York Foundation Trust R&D Unit
SOP
Pharm/S106

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 R&D Newsletter 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: www.northyorksresearch.nhs.uk/sops.html

SOP Reference:	Pharm/S106
Version Number:	1.0
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Implementation date of current version:	19th October 2015

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	Date:	21st September 2015
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	Signature:	Signed copy held by R&D Unit
	Date:	21st September 2015

This SOP will normally be reviewed every 2 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	Details of significant changes
1.0	19th October 2015	

Contents

1 Introduction, Background and Purpose

The Pharmacy Site File contains essential documents for the conduct of a clinical trial at site. Pharm/F52 – Pharmacy Clinical Trial File Contents provides a list of the required contents of a Pharmacy file.

Two of these documents are of particular importance for the conduct of the trial, the Protocol and the Investigator Brochure (IB). Both documents give valuable safety information. In the non-commercial sector, a full IB is not always required as authorised products are more commonly used in these clinical trials. Where an IB is not required, the appropriate section on the Summary of Product Characteristics (SmPC) may be used as the reference safety information. For further information on the contents of these documents please refer to ICH-GCP.

In the event of a medical emergency in a trial participant, the physician responsible for the patient or the Chief Investigator (CI)/Principal Investigator (PI) for the trial, may request access to the trial Protocol or Investigator Brochure (IB) to help understand how best to treat the patient going forward. This request may come prior to a request to code break (for a double blind trial) and therefore this Standard Operating Procedure (SOP) should be used in conjunction with Pharm/S54 – Managing Code break procedures. This may occur either during normal pharmacy working hours or out of hours. During normal working hours, this request will be dealt with by a member of the Pharmacy clinical trials team, although in most circumstances during normal working hours this request can be directed to the research team of the relevant speciality with responsibility for the trial in the Trust.

In the event that access to the protocol or IB is requested out of hours the on-call pharmacist will be responsible for providing this access and they must be contacted via the hospital switchboard.

In both cases, the person dealing with the request should follow the procedures outlined below to access these documents.

2 Who Should Use This SOP

This SOP should be used by all members of the pharmacy clinical trials team (& on-call Pharmacists) in York and Scarborough Hospital, which form part of York Teaching Hospital 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.

4 Procedure(s)

Pharmacy Site Files for all clinical trials being hosted or sponsored by York Teaching Hospital NHS Foundation Trust can be located in the clinical trials dispensary (York) or the clinical trials room (Scarborough).

4.1 Access to Clinical Trial Protocols and Investigator Brochures

1. Locate the Pharmacy Site File for the study for which access to the protocol &/or Investigator Brochure is being requested.

2. 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.

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

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

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

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

7. File the completed form in the relevant section of the Pharmacy file (with the document to which access was requested).

8. 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.

9. If the request took place out of hours the on-call pharmacist must inform the Pharmacy Clinical Trials Manager (or delegate) of the request on the next working day. The Clinical Trial Manager (or delegate) must then check that all necessary parties are aware of this.

4.2 Maintenance of Clinical Trial Protocols and Investigator Brochures in Pharmacy

The latest version of both documents should be present in the Pharmacy Site File to ensure that they are available to provide the most up to date information regarding the trial and trial Investigational Medicinal Product.

The following aspects should be considered to ensure the most current version of each document is present;

- Protocol and IB amendments should be processed by the pharmacy clinical trials team in a timely manner once an implementation date is agreed.

It is the sponsor's responsibility to communicate any updates to the reference safety information, in either IB or SmPC, in a timely manner. Any updates to the reference safety information within the IB should be received from the sponsor as substantial amendment.

- A paper copy of all protocols and Investigator Brochures should be printed and placed in the Pharmacy Site File when required to do so.
- Pharmacy Site Files removed from the clinical trial dispensary for maintenance should be replaced at the end of the day to ensure their availability if access is required out of hours.
- The trial status inventory list should be maintained with the current version of each study protocol and IB/SmPC being used. See Pharm/S61 – Maintenance of the trials status inventory list for more details.

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/S61 – Maintenance of the Trials Status Inventory Dispensary List

Pharm/F52 – Pharmacy Clinical Trial File Contents Page

International Conference on Harmonisation – Good Clinical Practice

Pharm/S79 - Receipt and review of Protocol amendments in Pharmacy