


TAGORE MEDICAL COLLEGE AND HOSPITAL 	Exemption from the Ethics Review for Research Projects		Institutional Ethics Committee
			TMCH/IEC/SOP/6
Amendment No: 00	Issue No: 01	Issue Date: 02/11/2020	PAGE 1 OF 6

Exemption from the Ethics Review for Research Projects

For Institutional Ethics Committee

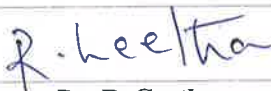

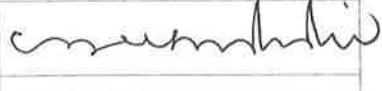
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Issue No : 01
Issue Date : 02.11.2020
Copy No : 01/10
Copy Holder Name
and Designation : Dr. R. Geetha, Member Secretary, IEC

Prepared By	Reviewed By	Approved By
 Dr. R. Geetha Member secretary of IEC	 Dr. I. Kannan Member of IEC	 Dr. S. Seethalakshmi Chairperson of IEC

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1. Purpose



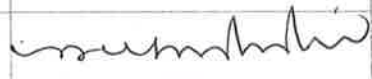
The purpose of this Standard Operating Procedure (SOP) is to describe which clinical research projects can be exempted from ethics review and do not require the approval of the Institutional Ethics Committee (IEC). The Exemption Form is designed to standardize the process of exemption.


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.

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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, 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

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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.

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.

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Communicate the decision to the Investigator and 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.



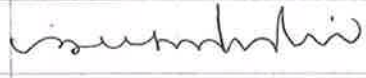
6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22nd October 2020).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22nd October 2020).

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3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017.

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