


<b>TAGORE MEDICAL COLLEGE AND HOSPITAL</b> 	<b>Reviewing proposals involving vulnerable Populations</b>		<b>Institutional Ethics Committee</b>
			<b>TMCH/IEC/SOP/7</b>
<b>Amendment No: 00</b>	<b>Issue No: 01</b>	<b>Issue Date: 02/11/2020</b>	<b>PAGE 1 OF 7</b>

## Reviewing proposals involving vulnerable Populations

For Institutional Ethics Committee

**Tagore Medical College and Hospital**



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**Copy Holder Name  
and Designation : Dr. R. Geetha, Member Secretary, IEC**

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## 1. Purpose

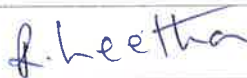


The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations. The SOPs provide clear, unambiguous instructions so that the related activities of the Board are conducted in accordance with Indian laws and relevant, National and International Guidelines. It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.


## 2. Scope

This SOP covers the policies and procedures applied to all research dealing with vulnerable population submitted to the IEC.

## 3. Responsibility

- It is the responsibility of the Secretariat of IEC to maintain up-to-date tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.
- IEC Chairperson/ Member Secretary is responsible for ensuring that IEC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.
- IEC member is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

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### ***3.1 Secretariat of the Institutional Ethics Committee will***

- Maintain on file the update checklist (1-5) which conforms to applicable regulations and guidelines.
- Document review of risk assessment in IEC minutes for the protocols involving vulnerable population.
- Confirm that the complete informed consent and assent documents as relevant.

### ***3.2 Chairperson / Member Secretary will:***




Select appropriate primary reviewer(s).


### ***3.3 IEC members will:***

- Complete checklist during review of research with vulnerable populations and present recommendations at the convened meeting.

## **4. Flow chart**

<b>No.</b>	<b>Activity</b>	<b>Responsibility</b>
1	Reviewing the protocol with vulnerable population	Any member of IEC and designated reviewer, secretariat or administrative staff
2	Appoint one or more reviewers	Chairperson/ Member Secretary
3	Review the protocol	IEC members

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## 5. Detailed instructions




### 5.1 Reviewing the protocol with vulnerable population


Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished people, patients in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchal society.

The protocol should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion

- measure to protect autonomy,
- risk/benefit determinations with respect to the vulnerability
- bearing unequal burden in research.

Any member of the IEC or Secretariat who would be dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study. The checklist for different vulnerable population is being provided in Annexure (1-5). Special justification is required for inviting vulnerable individuals to serve as research participants

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and, if they are selected, the means of protecting their rights and welfare must be strictly applied.


### ***5.2 Appoint the Reviewers***

The Chairperson will appoint two or more members of the IEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. The reviewers should be familiar and trained in the concept of vulnerability and protections for participants with diminished autonomy.

### ***Secretariat duties***

- Provide a suitable checklist according to the participants to be recruited in study to the investigator. Inform the investigator to download the appropriate application form and informed consent document/ assent form. If the checklists are not available (for eg. critically/terminally ill or socially/economically disadvantaged/HIV/Leprosy patients/marginalized population) the investigators want to include the above-mentioned population in the study. They have to mention in the protocol details regarding justification of including the vulnerable population for the study, risk and benefits to the study participants along with mechanism of minimizing risks, measures to protect their autonomy, measures for recruitment of such participants along with measures taken for protection of privacy and confidentiality.
- IEC can recommend for written / verbal Informed consent /audio –visual consent /audio consent (leprosy patients) in the vulnerable population. This decision will be taken on case-to-case basis. All the protocol dealing with vulnerable population will be considered for Full Board review.
- Provide appropriate reference material or help reviewer locate such material related to vulnerable populations when specifically requested for, by a reviewing member.

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### ***5.3 Review the protocol***

#### ***Reviewers responsibility***




- IEC Members will review the protocol and the informed consent document or assent form.
- The reviewers' comment will be discussed in the IEC meeting and the final comments will be sent to the PI.
- The discussion will be documented in the minutes.
- The member secretary will confirm that the IEC recommendations have been incorporated in the revised protocol and in the final draft of informed consent document or assent form.
- Research involving vulnerable populations will not be considered for expedited review or exemption from review.

#### ***Approval of the protocol***


- The final version of the protocol will be approved by the board with the appropriate checklist.
- Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes for e.g.; unconscious patient gaining consciousness, then the protocol and ICD should be amended and resubmitted to the IEC for reconsideration and approval
- Following which the participant should be re-consented and reconsidered for the same.

## **6. References**



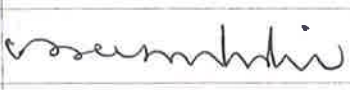
1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-  
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22<sup>nd</sup> October 2020).

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2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22<sup>nd</sup> October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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