In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR VULNERABLE POPULATIONS IN RESEARCH

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1. PURPOSE

This SOP describes the considerations that the P.I should make when including vulnerable populations in research to ensure that they receive adequate protections against undue influence or coercion.

2. SCOPE

This SOP is applicable to P.Is who are submitting proposals that enroll vulnerable populations in their research.

3. INTRODUCTION

3.1 Principal investigators who enrol vulnerable populations such as children, prisoners, human foetuses/neonates, pregnant women, and individuals with consent capacity impairment in their studies need to ensure that they take special consideration in protecting the welfare of their participants.

3.2 The SERU reviews proposed research to ensure that economic, social, physical, and environmental conditions that may put vulnerable subjects at increased risk are adequately addressed. Where necessary, SERU may require the P.I to incorporate additional safeguard measures to protect potentially vulnerable populations.

4. TERMS & DEFINITIONS

4.1 Vulnerable populations: - these are defined as individuals who require additional protections during research because they are vulnerable to undue influence or coercion, or they have limited comprehension or understanding of the study. They include prisoners, pregnant women, human foetuses and neonates, prisoners and children. Other populations that may be considered to be vulnerable by the SERU include: homeless youths, decisionally-impaired persons, internally displaced persons, economically or educationally disadvantaged persons, marginalized social groups or individuals with terminal illnesses

4.2 Undue Influence - an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance

4.3 Coercion - an overt threat of harm intentionally presented by one person to another in order to obtain compliance.

5. OBJECTIVES

To ensure that the Vulnerable Population is well guarded during research.

6. INPUTS/RESOURCES

6.1 Personnel

6.2 Stationery and office equipment

6.3 Budget

7. EXPECTED OUTPUTS

7.1 Recruited participants

8. KEY PERFORMANCE INDICATORS

8.1 No of participants recruited

9. RESPONSIBILITY AND AUTHORITY

9.1 SERU committee - requires that exceptional consideration is given to protecting the welfare of particularly vulnerable groups, such as children, pregnant women, neonates, foetuses, homeless youths, decisionally-impaired persons, internally displaced persons, economically or educationally disadvantaged persons, marginalized social groups or individuals with terminal illnesses or prisoners

9.2 Investigator – demonstrates in his proposal, the specific measures taken to ensure additional protections for the vulnerable populations to be included in the research

10. DETAILS OF PROCEDURE

10.1 The P.I demonstrates the following in the study proposal:

10.1.1 The objective of the proposed research is to obtain knowledge relevant to the health needs of the vulnerable population under study.

10.1.2 That the research question cannot be answered if the study is carried out among a less vulnerable group.

10.1.3 The study participants are explicitly told that they are taking part in research.

10.1.4 The requirements for obtaining and documenting consent are tailored to the needs of the individual from the chosen vulnerable group. .i.e. use of appropriate language, content of the consent/assent document and explanation of the procedures to be followed.

10.1.5 The risks from procedures that do not confer direct health-related benefits are justified by the benefit and are similar to those from routine medical or psychological tests.

10.1.6 The specific requirements for obtaining and documenting consent whenever any vulnerable groups are involved in research studies are clearly addressed

10.1.7 The choice of vulnerable population from which the study participants will be drawn is clearly justified

10.1.8 The inclusion of vulnerable populations in genetic studies is clearly justified

10.2 The P.I makes the following considerations when designing research that involves vulnerable populations:

10.2.1 Research involving pregnant women, foetuses: -

10.2.1.1 Research should involve the least possible risk. The P.I should demonstrate the specific measures taken to minimize the potential for risk or harm to the foetus, and additional considerations for obtaining informed consent

10.2.1.2 That women are not encouraged to discontinue nursing for the sake of participation in research except in the cases where breast-feeding is harmful to the infant, and that if breastfeeding discontinuation is necessary, there are alternative arrangements for adequate supplementary food.

10.2.1.3 That research related to pre-natal diagnostic techniques is limited to detection of foetal abnormalities or genetic disorders and not for sex determination.

10.2.2 Research involving Prisoners: - the P.I ensures that prisoners' limited ability to make truly voluntary and un-coerced decisions about whether or not to participate in research is protected.

10.2.3 Research involving children:

10.2.3.1 Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research. (In Kenya, the legal age for consent is 18 years).

10.2.3.2 The proposed clinical research falls within one of the four following categories:

10.2.3.3 Research not involving more than minimal risk

10.2.3.4 Research involving greater than minimal risk, but presenting the prospect of direct benefits to the individual subjects

10.2.3.5 Research involving greater than minimal risk, but yielding knowledge that can be generalized about subject's disorder or condition

10.2.3.6 Research not falling under the above categories but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children.

10.2.4 Parental/Legally acceptable representative Permission: - adequate provisions are made to solicit the permission of each child's parents or guardian/legally authorized representative.

10.2.5 Assent of the Child: -

10.2.5.1 Provisions are made in the protocol to obtain the child's assent for children aged >12 years but <17 years who are capable of assenting.

10.2.5.2 The P.I. respects the child's refusal to participate in the research and is cautious in allowing parents/ legally accepted representatives to overrule the child's decision

10.2.5.3 The P.I ensures that the assent form is tailored for the child, with respect to his or her level of understanding.

10.2.6 Research involving decisionally -impaired participants: - The P.I considers selection issues, privacy and confidentiality, coercion and undue influence, and risk-benefit analysis and ensures that additional protections are included to protect these participants.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	**Risk**	**Risk source**	**Mitigation**
Vulnerable population in Research	Exploitation of vulnerable groups	Recruitment of vulnerable populations under undue influence or coercion	Ensure special considerations to protect vulnerable populations

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Vulnerable population in Research	Research to come up with more measures to protect vulnerable groups	Regular training and research on vulnerable populations in research

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

12.2 External References

12.2.1 45 CFR 46 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb; https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartc; https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd.

12.2.2 SOP 14 Title: Research involving vulnerable subjects (general considerations) -

12.2.3 (https://ohsr.od.nih.gov/public/SOP_14A_v3_2-17-17.pdf)

12.2.4 SOP Title: Protection of vulnerable population in clinical research - http://mcc.kerala.gov.in/IRB/SOP15_VER1Protection_VulnerablePopulation.pdf

12.2.5 SOP 501 Vulnerable populations in research - https://irb.utah.edu/_pdf/IRB%20SOP%20501%20version%20L0315.pdf