Title: **Exemption from the Ethics Review for Research Projects**

SOP Code: **SOP 05-C/V5.1 dated 2nd April 2018**

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe which clinical research projects can be exempted from ethics review and do not require the approval of the Institutional Ethics Committee (IEC). The Exemption Form *AX 01/SOP 05-C/V5.1* is designed to standardize the process of exemption.

2. Scope

This SOP applies to the all protocols submitted for exemption from review by the IEC. The specific points in the Exemption Form should guide the Member Secretary to determine whether the protocol qualifies for exemption from review. The decision should be taken by the Member Secretary in consultation with the Chairperson and should be informed to the Members in the forthcoming IEC meeting.

3. Responsibility

It is the responsibility of the Member Secretary to record the decision in the Exemption Form with reasons. The IEC Secretariat is responsible for recording and filing the decision including the reasons for that decision. The Chairperson/ Member Secretary must sign and date letter conveying the decision *AX 01/SOP 05-C/V5.1*.

4. Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents.	IEC Secretariat
2	Review of protocol and Exemption Form	Member Secretary
3	Recording the decision on Exemption Form in consultation with the Chairperson	Member Secretary
4	Communicate the decision to the Investigator & IEC members in forthcoming meeting	Member Secretary / IEC Secretariat

5. Detailed instructions

5.1 Receive the submitted documents.

- The Secretariat will receive the Exemption from review Application Form *AX 01/SOP 05-C/V5.1,* Protocol and other documents submitted by the investigators.

5.2 Determine protocols eligible for exemption from review

The proposal submitted for initial review or where investigator have requested for the exemption from review stating the reason in the 'Review Exemption Application Form' to the IEC will be evaluated for the exemption from review.

Proposals which involve less than minimal risk fall under this category.
Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of the general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like

surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life (ICMR 2006).
The IEC Member Secretary will determine whether a protocol qualifies for exemption from review based on the following criteria. Final decision will be made by the Chairperson.

The research proposals which do not involve live human participants or data derived from them are exempt from ethics review. For example,

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain

In some circumstances research which appears to meet low 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.

5.3 **Recording the decision on Exemption Form in consultation with the Chairperson**

- If the protocol and related documents satisfy the criteria as listed in 5.2, the Member Secretary in consultation with the Chairperson will review the brief summary of the project and the Exemption Form. The Member Secretary records the decision

5.4 Communicate the decision to the Investigator & IEC members in forthcoming meeting

- The Secretariat communicates the decision to the Principal Investigator within 14 days after the decision regarding the exemption is taken.
- The Member Secretary informs the IEC members about the decision at the next full board meeting and minute it in the meeting notes.
- The Member Secretary / Chairperson may keep the application for review and decision regarding exemption at the next full board meeting.
- Any changes to the protocol must be brought to the notice of the IEC prior to implementation by the investigator. Any correspondence with the IEC office regarding this action should mention the allocated study number indicated at the top of this letter.

  The IEC will determine if requested protocol changes alter the risks: benefits analysis of the study, thereby requiring a change in review or exemption category. In such cases investigator will have to resubmit the study protocol and related documents for change review process.

6. Glossary

Exemption from review	A research study is said to be exempt from review when it does not require the Ethics Committee approval for its conduct

7. References

[1] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - *http://www.icmr.nic.in/ethicalguidelines.pdf* (last accessed 31st July 2017)

8. Annexure

Annexure 1 *AX 01/SOP 05-C/V5.1* Review exemption application form

Annexure 2 *AX 02/SOP 05-C/V5.1* Approval for Exemption from Review

Annexure 1

AX 01/SOP 05-C/V5.1

Review Exemption Application Form

1 Principal Investigator's Name: _____

2 Department: _____

3 Title of Project: _____

_____

_____

4 Names of other participating staff and students:

_____

_____

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, participants' description, and procedures/methods to be used in the project:-

6 State reasons why exemption from ethics review is requested?

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory

- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain
- ✓ Any other

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Principal Investigator's signature: _____Date _____

Forwarded by the Head of the department:

Name: _____ Signature: _____ **Date**_____

Recommendations by the IEC Member Secretary:

☐ Exemption

☐ Can not be exempted, Reasons_____

☐ Discussion at full board

Signature of the Member Secretary: _____ Date _____

Final Decision:

☐ Exemption

☐ Can not 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 _____

No research can be counted as low 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 behaviour(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. Low 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 low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

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

Annexure 2

AX 02/SOP 05-C/V5.1

Approval for Exemption from Review

Date:

To,

Name of the PI_____
Dept. Of _____

Ref: Your project no. _____entitled **"_____".**

Sub: _____.

Dear Dr. **_____,**

This letter certifies that the application for the protocol stated above has been reviewed by Institutional Ethics Committee designated reviewer/Member Secretary and Chairperson. The Institutional Ethics Committee has given due consideration and concludes that the said proposal is exempt from IEC review as it does not involve direct contact with human participants. (SOP 05-C/V5.1; ICMR 2006 chapter I Ethical review procedures page no.11). Please note that the provision to collect the identifiable (indirectly identifiable) information viz Initials, Age and Gender needs to be removed from the case record form.

Please note that any changes to the protocol must be brought to the notice of the IEC prior to implementation. The IEC must determine whether the requested protocol changes alter the risks: benefits analysis of the study, thereby requiring a change in review or exemption category.

Please contact the IEC office if you have any questions. Any correspondence with the IEC office regarding this action should mention the allocated study number indicated at the top of this letter.

With Regards,

Sincerely yours,

_____
Chairperson / Member Secretary

Exemption From Review

Submission of project proposal by Investigator
[as per checklist –AX 02/SOP 05/V5.1 with Review Exemption Application form (Annexure 1, SOP 05-C)

↓

Documents checked by the Administrative officer

Complete	Incomplete
↓	↓
Received by IEC	**Returned**

↓

The IEC Member Secretary will determine whether a protocol qualifies for exemption from review based on the following criteria as per SOP 05-C/ V5.1

↓

The research proposals which do not involve live human participants or data derived from them are exempt from ethics review. For example,

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain

In some circumstances research which appears to meet low 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.

↓

Final decision will be made by the Chairperson as per SOP.

↓

Decision communicated

To the investigator within 14 days] the decision (Approval/Disapproval with reasons)

→ Member Secretary will inform

at its upcoming full board meeting.

→ Member Secretary may keep the application for review and decision regarding exemption at the next full board meeting.