STANDARD OPERATING PROCEDURE FOR ARRANGING AND TESTING 24 HOUR MEDICAL COVER FOR CLINICAL TRIALS OF AN INVESTIGATIONAL MEDICINAL PRODUCT

SOP NUMBER:	**Fife R&D SOP 39**
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1. PURPOSE

This standard operating procedure (SOP) describes the process that must be followed by all research staff in NHS Fife to ensure that appropriate medical care and advice on study related matters and unblinding (where relevant) is available at all times to patients and medical personnel.

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research) or, for guidance, contact the R&D Quality and Performance Lead in the R&D Office, Queen Margaret Hospital (julieaitken2@nhs.net).

2. APPLICABILITY

This SOP applies to Clinical Trials of an Investigational Medicinal Product (CTIMPs) hosted by NHS Fife. Staff must also adhere to any additional arrangements for individual studies, as per the trial protocol.

3. POLICY

3.1 The Medicines for Human Use (Clinical Trials) Regulations which govern the conduct of CTIMPs require that Sponsors must have an appropriate system in place for trial patients and medical personnel to contact a member of the study team for advice on safety and unblinding (if relevant), including outside usual clinical hours.

3.2 The Principal Investigator is responsible for:

- Ensuring the site has adequate medical cover arrangements in place for the trial and a robust process for unblinding, if relevant.
- Ensuring that the contact details provided to study patients are suitable and correct. This information permits the patient to contact the local Research Team in the event of any trial related questions or for reporting of any adverse events (AEs).
- Arranging and testing the arrangements for medical cover, including outside usual clinical hours and for ensuring that any proposed changes to these arrangements are tested prior to implementation.

3.3 All staff on an 'Out of Hours' rota must be made fully aware of their responsibilities and the importance of providing a prompt, round-the-clock response to medical emergencies and other urgent requests for information by the PI.

4. PROCEDURE

4.1 The Sponsor's requirements for medical cover and unblinding must be reviewed by the study team at the feasibility stage to ensure these can be fulfilled.

4.2 The first point of contact for trial related medical queries will usually be the PI but there must also be another medically qualified doctor who is knowledgeable about the trial and any IMP being used, added to the Delegation of Duties Log to ensure medical advice is available in the absence of the PI.

4.3 If 24 hour medical cover for trial related queries is required (as risk assessed by the Sponsor) and NHS Fife is unable to provide suitable cover, then the Sponsor must be asked by the study team to confirm if it is acceptable for the Trial Co-ordinating Centre or Sponsor's Medical Monitor to fulfil this role. The outcome of this discussion must be documented on the Study Summary & Set-Up Checklist (Doc Ref 45-01)

4.4 The PI/delegate must discuss the 24 hour medical cover arrangements with the Sponsor and Senior Clinical Trials Pharmacist and complete the Research Team Contact Details and Code Break Instructions Form (Doc Ref 39-01). A copy of the completed Research Team Contact Details and Code Break Instructions Form must be filed within the Investigator Site File and the Pharmacy File by the Research Team and Clinical Trials Pharmacy Team.

4.5 An alert must be added to the TrakCare record of each patient recruited (see WI09 - R&D Trial Patient Alert Procedure). This will highlight to clinical staff that the patient is taking part in clinical research, provide contact details for the Local Research Team and, in situations where the Local Research Team cannot be contacted, provide the information required when contacting the Pharmacy Department or other Out of Hours Contact.

4.6 A copy of the Patient Information Sheet (PIS) and Informed Consent Form (ICF) must be uploaded to SCI-Store (see WI22 (Fife) - Recording Details of Research in Medical Records) to ensure that all clinical staff have 24 hour access to information about the trial.

4.7 Study patients must be provided with appropriate contact information once they have consented to take part in a trial. The contact details must be in place and tested prior to being given to the patient. If the contact information changes, this should be re-tested successfully before being given to the patient.

The contact details provided to patients must be present in:

- the Patient Information Sheet; *and*
- the Patient Identification Card (if available). Some research studies require the patient to always carry a card which lists study contact details. The CI/PI/Research Nurse should check at every visit that the patient has the most up-to-date card available.

4.8 Contact details provided to patients can include:

- Study specific mobile phone numbers - the contact details would usually be a mobile phone or pager number carried by a suitably qualified member of the research team who has been trained on the study protocol.
- Investigator's office number - this number would normally be manned during office hours with an 'Out of Hours' number left on the answer phone.

If contact cannot be made with a member of the local research team then the patient/carer can contact the NHS Fife Pharmacy Department, within working hours, if the question is regarding their medication supply. The telephone number for the Pharmacy Department is included on every medication label.

4.9 In the event of a medical emergency or if there is the need to unblind a patient and the Local Research Team cannot be contacted, the hospital switchboard number can be used by medical personnel to contact the NHS Fife Pharmacy Department. The Clinical Trials Pharmacy Team or On-Call Pharmacist will be able to direct medical personnel to the trial information on the Clinical Portal and provide contact details for appropriate 24 hour medical cover.

Note: For some studies the Sponsor may determine that a trial specific 24 Hour Emergency Contact Number is not required and in these circumstances the patient must be advised to contact their GP or NHS 24. This should be documented in the Research Team Contact Details and Code Break Instructions Template (Doc Ref 39-01).

4.10 Informing the Patient's GP

4.10.1 The PI/Research nurse must inform the patients' GP (with patient's consent) that the patient is involved in a CTIMP. This ensures that if a patient goes to their GP for medical advice, the GP is aware of the CTIMP and can seek advice from the CI/PI if required.

4.10.2 When sending out the REC approved letter to the patient's GP, the PI/Research nurse should add a sticker (Doc Ref 39-02) to the GP letter requesting that the GP add details of the study to the Emergency Care Summary for that patient.

4.11 Unblinding Process

4.11.1 The PI is responsible for arranging this process in conjunction with the Sponsor and NHS Fife Clinical Trials Pharmacy Team.

4.11.2 A Research Team Contact Details and Code Break Instructions Form (Doc Ref 39-01) must be completed to detail the procedure to be followed and list the authorised personnel who can perform the unblinding.

A copy of this form must be filed within the Investigator Site File and the Pharmacy File.

4.11.3 Care must be taken to ensure that no unnecessary unblinding of the study team occurs to protect the integrity of the study.

4.11.4 Details of any emergency unblinding shall be documented fully in the Investigator Site File and Pharmacy File(s) using Doc Ref 39-05.

4.11.5 If the NHS Fife Clinical Trials Pharmacy Team or an individual named on the Delegation Log has performed the unblinding procedure, they must inform the Sponsor and provide the trial identifier, and name and title of the person making the request, but NOT the result.

4.12 Testing Medical Cover and Unblinding Arrangements

4.12.1 24 Hour Emergency Contact Number

4.12.1.1 If appropriate, any 24 Hour Emergency Contact numbers provided on Doc Ref 39-01 and the patient's documents should be tested by the PI or delegate prior to recruitment of the first patient and every 6 months during the study.

4.12.1.2 The outcome of the test call(s) should be recorded using Doc Ref 39-03- Medical Cover Test Record and retained in the Investigator Site File (ISF).

4.12.1.3 The call is deemed unsuccessful if the tester was:

- Unable to make any contact on the telephone number(s) provided for any reason, including a wrong number or continuous ringing for more than 1 min.

- Unable to contact anyone on the telephone number provided who has appropriate understanding or experience of the study or access to study related documentation

If the test call is unsuccessful participants should not be recruited until all necessary corrective actions have been put in place and successful test call(s) have been completed.

4.12.2 Local Research Team Contact Details

4.12.2.1 As part of their regular document audit (see CTP030) the Clinical Trials Pharmacy Team must send a copy of the most recent completed version of Doc Ref 39-01 held in the Pharmacy File, by email to the PI or delegate for each trial to request confirmation that all contact details are still accurate.

4.12.2.2 The PI or delegate must either confirm by email that the contact details are still accurate or provide the Clinical Trials Pharmacy Team with an updated copy of Doc Ref 39-01.

4.12.3 On-Call Pharmacist

4.12.3.1 The R&D Quality & Performance Lead or delegate must perform a test call to the NHS Fife On-Call Pharmacist every 6 months.

4.12.3.2 The On-Call Pharmacist must be contacted via the hospital switchboard (Tel: 01592 643355) and asked to confirm how they would access study information if contacted. They must also be able to explain how this information could be obtained if they were provided with only the Patient's name and Date of birth.

4.12.3.3 The outcome of the test call(s) should be recorded by the R&D Quality & Performance Lead using Doc Ref 39-04 and retained in the Quality Assurance Folder in S:\Research\QUALITY ASSURANCE\STUDY SPECIFIC & PROCESS AUDIT REPORTS\OUT OF HOURS CONTACT TESTS.

4.12.3.4 The call is deemed unsuccessful if the tester was:

- Unable to make contact with the On-Call Pharmacist after 3 attempts.

- Unable to contact anyone with access to information relating to clinical trials

5. ASSOCIATED DOCUMENTS

WI09 - R&D Trial Patient Alert Procedure
WI22(Fife) - Recording Details of Research in Medical Records
CTP030 - Active Pharmacy File Review and Audit
Doc Ref 39-01 - Research Team Contact Details and Code Break Instructions Template
Doc Ref 39-02 - Stickers for GP Letters
Doc Ref 39-03 - Out of Hours Medical Cover Test Record
Doc Ref 39-04 – On-Call Pharmacist Test Record
Doc Ref 39-05 – Unblinding Record
Doc Ref 45-01 - Study Summary & Set-Up Checklist

6. ABBREVIATIONS

AE	Adverse Event
CTIMP	Clinical Trial of Investigational Medicinal Product
CI	Chief Investigator
PI	Principal Investigator
R&D	Research & Development
SOP	Standard Operating Procedure

7. REFERENCES

Medicines for Human Use (Clinical Trials) Regulations 2004.
(*http://www.opsi.gov.uk/si/si2004/20041031.htm*).
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	09 Aug 2018	N/A – new SOP
2	Julie Aitken R&D Quality & Performance Lead		Reference to NHS Fife Sponsored Trials removed. Further information added to clarify the process for documenting and testing appropriate 24 Hour Cover.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	27/02/2020

APPENDIX A

Summary

PRIOR TO RECRUITMENT COMMENCING

Sponsor/CI/PI/Clinical Trials Pharmacy Team

- Agree Medical Cover Arrangements and Unblinding Procedure (if relevant)
- If trial specific 24 hour cover is required and cannot be provided by local Research Team then Sponsor must confirm Trial Co-ordinating Centre or Sponsor's Medical Monitor can fulfil this role

CI/PI

- Complete a 'Research Team Contact Details Form (Doc Ref 39-01).
- Copies must be filed in Investigator Site File and Pharmacy File

FOLLOWING RECRUITMENT OF EACH PATIENT

Local Research Team

- Provide recruited patients with contact details in the Patient Information Sheet and Patient Identification Card (where available)
- Upload a copy of the PIS and signed consent to the patient's record on SCI-Store (see WI 22).
- Add a 'R&D Trial Patient' alert to the patient's record on TrakCare (see WI09)

APPENDIX B

IN THE EVENT OF A QUERY, MEDICAL EMERGENCY OR NEED TO UNBLIND

Patients/Carer

Patient/Carer should use contact details provided on PIS or Patient Identification Card to contact the research team.

If contact cannot be made with a member of the local research team then the patient/carer can contact the Pharmacy Department, within working hours, if the question is regarding their medication supply. The telephone number for the pharmacy department is included on every medication label.

Out of hours, if contact cannot be made with a member of the local research team then the patient/carer should present through the normal channels according to their needs (GP, NHS24, A&E).

Clinical Staff

Medical personnel should check the 'R&D Trial Patient' alert on TrakCare for information about the trial and to obtain contact details for the Local Research Team.

View further study information in uploaded documents on the Clinical Portal.

If further information required or unblinding required, contact Local Research Team using contact details on 'R&D Trial Patient' alert.

If the local research team are not available then contact the Clinical Trials Pharmacy Team or On-call pharmacist via switchboard. The following information from the 'R&D Trial Patient' alert on TrakCare may be required by the Clinical Trials Pharmacy Team, On-Call Pharmacist and/or Sponsor's Medical Monitor:

- Study Name
- R&D Number
- Centre Number
- Patient Study ID Number