University of Hertfordshire

MANAGEMENT OF HEALTHY VOLUNTEERS IN RESEARCH STUDIES

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the Management of Healthy volunteers in research studies of Investigational Medicinal Products sponsored by the University of Hertfordshire

SOP Number: gSOP-38-01	**Effective Date:** 26th April 2018
Version Number: 1.0	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire standard operating procedure.

2. PURPOSE

This SOP details the steps required when conducting Clinical Trials of Investigational medicinal products with healthy volunteers when research activity investigates any or all of the following:

- Absorption
- Distribution
- Metabolism
- Excretion

Commonly known as 'ADME' studies. Healthy volunteers can be members of the general public, students, or members of staff at the University of Hertfordshire. There must be no differentiation in the treatment of volunteers from these groups.

3. APPLICABLE TO

For use by research staff working on Clinical Trials of Investigational Medicinal Products in healthy volunteers (CTIMPs) sponsored by the University of Hertfordshire.

4. RESPONSIBILITIES

This applies to any UH employee involved with research which requires UH sponsorship/co-sponsorship including but not limited to: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Managers, Clinical Studies Officers, Data Managers and Research Assistants.

It is the responsibility of the Chief Investigator to appropriately delegate individuals to operate The Over-Volunteering Prevention System (TOPS) database and ensure all personnel are trained to consent to TOPS registration. It is the Chief Investigator's responsibility to ensure adequate documentation is maintained on the volunteer medical record and make any decision on continuation of any volunteers onto the study.

5. PROCEDURE

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

- The subject might be exposed to interacting substances in consecutive studies
- The results of a study might be influenced by the subject's participation in a previous study
- An excessive volume of blood might be removed from the subject
- It is unethical for subjects to be exposed too frequently to pharmaceutical products from which they can derive no benefit

The UK clinical trials regulations state that applications to the 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, TOPS must also be used.

CTIMP studies involving healthy volunteers will be highlighted during the feasibility and sponsor review of the study. If it is deemed appropriate to implement The Over-Volunteering Prevention System (TOPS) this must be documented in the feasibility and sponsor risk assessment.

As sponsor UH expects that a separate TOPS consent form be used alongside the study consent form and that within the participant information sheet an explanation about the requirement to be registered onto TOPS and the information required to facilitate this be included. Suggested wording is as follows:

"You must not take part in too many studies because it is not good for you. So to help the research units the Health Research Authority keep a database of healthy volunteers and when they take part in studies. This is called TOPS).

We will enter onto the database:

- *Your national insurance number (if you are a UK citizen) OR*
- *Your passport number and country of origin (if you are not a UK citizen) and*
- *The date of your last dose of study medicine*

If you withdraw from the study before you receive any study medicine, the database will show that you never received a dose.

Only staff at UH and other medicines research units can use the database. We may call other units or they may call us to check your details.

We will not keep your data for any longer than 2 years. If we need to contact you about the study after you have finished it, but we can't because you have moved or lost contact with your GP, we might be able to trace you through the information on the database."

5.1 Identifying and registering a subject

- The individuals responsible for recruiting healthy volunteers must make the volunteers aware that they need their national insurance number or passport number to take part using the TOPS scheme.
- Any one named in the delegation log may not be entered as a participant
- The first time a volunteer presents themselves for a relevant study, the responsible individual must ensure that the volunteer has been consented for their details to be added to the TOPS database. If consent has been withheld the volunteer must not be allowed to continue.
- Once consent to be included in the TOPS database has been confirmed their unique identifier (national insurance number, passport number) must be entered into the TOPS database before the first dose of IMP is administered.

5.2 Identification of existing volunteer on TOPS

Occasionally a volunteer may already be registered on the TOPS system. A review of the existing record must be undertaken, a decision made and documented as to whether or not a volunteer may continue in the study.

The reasons for continuation or halting continuation in the study must be clearly documented in the volunteer notes or the case report form.

5.3 Steps to be taken after registration

Once a subject has consented to participate in the research activity, and their inclusion in the activity has been confirmed, every attempt to confirm relevant medical history must be made. It is not always necessary to contact the volunteers GP but as a minimum a declaration from the volunteer confirming that the information they have given is correct must be obtained.

A set of volunteer notes must be generated for each volunteer. The appropriateness of records will be discussed at the sponsor review meeting.

It is possible that other units registered on TOPS may make contact to discuss the study and the volunteers' involvement. Every effort must be made to assist them and the appropriate investigator contacted.

6. RELATED DOCUMENTS

- gSOP-33 Risk assessment and rating for research studies
- gSOP-04 Informed consent

- gSOP-20 Participant Information

7. APPENDICES

- Appendix 1 – Definitions

8. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author

Signature **Date**

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature **Date**

10. AGREEMENT

Please detach and retain within <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-038-01) and accept to follow University policies implementing it.

Recipient

Signature: ……Date: ……..

Name & Position: ……

Please retain copy of the signed form for your reference in your training file

Appendix 1: Definitions

Case Report Form (CRF)
A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the Sponsor on each trial subject.

Chief Investigator (CI)
A registered Physician, Dentist, Pharmacist or Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial
A study that looks at the safety or efficacy of a medicine/food stuff/placebo in humans as defined by the Medicines for Human Use Regulations (2004).

Good Clinical Practice (GCP)
As defined in the Regulations.

International Conference on Harmonisation (ICH)
The ICH produced a series of guidelines in 1996, E6 being the guideline on Good Clinical Practice, otherwise known as (ICH-GCP).

Principal Investigator (PI)
A registered Physician, Dentist, Pharmacist or Nurse who has responsibility for the conduct of the trial at a host site.

The Medicines & Healthcare products Regulatory Agency (MHRA)
UK competent authority responsible for regulation of clinical trials.

The Regulations
Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.