BHOPAL MEMORIAL HOSPITAL & RESEARCH CENTRE

APPLICATION FOR RESEARCH PROPOSAL SUBMITTED FOR INSTITUTIONAL ETHICS COMMITTEE

TITLE

INVESTIGATORS

S.No	Name	Department	Qualification / Designation	Role	Signature
1					
2					
3					
4					

PROPOSAL TYPE

☐New
☐Renewal
☐Closure

Human subject research
☐Yes
☐No

Study type
☐Experiment
☐Observational
☐Other

If a waiver of consent sought
☐Yes
☐No

RESEARCH PARTICIPANTS

Proposed number of human subjects

Proposed number of healthy volunteers

Does study involve minors (age <18 yrs)
☐Yes
☐No

Does study involve those cognitively compromised
☐Yes
☐No

RESEARCH PROCEDURES

Minimal risk
☐Slide /sample review
☐Chart review
☐Interviews / Exam
☐Other (specify)

Non-invasive samples
☐Urine
☐Sputum
☐Surface swabs
☐Other (specify)

Invasive samples
☐Blood / Serum
☐CSF / Body fluid
☐Tissue/ cells
☐Other (specify)

Special procedures
☐Video/Audio recording
☐Radiologic imaging
☐Photographs
☐Other (specify)

INTERVENTIONS

(Applicable if experimental study design)

Applied to
☐Individuals
☐Groups / Clusters

Type of intervention
☐New Drug / Device
☐Approved Drug / Device
☐Diagnostic intervention
☐Health system research
☐Other (specify)

Type of allocation
☐Randomized
☐Non-randomized

Patient safety measures
☐DSMB
☐SAE reporting
☐Risk coverage
☐Other

DURATION

CONSENT FORM

MISC INFORMATION

Total Duration of Research-

Data collection-

Information sheet and informed consent form attached:

☐Yes
☐No

Case Reports:

Any patient identifiers included
☐Yes
☐No

Case Reports:

Participant consent obtained
☐Yes
☐No
If Yes, attach copy of signed consent form

Human subject research includes all interventions and interactions with human subjects for research, including advertising, recruitment and/or screening of potential humans. Human subject research also include observational studies such as surveys and questionnaires, interviews and focus groups, analyses of existing data or biological specimens, epidemiological studies, evaluations of social or educational programs, cognitive and perceptual experiments, medical chart review .
Research participants include all humans who will be involved in research
Research procedures are all those procedures performed beyond standard treatment administered as part of clinical care.
DSMB- Data safety monitoring board; SAE – Serious adverse effects

UNDERTAKING

1. This research/clinical study proposal is routed to the IEC for approval and recommendations of that Board. A copy of the protocol is enclosed with the application form.
2. The Proposal is accompanied by full details on funding.
3. If the research proposal is undertaken on ***behalf*** of a pharmaceutical company, the company will underwrite all expenses such that neither the hospital nor the patients are made to spend. In the event of complications, the company will underwrite the cost of management of these.
4. We state that the research officers do/do not stand to gain materially from the project (except for salaries or reimbursement of expenses).
5. The data collected under any research project undertaken, including that carried out using funds from a commercial organization such as a pharmaceutical company (but not on behalf on these sponsors), will remain the property of Bhopal Memorial Hospital & Research Center and the records will be preserved on its premises. The analysis of such data and conclusions from it shall be made by the Research Officers and not by the sponsoring company.
6. Interim and final report to be presented to IEC. Publication and presentation as per ICMR rules after obtaining approval. Protocol deviation, SAE to be reported.
7. The form we shall use to ensure informed consent is attached. It explains the main features of the study/trial and side effects if any.
8. Any mishap during the study / trial arising due to non-standardized or non-established Procedures / drugs / investigations / interventions will be the responsibility of the principal investigators. Moreover if any adverse events occur, these will be reported to the IEC within 72 hrs.

WE AGREE TO THE ABOVE

Name of Principal Investigators	Signatures	Date
1……..		
2……..		
3……..		
4……		

Application form includes Page 1& 2. Kindly submit application form with the research proposal. You can extend the columns wherever required in the form.

Please include the following details in your study proposal:

1.Please provide a precise description of how human subjects will be involved in the research, including a clear description of all activities and responsibility of the subjects.

2. What is the pool of subjects and will there be minors?

3. How are the subjects to be recruited?

4. What are the risks to the subjects?

5. In what way the confidentiality and privacy of the subject's be ensured?

6. If this is a controlled study have you ensured that the subjects in control arm receive a currently acceptable form of treatment?

7. If the procedures are physically invasive or potentially harmful, describe arrangements made for medical referral and treatment?

8. Who would bear the cost of treating the complications arising from this trial ?

9. If the procedures are emotionally upsetting describe arrangements made for psychological counseling?

10. What provisions have been made for cultural & language problems?

11. Who will be maintaining the trial records and where?

12. How and why is the new protocol / therapy an improvement on the existing protocol / therapy?

13. Have you made provision for insurance for yourself and the institution against any legal action out of the project?

FOR SUBMISSION OF PROJECTS

1. Covering letter addressing to Chairperson of IEC and mentioning the type of project and also the Name, Residential and Official address, Mobile number and e-mail address of Principal Investigators and Co Investigators.
2. Properly filled Application form. Take it from BMHRC website.
3. Protocol/Synopsis. Please insert page numbers on each page. Ex-Page 1 of 20.
4. Patient information sheet with Bilingual consent form (i.e. both in Hindi and English with signatures of two witness). In the procedure section, please write in simple lay man language about the procedure that you will be going to do and the type of sample that you will take and for how many times. If there are questionnaires, that also should be mentioned.
5. Note: Sample copy of consent form is available in the IEC office.
6. Send SOFT COPY of the above (i.e. of points 1, 2, 3 and 4 shall be incorporated in **single file)** either in MS word or PDF format to the member secretary. Do not make multiple folders. Keep the **file size small**.
7. Please note: Incomplete proposal will not be accepted
8. For submission please contact- Office Bearers of IEC
   1. Dr. Anjali Sharma, Member Secretary (mob-9039787213, Extn- 2007)
   2. Mrs. Laxmi Mishra (mob-9755987503, Extn-8801, 8807)