York and Scarborough Teaching Hospitals NHS 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/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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

SOP Reference:	Pharm/S106
Version Number:	3.0
Author:	Poppy Cottrell-Howe
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Approved by:	Name/Position:	Stuart Parkes (Deputy Chief Pharmacist)
	Signature:	
	Date:	5th December 2019
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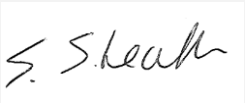
	Signature:	
	Date:	5th December 2019

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	Details of significant changes
1.0	19th October 2015	
2.0	28th February 2018	Reworded for clarity Author change
3.0	2nd 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.

Contents

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

1. 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.

2. 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.

3. 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.

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

5. 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.

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

7. 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.

8. Give the completed form to the pharmacy clinical trials team on the next working day, or arrange for the form to be sent in the internal mail if the form was not completed on the York site. The clinical trials team will file the form in the relevant section of the Pharmacy file (with the document to which access was requested).

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

10. 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.

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