# Katihar Medical College, Katihar

Affiliated to Al-Karim University, Katihar, Recognised by the Medical Council of India and the Ministry of Health & Family Welfare, Govt. of India.
**KARIM BAGH, POST BOX-23, KATIHAR – 854 105 (BIHAR) INDIA**
**Telephone:** (06452) 239202, 239203, 239208 Fax: 06452-239208

## 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** :<br>1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐<br>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 ☐<br>Clinical: Single center ☐ Multicentric ☐ Behavioral ☐ | | |
| **2. Status of Review:** New ☐ Revised ☐ | | |
| **3. Clinical Trials:**<br>**Drug /Vaccines/Device/Herbal Remedies :**<br>**i.** Does the study involve use of :<br>Drug ☐ Devices ☐ Vaccines ☐<br>Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐ | | |
| **ii.** Is it approved and marketed<br>In India ☐ UK & Europe ☐ USA ☐<br>Other countries, specify ☐ | | |
| **iii.** Does it involve a change in use, dosage, route of administration?<br>**If yes**, whether DCGI's /Any other Regulatory authority's Permission is obtained?<br>**If yes,** Date of permission : | Yes<br>Yes | No<br>No |
| **iv.** Is it an Investigational New Drug?<br>**If yes,** IND No: | Yes | 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 ?<br>**If Yes**, attach details | Yes | No |

**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 ☐
(Tick the appropriate boxes)

| | | | | | |
|---|---|---|---|---|---|
| pregnant women | ☐ | children | ☐ | elderly | ☐ |
| fetus | ☐ | illiterate | ☐ | handicapped | ☐ |
| terminally ill | ☐ | seriously ill | ☐ | mentally challenged | ☐ |
| economically & socially backward | ☐ | any other | ☐ | | |

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

| | | | | | |
|---|---|---|---|---|---|
| captives | ☐ | institutionalized | ☐ | employees | ☐ |
| students | ☐ | nurses/dependent | ☐ | armed forces | ☐ |
| any other | ☐ | staff | ☐ | | |

**6. Privacy and confidentiality**

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
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?<br>**If Yes, justify with details of collaborators** | Yes | No |
| 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 | ☐ | ight to withdraw | ☐ |
| Benefits | ☐ | onsent 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:**<br>i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? | Yes | No |
| ii. Is there physical / social / psychological risk / discomfort?<br>**If Yes,** Minimal or no risk ☐<br>More than minimum risk ☐<br>High risk ☐ | Yes | No |

Iii.Is there a benefit a) to the subject ?
Direct ☐ Indirect ☐
b) Benefit to society ☐

| | | |
|---|---|---|
| **11. Data Monitoring**<br>i. Is there a data & safety monitoring committee/ Board (DSMB)? | Yes | No |

| | | |
|---|---|---|
| ii. Is there a plan for reporting of adverse events?<br>**If Yes,** reporting is done to :<br>Sponsor ☐ Ethics Committee ☐ DSMB ☐ | Yes | No |
| iii. Is there a plan for interim analysis of data? | Yes | No |
| iv. 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 – 1 Copy | ☐ |
| 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: