**Preamble:**

The R & D Section, CIT Kokrajhar, a Deemed-to-be University Centrally Funded Technical Institution (CFTI) under the Ministry of Education, Government of India is steadfast to expedite various R&D and consultancy activities of the Institute in terms of intra- & inter-departmental associations and Industry-Institute Partnership / interactions. The objective of Institute Ethics Committee (*abbreviated as* IEC) at CIT Kokrajhar is to establish a transparent and consistent review mechanism to review the research proposals/work which involves testing on human, animal, biological samples, vulnerable population and/or sharing of confidential information involving human subjects, with a view to safeguard the dignity, rights, safety and well-being of all actual and potential subjects.

The IEC will look after following sub-committee:

- Human Ethics Committee
- Animal Ethics Committee
- Bio-safety Committee

## 1. Role of the IEC

The review, conduct and monitoring of collaborative research shall be overseen by IEC and stakeholders must be aware of the requirements of various regulatory and funding agencies.

**[a]** IEC will ensure that the proposed methodology adheres to the cardinal principles of research ethics viz., Autonomy, Beneficence, Non-malfeasance and Justice, are included in the planning, conduct and reporting of the proposed research.

**[b]** IEC will investigate the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit, and provisions for appropriate compensations wherever required.

**[c]** IEC will review proposals before start of the study, and after completion of the study through documented procedures. IEC will not review / approve a study retrospectively.

**[d]** •IEC should review the protocols in the local social and cultural context and ensure respect for sensitivities and values of participants and communities at collaborative sites.

**[e]** IEC shall examine whether the researcher has the required expertise and training in the area of collaboration; and it shall protect the interests and rights of the collaborating researcher(s) and ensure that they are not treated as mere collectors of samples or data.

**[f]** Institutions are responsible for fair contract negotiation in collaborative research partnerships (including benefit sharing and avoiding unauthorized use of their expertise, biological samples and data) to safeguard the interests of participants, researchers and institutions.

**[g]** Institutions should provide opportunities for collaboration to build capacity and engage in research which is mutually beneficial.

## 2. Composition of the IEC

IEC will be multidisciplinary in composition. The number of persons in the IEC will be in line with the requirements and scope of work. The composition will be as follows:

- Chairperson – the Chairperson of IEC shall be from outside CIT Kokrajhar, preferably with a higher medical qualification.
- Member Secretary – shall be from R & D section, CIT Kokrajhar.
- Legal expert – the legal expert shall be from outside CIT Kokrajhar.
- One or more basic scientists – preferably be from the academic units of CIT Kokrajhar. In case of non-availability of in-house scientists, external scientists shall be considered.
- One or more Clinicians – including the Medical Officer (*ex officio*), CITK Hospital
- One or more Social scientists / philosophers / ethicists / theologians – may be from the Department of Humanities and Social Sciences of CITK or other institutes
- One or more persons from the local community
- Safety Officer, CITK (*ex-officio*)

If required, subject experts may be invited by the Member-Secretary or Members or Chairperson, to seek their views. It is generally accepted that a minimum of five persons is required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals. The chairperson of the committee should be from outside the institution to maintain the independence of the committee. The Member Secretary generally belongs to the institution.

## 3. Authority for Constitution of IEC

The Director, CIT Kokrajhar shall authorize constitution of the IEC.

## 4. Membership Requirements

- The members shall have a term of three years, which can be renewed at the end of the term.
- A member can be replaced in the event of his / her long-term non-availability. A member can tender resignation from the committee stating the reasons to do so.
- All members must maintain absolute confidentiality of the deliberations of the committee. A non-disclosure agreement shall be signed by all members at the time of appointment. The members shall not disclose any information obtained by him during his tenure to any individual or authority without the written permission from the IEC, CIT Kokrajhar. Disclosures to be made to any statutory authorities if required under any law shall be exempted thereof.

## 5. IEC Office Execution

**[a]** The Chairperson will conduct all meetings of the IEC. If the Chairperson is not available for reasons beyond control, the Chairperson may nominate a co-chair for the meeting.

**[b]** The Member Secretary will be responsible for organizing meetings, maintaining records and communicating with all concerned. The Member Secretary shall prepare the minutes of meetings and circulate the comments to Principal Investigator (abbreviated as PI, pl. PIs) after decisions are declared in the meeting.

**[c]** So as to maintain independence, the Director should not be part of the IEC but should act as an appellate authority to appoint the committee or to handle disputes.

**[d]** The IEC can also have a set of alternate members who can be invited as members with decision-making powers to meet the IEC Meeting requirements. These members shall have the same terms of reference as regular members and can attend meetings in the absence of regular members.

**[e]** The EC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a cardiologist for research on heart disorders. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power / voting rights.

**[f]** The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision-making power.

**[g]** IEC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

## 6. Procedure of Application to the IEC

The proposal signed by the PI, containing all the relevant information including the enclosures like the Informed Consent Forms (ICFs) and their translations must be submitted as a single pdf file, via e-mail to the Member Secretary.

- Member Secretary will forward the proposals by electronic mail to the IEC members for review and comments.
- Members will opine on the proposal and may seek clarifications as and when necessary.
- Comments by members will be compiled by the Member Secretary and forwarded to the PI in advance so that PIs can come prepared with responses for clarifications sought.
- PI shall make the presentation for the IEC meeting and may bring along co- PIs only.
- IEC members will have closed door discussions on the proposal, recommendation and /or decision.
- The recommendations and decisions of the IEC on the proposal will be communicated by electronic mail, to the PI by the Member Secretary.
- If revision is to be made, the revised document should be submitted to the Member Secretary. The revised version will be forwarded to members

## 7. Documentation / Details Required from the PIs / Co-PIs

All research proposals must be submitted with the following details:

I. Name of the applicant (CIT Kokrajhar Faculty / Staff, along with designation and Department) provisionally eligible to be PI as per the norms of CIT Kokrajhar and the agency (Govt / UT / PSU / Private) funding the proposal under review.

II. Details of the Site / Institute / Hospital / Field area where research will be conducted.

III. Protocol of the proposed research should highlight complete details on:

- **a.** Scientific Rationale (including references of relevant previous animal / human experiments, if any)
- **b.** Hypothesis
- **c.** Study Design
- **d.** Risks Involved in the design of the study to be categorized by the PI as one of the following:
  - **(i)** *Less than Minimal / No Risk* – Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
  - **(ii)** *Minimal Risk* – those which may be anticipated as harm or discomfort not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This includes procedures such as questioning, observing, and measuring the anthropometric parameters (such as height and weight) in children, provided that procedures are carried out in a child friendly way, respecting the child's wishes, and that consent has been given by appropriate persons. Procedures with minimal risk include history taking, physical examination, chest X-ray, obtaining bodily fluids without invasive intervention, for example, taking saliva or urine samples, etc. It is expected that the harm caused by the minimum risk level research would be very slight and temporary.
  - **(iii)** *Low (Minor Increase over Minimal) Risk* – slight increase in the potential for harm or discomfort beyond or more than minimal risk (as defined in relation to the normal experiences of average, healthy, normal children). These include procedures that might cause no more than transient pain or tenderness, small bruises or scars, or very slight, temporary distress, such as a blood test, oral sedation for diagnostic procedures, etc.
  - **(iv)** *High (More than Minimal) Risk* – All research procedures which have a risk over-and-above low risk are classified as high risk. These include procedures such as lumbar puncture, lung or liver biopsy, intravenous sedation for diagnostic procedures, etc.
- **e.** Statistical Validation of the Experimental Methodology, wherever applicable.
- **f.** Potentially Harmful Effects that can be effectively detected, prevented, or treated

**8. Review procedures (as per ICMR Guidelines)**

All research proposals shall be reviewed as follows:

- The meeting of the IEC will be held on scheduled dates / intervals.
- PIs will be invited to provide clarifications, if needed.

- Independent consultants / Experts may be invited to offer their opinion on specific research proposals, if needed.
- Decisions will be recorded, confirmed by members and Chairperson, and the minutes thereof shall be formally placed in the next meeting.

**9. Statement of General Principles as per ICMR**

Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities. Therefore, protection of participants should be built into the design of the study. Do no harm (non-maleficence) has been the underlying universal principle guiding health care in all systems of medicine around the world. While conducting biomedical and health research, the four basic ethical principles namely; (i) respect for persons i.e. autonomy, (ii) beneficence, (iii) non-maleficence and (iv) justice have been enunciated for protecting the dignity, rights, safety and well-being of research participants. *These four basic principles have been expanded into 12 general principles described below,* and are to be applied to all biomedical, social and behavioural science research involving human participants, their biological material and data.

I. *Principle of Essentiality*, whereby after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered to be essential for the proposed research. This should be duly vetted by an ethics committee (EC) independent of the proposed research.

II. *Principle of Voluntariness,* whereby respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount. The informed consent process ensures that participants' rights are safeguarded.

III. *Principle of Non-Exploitation*, whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Enough safeguards to protect vulnerable groups should be ensured.

IV. *Principle of Social Responsibility*, whereby the research is planned and conducted so as to avoid creation or deepening of social and historic divisions or in any way disturb social harmony in community relationships.

V. *Principle of Ensuring Privacy and Confidentiality*, whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.

VI. *Principle of Risk Minimization*, whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.

VII. *Principle of Professional Competence*, whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the

appropriate and relevant qualification, experience and/or training.

VIII. *Principle of Maximization of Benefit*, whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society.

IX. *Principle of Institutional Arrangements*, whereby institutions where the research is being conducted, have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.

X. *Principle of Transparency and Accountability*, whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately. The research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/ audit.

XI. *Principle of Totality of Responsibility*, whereby all stakeholders involved in research are responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.

XII. *Principle of Environmental Protection*, whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

**10. Elements of Review**

As per ICMR guidelines, all research proposals shall be reviewed for the following:

I. Scientific rationale, hypothesis, study design and conduct of the study
II. Approval of appropriate scientific review committees, if available
III. Examination of predictable risks/harms
IV. Examination of potential benefits
V. Procedure for selection of subjects in methodology including inclusion / exclusion / withdrawal criteria and other issues like advertisement details
VI. Management of research related injuries, adverse events, etc. wherever applicable
VII. Provisions for compensation, especially for field studies and distant travel involved in the study
VIII. Participant information sheet and ICF in local language(s)
IX. Protection of privacy and confidentiality
X. Plans for data analysis and reporting
XI. Adherence to all regulatory requirements and guidelines
XII. Competence of the investigators
XIII. Facilities and infrastructure of study sites, as applicable
XIV. Criteria for withdrawal of participants, suspending or terminating the study

**11. Miscellaneous Issues and Concerns**

The IEC shall ensure to take care of the following aspects / issues / concerns with due importance to the spirit of high-quality research.

a. ***Privacy and Confidentiality.*** Privacy is the right of an individual to control or influence the information that can be collected and stored and by whom and to whom that information may be disclosed or shared.
   i. Confidentiality is the obligation of the researcher/research team/organization to the participant to safeguard the entrusted information. It includes the obligation to protect information from unauthorized access, use, disclosure, modification, loss or theft.
   ii. The researcher should safeguard the confidentiality of research related data of participants and the community.
   iii. Potential limitations to ensure strict confidentiality must be explained to the participant. Researchers must inform prospective participants that although every effort will be made to protect privacy and ensure confidentiality, it may not be possible to do so under certain circumstances.
   iv. Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.

b. ***Distributive Justice.*** Efforts must be made to ensure that individuals or communities invited for research are selected in such a way that the benefits and burdens of research are equitably distributed.
   i. Vulnerable individuals / groups should not be included in research to solely benefit others who are better-off than themselves.
   ii. Research should not lead to social, racial or ethnic inequalities.
   iii. Plans for direct or indirect benefit sharing in all types of research with participants, donors of biological materials or data should be included in the study, especially if there is a potential for commercialization. This should be decided a priori in consultation with the stakeholders and reviewed by the EC.

c. ***Payment for Participation.*** If applicable, participants may be reimbursed for expenses incurred relating to their participation in research, such as travel related expenses. Participants may also be paid for inconvenience incurred, time spent and other incidental expenses in either cash or kind or both as deemed necessary (for example, loss of wages and food supplies).
   i. Participants should not be made to pay for any expenses incurred beyond routine clinical care and which are research related including investigations, patient work up, any interventions or associated treatment. This is applicable to all participants, including those in comparator/control groups.
   ii. If there are provisions, participants may also receive additional medical services at no cost.
   iii. IEC shall review and approve the payments (in cash or kind or both) and free services and the processes involved, and also determine that this does not amount to undue inducement.

d. ***Compensation / Indemnity for Research Related Harm.*** Research participants who

suffer direct physical, psychological, social, legal or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, participant's dependents are entitled to financial compensation. The research proposal should have an in-built provision for mitigating research related harm.

e. ***Applicable Law & Jurisdiction of Courts.*** The IEC shall be established as a registered legal entity, governed by individuals who may be members of the IEC / otherwise and who will oversee and monitor the functioning of the IEC. All legal matters will be dealt with as per extant provisions of the Institute with point of jurisdiction and resolution of disputes or the same falling in the District Court of Kokrajhar.

f. ***Conflict of interest (COI).*** This is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors.

   i. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
   ii. CIT Kokrajhar will develop and implement policies and procedures to identify, mitigate conflicts of interest and educate their staff about such conflicts.
   iii. Researchers must ensure that the documents submitted to the IEC include a disclosure of interests that may affect the research.
   iv. IEC shall evaluate each study in light of any disclosed interests and ensure that appropriate means of mitigation are taken.

g. ***Community Engagement.*** Community can be defined as a social group of people of any size sharing the same geographical location, beliefs, culture, age, gender, profession, lifestyle, disease, etc. The community should be meaningfully engaged before, during and after the research to mitigate culturally sensitive issues and ensure greater responsiveness to their health needs and requirements.

   The community can be engaged in many ways and can provide valuable opinions. The degree of community engagement should depend on the type of research that is being conducted.

## 12. Communicating the decision

The Member Secretary shall communicate recommendations of IEC vide its minutes for revision / further review / any other decision, whichever applicable, to the PI(s) / Co-PIs via e-mail.

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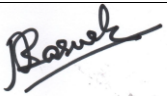
| 1. Chairperson | Dr. Anuj Kumar Baruah, Chief Medical Officer, IIT Guwahati |  Signature |

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| 2. Member Secretary | Dr. Avik Mukherjee, Dean – Research & Development, CIT Kokrajhar | Signature |
| | | |
| 3. Legal Expert | Dr. Madhumita Kothari, Advocate, Honourable Supreme Court of India | Signature |
| | | |
| 4. Scientists / Professors | Prof. (Dr.) Tapan Kumar Maiti, Professor, Department of Instrumentation Engineering, CIT Kokrajhar | Signature |
| | Dr. Subhajit Ray, Associate Professor, Department of Food Engineering & Technology, CIT Kokrajhar | Signature |
| | | |
| 5. Clinician | Dr. Jadav Ch. Baro, Chief Medical Officer (ex officio), CIT Kokrajhar Hospital | Signature |
| | | |
| 6. Faculty from Humanities and Social Sciences | Dr. Pradip Brahmachary, Associate Professor, Department of Humanities and Social Sciences, CIT Kokrajhar | Signature |
| | | |
| 7. Safety Officer | Dr. Pranjal Kalita, Associate Professor, Department of Chemistry, CIT Kokrajhar | Signature |
| | | |
| 8. A person from local community | Village Headman | Signature |