TWELVE WEEK EXCEPTION GUIDELINES

Joint Policy Guidelines on the participation of Human Participants in Research

Version 2.2 October 2021

In order to ensure participant safety and to comply with Research Governance regulations, University Hospital Southampton NHS Foundation Trust (UHS) in partnership with the University of Southampton (UoS) has compiled the following guidelines.

These guidelines have been developed following revision of the policy originally developed in 1997 by UHS and the UoS, entitled: "Policy on the use of staff and students as human volunteers in research studies"

Who are the Guidelines for?
All researchers working within University Hospital Southampton NHS Foundation Trust and the University of Southampton.

Who do the Guidelines apply to?
All staff, healthy participants, or NHS patients, who are to be involved in more than one ethically approved research study. These participants will require a twelve week interval between research studies unless otherwise agreed by the research sponsor of all studies involved.

1 Procedures

On consenting any human volunteer to participate in a research project, the Principal Investigator (PI) should ascertain whether a 12-week 'washout' period has been observed. If the human participant has been involved in a research project within this 12-week period, the Principal Investigator should check the following:

- Review study records and / or NHS medical notes
- Ascertain what procedures have previously been undertaken and to what extent / type.
- Check the protocols of all studies to ensure exemption will not result in non-compliance with the eligibility criteria.
- Ascertain participant's current state of health
- Discuss details with Principal Investigator of other study/studies if necessary

Following review, if the Principal Investigator is satisfied that it is safe and ethical for the human participant to be recruited, and that the data in any of the studies will not be compromised and both studies are open, then the Principal Investigator must inform their research sponsor and UHS R&D by completing and submitting a 12-week exemption statement (below).

2 Compliance

Approved 12-week exemption statement (original) must be retained in the Investigator Site File (ISF) and be available for monitoring as required. A copy should be filed in the patient's medical notes, and ISF for other study/studies. UHS R&D retains a copy in each project file.

12-WEEK EXEMPTION STATEMENT (V 2.2)
(Please refer to Twelve-week exemption guidelines)

Please list below the details of the study that you wish to enter a participant into should they be
a) currently in a research study or
b) have been involved in a research study in the past 12 weeks:
(Note: for example a participant might be in a trial but wishes to assist in a questionnaire study)

1. Details of new study that the participant is to be entered into

Research Project Title:

EudraCT no (if applicable):
REC No: R&D No: RHM
Principal Investigator:
Participant initials + ID number:
(or request to apply to all consenting participants)

As Principal Investigator (PI), I verify that I have undertaken the relevant checks as detailed in the UHS / UoS Twelve-week exemption guidelines and it is safe and ethical for this individual to be included in the above research projects and the data for these projects will not be compromised.

PI Print Name: Date:

Signed:

2. Previous study details:

Research Project Title:

EudraCT no (if applicable):
REC No: R&D No: RHM
Principal Investigator:
Participant initials + ID number:
(or request to apply to all consenting participants)

As Principal Investigator (PI), I verify that I have undertaken the relevant checks as detailed in the UHS / UoS Twelve-week exemption guidelines and it is safe and ethical for this individual to be included in the above research projects and the data for these projects will not be compromised.

PI Print Name: Date:

Signed:

3. Exemption statement:

Justification for breaching 12-week interval, assess risk to participant safety and risk to scientific validity (e.g. could concomitant medication impact on results?):

4. R&D approval:

Date:

Print Name: .....

Signed: .....

PLEASE POST (SGH Mailpoint 138) or EMAIL TO researchsafety@uhs.nhs.uk TO UHS R&D FOR AUTHORISATION TO PROCEED