Re-imbursement of study participants		
Document type	Identification code	Effective Date
Policy Document	POL-CTS-004	25 September 2025

1. A purpose statement

The conduct of clinical trials in accordance with good clinical practice (GCP) requires careful consideration of patient payments to ensure that neither problem of coercion nor undue influence on the trial subjects is present. These considerations extend to all medical research studies involving human participants (clinical trials and observational studies). Payments to a participant should be prorated and not wholly contingent on the completion of the trial by the participant, and both the method and the sum of payment should be provided in the patient's information.

It is the MRC Unit The Gambia at the London School of Hygiene & Tropical Medicine (MRCG at LSHTM) practice that payments to participants are limited to reimbursements as defined below (section 5). These are to be provided by the study team and are exclusively made to reimburse patients for expenses accrued by study participation. In the past, variability within the Unit regarding the amount of reimbursement for comparable expenses was observed.

Considering that The Gambia is a low-income country, and the participants are mostly economically challenged, a unique policy for the Unit became necessary to define an appropriate amount of money to be paid to study participants as reimbursement of loss of wage based on viable time spent at clinical sites during clinical visits instead of engaging in economic activities and transport.

2. Applicability and scope

This policy applies to medical research projects involving human participants, in which participants are invited to a study site and incur incidental expenses or loss of earnings (or lost wages) due to their study participation.

This policy also applies to other research including social science studies in which individuals are selected for participation within their communities or at a clinical/hospital setting for data collection activities, and where data collection is likely to take time away from their routine daily tasks and/or add time to their healthcare-seeking within the facility. This would include survey questionnaires, qualitative interviews, group discussions, and participatory action research.

Reimbursement does not apply to hospital-based studies in which persons seeking care are approached within their in-hospital patient flow for questionnaire/sample collection or administration of study intervention without altering this hospital flow or requiring study-related invasive procedures (excluding routine sample collection).

3. Definitions

A healthy volunteer as a participant is an individual with no known significant health problems who participates in research to test a new drug, device, or intervention.

It is also recognised that participants can be selected for observational or intervention studies due to a particular health condition or experience they have had, e.g., pregnant women, individuals with hypertension, etc., for a better understanding of their perceptions and lived experiences of the condition and/or available treatments.

An invasive procedure is one where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation

via a natural orifice. It begins when entry to the body is gained and ends when the instrument is removed and/or the skin is closed. Invasive procedures are performed by trained healthcare professionals using instruments, including, but not limited to, endoscopes, catheters, scalpels, scissors, devices and tubes.

In this policy, the term 'invasive procedure' excludes routine sample collections, such as phlebotomy, nasal, pharyngeal, or rectal swabs.

4. Responsibilities

It is the responsibility of the Principal Investigator (PI) of a clinical trial or study to reimburse participants for their expenses and loss of earnings/lost wages as applicable.

The PI should state the manner and amount of reimbursement in the informed consent documents (ICD), which will need to be reviewed and granted a favourable opinion by The Gambia Government / MRCG Joint Ethics Committee.

The PI is also responsible for:

- Including the anticipated costs for reimbursement in the research budget
- Stating the manner and amount of reimbursement in the ICD

The PI delegates a staff in the study team to be responsible for:

- Reimbursing participants at the rates outlined in this policy and in attachment 01
- Documenting the reimbursement of participants.

5. Policy Statement (s)

5.1 For the studies within the scope of this policy, 3 categories of study participants are distinguished:

- Category 1: Healthy volunteers and other participants of observational and non-clinical intervention studies, phase 2, phase 3 and phase 4 trials, trials with nutritional supplements or trials with already licensed or repurposed drugs.
- Category 2: Healthy volunteers and participants of studies with invasive procedures (**excluding** minimally invasive procedures such as phlebotomy for sample collection, capillary blood collection, and nasopharyngeal or rectal swabs).
- Category 3: Healthy volunteers and other participants of observational and non-clinical intervention studies who are invited for **short (under 2.5 hours)** individual interviews or group-based discussions that take place in the home or nearby in the community. Research activities over 2.5 hours will fall into Category 1.

5.2 Trial or study participants of all categories should be reimbursed for their:

- anticipated loss of earnings/lost wages while participating in a study, dependent on the time taken by the research activities.
- incidental costs such as transport to attend study visits.
- refreshments can be provided during the research activities

5.3 Reimbursement is not applicable for home visits for the purpose of follow-up clinical visits.

5.4 Reimbursement for lost wages is not applicable for unscheduled study visits initiated by the participants (usually for adverse events). Only transport costs should be covered at a standardised rate for these visits.

5.5 When the participants are transported by MRCG at LSHTM vehicle from their homes to the study

centre and back to their homes at the end of the visit, only anticipated loss of wages should be reimbursed.

5.6 For logistic reasons, the following flat rates, rather than individual costing, will be provided to the participants at the end of each scheduled study visit (Attachment 1 provides the standardised transport costs).

	Category 1 participants	**Category 2 participants**	**Category 3 participants**
Participants transported by MRCG vehicles	D300	D800	D200
Participants NOT transported by MRCG vehicles	D300 + transport cost	D800 + transport cost	D200 + transport cost
Participants coming for Unscheduled visits	Transport costs only	Transport costs only	N/A

5.7 Reimbursements are made for each study visit after it has occurred. They can be made in cash, cheque, mobile money transfer, gift etc., whichever is convenient for the participant and the study, and they must be documented appropriately.

5.8 Reimbursement is done directly to the study participants, to their legal guardian or their caregiver as applicable and documented in a reimbursement log.

5.9 The reimbursement must be made at the end of the visit..

5.10 A thank-you gift may be given at the end of study participation.

5.11 The Head of Governance and the MRCG ethics committee are responsible for ensuring that PIs and their team comply with this policy.

Additional Information

Appendix 01 – Document version history

Version number	**Change history**	**Author**	**Date**
6.0	*Added consideration for social sciences interviews and group based discussions*	*Joanna Busza/ Armel Zemsi*	*23 July 2025*

5.0	*Defining healthy volunteers and invasive procedures in the policy* *Updating the scope of the policy* *Defining various categories of participants and their loss of wages* *Revision of timing of reimbursement and to include modality of payment*	*Armel Zemsi*	*30 April 2024*
4.0	*Revision of tariff to reflect current cost of transportation*	*V. Thomas*	*17 March 2020*
3.0	*Editorial; Change of MRC Unit to MRC Unit The Gambia at LSHTM*	*V. Thomas*	*30 July 2018*

2.0	*This policy has been revised earlier before its due date because of the recommended changes received from the local Ethics Committee to the wording of the text and the amount for reimbursement for loss of earnings/lost wages.*	*V Thomas*	*25 July 2016*
1.0	*New document*	*J. Lexow*	*27 April 2016*

Review information

Version Number:		**5.0**	
1st Review Date:		**2 Years after effective date stated above**	
Reviewed and no changes required? *(Please check the textbox to indicate if no changes are required after reviewing document. Initial and date in the appropriate review section)*		**Initials:**	**Date:**
		2nd Review Date: *(2 Years after the 1st review)*	
		Initials:	**Date:**
		Valid until: *(2 years after 2nd review)*	

Document location

Document	Specific location
Master	Quality department
Electronic	Intranet; Q-Pulse
Confidential, unauthorised copying prohibited	

Controlling the distribution of a document prevents inadvertent use of superseded documents.