UNIVERSITY OF LEICESTER

Research Governance Office Sponsorship Standard Operating Procedures

Management of Healthy Volunteers in Research Studies of Investigational Medicinal Products

SOP Reference	S-1041
Version and Date	V3.0 September 2026
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Date	01 September 2026
Effective Date*	01 September 2026
Next Review Date	September 2029

1.0 Introduction and Scope

This Standard Operating Procedure (SOP) applies to all research studies (referred to as 'trials' hereafter) sponsored by the University of Leicester (UoL) and details the steps required when conducting Clinical Trials of Investigational Medicinal Products (CTIMPs) with Healthy Volunteers.

2.0 Procedure

There are scientific, safety, and ethical reasons why healthy volunteers should not participate too frequently in CTIMPs of potential new medicines and there exists a need to monitor their participation in them for their safety and protection. Healthy volunteers who participate recurrently in CTIMPs place themselves at risk whereby:

- The participant might be exposed to interacting substances in consecutive trials
- The results of a trial might be influenced by the participant's involvement in a previous trial
- An excessive volume of blood might be removed from the participant
- It is unethical and scientifically questionable to expose healthy people too often to interventions (medicines/radiation) they do not need

For Phase I clinical trials involving healthy volunteers, applicants should describe the measures that will be used to ensure that participants are not currently taking part in, or have not recently taken part in, another clinical trial. In addition to obtaining this information directly from the volunteer, The 'Over-volunteering Prevention System' (TOPS) should be used where applicable. TOPS is a database maintained by the Health Research Authority (HRA), available free of charge to UK organisations conducting Phase I trials in healthy volunteers. The system aims to prevent over-volunteering by helping identify individuals who may be participating too frequently in CTIMPs. Registration of healthy volunteers on TOPS is a standard condition of ethical approval for Phase I healthy volunteer studies.

Where use of TOPS is considered applicable, this should be documented within the feasibility assessment, Sponsor risk assessment, Sponsor review records and the trial protocol.

Access to the TOPS database will be administrated by the Research Governance Office. Usernames and Passwords for each trial will be issued to the Chief and Principal Investigator(s) (CI and PI, respectively).

2.1 Identifying and Registering a Participant

As Sponsor, the UoL expects that, when discussing participation with a potential healthy volunteer, the Principal Investigator (PI) (or delegate) explains the purpose of TOPS and obtains the volunteer's written consent (see appendix 1) before entering their details onto the database. Information regarding the use of TOPS should also be included within the Participant Information Sheet (PIS). Participants must provide permission before their details are entered onto TOPS.

The individuals responsible for recruiting the healthy volunteers must inform potential participants that they will be required to provide their national insurance number or passport number to take part in a trial using the TOPS scheme.

Once consent has been obtained, their unique identifier (NI Number or Passport Number) must be entered into the TOPS database. In accordance with HRA guidance, volunteers should be registered on TOPS when they attend the research unit for screening and, in all cases, before administration of the first dose of investigational medicinal product (IMP).

2.2 Identification of existing Volunteer on TOPS

Occasionally, a volunteer may already be registered on the TOPS database. In such cases, the existing TOPS record must be reviewed and a documented assessment made regarding the volunteer's suitability.

Where the TOPS record indicates that the volunteer has recently participated in another CTIMP, enrolment into the current trial should be paused until information has been reviewed and a decision regarding suitability to participate in the current (new) trial has been made.

The information obtained from TOPS must be reviewed by the PI. Further advice my be sought from by the CI where required. Consideration should be given to factors including the nature and timing of the previous trial, any IMP(s) received, the volume of blood taken, relevant protocol eligibility criteria and any potential risks to the volunteer.

Before any further trial procedures are undertaken, the PI must be satisfied that the volunteer's continued participation is appropriate and does not present an unacceptable risk.

Any decision to enrol a volunteer who has recently participated in another clinical trial should be based on a documented clinical assessment and risk evaluation, taking into account participant safety, protocol requirements and the principles of preventing over-volunteering.

2.3 Steps to be taken after Registration

Once a volunteer has provided informed consent and their preliminary eligibility has been confirmed, reasonable steps must be taken to verify relevant medical history and assess suitability for participation. This should be assessed for all volunteers, regardless of whether a previous trial participation record is identified through TOPS as per section 3.2 above.

The extent of verification required should be proportionate to the nature of the trial, associated risks and protocol requirements. Where verification of medical history from a volunteer's GP or other healthcare provider is required, appropriate arrangements and funding should be in place to support this activity.

A volunteer research record must be maintained for everyone. The format and location of these records should be appropriate to the trial and enable all trial-related activities, assessments and decisions to be adequately documented. Where no existing clinical record is available, a dedicated research record must be created. The suitability of the proposed record-keeping arrangements should be considered during the Sponsor review process.

Organisations participating in the TOPS scheme may contact the research team to verify information relating to an individual's participation in a trial. Such requests should be dealt with promptly and referred to an appropriately qualified member of the research team. Information should only be disclosed where this is permitted by the participant's consent, trial documentation and applicable data protection requirements.

Likewise, where clarification regarding a volunteer's previous involvement in another trial is required, the research team should make reasonable efforts to obtain relevant information from the previous research unit in order to support an informed assessment of the individual's eligibility and safety. The outcome of any enquiries and resulting decisions should be documented within the participant's research records.

3.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
September 2026	3.0	• Updates throughout to clarify and refine process. • Update to confirm requirements as per HRA guidance. • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP development record; only the latest approved revision is now displayed, with prior versions retained in the document archive.