



*Standard Operating Procedures (SOP) for
Selection and Responsibilities of
representatives of the vulnerable populations*

KIMS/SOP-05/V2:
Effective Date: 10/07/2019

Title: Selection and Responsibilities of *representatives of the vulnerable populations*

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging the Representatives of the Vulnerable Population as '(RVP)' to the Institutional Ethics Committee (IHEC).

2. Scope

This SOP covers the procedures for selecting, appointing Representatives of the Vulnerable Population and getting their representation during the IHEC review process. It also defines the responsibilities of Representatives of the Vulnerable Population.

3. Responsibility

It is the responsibility of the Chairperson/ Member Secretary/ IHEC member/s to nominate the name of one or more Representatives of the Vulnerable Population. The Chairperson is responsible for endorsing the choice of RVP nominated by IHEC Member Secretary/IHEC member/s. The administrative procedures regarding selection, confidentiality agreement and maintenance of roster of ICs will be carried out by IHEC secretariat.

4. Detailed instructions

4.1 Recommendation of names of Representatives of the Vulnerable Population and making a roster of Representatives of the Vulnerable Population for the IHEC

- Chairperson/ Member Secretary/ IHEC members will nominate the names of Representatives of the Vulnerable Population from the concerned vulnerable population included in the proposed study
- Member Secretary in consultation with Chairperson will select Representatives of the Vulnerable Population for the IHEC.
- Member Secretary will issue an appointment letter to the Representatives of the Vulnerable Population after confirming their willingness through telephonic/ electronic communication.
- After receiving written approval from Representatives of the Vulnerable Population, the details of each Representatives of the Vulnerable Population (Name, designation, affiliation, contact details and updated curriculum vitae) will be maintained in the IHEC records.

4.2 Consulting an RVP during IHEC review process

- An IHEC member/ Member Secretary/ Chairperson may suggest that the opinion may be sought from one or more Representatives of the Vulnerable Population if the study involves vulnerable population and during the review process of the given research study and IHEC feels the requirement of the opinion of Representatives of the Vulnerable Population.

- The Member Secretary in consultation with Chairperson will decide identify and select the Representatives of the Vulnerable Population based on the representation, independence and availability.
- Member Secretary on behalf of the IHEC will invite Representatives of the Vulnerable Population in writing to assist in the review of the research study and provide his/ her contribution during the review process at the meeting.

4.3 Communication with RVPs

- The Secretariat may request a copy of the updated curriculum vitae of the Representatives of the Vulnerable Population for IHEC records and future reference.
- The Member Secretary will request RVP to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the Confidentiality Agreement (*ANX 01-A/KIMS/SOP-05/V2*) and Conflict of Interest Agreement (*ANX-01-B/KIMS/SOP-05/V2*) for careful reading, understanding and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the Representatives of the Vulnerable Population if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert/ IHEC members.

4.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The Representatives of the Vulnerable Population will sign and date the Confidentiality and Conflict of Interest Agreement.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to Representatives of the Vulnerable Population.

4.5 Participation of Representatives of the Vulnerable Population in Review of research study proposal

- The Representatives of the Vulnerable Population will be invited to attend the proceedings of the concerned study and participate in the discussion process.
- The Representatives of the Vulnerable Population can propose their views during the discussion
- No voting right will be there for the Representatives of the Vulnerable Population.

4.6 Tenure of Services of Representatives of the Vulnerable Population

- The tenure of the appointment will be for 5 years or as required.
- The appointment for a particular study will expire immediately after the discussion or the final decision on the study is taken.

4.7 Responsibilities of Representatives of the Vulnerable Population

- Represent the group which he/she represents and participate in the discussion process

5. Glossary

Vulnerable populations (as per ICMR October 2017)

Individuals may be considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and therefore susceptible to being exploited;
- Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;
- Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

Following are some examples of vulnerable populations or groups:

- economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);
- unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent; children (up to 18 years);
- women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare); tribals and marginalized communities;
- refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
- afflicted with mental illness and cognitively impaired individuals, differently-abled, mentally and physically disabled;
- terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or
- have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

6. Annexures

- Annexure 1 *ANX-01A/KIMS/SOP-05/V2* - Confidentiality Agreement for a RVP
- ANX-01B/KIMSSOP-05/V2* - *Conflict* of Interest Agreement for a RVP

Annexure 01-A: ANX 01-A/KIMS/SOP-05/V2

Confidentiality Agreement Form for Representative Vulnerable population

I, _____
_____ (Name and Designation) as a non-member of Institutional Ethics Committee (IHEC) understand that the copy / copies given to me by the IHEC is/are confidential. I shall use the information only for the indicated purpose as described by the IHEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IHEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Signature of the Representatives of the Vulnerable Population	Date
Signature of the IHEC Chairman	Date

Annexure 01-B: ANX-01-B/KIMS/SOP-05A/V2
Conflict of Interest Agreement Form for Representative Vulnerable population

- I understand that it is the policy of the IHEC that no reviewer may participate in the review, comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by the IHEC.
- I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the IHEC to me.
- In the event that I develop any conflict of interest in relation to the particular proposal during the review process, I will declare it to IHEC and refrain from reviewing it.

I, _____ (name) have read and accept the
aforementioned terms and conditions as explained in this Agreement.

Signature of Representatives of the Vulnerable Population

Date

IHEC Chairperson's Signature

Date

7. Flow Chart

