# Standard Operating Procedure – Trust-wide

North Bristol NHS Trust

## Management of Healthy Volunteers in research studies

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| Reference | RI/QMS/SOP/020 |
| Date Adopted | 08-03-21 |
| Version | 1.0 |
| Review Date | 08-03-23 |

### Purpose

The purpose of this Standard Operating Procedure (SOP) is to detail the steps required when Healthy Volunteers are enrolled as participants in research projects where North Bristol NHS Trust (NBT) are the HOST organisation or Research SITE.

NBT does not currently host or act as a research site for phase 1 CTIMPs or ATIMPs involving healthy volunteers.

### Key messages

All Researchers recruiting Healthy Volunteers must, in addition to the clinical due diligence, also exercise holistic care due diligence in the preparation and execution of study visits.

### You may also need to refer to the following policies and guidance

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| RI/QMS/SOP/007b | NBT Terms & Conditions of Sponsorship |
| RI/QMS/SOP/007c | Delegation of Responsibilities |
| RI/QMS/SOP/007d | Delegation of Responsibilities Log |
| RI/QMS/SOP/017 | Data Management |

### Operational areas included

All trust areas undertaking research with Healthy Volunteers.

### Operational areas excluded

None

## Who should read this?

This SOP should be used by R&I staff, and investigators engaged in studies involving healthy volunteers.

## Roles responsible for carrying out this procedure

The Principal Investigator for a study is responsible for the adherence to the protocol, ICH GCP and NBT research SOPs.

## Core accountabilities:

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| Author(s) | Helen Lewis-White, Research Operations Manager |
| Executive Sponsor | Dr Rebecca Smith, Deputy Director of Research |
| Approving Committee | Research & Innovation Group |

## Version history

| Version Number | Effective Date | Summary of changes since previous version |
|---|---|---|
| 1.0 | 08-03-21 | N/A |

## 1. PURPOSE AND SCOPE

The purpose of this Standard Operating Procedure is to detail the steps required when Healthy Volunteers are enrolled as participants in research projects where North Bristol NHS Trust are the HOST organisation or Research SITE.

## 2. DEFINITION Of TERMS

| | |
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| ATIMP | Advanced Therapy Investigational Medicinal Product |
| CTIMP | Clinical trial of an Investigational Medicinal Product |
| Healthy Volunteer | Any participant who is recruited into a study which falls within the governance of the HRA for any reason other than their own personal health or medical condition.<br><br>A non-exclusive list of Healthy Volunteers are:<br>• Members of staff participating in research related to their role.<br>• Students.<br>• Friend or relatives sued within studies as comparison cohorts.<br>• Members of the public participating is prophylactic studies eg vaccine trials. |
| Host | Host organisations , for the purpose of this SOP, refer to organisations working with the sponsor in the central management and delivery of the study |
| HRA | Health Research Authority |
| ICH GCP | International Conference on Harmonisation Guidelines for Good Clinical Practice |
| IMP | Investigational Medicinal Product |
| NBT | North Bristol NHS Trust |
| PI | Principal Investigator |
| Research Site | Research sites are the organisations with day-to-day responsibility for the locations where a research project is carried out. In health and social care research, they are often providers of health or social care and/or the employer of members of the research team. |
| Research Study | For the purpose of this SOP a research study will refer to an observational research project. |
| Research Trial | For the purpose of this SOP a research study will refer to an interventional research project, where the Healthy Volunteer will receive a health related intervention, eg a CTIMP, device, or non-medicinal intervention |
| SOP | Standard Operating Procedure |

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| Sponsor | The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the Chief Investigator in the case of non-commercial research, as described in the UK Policy Framework for Health and Social Care Research. |
| Study Team | Research staff working with the PI to ensure the safe and effective delivery of the research study / trial |

## 3. ROLES AND RESPONSIBILITIES

Principal Investigator: Responsible for ensuring the safety and wellbeing of Healthy Volunteers is maintained, within the scope of the HRA approved protocol, by ensuring delivery plans for studies provide sufficient assurance of:

- The eligibility of Healthy Volunteers to participate in studies / trials.
- Effective and timely communication with Healthy Volunteers.
- Efficient appointment scheduling and communication.
- Clear information for the Healthy Volunteers about how to contact the study team.

Study Team: The research members of staff as defined on the delegation of responsibilities will support the delivery of the research study / trial.

## 4. WHO SHOULD USE THIS SOP

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

## 5. WHEN SHOULD THIS SOP BE USED

This SOP should be referred to for all studies where recruitment includes Healthy Volunteers.

## 6. PROCEDURE

### 6.1 Risk assessment and additional considerations

While phase II / III / IV trials are not first in man studies, by their nature, due diligence must be exercised. There are scientific, safety and ethical reasons why Healthy Volunteers should not participate too frequently in studies of potential new medicines / interventions:

- The participant might be exposed to interacting substances in consecutive studies.
- The results of a study might be influenced by the participant's previous participation

in a study.

It is expected that the Sponsor will have appropriate mechanisms within the protocol and study documents to confirm medical history, participant identity, inclusion / exclusion criteria and previous participation in interventional trials. The appropriateness of these mechanisms should be confirmed as part of the feasibility and set up process.

- The PI is responsible for ensuring, during feasibility and throughout the study, that the protocol and study documents contain appropriate mechanisms for the safety and wellbeing of participants to be protected.

## 6.2 Additional inclusion considerations

Healthy Volunteers may not have prior medical interactions with NBT and therefore this information may need to be accessed from other Trusts / organisations, sufficient time to permit this to happen needs to be planned into the visit scheduling.

Where participants' inclusion in interventional studies is subject to clinical evaluations e.g. biochemistry, immunological data, imaging data etc.

It is the responsibility of the PI to identify the information needed and to:

- Liaise with the healthcare team to ensure access to the data is available; or
- Ensure the participant is aware of the need for this information prior to inclusion in the study.

Where neither of these options is open to the PI, due to the HRA approved protocol or logistical / time constraints these populations should not be invited to participate until appropriate measures are established.

It is the responsibility of the PI to ensure confirmation of relevant medical history will be conducted in accordance with the study protocol. It is not always necessary to contact the volunteer's General Practitioner (GP), but as a minimum a declaration from the volunteer confirming that the information they have provided is accurate should be obtained.

Participant Registration

Once consent has been completed and the Healthy Volunteer's enrolment in the activity has been confirmed, a volunteer record should be generated.

## 6.3 Scheduling

Where recruitment to Healthy Volunteer studies is undertaken on mass, e.g. vaccine trials, to ensure the most efficient use of resource and IMP, and recognising a potential for screen failures of people not attending, it is permissible to 'over book' a recruitment day.

Where 'over booking' is permitted the following actions must be undertaken:

- The Sponsor must confirm the number of people who can be recruited above the agreed target, before all the booking is complete.
- Participants should be booked as reserve slots in the last visit slots of the session / day.
- Participants booked into 'reserve' slots must be made explicitly aware that inclusion cannot be guaranteed.
- On the day of the clinic the trial manager or lead nurse (senior on for the day) must identify the individual responsible for confirming or declining people on the reserve list. This must be undertaken in a timely manner. Where possible they should be offered booking or reserve slots.

## 7. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

## 8. REFERENCES


- Health Research Authority
  *UK Policy Framework for Health and Social Care Research*
  www.hra.nhs.uk

- ICH Secretariat
  *Guidelines for Good Clinical Practice (E6 R2, Step 4, 2016)*
  www.ich.org

- UK Government
  *Medicines for Human Use (Clinical Trials) Regulations 2004*
  www.legislation.gov.uk