STANDARD OPERATING PROCEDURE FOR ARRANGING AND TESTING MEDICAL COVER FOR CLINICAL RESEARCH STUDIES

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 always available to patients and medical personnel.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D tab of the Research, Innovation and Knowledge section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This SOP applies to clinical research studies sponsored and hosted by NHS Fife. Staff must also adhere to any additional arrangements for individual studies, as per the trial protocol.

3. PRINCIPLES

3.1 The Medicines for Human Use (Clinical Trials) Regulations which govern the conduct of Clinical Trials of Investigational Medicinal Product (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 of 9am - 5pm 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, or at least prior to site selection, to ensure these can be fulfilled.

4.2 The first point of contact for study related medical queries will usually be the PI but there must also be another medically qualified doctor who is knowledgeable about the study 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 study related queries is required (as risk assessed by the Sponsor) and NHS Fife is unable to provide this cover, then suitable alternative arrangements must be discussed and agreed with the Sponsor. The outcome of this discussion must be documented in the 'Research Team – Study Summary Checklist' Workflow on EDGE.

4.4 Contact details for all research team staff must be documented in a 'Research Team – Research Team Contact Details' Workflow on EDGE.

4.4.1 For CTIMPs, the PI or delegate must discuss the medical cover arrangements with the Senior Clinical Trials Pharmacist and forward a copy of the completed 'Research Team – Research Team Contact Details' Workflow to the Clinical Trials Pharmacy Team (fife.clinicaltrials@nhs.scot).

4.4.2 A copy of the completed 'Research Team – Research Team Contact Details' Workflow must be filed in the Investigator Site File (hard copy or eISF depending on which is being used) by the Research Team and the Pharmacy Site File (where relevant) by the Clinical Trials Pharmacy Team.

4.4.3 Any changes to the contact details or unblinding process must be recorded by the Research Team in the 'Research Team – Research Team Contact Details' Workflow' on EDGE and an updated copy filed in the ISF/eISF. and, where appropriate, sent to the Clinical Trials Pharmacy Team for their files.

4.5 A report (Study Contact Details and Unblinding Instructions for Pharmacy) containing the information from each 'Research Team – Contact Details' Workflow is stored in \\san2a\vhkdata\DIRECTORATE_SHARES\Pharmacy\Service Delivery\Clinical\Acute\On-call\On Call Information\5 - Clinical Trials\Emergency Contact Information so that this information can be accessed by the On-call Pharmacist. This report must be refreshed each

working day (not at weekends or on Public Holidays) by the Quality & Performance Team.

4.6 Where appropriate, 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.

4.7 Where appropriate, a copy of the Patient Information Sheet (PIS) and Informed Consent Form (ICF) must be uploaded to SCI-Store (see R&D WI22 - Recording Details of Research in Medical Records) to ensure that all clinical staff have 24-hour access to information about the study.

4.8 Study patients must be provided with appropriate contact information once they have consented to take part in a study. The contact details must be in place and tested (where appropriate) 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/Clinical Research Practitioner or Assistant should check at every visit that the patient has the most up-to-date card available and document this in their EPR on TrakCare.

4.9 Contact details provided to patients can include:

- Research Team 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. Patients should be made aware of the Research Team's availability and when this mobile will be manned.

- Investigator's office number - this number would normally be manned during office hours with an 'Out of Hours' number left on the answer phone.

For CTIMPs, 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.

4.10 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 – Study Summary Checklist' Workflow on EDGE.

4.11 Informing the Patient's GP

4.11.1 For CTIMPs the PI/Research nurse must inform the patient's GP (with patient's consent) that the patient is involved in a CTIMP, using the Sponsor provided GP letter. 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.

4.11.2 For CTIMPs, where the Sponsor has not provided a GP Letter, then the Research Team must query this with the Sponsor and record the outcome in the appropriate question in the Study Summary Workflow on EDGE.

4.12 Process for Unblinding for CTIMPs

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

4.12.2 Details of the process for unblinding must be recorded in the 'Research Team – Research Team Contact Details' Workflow on EDGE.

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

4.12.4 Details of any unblinding occurrences must be reported and documented following the process agreed with the study Sponsor. Details must also be recorded in EDGE using a 'Research Team – Unblinding Record' Workflow.

Where the Sponsor has not provided a study specific unblinding record then a copy of the completed 'Research Team – Unblinding Record' Workflow must be printed to pdf and emailed to the Sponsor.

Where access to EDGE is not available at the time of unblinding then Doc Ref 39-05 can be used to record details of the unblinding, and the information subsequently transcribed to a 'Research Team – Unblinding Record' Workflow on EDGE by a member of the research team.

The PI, Research Team (via generic email address) and the NHS Fife Clinical Trials Pharmacy Team must also be informed that that unblinding has occurred but ***NOT*** informed of the result.

4.12.5 A copy of the unblinding record and/or completed Research Team – Unblinding Record' Workflow and all associated correspondence must be filed in the Investigator Site File (or Electronic Site File if used instead) and copies sent to the Clinical Trials Pharmacy Team for filing in the Pharmacy File(s)

4.13 Checking and Testing Medical Cover and Unblinding Arrangements

4.13.1 Contact Details, including any 24-hour Emergency Contact Numbers

4.13.1.1 Contact details and any 24-Hour Emergency Contact numbers provided in the 'Research Team – Research Team Contact Details' Workflow and the patient's documents must be checked and, where applicable, tested by the PI or delegate prior to recruitment of the first patient and every 12 months during the study.

4.12.1.2 The outcome of the check and any test call(s) must be recorded in a 'Research Team – Out of Hours Test Call' Workflow in EDGE. A copy of this Workflow must be retained in the Investigator Site File (ISF)

4.12.1.3 A test 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.
- A voicemail was left on the telephone number(s) but no response was received within 1 hour of the voicemail.
- The tester was unable to contact anyone on the telephone number provided who has appropriate understanding or experience of the study or access to study related documentation.

4.12.1.4 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. Patients already recruited into a study must be made aware of any updated contact details. The sharing of this information should be documented on an EPR within each patient's TrakCare record. The Research Team should ensure any patient facing documents that include the updated contact details, including those kept in clinical areas for future recruits, are updated.

4.13.2 Clinical Trials Pharmacy Team Audit of Contact Details

4.13.2.1 As part of their regular document audit (see CTP030) the Clinical Trials Pharmacy Team must send a copy of the most recent completed 'Research Team – Research Team Contact Details' Workflow held in the Pharmacy File, by email to the PI or delegate for each study, to request confirmation that all contact details are still accurate.

4.13.2.2 The PI or delegate must either confirm by email that the contact details are still accurate or update the 'Research Team – Research Team Contact Details' Workflow in EDGE and provide the Clinical Trials Pharmacy Team with an updated copy.

5. ASSOCIATED DOCUMENTS

R&D WI09 - R&D Trial Patient Alert Procedure
R&D WI22 - Recording Details of Research in Medical Records
CTP030 - Active Pharmacy File Review and Audit
Doc Ref 39-05 – Unblinding Record

6. ABBREVIATIONS

AE	Adverse Event
CTIMP	Clinical Trial of Investigational Medicinal Product
CI	Chief Investigator
ECS	Emergency Care Summary
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	02 Mar 2020	Reference to NHS Fife Sponsored Trials removed. Further information added to clarify the process for documenting and testing appropriate 24-Hour Cover.
3	Julie Aitken R&D Quality & Performance Lead	20 July 2022	SOP title amended as this SOP now relates to all studies requiring medical cover, rather than just CTIMPs. Added requirement for 'Research Team – Research Team Contact Details' Workflow to be checked for all studies every 6 months. Reference to Doc Ref 39-01, 39-03, 39-04 and 45-01 deleted as these

			documents have been replaced with EDGE Workflows. Reference to Doc Ref 39-02 deleted. Section 4.10 now states that the Research team must contact the GP to request that the GP add details of the study to the Emergency Care Summary for that patient, if required by the Sponsor. The 'Research Team – Study Set-up Checklist' Workflow on EDGE has been updated to capture the outcome of this discussion with the Sponsor. Reference to 'Research Team – Unblinding record' added as this is now an option for recording details of unblinding.
4	Sophie Jeffrey Clinical Research Practitioner	10 July 2025	Added details of a new 'Study Contact Details and Unblinding Instructions for Pharmacy' report containing information from Contact Details workflows, which is saved in the Pharmacy Shared drive and refreshed daily by the Q&P Team. Clarified the process for recording unblinding and situations where Doc Ref 39-05 can be used prior to adding details to the 'Research Team – Unblinding Record' workflow in EDGE. Revised frequency for testing Emergency Contact numbers from 6 monthly to 12 monthly. Removed requirement for Q&P team to do a test call with the on-call pharmacist.

9. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director Research, Innovation & Knowledge, NHS Fife Signature: 	10 July 2025

APPENDIX A

Summary

PRIOR TO RECRUITMENT COMMENCING

Sponsor/Research Team/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 arrangement

Research Team

- Complete a 'Research Team - Contact Details' Workflow in EDGE
- Copies must be filed in Investigator Site File and Pharmacy File

FOLLOWING RECRUITMENT OF EACH PATIENT

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 R&D WI 22).
- Add a 'R&D Trial Patient' alert to the patient's record on TrakCare (see R&D 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.

For CTIMPS, 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 study 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 or other trial-specific point of contact using contact details on 'R&D Trial Patient' alert.

For CTIMPs, 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 representative:

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