In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR

PARTICIPANT REIMBURSEMENT AND COMPENSATION IN RESEARCH STUDIES

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1. PURPOSE

This SOP provides guidance to investigators on compensation/reimbursement of human participants taking part in their studies to ensure that participants are not under undue influence or coercion.

2. SCOPE

This SOP is applicable to investigators who wish to provide compensation or reimbursement to their research participants. This SOP does not cover payment to research participants for the risks, harms or discomforts related to participation in the studies.

3. INTRODUCTION

Reimbursement and compensation of study participants poses various ethical dilemmas such as when and how much is appropriate to compensate/reimburse the participant. There is need for ethical review committees to provide guidance on ethical acceptability of compensation for research participants taking into consideration various factors that may inform decisions on what is considered a fair amount and type of reimbursement/compensation to the participant.

4. TERMS & DEFINITIONS

4.1 Participant reimbursement - money given to the research participant that reflects out of pocket expenses associated with participating in a research study (e.g. transportation)

4.2 Participant compensation – refers to money or other items given to the participant in recognition of the time or effort they have provided in the study, or the approximate wages lost due to their participation in the research.

4.3 Undue Influence - an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. This is defined relative to the participant's or community's (for cluster studies) way of life, income level and subjective assessment of their lifestyle.

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

5. OBJECTIVES

To ensure that participants are reimbursed and compensated in research studies without causing undue influence or coercion.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Email
6.4 Phone

7. EXPECTED OUTPUTS

7.1 Agenda
7.2 Record of received application

8. KEY PERFORMANCE INDICATORS

8.1 No. of applications Received.

9. RESPONSIBILITY AND AUTHORITY

9.1.1 **Investigator** – ensures that the amount, frequency or nature of compensation and reimbursement is included in the study protocol, consent documents and any recruitment materials as appropriate and that the amounts, frequency and nature of compensation do not result in undue influence or coercion

9.2 SERU Committee:

9.2.1 Reviews compensation and reimbursement information contained in the study protocol, consent documents and any recruitment materials to ensure that are not coercive or present undue influence and do not over-emphasize the reimbursement/compensation amounts.

9.2.2 May also make recommendations to increase or decrease the amounts, frequency and nature of reimbursements to ensure that the principles of respect for autonomy, beneficence and justice are observed in the conduct of a study.

10. DETAILS OF PROCEDURE

10.1 SERU guidelines on participant reimbursement and compensation:

10.1.1 Study participants or their parents/guardians, literate witnesses can be reimbursed for research-related costs e.g. transportation expenses or compensated for their time or lost wages. These amounts should be approximate to the participant's daily wage or income, within a 5% margin. For transport costs, these should be commensurate with actual costs in the study area.

10.1.2 Reimbursements/compensations should not be so high relative to the participant/community's income and way of life as to unduly influence' or induce that could compromise the prospective participant (s) objective assessment of the risks or interfere with their voluntariness to participate in the study.

10.1.3 Payment for harm or discomfort must be ethically justified.

10.1.4 It should be clearly stated that if the study participant withdraws from the research, there will be appropriate pro-rated reimbursement/compensation, where applicable.

10.1.5 Entire reimbursement/compensation should not be contingent upon the participant completing the entire study, unless the study is of short duration or involves only a one-time contact with the study team.

10.1.6 Tokens of appreciation at the end of the study should not be of such a high value, relative to the participant's/community's income and way of life as to unduly influence participants to stay in the study when they would otherwise have withdrawn

10.1.7 SERU may recommend participants/communities to be reimbursed for research related costs, where the Committee deems this to be appropriate, but the investigator has not put in place such measures.

10.1.8 Reimbursement amounts, incentives should not be described on any advertisement materials as these may unduly influence potential participation without the opportunity to discuss risks, benefits and alternatives to study participation.

10.2 The Investigator provides a detailed description of the proposed reimbursements/compensations to research participants in the initial protocol submitted to SERU for review and approval as follows:

10.2.1 Amount of money reimbursed to the participant

10.2.2 Rationale behind the proposed reimbursement/compensation amounts

10.2.3 Timing and frequency of reimbursements and the amounts reimbursed at each time-point where this varies

10.2.4 Pro-rating schedule for reimbursements/compensation

10.2.5 Method of payment e.g. cash, Mpesa, etc

10.2.6 Reimbursements/compensation to participants who withdraw before completion of the study.

10.2.7 Arrangements put in place to ensure that reimbursement/compensation to research participants does not potentially violate the participants' privacy.

10.2.8 Any token of appreciation to be presented at the completion of the study must be clearly described in the study protocol but should not be mentioned in the consent document to avoid undue influence.

10.3 The P.I includes information concerning reimbursement/compensation in the informed consent document as follows:

10.3.1 Amount of money reimbursed to the participant

10.3.2 Timing and frequency of reimbursements/compensation and the amounts reimbursed at each time-point where this varies

10.3.3 Mode of payment e.g. cash. Mpesa, etc

10.3.4 Reimbursements/compensation to participants who withdraw before completion of the study

(NB: Reimbursements/compensation are not a study benefit and should therefore not be included in the benefits section of the informed consent document).

10.4 The P.I submits any alterations in reimbursements/compensation to research participants as an amendment to the protocol and informed consent documents, for SERU approval, prior to implementation.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Participant reimbursement and compensation in research studies	Coercion	Biased compensation to research participants.	Ensure compensation policy is clear and to what extend it covers.

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Participant reimbursement and compensation in research studies	Clear consenting process	Ensure that during consenting process there is detailed, comprehensive information

12. REFERENCE DOCUMENTS

12.1 Internal References

None

12.2 External References

12.2.1 45 CFR 46.116 General requirements for informed consent. (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)

12.2.2 SOP Title: Payments to research participants – Syracuse University (http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-037-Payments-to-Research-Participants.pdf)

12.2.3 Guidelines for Compensation and Reimbursement of Research-Participants – University of Toronto (http://www.research.utoronto.ca/wp-

content/uploads/2010/01/Guidelines-for-Compensation-and-Reimbursement-of-Research-Participants-Approved-Feb-16-11.pdf)

13. ANNEXES

13.1 Flow chart Procedures.

ANNEX 1: PROCESS FLOW CHART

Players	**Activity**	**Flow Chart**
Principal Investigator	Submitting an application to SERU	
Centre Compliance Officer	Receives, pre-reviews and records all applications submitted to SERU