

Out of hours access to clinical trial protocols and investigator brochures in pharmacy

IT IS THE RESPONSIBILITY OF **ALL** USERS OF THIS SOP TO ENSURE THAT
THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: <https://www.research.yorkhospitals.nhs.uk/sops-and-guidance/> and/or Q-Pulse

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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	19 th October 2015		
2.0	28 th February 2018		Reworded for clarity Author change
3.0	2 nd January 2020		Change of link to R&D website. Updated to include request of information out of hours if files are not kept on the York site.
4.0	21 st February 2024	Rachel Spooner	Change of Trust name. Added details of how to access electronic records via pharmacy x:drive and details of how to contact members of the team out of hours.

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1 Introduction, Background and Purpose

The Pharmacy Site File contains the essential documents for the conduct of a clinical trial. The Protocol and the Investigator Brochure (IB) both contain valuable safety information, however, a full IB is not required for every trial and where this is the case, the Summary of Product Characteristics (SmPC) may also be a valuable source of safety information.

In the event of a medical emergency involving a trial participant, the physician responsible for the patient or the Chief Investigator (CI) or Principal Investigator (PI) for the trial, may request access to the trial Protocol or IB to determine how best to treat the patient.

During normal working hours, the request will be handled by the pharmacy clinical trials team or the research team of the relevant speciality. Out of hours requests will be made via the on-call pharmacist who should be contacted via the hospital switchboard.

2 Who Should Use This SOP

This SOP should be used by all members of the pharmacy clinical trials team and on-call Pharmacists in York and Scarborough Teaching Hospitals NHS Foundation Trust

3 When this SOP Should be Used

This SOP should be used in the event that a request is received to access a trial protocol and / or Investigator Brochure

This SOP should not be used when a request to un-blind a trial is made. In this case follow Pharm/S54 – Managing Code Break Procedures and the specific trial instructions.

4 Procedure

4.1 Access to Clinical Trial Protocols and Investigator Brochures

Electronic access – Via the Pharmacy X: drive

Depending on the nature of the unblinding process/each individual trial there maybe different routes to obtain the information needed out of hours.

In the first instance to avoid coming into site, search on the Clinical Trials section of the X:drive found at the below route:

X:\Clinical Trials\Studies\3. Open to recruitment (patients receiving treatment)

In section one of the electronic file specific to the study will be the Pharmacy Trials Instructions. The Trial Summary will have a brief overview of the study and will include the Unblinding information.

Also available in the study specific electronic folder is the Protocol in section 12 and the Investigator Brochure and SmPC in section 13.

Ensure the most current version is referred to when accessing electronic documents.

On site access - Via the Pharmacy Site File

If needed (e.g., code break envelopes are used in the unblinding process) Pharmacy Site Files for all clinical trials being hosted or sponsored by York and Scarborough Teaching Hospitals NHS Foundation Trust can be located in the clinical trials dispensary (York). This includes studies that are conducted on the Scarborough site.

Locate the Pharmacy Site File for the study for which access to the protocol &/or Investigator Brochure is being requested. If you are working at Scarborough, call the pharmacy clinical trials team during working hours or call the on call pharmacist for York to access the information you require put of hours.

Locate the document being requested. A contents page (Pharm/F52) at the front of the file details the numbered section of the Pharmacy Site File in which the document can be found.

Use the contents page of the Protocol or IB to locate the section most relevant to the question being asked / information being requested.

Provide the requested information. In most circumstances this will be to a Clinician looking after the patient or the Chief Investigator (CI)/Principal Investigator (PI) for the trial.

Record or access to Clinical Trial information

Document the request and outcome on Pharm/F111 – Record of access to a clinical trial protocol and IB form.

If the request progresses to a request to break the code for the trial, follow the procedures detailed in Pharm/S54 – Managing Code Break Procedures.

Give the completed form to the pharmacy clinical trials team on the next working day or arrange for the form to be sent to the Pharmacy Clinical Trials Team joint mailbox by calling the office. The clinical trials team will file the form in the relevant section of the Pharmacy file (with the document to which access was requested).

Inform the Pharmacy Clinical Trials Manager (or delegate) of the request on the next working day.

The clinical trials team will notify all necessary parties of the request as appropriate (i.e. CI/PI, Clinical Research Associate or Sponsor, Research & Development Unit, Research Nurse) and the outcome as soon as possible.

If you can not locate the information you require, urgently contact the Pharmacy Clinical Trials Manager or Specialist Pharmacy Clinical Trials Technician, on the Pando app or their contact details are in the on call folder.

5 Related SOPs and Documents

Pharm/F111 – Record of Access to a Clinical Trial Protocol &/or Investigator Brochure Form

Pharm/S54 – Managing Code Break Procedures

Pharm/F52 – Pharmacy Clinical Trial File Contents Page

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