1. Introduction

This Standard Operating Procedure (SOP) details the steps required when Healthy Volunteers are enrolled as participants in Clinical Trials of Investigational Medicinal Products (CTIMPS) or Advanced Therapy Investigational Medicinal Products (ATIMPS) where the University Hospitals of Leicester NHS Trust (UHL) are the host organisation or Research site).

Healthy Volunteers can be members of the general public, students, or members of staff from the Trust.

2. Scope

This SOP should be followed by all staff, and any external individuals who are associated with any research activity where UHL is acting as the Host organisation or as a Research Site.

3. Procedure for Phase I Trials

There are scientific, safety, and ethical reasons why healthy volunteers should not participate too frequently in studies of potential new medicines:

- The participant might be exposed to interacting substances in consecutive studies
- The results of a study might be influenced by the participant's participation in a previous study
- An excessive volume of blood might be removed from the participant
- It is unethical for participants to be exposed too frequently to pharmaceutical products from which they derive no benefit
- The length of time between administration of IMPs can vary i.e., radioactive drugs may need a longer gap and this should be taken into account

The UK Clinical Trials Regulations state that applications to the HRA/ REC should include information about how to check volunteers aren't taking part or have recently taken part in other trials. In addition to asking the volunteer to confirm their medical history it is expected that the Sponsor will facilitate access to the Over Volunteering Prevention System (TOPS) or a similar database.

It is expected that the sponsor will have appropriate mechanisms within the Protocol to confirm medical history and participant identity. This should be confirmed as part of the feasibility and set up process.

4. Procedure for post-phase I stage trials, including post-marketing

Similar issues to those stated for phase 1 trials are true for phase II/III/IV trials, although these by nature are not the first time human participants have received the intervention. Care should still be taken to ensure appropriate time has elapsed between trials. The protocol will stipulate inclusion / exclusion criteria for the trial. Similar safeguards to confirm medical history and participant identity should be discussed with the sponsor during feasibility and set up of the study.

5. Procedure following invitation to participate

Healthy volunteers may not have had any interaction with UHL prior to participation in a research study. It is expected that screening, eligibility and recruitment will be detailed in the approved protocol and appropriate Case Report Forms provided by the sponsor.

Once consent has been completed and the Healthy Volunteer's enrolment in the activity has been confirmed, a Volunteer Record should be generated. This may be paper or electronic or a combination of both. There is no requirement to create a medical record or a hospital number. Every attempt to confirm relevant medical history should be made. It is not always necessary to contact the volunteer's General Practitioner (GP) and this may not be funded within the study, but as a minimum a declaration from the volunteer confirming that the information they have given is correct should be obtained. If the Sponsor does not provide an appropriate declaration, it is recommended that one is produced internally for the study.

In addition, it is a statutory requirement that volunteers are provided with a notification card. This card provides key contact information and basic study details. The volunteers are encouraged to carry this at all times in case of medical emergencies.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1	PI / Study Team	PI / Study Team	Ensure confirmation of medical history is received from the volunteer & confirm with Sponsor at Feasibility / Study Set up arrangements for confirmation of Medical history.
2	PI / Study Team	PI / Study Team	Generate Volunteer Notes.
3	PI / Study Team	PI / Study Team	Registration of participants on TOPS where applicable.

7. Supporting Documents and Key References

None applicable.

8. Key Words

Research, Innovation, Volunteers, Participants, ATIMPS, CTIMPS, Trials

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