Sheffield Teaching Hospitals NHS
NHS Foundation Trust

STANDARD OPERATING PROCEDURE

Healthy Volunteers

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Date effective	18 June 2018	**Author**	Luke Barron
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Approved by (name & role)	Dr Dipak Patel, Research Manager	**Date**	21 May 2018
Signature:			

Standard Operating Procedure: Research Department

Healthy Volunteers

This SOP has been produced in accordance with the Department of Health's UK Policy Framework for Health and Social Care Research 2017. This SOP will outline the procedure for registering all healthy volunteers taking part in research studies undertaken at Sheffield Teaching Hospitals NHS Foundation Trust (STH).

1. Background

A healthy volunteer is an individual who has either no known significant health problems or who more specifically does not have the condition studied within a particular research project and consents to participate in research. Healthy volunteers play an integral role in some pieces of research by providing health information which can be used as a comparator. Research with healthy volunteers is designed to develop new knowledge and does not provide direct benefit to study participants. Healthy volunteers participation in research may range from Phase I studies of new medicines to non-invasive observational studies.

A healthy volunteer should be protected from coercion and from undue inducements (an excessively attractive offer) when approached to participate in research. It is fairly common to offer payments and/or cover travel costs for healthy volunteers. It must however be recognised that payments should never be related to risk. In circumstances where a study involving healthy volunteers is sponsored by STH a full schedule of intended payments to healthy volunteers (with details of amounts and justification) must be listed within the IRAS form prior to submission to Research Ethics Committee (REC) and the Health Research Authority (HRA). For further information please refer to the HRA website which discusses the topic more holistically.

The UK Clinical Trials Regulations state that applications to the REC should include information on how to check volunteers aren't taking part or have not recently taken part in other trials. In addition to asking to check the healthy volunteers' medical history it may be required to use The Over-Volunteering Prevention System (TOPS) if the research is a Phase I trial.

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2. Acronyms

ICF	Informed Consent Form
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STH	Sheffield Teaching Hospitals NHS Foundation Trust
TOPS	The Over-Volunteering Prevention System

3. Definitions

A healthy volunteer is an individual who has either no known significant health problems or who more specifically does not have the condition studied within a particular research project and consents to participate in research.

4. Procedure

1. It is the responsibility of the Principal Investigator (PI) or delegate to identify potentially eligible Healthy volunteers in accordance with the procedure agreed within the IRAS application. For clinical trials, a healthy volunteer cannot be a member of the research team who is present on the study delegation log.

2. When approaching a healthy volunteer they must be given study related information (Participant Information Sheet (PIS) and Informed Consent Form (ICF)) approved by the HRA, REC and Sponsor. A clear description should be provided to the potential healthy volunteer and they must be given time to read these and ask questions regarding the study.

3. Once the healthy volunteer has expressed willingness to participate they can be duly consented in accordance with the procedure agreed within the IRAS application and Informed Consent SOP. For clinical trials, following consent a healthy volunteer file will be set up if the individual does not already have medical notes at STH (a file may be set up for other types of studies where considered appropriate).

4. Where a healthy volunteer does have medical notes, the research team will not have access to these until the participant has provided consent.

5. The PI or delegate must ensure that the healthy volunteer is eligible to take part in the study. Any outstanding health condition relevant to the inclusion / exclusion criteria for the study must be taken into consideration through screening.
   5.1 Where applicable for safety reasons, as part of the consent procedure a healthy volunteer must formally declare they have no outstanding health condition which will influence participation in the study.
   5.2 For studies involving the administration of a medicinal product the PI or delegate will consider whether the participants GP will be consulted over their planned inclusion.

6. If the PI or delegate deems the participant unable to enter the study the healthy volunteer must be fully provided with the reasons why. The reasons for exclusion and the discussion with the healthy volunteer must then be documented in the Investigator Site file.

7. The PI must contact the relevant medical team (if necessary) should the healthy volunteer be excluded due to new medical reasons which have been discovered through the screening process.

8. Further to the TOPS SOP, when the study is a Phase I clinical trial the PI or delegate must obtain a photo ID from the healthy volunteer in order to verify the identity of the healthy volunteer and insert a photocopy in the healthy volunteer file. The volunteer must present the Photo ID at all study visits for verification purposes. For all other trials and studies the healthy volunteer's full contact details must be verified at each study visit.

9. As discussed above the PI or delegate must ensure (where appropriate) that a file is set up for each healthy volunteer containing the following information:

    a. Full contact details of the healthy volunteer (including emergency contact information)

    b. Full details of the study (STH study number, IRAS study ID number, PIS, signed ICF, and any study related documents).

c. Source data for any outcomes recorded as per study protocol (such as blood pressure, weight, adverse events, etc) must be stored within the healthy volunteer file.

d. Any other study relevant information.

10. At the end of the study the healthy volunteer file must be archived alongside other study documentation.

Appendix 1 SOP revisions and history

SOP number & version	Effective date	Reason for change	Author
THIS SOP			
PREVIOUS SOPs			