Our Vision
To provide every patient with the care we want for those we love the most

SOP 510 Medical Cover for Clinical Trials

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Medical cover, Clinical Trials
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Date of approval:	03/08/2020
To be reviewed before: This document remains current after this date but will be under review	03/08/2023 (3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	14180
Version No:	2
Description of changes:	Updated to new template Updated through to reflect current practices

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CRF	Clinical Research Facility
CRTU	Clinical Research and Trials Unit
CTIMP	Clinical Trial of an Investigational Medicinal Product
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
JRGC	Joint Research Governance Committee
PI	Principal Investigator
R&D	Research and Development
RIN	Research Innovation Services
SI	Statutory Instrument
SOP	Standard Operating Procedure

3. Objectives

To document the procedure and requirements for providing medical cover for clinical trials.

4. Scope

This applies to all clinical trials carried out by NNUH and UEA.

5. Purpose

A qualified physician (or dentist, where appropriate) who is an investigator or a sub-investigator for the study must be responsible for all study-related medical (or dental) decisions.

During and following a subject's participation in a study, the investigator / institution shall ensure that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the study.

The investigator / institution will inform a participant when medical care is needed for inter-current illness or illnesses of which the investigator becomes aware.

6. Contact Details

Investigator Contact Details

- Contact details for each investigator for a specific study will be given by the Chief Investigator (CI) / Principal Investigator (PI) to the study team, Sponsor, R&D Office and Clinical Research and Trials Unit (CRTU) / Clinical Research Facility (CRF) administration as appropriate
- Copies of contact details should also be made available in wards/department where patients are recruited or treated
- The contact details will include contact numbers both for use during office hours and out of office hours

Participant's Contact Card

- Each participant in the study will receive a Participant Information Sheet and / or a Participants Contact Card which will include contact details of the CI or nominated study team member(s) for advice or in an emergency, both during and out of office hours see **SOP 310 - Development of Participant Information Sheet and Informed Consent Form**

Examples of reasons why a participant may wish to contact the Research Team out of hours

- Missed medication doses
- Adverse reaction that participant attributes to the research intervention
- Concern about missing or changing an appointment
- Patient failed to collect medication

7. Responsibilities for Provision of Medical Cover

Medical Cover

- The Sponsor is responsible for ensuring that there is medical cover for a study
- The CI has overall responsibility for making sure that the medical cover exists and is appropriate

Provision of Medical Cover Where Study Involves NNUH Patients

- It is the responsibility of the CI / PI to ensure that medical cover is available to all participants in the study at all times to ensure their safety and well-being
- The CI / PI is responsible for arranging alternative cover when those normally responsible are not available (e.g. holiday or sick leave)

Provision of Nursing and other Supportive Cover

- The CI / PI should ensure that there is continuity of care for subjects within a particular study
- That appropriate numbers of staff are in place, and that annual leave and sickness episodes are covered

Nursing Cover in the CRTU and CRF

- When using the CRTU / CRF, if clinical assessments or interventions are to be performed, and it is deemed appropriate, two members of staff must be present when any study subjects are attending. This should normally include one registered nurse and another member of staff who is trained in NNUH emergency procedures.
- For CTIMP and interventional visits, the second member of staff doesn't need to be in the same room as the patient and the first nurse / practitioner, but must be aware of the visit (well in advance), including the location and duration, be a named person available in the event of an emergency situation, both parties to have contact details of each other and the means to access said person in an emergency situation.

Emergency Cover

- The Participant Information Sheet and Contact Card should advise participants to contact the emergency services (via 999) in the case of a medical emergency.

Out of Hours Cover

- The CI / PI is responsible for arranging and maintaining a reliable system for participants to contact a member of the study team outside usual clinic hours, at weekends and during holidays. The system must also provide arrangements for covering sickness of the nominated contact
- The contact details would usually be a to contact the Clinician on Call for the relevant speciality. Alternatively a reliable mobile phone or pager number carried by a suitably qualified member of the Research Team, or a medical colleague who has been fully informed about the study protocol.

The NNUH main switchboard number on its own is not sufficient

8. Testing of Contact Details

	Contact details provided by the CI / PI can be tested at any time by the R&D / Research Innovation Services (RIN) Office during the period of the research
	If contact details do not provide participants with the necessary support the CI / PI will be contacted immediately by the R&D Office
	If the failure is not resolved the R&D Office will inform the Joint Research Governance Committee (JRGC)and the Sponsor (if this is not NNUH)

Research Governance approval may be suspended until the Out of Hours process is seen to be working

9. Procedures for Provision of Medical Cover where the Study Involves Patients from Outside NNUH

It is the responsibility of the CI / PI to ensure that medical cover is provided to all participants in the study at all times to ensure their safety and well-being.

This should follow the procedures of any other NHS Trust from which the participant is recruited and should not be less than that offered to patients from NNUH.

The same principle will apply for subjects who are not primarily under the care of a Hospital Trust (as for example in the case of patients recruited from primary care).

10. Providing Information to Participant's Primary Physician

It is recommended that the participant's primary physician (General Practitioner) should be informed about the participant's involvement in the study, where relevant to the general care of the participant.

Where this is required the Participant Information Sheet and Consent Form should specifically request the participant's consent for this to be done see **SOP 310 Development of Participant Information Sheet and Informed Consent Form**

11. Reporting

The CI / PI shall ensure that all individual adverse events, serious adverse events, suspected unexpected serious adverse reactions and serious breaches are reported in an appropriate and timely manner to the relevant organisation.

See the following SOP's

SOP 205	Identifying, Recording and Reporting Adverse Events for Clinical Trials of Investigational Medicinal Products
SOP 206	Identifying, Recording and Reporting Adverse Events for Healthcare Research Studies that are not CTIMPS
SOP 207	Identifying, Recording and Reporting Adverse Events for device trials
SOP 210	Managing protocol and Regulatory Non - Compliance including Serious Breaches

12. References and Related Documents

References

ICH GCP E6 / SI 2004/1041

SOP No.	SOP Title
SOP 205	Identifying, Recording and Reporting Adverse Events for Clinical Trials of Investigational Medicinal Products
SOP 206	Identifying, Recording and Reporting Adverse Events for Healthcare Research Studies that are not CTIMPS
SOP 207	Identifying, Recording and Reporting Adverse Events for device trials
SOP 210	Managing protocol and Regulatory Non - Compliance including Serious Breaches
SOP 310	Development of Participant Information Sheet and Informed Consent Form

13. Approval

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14. Reason for new version and Training Implication

This SOP replaces the previous version number V 1.4

Changes made	
Reason	• New layout • Updated to reflect current practice
Training Implication	**Yes**
Actions required	• Matrix to be updated