMS AND OBJECTIVES:
5. REVIEW OF LITERATURE:
6. WORK ALREADY DONE (*If any pilot studies or others specify*):
7. MATERIALS AND METHODS:
   a. Study Design:
   b. Study Setting (*Exact place where the study will be conducted*):
   c. Approximate Total Duration of The Study:
   d. Number of Groups to Be Studied:
   e. Detailed Description of The Groups:
   f. Sample Size of Each Group (with justification/rationale):
   g. Total Sample Size of the Study (with justification/rationale):
   h. Scientific Basis of Sample Size Used in The Study:
   i. Sampling Technique Used in the Study:
   j. Inclusion Criteria:
   k. Exclusion Criteria:
   l. Whether Placebo Used in Study (Yes/No):
   m. Whether Drugs/human sample(s)/Recombinant sample/Medical Devices will be used in the Study (Yes/No):
   n. **IF DRUGS/HUMAN SAMPLE(S)/RECOMBINANT SAMPLE/ MEDICAL DEVICES USED:**
      i. Whether the Drug/Human sample(s)/Recombinant Sample/Medical Device used is for a **Newer Indication**: YES/NO

ii. Whether the Drug/Human Sample(s)/Recombinant Sample /Medical Device used is for the **First Time in Human Beings**: YES/NO

iii. If used for a newer indication/first time in human beings, whether the permission is obtained from the **Drug Controller General of India (DCGI)** and/or **Institutional Bio-Safety Committee (ISBC)**: YES/NO. **Kindly attach a copy of the approval letter and also provide BioRRAP ID.**

iv. Formulation of The Drug Used:

v. Name of the Drug/Human sample(s)/Recombinant Sample Medical Device Used (Non-Proprietary Name, Brand Name, Company/Manufacturer's Details):

vi. Dose/s of the Drug Used:

vii. Frequency of the Drug Used:

viii. Route of the Drug Used:

ix. Duration of the Drug Used:

x. Steps to be taken to prevent Adverse Drug Reactions (ADRs):

xi. In Case of Severe ADR, Mode of Management:

xii. In Case of Drug-Related Injury, Agreement of Compensation:

xiii. Any Other Relevant Details:

o. **Parameters to be Studied [**If *quantitative data mentions the units of measurement (MUST)*]**:**

p. **Method(s)/Technique(s)/Instrument(s)/Reagent(s)/Kit(s) etc. Used to Measure the Quantitative Parameters Along with Their Manufacturing Source Details [MUST]:**

q. **Procedure in Detail (***Explain, if Possible, with Flowchart***):**

r. **Statistical Methods of Analysis:**

i. Significance Level Decided Before Starting the Study:

ii. Statistical Tests to Be Used for Data Analysis:

iii. Software(s) To Be Used for Statistical Analysis:

8. HYPOTHESIS (*If any***):**

9. REFERENCES (*Minimum 10 References in Vancouver Format Only***):**

10. GIVE DETAILS OF THE FOLLOWING:

A. Whether the Study is **multi-institutional**: YES/NO

B. If **multi-institutional**, Whether Consent Obtained from the Department (s) Concerned:

C. Any Extra Materials / Finance Required/Obtained to Carry Out the Study:

D. If Yes, Write in Detail About the Source of Finance:

(*Whether From Funding Agencies/Institute/Investigator (Self)/Others If Any Specify*):

UNDERTAKING BY THE INVESTIGATORS

1. Full name, address, and title of the Principal Investigator.
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details, including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Statement of Undertaking:
   i. I certify that the research proposal submitted herein is original and is not a duplication of any previously conducted or reported study, except where appropriately cited.
   ii. I have reviewed the protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
   iii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or change to the protocol without the prior review and documented approval or favorable opinion from the ethics committee for the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
   iv. I will use the sample collected for this approved study. It will not be used for any other study without the due regulatory approval from the Ethics committee and IBSC, or any concern authority.
   v. I agree to report all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements.
   vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
   vii. I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are suitably qualified and experienced, and they have been informed about their

obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make them available for audit or inspection by the ethics committee, the Central Licensing Authority, or their authorized representatives, in accordance with regulatory provisions. I will fully cooperate with any study-related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee any changes in protocol and any unanticipated problems involving risks to human subjects or others.

x. I will maintain the confidentiality of the identification of all participating subjects and ensure the security and confidentiality of study data.

Signature and Name of the Research Scholar

Signature and Name of the PI **Signature and Name of the Co-PI's**

Date:

Place: