**INDIAN COUNCIL OF MEDICAL RESEARCH**

# Model form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)

(for attachment to each copy of the proposal)

| **Serial No of IEC Management Office:** |
|---|
| |

**Proposal Title:**

| | **Name, Designation & Qualifications** | **Address Tel & Fax Nos. Email ID** | **Signature** |
|---|---|---|---|
| **PI** | | | |
| **Co-PI / Collaborators 1.** | | | |
| **2.** | | | |
| **3.** | | | |
| **Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).** | | | |

***Tick appropriately***

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sponsor Information** : | | | | | | | |
| 1. Indian | a) Government | ☐ | Central | ☐ | State | ☐ | Institutional ☐ |
| | b) Private | ☐ | | | | | |
| 2. International | Government | ☐ | Private | ☐ | UN agencies | ☐ | |
| 3. Industry | National | ☐ | Multinational | ☐ | | | |
| **Contact Address of Sponsor:** | | | | | | | |

| **Total Budget** : |
|---|

| | | | |
|---|---|---|---|
| **1.Type of Study :** | Epidemiological ☐ | Basic Sciences ☐ | Animal studies ☐ |
| Clinical: | Single center ☐ | Multicentric ☐ | Behavioral ☐ |
| **2. Status of Review:** | New ☐ | | Revised ☐ |
| **3. Clinical Trials:** **Drug /Vaccines/Device/Herbal Remedies :** | | | |
| **i.** Does the study involve use of : | Drug ☐ | Devices ☐ | Vaccines ☐ |
| | Indian Systems of Medicine/ Alternate System of Medicine ☐ | Any other ☐ | NA ☐ |
| **ii.** Is it approved and marketed | In India ☐ | UK & Europe ☐ | USA ☐ |
| | Other countries, specify ☐ | | |

| | | |
|---|---|---|
| **iii.** Does it involve a change in use, dosage, route of administration? | Yes | No |
| **If yes**, whether DCGI's /Any other Regulatory authority's Permission is obtained? | Yes | No |
| **If yes,** Date of permission : | | |
| **iv.** Is it an Investigational New Drug? | Yes | No |
| **If yes,** IND No: | | |
| a). Investigator's Brochure submitted | Yes | No |
| b). *In vitro* studies data | Yes | No |
| c). Preclinical Studies done | Yes | No |
| d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ | | |
| e). Are you aware if this study/similar study is being done elswhere ? | Yes | No |
| **If Yes**, attach details | | |

**4. Brief description 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 (Attach sheet with maximum 500 words):

| | | | |
|---|---|---|---|
| **5. Subject selection:** | | | |
| i. | Number of Subjects : | | |
| ii. | Duration of study : | | |
| iii. | Will subjects from both sexes be recruited | Yes | No |

| | | | |
|---|---|---|---|
| iv. | Inclusion / exclusion criteria given | Yes | No |
| v. | Type of subjects Volunteers ☐ Patients ☐ | | |
| vi. | Vulnerable subjects Yes ☐ No ☐<br>(Tick the appropriate boxes)<br>pregnant women ☐ children ☐ elderly ☐<br>fetus ☐ illiterate ☐ handicapped ☐<br>terminally ill ☐ seriously ill ☐ mentally challenged ☐<br>economically & socially backward ☐ any other ☐ | | |
| vii. | Special group subjects Yes ☐ No ☐<br>(Tick the appropriate boxes)<br>captives ☐ institutionalized ☐ employees ☐<br>students ☐ nurses/dependent ☐ armed forces ☐<br>any other ☐ staff | | |
| **6. Privacy and confidentiality** | | | |
| i. | Study involves - Direct Identifiers ☐<br>Indirect Identifiers/coded ☐<br>Completely anonymised/ delinked ☐ | | |
| ii. | Confidential handling of data by staff | Yes | No |
| **7. Use of biological/ hazardous materials** | | Yes | No |
| i. | Use of fetal tissue or abortus | | |
| ii. | Use of organs or body fluids | Yes | No |
| iii. | Use of recombinant/gene therapy | Yes | No |
| | **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained? | Yes | No |
| iv. | Use of pre-existing/stored/left over samples | Yes | No |
| v. | Collection for banking/future research | Yes | No |
| vi. | Use of ionising radiation/radioisotopes | Yes | No |
| | **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained? | Yes | No |
| vii. | Use of Infectious/biohazardous specimens | Yes | No |
| viii. | Proper disposal of material | Yes | No |
| ix. | Will any sample collected from the patients be sent abroad ? | Yes | No |
| **If Yes, justify with details of collaborators** | | | |
| | a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? | Yes | No |

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐
If so, reasons…

**8. Consent :** *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

| | | | |
|---|---|---|---|
| Understandable language | ☐ | Alternatives to participation | ☐ |
| Statement that study involves research | ☐ | Confidentiality of records | ☐ |
| Sponsor of study | ☐ | Contact information | ☐ |
| Purpose and procedures | ☐ | Statement that consent is voluntary | ☐ |
| Risks & Discomforts | ☐ | Right to withdraw | ☐ |
| Benefits | ☐ | Consent for future use of biological material | ☐ |
| Compensation for participation | ☐ | Benefits if any on future commercialization | ☐ |
| Compensation for study related injury | ☐ | eg. genetic basis for drug development | |

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

| | | |
|---|---|---|
| **9. Will any advertising be done for recruitment of Subjects ?** (posters, flyers, brochure, websites – if so kindly attach a copy) | Yes | No |
| **10. Risks & Benefits:** i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? | Yes | No |
| ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐ | Yes | No |
| Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐ | | |
| **11. Data Monitoring** i. Is there a data & safety monitoring committee/ Board (DSMB)? | Yes | No |
| ii. Is there a plan for reporting of adverse events ? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐ | Yes | No |
| iii. Is there a plan for interim analysis of data? | Yes | No |

| | | |
|---|---|---|
| vi. Are there plans for storage and maintenance of all trial database?<br>**If Yes,** for how long ? | Yes | No |
| **12. Is there compensation for participation?**<br>**If Yes,** Monetary ☐ In kind ☐<br>Specify amount and type: | Yes | No |
| **13. Is there compensation for injury?**<br>**If Yes,** by Sponsor ☐ by Investigator ☐<br>by insurance company ☐ by any other ☐ | Yes | No |
| **14. Do you have conflict of interest? (financial/nonfinancial)**<br>**If Yes, specify :** | Yes | No |

**Checklist for attached documents**:

| | |
|---|---|
| Project proposal – 20 Copies | ☐ |
| Curriculum Vitae of Investigators | ☐ |
| Brief description of proposal | ☐ |
| Patient information sheet | ☐ |
| Informed Consent form | ☐ |
| Investigator's brochure for recruiting subjects | ☐ |
| Copy of advertisements/Information brochures | ☐ |
| Copy of clinical trial protocol and/or questionnaire | ☐ |
| Institutional Ethics Committee clearance | ☐ |
| Institutional Animal Ethics Committee clearance | ☐ |
| CPCSEA clearance, if any | ☐ |
| HMSC/DCGI/DBT/BARC clearance if obtained | ☐ |

Place: Signature & Designation of PI/Co-PI/Collaborator
Date:

INDIAN COUNCIL OF MEDICAL RESEARCH

# Institutional Ethics Committee

## Model Form to be filled by Reviewers

**Serial No of IEC Management Office:**

**Proposal Title:**

**Principal Investigator:** **Co-investigator:** 1.
2.
3.

**Supporting Agency**: ICMR/ non ICMR

If non ICMR, name of agency:

**Project Status**: New ☐ Revised ☐

**Review:** Regular ☐ Interim ☐

**Date of Review**:

### 1. Research Design

i. Scientifically sound enough to expose subjects to risk Yes ☐ No ☐

ii. Relevant to contribute to further knowledge Yes ☐ No ☐

iii Of national importance Yes ☐ No ☐

### 2 Risks

a. Is there physical/social/psychological risk/discomfort? Yes ☐ No ☐

b. Is the overall risk/benefit ratio Acceptable ☐ Unacceptable ☐

### 3 Benefits

Direct: Reasonable ☐ Undue ☐ None ☐

Indirect: Improvement in science/knowledge ☐ Any other ☐

**4 Subject selection :**

i Inclusion / exclusion criteria addressed? Yes ☐ No ☐

ii Vulnerable subjects (woman, child, mentally challenged, seriously or terminally ill, foetus, economically or socially backward and healthy volunteers) adequately protected ? Yes ☐ No ☐

iii. Special group subjects (captives, students, nurses & dependant staff) adequately protected? Yes ☐ No ☐

**5 Privacy & Confidentiality maintained?** Yes ☐ No ☐

**6 Patient Information Sheet:** Adequate ☐ Inadequate ☐

7. **Consent form components addressed adequately?** Yes ☐ No ☐

**8. Compensation, (if applicable) addressed adequately?** Yes ☐ No ☐

**9. Is there a Conflict of Interest?** Yes ☐ No ☐

If yes, Acceptable ☐ Unacceptable ☐

**10. Budget:** Appropriate ☐ Inappropriate ☐

**11. Decision of review**

Recommended ☐ Recommended with suggestions ☐

Revision ☐ Rejected ☐

**Any other remarks/suggestions:**

**Reviewer's name and Signature**

**INDIAN COUNCIL OF MEDICAL RESEARCH**

**Communication of Decision of the Institutional Ethics Committee(IEC)/ Institutional Review Board(IRB)**

**IEC/IRB No:**

| |
|---|
| Protocol title: |
| Principal Investigator: |
| Name & Address of Institution: |
| ☐ New review ☐ Revised review ☐ Expedited review |
| Date of review (D/M/Y):<br>Date of previous review, if revised application: |
| Decision of the IEC/ IRB:<br>☐ Recommended ☐ Recommended with suggestions<br>☐ Revision ☐ Rejected |
| Suggestions/ Reasons/ Remarks: |
| Recommended for a period of : |

**Please note ***

- **Inform IEC/IRB immediately in case of any Adverse events and Serious adverse events.**
- **Inform IEC/IRB in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to IEC/IRB.**
- **Members of IEC/IRB have right to monitor the trial with prior intimation.**

Signature of Member Secretary
IEC/IRB