Title: Exemption from ethics review of research study protocols

SOP Code: SOP07C/v2

Effective Date: 01/08/2016

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1. Purpose

The purpose of this SOP 7 C is to describe in detail the method of exemption from ethics review of a research protocol submitted to the YUEC for ethical clearance.

2. Scope:

2.1 The SOP applies to the initial review of all research protocols submitted to the YUEC for ethical clearance categorized by the Member secretary under "exemption from review" as per the ICMR Ethical guidelines for research on human participants and fulfils the criteria for 'exemption from review 'as per SOP 07 version

3. Responsibility:

3.1 Member secretary

3.1.1 The member secretary will do an initial screening of the protocol

3.1.2 The member-secretary will categorise the protocols into 'exemption from review' as per the ICMR ethical guidelines for research on human participants based on the initial screening and in consultation with the Chairperson.

3.1.3 The member secretary will record the reasons for include the protocol under the category of 'exemption from review'.

3.1.4 The secretariat will list the protocol in the 'exemption from review' category in the agenda of the next YUEC meeting.

3.2 Secretariat:

3.2.1 It is the responsibility of the secretariat for recording and filing of the decision of the member secretary and the chairperson to

include the protocol under the category of 'exemption from review' including the reasons stated

3.3 Chairperson:

3.3.1 It is the responsibility of the chairperson to approve the letter of communication to the principal investigator stating that the protocol is exempted from ethical review**.**

4. Detailed instructions:

4.1 Receiving the submission of protocol

4.1.1 Once the secretariat receives the complete protocol submission from the principal investigator, the secretariat will check for the completion of protocol

4.1.2 The secretariat will also file any request for exemption from review from the principal investigator

4.2 Categorization of protocol into 'exemption from review':

4.2.1 The member secretary will consider the protocol for exemption from review based on the criteria laid down in the ICMR ethical guidelines for research on human participants, when the protocol involves less than minimal risk

4.2.2 After the protocols are classified under the category of 'exemption from review' by the member-secretary in consultation with the chairperson, the secretariat records the decision in the file along with the reasons

4.3 Exemption process:

4.3.1 The member secretary in consultation with the chairperson goes through the project summary and the exemption request.

4.3.2 If the protocol and related documents satisfy the criteria stated in the ICMR ethical guidelines for research on human participants and fulfil the criteria for inclusion in the 'exemption from review category as described in SOP 7, the Member Secretary in consultation with the Chairperson, takes a decision.

4.3.3 The Member Secretary records the decision on the Exemption Form (form reference)

4.3.4 The exemption approval is signed by the Chairperson/Member secretary with date.

4.3.5 The protocol is included in the next YUEC meeting agenda for ratification of the decision.

4.4 Communication of the decision:

4.4. The decision regarding request for Exemption from review, signed by the IEC Chairperson, will be forwarded by the Secretariat to the Principal Investigator within14working days after the decision regarding the exemption is taken.

5. References to other SOPs:

5.1 SOP07/v2: Categorization of Submitted Protocols for Ethics Review

5.2 SOP07-A/v2: Initial Full-Board Review of Research Study Protocols

6. Annexures:

6.1 Ann01/SOP7C/v2 - Review Exemption Application Form

6.2 Ann02/SOP 7C/v2 - Decision form for review exemption

Annexure 1: Ann01/SOP7C/v2

Review Exemption Application Form

Name of the Principal investigator

Department:

Institution:

Title of the project:

Name of the other participating staff:

Brief description of the project:

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

State reasons why exemption from ethics reviews requested?

- Audits of educational practices
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Researchoncadaversordeathcertificatesprovidedsuchresearchrevealsnoidentifying personal data

- Analysis of data freely available in public domain
- Any other_____

(This should include justification for exemption e.g. the study does not involve human participants. If exemption is being requested on the basis of the low risk involved in the study, refer to the following:

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

Please note that No research can be counted as low risk if it involves

- Invasive physical procedures or potential for physical harm
- Procedures which might cause mental/emotional stress or distress, moral or cultural offence
- Issues involving personal or sensitive aspects
- Vulnerable groups
- Cross cultural research
- Investigation on illegal behaviour
- Research involving invasion of privacy
- Collection of information that may be disadvantageous to the participant
- Use of information already collected that is not in the public arena which might be disadvantageous to the participant
- Use of information already collected which was collected under agreement of confidentiality
- Participants who are unable to give informed consent

- 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
- Deception
- Audio or visual recording without consent
- Withholding benefits from "control "groups
- Inducements
- Risks to the researcher

This list is not definitive but is intended to sensitise 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.

Signature and name of the principal investigator with date

Forwarded by the Head of the department:

Name and signature of the HOD

Ann02/SOP 7C/v2

Decision form for review exemption

Protocol Number:

Date:

Name of the Principal investigator

Department:

Institution:

Title of the project:

Recommendations of the YUEC member secretary

- Exemption
- Cannot be exempted
  Reasons for no exemption:
  State reasons:

Discussion at YUEC meeting:

Final decision at the YUEC meeting:

Signature of the Chairperson/ Member secretary with date:

7. 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 Secretariat
5	Informing the decision to the members in The forthcoming meeting	Member Secretary
6	Recording and filing the decision	IEC Secretariat