Title: Protocols involving vulnerable populations: Review and Management
SOP Code: SOP19/v4
Effective Date: 01/07/2023
Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date 1/6/2023

Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with Date 2/6/23

Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date 6/6/23

Notified by:

Registrar Yenepoya (deemed to be University)	Signature with Date 7/6/23

Details of superseded SOP19

Name of the subcommittee convenor	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOPv4

Name of the SOP subcommittee convenor	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	1. Glossary section added in the SOP 2. Categorization of vulnerable population harmonized with SOP07 3. Checklist for involving marginalized populations added

Table of Contents:

1. **Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe the submission requirements, the type of review and monitoring mechanisms for research protocols involving vulnerable populations.

2. **Scope**

This SOP covers the procedures applied to all research dealing with vulnerable participants submitted to the YEC-1.

3. **Definitions:**

3.1. Vulnerable subjects:

3.1.1. Vulnerable subjects are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens, social justice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so[1].

3.1.2. In addition - for the purpose of this SOP - vulnerable populations are defined as individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation; of socio-economic disadvantage such that their exploitation potential is greater than that of other people; of a retaliatory response from senior members of a hierarchy in case of refusal to participate. in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent[2].

3.1.3. For the purpose of this SOP, following are examples of vulnerable population including but not limited to:

3.1.3.1. Economically and socially disadvantaged or marginalized sections of society (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – LGBTIQA+, etc.)

3.1.3.2. Legally defined minors (up to 18 years);

3.1.3.3. Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare, or those who are victims of gender-based violence);

3.1.3.4. Tribals and other marginalized communities;

3.1.3.5. Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations, people kept in detention, people experiencing communicable diseases of epidemic proportions;

3.1.3.6. People afflicted with mental illness, or cognitively impaired

[1] ICMR National Ethical Guidelines for Biomedical Research Involving Human Participants, 2017

[2] Modified and adapted from http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 19 August 2019 at 1745 hours.

individuals, differently abled – mentally and physically challenged;

3.1.3.7. Terminally ill or are in search of new interventions having exhausted all available therapies;

3.1.3.8. People with stigmatizing or rare diseases; or

3.1.3.9. Persons with diminished autonomy due to dependency or being within a hierarchical system (students - especially medical, pharmacy, dental and nursing students - employees especially subordinate hospital and laboratory personnel, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners)

4. **Mandate:** Gazette notification (GoI) G.S.R. 611 (E) dated 31st July 2015 has mandated audio-visual recording of informed consent process in case of vulnerable participants in clinical trials of new chemical entity/new molecular entity, and only audio IC process in the case of clinical trials involving people living with HIV and patients of leprosy[3].

5. **Responsibility:**

5.1. YEC-1 Chairperson will:

5.1.1. Ensure that all protocols involving vulnerable populations are reviewed and monitored appropriately

5.1.2. Ensure that all members present on the day of the meeting shall actively discuss the vulnerable research protocols.

5.2. YEC-1 Member-Secretary will:

5.2.1. Determine/identify protocols involving vulnerable population

5.2.2. Categorize protocols involving vulnerable population for "full review' if the risk is more than minimal

5.2.3. Categorize protocols involving vulnerable populations as expedited review only if the risk is 'minimal' or 'less than minimal'

5.2.4. Oversee and confirm that each protocol involving vulnerable populations has the necessary checklist attached, duly filled and signed by the PI.

5.2.5. Ensure that the monitoring mechanism for protocols involving vulnerable population is planned at the time of approval and in place during the conduct of the research

5.3. YEC-1 Member(s) will:

5.3.1. Review the checklist for risk:benefit assessment

5.3.2. Ensure adequate protection of vulnerable participants are strategized by the PI in the protocol

5.3.3. Deliberate on the issues of vulnerable participants, the risk:benefit assessment and the protection provided - during the YEC-1 meeting

5.4. YEC-1 Secretarial staff will:

5.4.1. Check whether every protocol involving vulnerable population

[3] http://www.ferci.org/wp-content/uploads/2014/07/Gazette-Notification-31-July-2015-AV-consent.pdf accessed on 12 July 2016 at 1722 hours.

includes the checklist for risk:benefit assessment and safeguards for the protection of vulnerable participants - duly filled and signed by the principal investigator

5.4.2. Ensure that the checklist for risk:benefit assessment and safeguards for the protection of vulnerable participants is sent to the reviewers during the review of protocols

5.4.3. Maintain a calendar for site monitoring (or audit) for protocols involving vulnerable populations, and remind the Member-Secretary of dates for due monitoring.

6. **Detailed instruction:**

6.1. Completion of protocol submission:

6.1.1. The Member-Secretary should identify the protocols involving vulnerable populations (as listed in this SOP).

6.1.2. The Secretarial staff must provide the appropriate checklists to the principal investigators, depending on the type of vulnerable populations involved in the research.

6.1.3. The Member-Secretary and/Secretarial staff must make sure that all checklists pertaining to the specific vulnerable population involved in the research are duly filled and signed by the principal investigator.

6.2. Categorization of the protocols: The member-Secretary should categorize the protocols as follows:

6.2.1. Protocols involving vulnerable populations, should be categorized as full review as per SOP7A/v4.

6.2.2. Protocols involving vulnerable populations, may be categorized as expedited review only if the risk is 'minimal' or 'less than minimal' and reviewed as per SOP7B/v4.

6.3. Selection of reviewers and review support:

6.3.1. The Member-Secretary should appoint two or more members of the YEC-1.

6.3.2. The Member-Secretary must provide appropriate reference material and /or help the reviewer locate the material relevant to review protocols involving vulnerable populations when specifically requested by a reviewer.

6.3.3. A representative from the vulnerable population may be consulted and invited to take part in the discussion during the full review meeting as per SOP05/v4

6.4. Review of the protocols:

6.4.1. YEC-1 members reviewing such protocols should be well versed with the potential harm or risk of such persons participating in the study.

6.4.2. Additionally, the reviewers should assess the following in the protocol and address all points in the checklists for different vulnerable populations (Annexures of SOP19/v4):

6.5. Discussion in the full review meetings:

6.5.1. While discussing full review protocols involving vulnerable populations, YEC-1 members should deliberate on the following

issues, but not limited to these :

6.5.1.1. Is there adequate justification for involvement of vulnerable populations in the research?
6.5.1.2. Can the research be performed in any other non-vulnerable participants?
6.5.1.3. Are there additional safeguards for the protection of the vulnerable participants from harm?
6.5.1.4. Are there direct benefits to the population under study? Do the benefits justify the risks?
6.5.1.5. Are the participants selected equitably?
6.5.1.6. Have measures to protect the autonomy of the vulnerable population been described?
6.5.1.7. Has the informed consent been appropriately described?
6.5.1.8. Have issues about audio-visual recording of informed consent been adequately addressed?

6.5.2. The YEC-1 members may consider a representative from the vulnerable population to attend the meeting, deliberate on the issues, but not take part in the decision making and voting. This will be done as per SOP05/v4.
6.5.3. The minutes will be prepared in detail as per SOP08/v4

6.6. Decision making:

6.6.1. Decision making for protocols will be done as per SOP7A/v4 for full review protocols and SOP7B/v4 for expedited review protocols
6.6.2. Post-approval plan should be incorporated in the final approval and should include the details and frequency of the following, whenever deemed essential:
6.6.2.1. Continuing review plan
6.6.2.2. Site monitoring plan
6.6.2.3. Audit plan of the protocol documents
6.6.3. YEC-1 approval should state that if in future the vulnerability status of the participants changes, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant will be re-consented, wherever deemed necessary.

6.7. Post-approval:

6.7.1. The continuing review, audit and site monitoring plans should be conducted as per the decision at the time of approval of the protocols.
6.7.2. Continuing review should be conducted as per SOP
6.7.3. Audit and Site monitoring should be conducted as per SOP.

7. **References:**

7.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017
7.2. Indian GCP Guidelines, 2001
7.3. New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Act, 1940

8. **Annexures**
   - 8.1. Ann01/SOP19/v4: Checklist for research involving children <18 years
   - 8.2. Ann02/SOP19/v4: Checklist for research involving pregnant women & fetuses
   - 8.3. Ann03/SOP19/v4: Checklist for studies involving neonates
   - 8.4. Ann04/SOP19/v4: Checklist for research involving cognitively impaired adults
   - 8.5. Ann05/SOP19/v4 - Checklist for research involving students, employees or residents
   - 8.6. Ann06/SOP19/v4 - Checklist for involving marginalized populations
   - 8.7. Ann07/SOP19/v4 -Checklist for involving populations for genetic research

Ann01/SOP19/v4

Checklist: Research Involving Children <18 years

Note to PI: *Children (minors) have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees in reviewing this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.*

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: **Clinical trial/ academic clinical trial/ observational study**	
6	Nature of intervention: Specify **(Drug/device/educational/others)**	
	Checklist item	**PI Response** **Please include these descriptions in relevant sections of the protocol**
1	**Does the research pose greater than minimal risk to children?: Yes/No**	

	a. If yes: Are there convincing scientific and ethical justifications to carry out the research as designed?	Yes/No Included in protocol: Yes/No Comment:
	b. If yes: Are adequate safeguards in place to minimize these risks?	Yes/No Included in protocol: Yes/No Comment:
	c. Is there an alternate study design that can achieve the same objectives without involving such vulnerable participants?	Yes/No Included in protocol: Yes/No Comment:
2	**Does the study involve healthy children? Yes/No**	
	a. If yes, is the inclusion of healthy children justified?	Yes/No Included in protocol: Yes/No Comment:
	b. If yes, have scientifically appropriate preclinical studies, including studies on animals, and clinical studies, including studies on children and/or adults, been conducted and do these provide data for assessing potential risks to children/minors?	Yes/No/Not applicable Included in protocol: Yes/No Comment:
	c. If your response is No to b, in the absence of animal studies or studies on adults, is it justified to conduct this study?	Yes/No/Not applicable Included in protocol: Yes/No Comment:
	d. Will older children be enrolled before younger ones?	Yes/No Comment
3.	**Is consent of both parents necessary?**	
	a. If yes, are conditions under which one of the parents may be considered: "not reasonably available"?	Yes/No Included in protocol: Yes/No Comment:

	b. Are the conditions acceptable?	Yes/No Included in protocol: Yes/No Comment:
4	**Is an attempt made to ensure voluntary informed consent of the parent and assent from the child?**	
	a. Will efforts be made to ensure that parents' consent to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?	Yes/No Included in protocol: Yes/No Comment:
	b. Are provisions made to obtain the written assent of children over 12 years, and oral assent of children between 7 and 12 years, and where appropriate, honor their dissent?	Yes/No Included in protocol: Yes/No Comment:
5	**Are specific safeguards available to protect the children included in research?**	
	a. Are provisions made to protect participants' privacy and the confidentiality of information gathered in the course of the research?	Yes/No Included in protocol: Yes/No Comment:
	b. Are there special problems that call for the presence of an external monitor during consent procedures?	Yes/No Included in protocol: Yes/No Comment:
	c. Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	Yes/No Included in protocol: Yes/No Comment:
6	**Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis C)**	
	a. Are there adequate mechanisms in place to deal with other members of the family, should there be a risk	Yes/No Included in protocol: Yes/No Comment:

	to such bystanders?	
	b. Are parents required to be present during the conduct of the research?	Yes/No Included in protocol: Yes/No Comment:
7	**Risk and benefit assessment**	
	a. What are the anticipated risks to the children from research participation?	
	b. Risk assessment	Minimal risk More than minimal risk
	c. What are the anticipated risks to the children from research participation?	
	d. Benefits assessment	Direct benefit Indirect benefit
	e. Risk: benefit ratio:	Favorable Not favorable
8	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
9.	**For YEC-1 use only**	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

* *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life*

** *Consent of both parents (and assent) may be needed as applicable*

Ann02/SOP19/v4

Checklist: Requirements for Research Involving Pregnant Women & Fetuses

Note to PI: *Pregnant women and their unborn or just born fetuses are considered as vulnerable participants in research and therefore subject to increased harm. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations.*

Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees in reviewing this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.

A	**Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)**	
1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: **Clinical trial/ academic clinical trial/ observational study**	
6	Nature of intervention: Specify **(Drug/device/educational/others)**	
A.	**If the research involves pregnant women and/or their fetuses, please fill this form and submit along with the research protocol:** **Please include these descriptions in relevant sections of the protocol**	
1	For clinical trials on pregnant women, have scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted and do these provide data for assessing potential risks to pregnant women and fetuses?	Yes/ No/ Not applicable Comment:
2	Is the risk to the pregnant woman or the fetus "not greater than minimal", or, any risk to the woman or the fetus, which is greater than minimal, is caused solely by the research intervention/procedure and this holds out the prospect of direct benefit for the woman or the fetus?	Yes/ No/ Not applicable Comment:
3	Is any risk that is likely to occur, the least possible for achieving the objectives of this study?	Yes/ No/ Not applicable Comment:

4	Is the woman's consent or the consent of her legally authorized representative (if the participant herself is unable to give consent) obtained in accordance with the informed consent provisions (as described in the ICMR National Ethical Guidelines for Biomedical Research involving Human Participants - 2017)?	Yes/ No/ Not applicable Comment:
5	Is the woman or her legally authorized representative (as appropriate), fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child?	Yes/ No/ Not applicable Comment:
6	Do individuals engaged in the research have a part in determining the viability of the fetus?	Yes/ No/ Not applicable Comment:
7	Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate the pregnancy?	Yes/ No/ Not applicable Comment:
8	Will any inducements, monetary or otherwise, be offered to terminate the pregnancy?	Yes/ No/ Not applicable Comment:
	Note: If the response to items 1-7 is NO, the research should not be approved. Point No 8 will be assessed on a case-to-case basis.	
B	**Fill in this section if the study involves fetuses of uncertain viability:** If the response for any of the items no. 1-4 is **NO**, then YEC-1 should not approve the research:	
1	Is the purpose of the research the development of important biomedical knowledge which cannot be obtained by other means?	Yes/No/Not applicable
2	Is any risk the fetus is exposed to, the least possible for achieving the objectives of the research?	Yes/No/Not applicable
3	Does the research hold out the prospect of enhancing the probability of survival of the enrolled fetus to the point of viability?	Yes/No/Not applicable
4	Will the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability,	Yes/No/Not applicable

	incompetence or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative be obtained?	
C	**Fill in this section if the study involves non viable fetuses:** If the response for any of the items no. 1-4 is **NO**, then YEC-1 should not approve the research:	
	Will vital functions of the neonate be artificially maintained in the course of the research, despite clinically being pronounced "non-viable"?	Yes/No/Not applicable
	Will the research-related risk to the neonate be less than minimal?	Yes/No/Not applicable
	Is the purpose of the research the development of important biomedical knowledge that cannot be obtained by other means?	Yes/No/Not applicable
	Will the legally effective informed consent of both parents of the neonate be obtained? Please note: If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. (The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.)	Yes/No/Not applicable
	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	This type of research can be conducted only after YEC-1 determines that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women and/or fetuses**.** The research will be conducted in accordance with applicable regulatory and ethical guidelines.**For YEC-1 use only**	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

Ann03/SOP19/v4

Checklist for studies involving neonates

Please fill this section of the checklist if the research involves neonates:

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: Clinical trial/ academic clinical trial/ observational study	
6	Nature of intervention: Specify (Drug/device/educational/others)	
	Checklist item If the research involves neonates, please fill this form and submit along with the research protocol: Please include these descriptions in relevant sections of the protocol	
1	Can this research be performed in any other non-vulnerable participants?	Yes/ No/ Not applicable Comment:
2	Is there adequate justification for involvement of neonates in the research?	Yes/ No/ Not applicable Comment:
3	Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?	Yes/ No/ Not applicable Comment:
4	Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?	Yes/ No/ Not applicable Comment:
5	Will any inducements, monetary or otherwise, be offered to terminate the pregnancy before enrolling the	Yes/ No/ Not applicable Comment:

	neonate?	
6	Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?	Yes/ No/ Not applicable Comment:
7	Do individuals engaged in the research have a part in determining the viability of a fetus?	Yes/ No/ Not applicable Comment:
8	**Signature of the principal investigator with date** *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For YEC-1 use only **Note:** If the response to item no. 1 is **YES** and item no. 2-7 is **NO**, the research should not be approved	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

Ann04/SOP19/v4

Checklist: Research Involving Cognitively Impaired Adults

Note to PI: *Cognitively impaired adults have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.*

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	

4	Department	
5	Type of study: **Clinical trial/ academic clinical trial/ observational study**	
6	Nature of intervention: Specify **(Drug/device/educational/others)**	
	Research Involving Cognitively Impaired Adults *All items should be answered and the substantiation for the same should be evident in the protocol (methodology) as well as in the participant information sheet and informed consent form)*	
1	Is recruitment of cognitively impaired participants justified considering the rationale and objectives of the study?	Yes/No Comment:
2	Is there an anticipated direct benefit to the participant?	Yes/No Describe the benefit:
	a. If there is anticipated benefit, is the risk justified by the anticipated benefit?	Yes/No Comment:
	b. If there is anticipated benefit, is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches?	Yes/No
	c. If there is no anticipated benefit, are the foreseeable risks to the participants low?	Yes/No
	d. If there is no anticipated benefit, is the negative impact on the participant‘s well-being minimized and low?	
	e. If there is no anticipated benefit, will the participants be closely monitored?	
4	Will the participants be withdrawn if they appear to be unduly distressed?	Yes/No Comment:
5	Is the proposed plan for the assessment of the capacity to consent adequate?	Yes/No Comment:
6	Will consent be taken from participants capable of being consulted?	Yes/No Comment:

7	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?	Yes/No Comment:
8	**Signature of the principal investigator with date** *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For YEC-1 use only	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

Ann05/SOP19/v4

Checklist-Research Involving Students, Employees or Residents

Note to PI: *Research participants drawn from institutions with hierarchical cultures, have reduced capacity to understand and give informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.*

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: Clinical trial/ academic clinical trial/ observational study	
6	Nature of intervention: Specify (Drug/device/educational/others)	
	Research Involving dependent participants (employees, students, residents) *All items should be answered and the substantiation for the same should be evident in the protocol (methodology) as well as in the participant information sheet and informed consent form)*	
1	Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?	Yes/No Comment:
2	Have the risks to participants been minimized and are such strategies described in the protocol?	Yes/No Comment:
3	Have participants been assured that participation is voluntary (no signs of coercion)?	Yes/No Comment:

4	Have participants been assured that privacy and confidentiality will be protected?	Yes/No Comment:
5	Is the research team member taking consent directly related to the welfare of the participants?	Yes/No Comment:
	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For YEC-1 use only	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

Annexure 06/SOP19 v4

Checklist: Research Involving Marginalized Sections of Society

Info to PI: *Persons from marginalized sections of society (such as tribal populations, homeless persons, LGBTIQA+ community) have reduced ability to exercise their rights and give voluntary informed consent. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.*

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: Clinical trial/social science study/observational study	

6	Is recruitment of cognitively impaired participants justified considering the rationale and objectives of the study?	Yes/No Comment:
7	Is the risk justified by the anticipated benefit?	Yes/No Comment:
8	Is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches?	Yes/No Comment:
9	Will the participants be withdrawn if they appear to be unduly distressed?	Yes/No Comment:
10	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?	Yes/No Comment:
11	Is the negative impact on the participant's well-being minimized and low?	Yes/No Comment:
12	Will adequate privacy be provided to the participants so as to not increase the risk of social stigma and discrimination?	Yes/No Comment:
13	Will the results of the study be shared with the participants?	Yes/No Comment:
14	Will anonymity be maintained at the time of presentation/publication	Yes/No Comment:
15	Will audio-visual recording of informed consent process be done?	Yes/No Comment:
	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For YEC-1 use only	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

Ann07/SOP19/v4

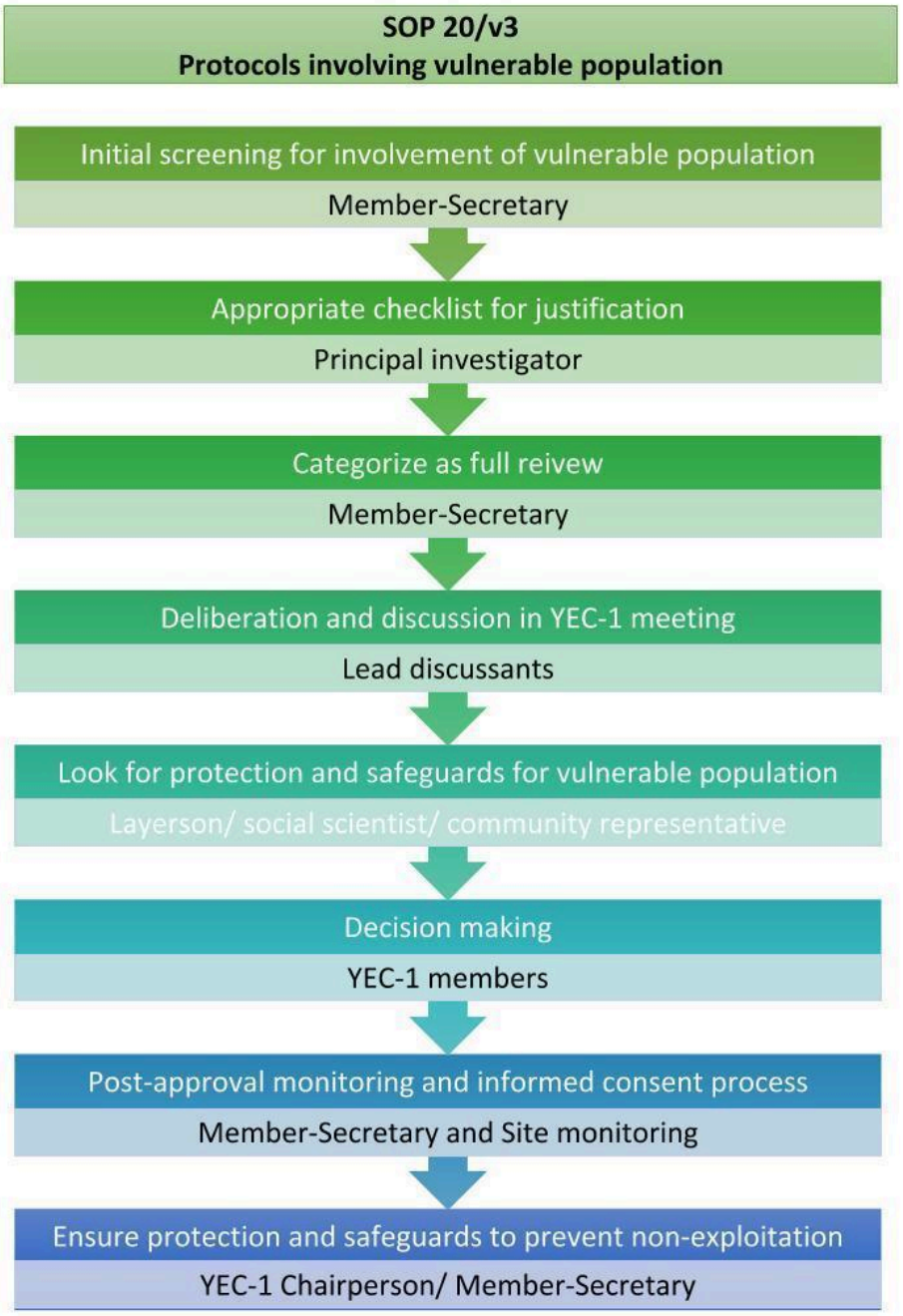
Checklist: Considerations for Genetic Research

Note to PI: *Genetic research is still poorly understood and there is much to be learned by the scientific community, for a fuller and more comprehensive understanding of the genetic functions of the human body. Potential participants may have difficulty in understanding the research details and thus give informed consent on less-than-optimal understanding. Such participants have decreased autonomy, and increased exploitative potential and are considered as vulnerable participants. Current regulations and guidelines require ethics committees to ensure that researchers provide ample safeguards in the research protocol for the protection of vulnerable populations. Filling out this checklist will help researchers in strengthening the research protocol, and ethics committees to review this study more systematically. Principal Investigators are requested to provide their responses in this checklist in an honest and forthright manner.*

	Checklist item for the PI to fill before submission (information provided here should also clearly and unambiguously reflect in the methodology, participant information sheet and informed consent form)	
1	YEC-1 Protocol No.	
2	Title:	
3	Name of the PI	
4	Department	
5	Type of study: Genomic study or gene therapy	
6	Will the samples be made anonymous to maintain confidentiality?	Yes/No Comment:
7	Will the results be disclosed to the participant or legally authorized representative?	Yes/No Comment:
	a. If yes, has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research results?	Yes/No Comment:
	b. If yes, will the results be used in management of the current condition of the patient?	Yes/No Comment:
8	Has the appropriateness of the various strategies for recruiting participants and their family members been considered?	Yes/No Comment:

9	Does the proposed study population comprise family members?	Yes/No Comment
10	Will family members be implicated in the studies without consent?	Yes/No Comment
11	Will the samples be destroyed in the future?	Yes/No Comment
12	Will the samples be used for future research?	Yes/No Comment
13	Will the human biological sample or the data associated with it, be shared with other researchers?	Yes/No Comment
14	Will genetic counseling be offered?	Yes/No Comment
	Signature of the principal investigator with date *(PI to confirm that all the relevant descriptions are included in the protocol)*	
	For YEC-1 use only	
	Comments of the Reviewer:	
	Signature of the reviewer with date	

9. **Flow Chart**



10. **Glossary:**

GCP: Good Clinical Practices
ICMR: Indian Council of Medical Research
NDCTR: New Drugs and Clinical Trials Rules, 2019
PI: Principal Investigator