AX1-V2/SOP-4b/V2

Expedited Review Application Form

BBCI, Guwahati Project No. *:*_____*(To be filled by IEC Secretariat)*

1. Principal Investigator's Name: _____
2. Department/DMG: _____
3. Title of Project: _____
4. Name of study team members: _____

   _____

5. Brief description of the project:

   _____

   _____

6. State reasons why expedited review from IEC is requested? (Tick applicable)
   - ☐ Risks to subjects is no more than minimal
   - ☐ Research involving non identifiable specimen and human tissue from sources like blood bank, tissue banks, left over clinical samples
   - ☐ Research involving materials (data, documents, records, or specimens) which are non-identifiable that have been collected, for non-research (clinical) purposes

   Are children included in the study? ☐ Yes ☐ No

   Does the research involve vulnerable population? ☐ Yes ☐ No

Any other reasons: _____

Principal Investigator's signature: _____ **Date** _____

Recommendations by the IEC Member Secretary:

- ☐ Consider for expedited review, Reasons
- ☐ Cannot consider for expedited review, Reasons _____

  _____

  _____

Final Decision: ☐ Expedited Review ☐ Full Board Meeting

Signature of the Member Secretary:

Date- _____

AX1-V2/SOP-4c/V2

Review Exemption Application Form

BBCI, Guwahati Project No.: _____ (To be filled by IEC Secretariat)

1. Principal Investigator's Name: _____
2. Department/DMG: _____
3. Title of Project: _____
4. Names of study team members:
   _____
5. Brief description of the project:

   Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, study population, and procedures/methods to be used in the project.

Please check that your application / summary includes:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

6. State reasons why exemption from IEC review is requested? (Tick applicable)
   - ☐ Audit of educational practices
   - ☐ Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
   - ☐ Quality control and quality assurance audits in the institution;
   - ☐ Comparison of instructional techniques, curricula, or classroom management methods;
   - ☐ Research on microbes cultured in the laboratory
   - ☐ Research on immortalized cell lines
   - ☐ Research on cadavers or death certificates which reveals no identifying personal data

- ☐ Analysis of data freely available in the public domain for systematic reviews or meta-analysis;
- ☐ Consumer acceptance studies related to taste and food quality; and
- ☐ Public health programmes by Govt. agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
- ☐ Any other (please specify) ----------

Principal Investigator's signature: _____ Date _____

Forwarded by the Head of the department:

Name: _____

Signature: _____

Date: _____

Forwarded by the DMG/ Scientific Committee Convener/Secretary:

Name: _____

Signature: _____

Date: _____

<u>Recommendations by the IEC Member Secretary:</u>

☐ Exemption, Reasons _____

☐ **Cannot be** exempted, Reasons _____

_____

☐ Discussion at full board

Signature of the Member Secretary: _____ **Date** _____

Final Decision:

☐ Exemption

☐ Cannot be exempted,

Reasons _____

_____

☐ Discussion at full board

Signature of the Chairperson: _____ **Date** _____

Final Decision at Full Board meeting held on _____

Signature of the Chairperson: _____ **Date** _____

NOTE:

No research can be counted as minimal risk if it involves:

i. Invasive physical procedures or potential for physical harm
ii. Procedures which might cause mental/emotional stress or distress, moral or cultural offence
iii. Personal or sensitive issues
iv. Vulnerable groups
v. Cross cultural research
vi. Investigation of illegal behavior(s)
vii. Invasion of privacy
viii. Collection of information that might be disadvantageous to the participant
ix. Use of information already collected that is not in the public arena which might be disadvantageous to the participant
x. Use of information already collected which was collected under agreement of confidentiality
xi. Participants who are unable to give informed consent
xii. Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
xiii. Deception
xiv. Audio or visual recording without consent
xv. Withholding benefits from “control” groups
xvi. Inducements
xvii. Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Minimal risk research would involve the same risk as might be encountered in normal daily life.

Please check that your application / summary has discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet minimal risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

- The publisher of the research
- An organization which is providing funding resources, existing data, access to participants etc.