Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Exempt from ethical review

SOP Code: 10/V1.1 Dated: 8th November 2024 Page Nos: 160 to 166

Exempt from ethical review

The proposals presenting less than minimal risk to research participants is involved may be subjected to exempt from ethical review.

10.1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe which clinical research projects can be exempted from ethical review.

10.2. Scope:

This SOP applies to the review and approval of study proposals submitted for exemption from ethical review by the IEC with less than minimum risk to participants.

10.3. Nature of Study Proposals considered for exempt from ethical review process:

Proposals with less than minimal risk where there are no linked identifiers fall under this category.

10.4. Flow chart

Sr. No.	Activity	Responsibility
1	Receive the submitted documents.	IEC Secretariat
2	Determine protocols for exempt from ethical review as per point 5.2. Agenda will mention the titles of study proposals and reasons for IEC referral as heading.	Member Secretary/ Alternate Member Secretary/ IEC assigned member with consultation and concurrence from the Chairperson.
3	Exempt review process online using email communication or virtual platform.	Member Secretary/ Alternate Member Secretary/ IEC assigned member along with Chairperson and Secretariat.
4	Communicate the decision with the IEC-full board and the Investigator.	Member Secretary.
5	Completion report at least within 2 months of the completion of study when changes approved by EC are incorporated.(limited IEC Review)	Principal Investigator

6	Review of completion report & communicating with Principal Investigator for limited IEC review	Chairperson/ experienced member designated by the Chairperson
7	Convey the comments to the Principal Investigator	IEC secretariat

10.5. Detailed instructions

10.5.1 Receive the submitted documents.

a. Receive the application documents submitted by investigators.
b. Inward Stamp which includes the receiving date on the letter and the documents.
c. Sign the receiver's name on the receiving documents.
d. Hand over the received documents to the IEC secretariat.
e. In case of emergencies, calamities and catastrophes such as COVID19 pandemics, social strife, unrest, etc., submission of e-copy of research protocol and relevant documents through mail is permitted. The screening by EC Secretariat for completeness will follow this.
f. The Member secretory & Chairperson will categorize, if the protocol falls under exempt from ethical review or need to be reviewed as expedited review/ emergency full committee review depending on the criteria below.
g. When the situation returns to normal, hard copy of the same should reach EC office for maintaining the records.

10.5.2 Determinate protocols for exempt from ethical review.

Member secretary/ Joint Member Secretary in concurrence with Chairperson along with at least one external member can determine whether a study is qualified for exempt from ethical review based on the following criteria.

Proposals with less than minimal risk where there are no linked identifiers fall under this category, such as:

1. Research conducted on data available in the public domain for systematic reviews or meta-analysis
2. Observation of public behavior when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person
3. Quality control and quality assurance audits in the institution
4. Comparison of instructional techniques, curricula, or classroom management methods
5. Consumer acceptance studies related to taste and food quality
6. Public health programs by Government agencies such as programs evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring (where there are no individual identifiers).
7. Studies involving commercial cell lines
8. Any other (please specify in 100 words): .....

10.5.3 Exempt Process:

Recording the decision on Exemption Form in consultation with the Chairperson

a. If the protocol and related documents satisfy the criteria as listed in 5.2, the Member Secretary/ Joint Member Secretary in consultation with the Chairperson along with one external members will review the brief summary of the project and the Exemption Form. The Member Secretary records the decision. This process can be online using various platforms

b. If it is doubtful that the study falls under exempt category the PI will be communicated the same. The PI then has to modify the proposal to be put forth to the full committee meeting.

c. If any protocol is disapproved, the reason for the same should be conveyed to the Principal investigator in writing. The protocol which is disapproved should be archived as per the achieving procedures set by the EC (Refer SOP 24).

d. Proposals exempted from review need not submit continuing review reports.

    i Research that only includes interactions involving educational tests, survey or interview procedures, observation of public behavior or benign behavioral interventions in conjunction with specified data collection methods, if that information can readily identify the identity of the participants either directly or through identifiers. Here the limited IRB review ensures that adequate provisions are in place to protect the privacy of participants and maintain confidentiality of the data.

    ii Research involving the storage and maintenance of identifiable private information or identifiable biospecimens for potential secondary research use, for which consent for future use is given. This exemption requires limited IRB review to determine that the requirements for this type of broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of participants and maintain confidentiality of the data.

    iii Secondary research involving identifiable private information or identifiable biospecimens, for which broad consent is required. This exemption requires an IRB to determine through limited review that there are adequate provisions in place to protect the privacy of participants and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent.

e. Limited IEC Review: In some instances, once the study is complete, completion reports may be submitted to EC for 'limited IEC review', by Chairperson or experienced member of IEC designated by the Chairperson (refer revised common rules). The instances are given below:

10.5.4 Communicate the decision to the investigator and IEC Members.

a. The Secretariat communicates the decision to the Principal Investigator within 5 days after the decision regarding the exemption.
b. The Member Secretary informs the IEC members about the decision at the next full committee meeting for ratification and minutes it in the meeting notes.
c. 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.
d. 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 in review process.

10.6. ANNEX

ANNEX 1	AF/01/10/V1.1	Approval letter for Exempt Review
ANNEX 2	AF/02/10/V1.1	Document History

ANNEX 1 **AF/01/10/V1.1**

Approval of request for Exempt from Ethical Review

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Recognized by: Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Forum for Ethics Review Committees in Asia and the Western Pacific Region (FERCAP) for its compliance with international and local standards in ethical review

CHAIRPERSON

MEMBERS

JOINT MEMBER SECRETARY

MEMBER SECRETARY

Ref.:D/ICEC/Sci-…/../ …. Date:
Name of the PI
Department ……
ICMR-NIRRCH

Subject: Reference to the project Title which will be approved, Version … dated ……..
Project No.: …… PI: Dr. ……

Dear Dr. ……,

This is with reference to the study proposal entitled .....Version …. dated ….. which was submitted to the Ethics Committee Secretariat on (date) ……. for granting approval under "Exempt from Review" process. The research study proposal falls under the category of less than minimal risk/ minimal risk (state actual reason)……. and no identifiable linked information is being collected or recorded for the study/ research, and therefore it is exempted from review.

Please note that any changes to the proposal should have prior approval by the ethics committee before being implemented.

You are requested to submit the Completion report at least within 2 months from the completion of study.

Due date for submission of Completion report:

Sincerely,

Dr. …… Dr. ……..

Member Secretary Chairperson

ANNEX 2 **AF/02/10/V1.1**

Document History

Author	Version	Date	Description of the Change
Dr. Beena Joshi	Version 1.0	1st May 2019	Separate SOP created for Exempt from Ethical Review
Dr. Vikrant Bhor	Version 1.1	8th November 2024	All bullets are numbered. ● Limited IEC review is added in the Flow chart as well as description