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Humber Health Partnership

Multicentre Site Initiation SOP

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Working in partnership:
Hull University Teaching Hospitals NHS Trust
Northern Lincolnshire and Goole NHS Foundation Trust

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This page should detail the version history for this SOP and the main changes corresponding to the versions.

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, 27.10.10	J Pacynko	Original SOP approved by R&D Committee on 27.10.10.
Version 2, 08.03.11	J Pacynko	Change of title of PI responsibilities to PI Agreement. PI Agreement is now a separate document, not part of the contract. Safety reports added to ISF contents checklist. Wording of PI agreement up-dated. Addition of Site Assessment Checklist.
Version 3, 24.03.11	J Pacynko	Improvement to CRF section of PI Agreement.
Version 4, 14.11.13	J Pacynko	Review PI Agreement changed to PI Responsibilities Site initiation report added as part of Sponsor checks PI Responsibilities amended
Version 5, 20.04.15	J Pacynko	Changes of wording – in red type Addition of pharmacy section
Version 6, 31.Mar.2022	G Constable	SOP into new format. Replacing reference to HEY with HUTH. Pagination adjusted. EudraCT number changed to IRAS Project ID in headers of Appendices documents.
Version 7, 27.04.2026	L.Cox	Section 1 – Introduction Added reference to ICH E6(R3) quality-by-design, critical-to-quality factors and proportionate, risk-based approaches. Section 2 – PI Responsibilities Added expectations for risk-proportionate site processes and updated feasibility wording to reflect representative populations and operational feasibility. Section 3 – Pharmacy Responsibilities Added requirements for proportionate investigational product processes and compliance of electronic systems with data governance expectations. Section 4 – CI Responsibilities

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		Added wording on quality-by-design, identification of critical-to-quality factors and risk-based oversight. Section 5 – Sponsor Responsibilities Added focus on critical-to-quality factors during green-light review and oversight of electronic systems used for trial conduct. Appendix 1 – TMF Checklist Added statement aligning TMF management with ICH E6(R3) data life-cycle and electronic system requirements. Appendix 2 – PI Delegation of Duties Added requirement for delegated staff to understand critical-to-quality factors and risk-mitigation measures. Appendix 3 – Pharmacy Study File Checklist Added proportionate IP management expectations and data governance requirements for electronic systems. Update from HUTH to HPP incorporating both HUTH and NLaG.

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Please note
- **For definitions of acronyms refer to Appendix 2 of Management of SOPs.**
- **Refer to Appendix 3 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.**
- **Contact either the R&D QA Manager or Monitor for access to documents referred to in this SOP which are only available on the Trust's Y: drive in GCP SOPs & forms.**

1 Introduction, purpose and who should use this SOP

- All CTIMPs must be conducted according to the UK Clinical Trial Regulations and may be inspected by the UK competent authority, the Medicines and Healthcare products Regulatory Agency, in order to check compliance with the Regulations.

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- Multi-centre CTIMPs are clinical trials of investigational medicinal products that have more than one centre/research site.

- The benefits of multicentre trials include (1) being able to recruit a larger number of participants from different geographic locations, (2) the possibility of inclusion of a wider range of population groups and (3) the ability to compare results among centres.

- The lead research site has a Chief Investigator (CI) and the other research sites have a Principal Investigator (PI) for each site. The CI takes primary responsibility for the conduct of the multi-centre study whereas PIs have responsibility for the conduct of the study at their site.

- The purpose of this SOP is to describe what approvals and documents are required at each participating research site prior to the initiation of the site in order to comply with the UK Clinical Trial Regulations.

- This SOP should be used by all investigators involved with HHP-sponsored multi-centre CTIMPs. It is particularly relevant to the Chief Investigator, trial co-ordinator and all other research staff at the HHP lead research site.

- If the study is set up and managed by a Clinical Trials Unit rather than the HHP lead site, then this SOP should be used by the relevant CTU staff.

- This SOP should also be used by all HHP R&D staff and all HHP pharmacy staff involved with clinical trials.

- The set-up and initiation of multi-centre CTIMPs should incorporate a risk-based and proportionate approach. Factors critical to participant safety, data integrity and operational feasibility should be identified during study set-up, and site-initiation activities should focus on ensuring these critical-to-quality factors are in place prior to recruitment. Site-level processes should avoid unnecessary complexity and should be operationally feasible for the participating site, taking into account local care pathways, staffing, facilities and participant burden.

2 Principal Investigator responsibilities

Risk-Proportionate Conduct of Site Activities
The Principal Investigator must ensure that site-level processes are proportionate to the risks associated with the trial and the importance of the data being collected. The PI should prioritise activities that protect participant safety, support reliable data generation and maintain compliance with the approved protocol and regulatory requirements.

- To ensure the following approvals and documents are in place in the **Investigator Site File** (ISF) prior to site initiation:

Approvals

- A copy of the MHRA notice of acceptance (for the study and modifications)
- A copy of the REC favourable opinion (for the study and modifications)
- A copy of the HHP R&D approval (NHS permission) as lead site (for the study and

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- modifications)
- The original signed and dated participating site SSI form
- The original participating site R&D approval

Site feasibility or expression of interest form

- A form completed by the site confirming their willingness to take part in the study, the expected number of patients to be recruited at the site and that it is feasible for the site to carry out the study (signed by PI).

This assessment should consider local resources, staffing, facilities, care pathways, expected participant population, and any factors that may impact the site's ability to recruit a representative population in line with the intended trial population.

Site initiation report

- To document that the trial documents and procedures were reviewed with the research and pharmacy staff prior to the start of the study (signed by PI and trained staff).

Clinical Trial Site Agreement (CTSA)

- An original fully signed and dated CTSA including:
  - Payments made to sites
  - Suitable indemnity/insurance arrangements for the site
  - Archiving arrangements of Investigator Site File and CRFs with details of address of archive, contact details of archivist, list of trial files and allowed date of destruction

Principal Investigator Delegation of Duties

- Appendix 2 is a template of the duties/functions delegated to the PI by the CI and Sponsor. This may be modified according to the trial arrangements and may be incorporated into the site contract rather than kept as a separate document.

Study documents

- The current approved version of the protocol
- The current approved version of the patient information sheet
- The current approved version of the informed consent form
- The current approved version of the GP/hospital consultant letter (as applicable)
- Any other REC approved study documents
- Patient study cards
- The current version of the CRF including:
  - Inclusion/exclusion criteria checklist to be signed off by PI or delegated doctor
  - Instructions for randomisation
  - Instructions for safety reporting
- Instructions for the informed consent procedure
- Instructions for lab procedures (if applicable)
- Instructions for unblinding (if applicable)
- Instructions for pharmacy (if applicable)
- SAE initial and follow-up report forms (or link)
- Summary of Product Characteristics (link to website – electronic version to be used as expectedness reference)

Site Research Staff

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- The original delegation and signature log (fully completed and signed)
- The contact sheet with up-to-date contact details for each staff member
- Original signed and dated CVs of all site staff involved with the study.
- Copies of GCP training certificates of all site staff involved with the study.

ISF checklist

- The original ISF checklist signed off by the Principal Investigator.
- The ISF checklist includes the above approvals and documents
- A suggested checklist is in Appendix 1.

3 Participating site pharmacy responsibilities

- To ensure the following documents are in place in the **Pharmacy Study File** (PSF) prior to site initiation:

Pharmacy green light
Pharmacy section of site initiation report

- To document that the trial documents and procedures were reviewed with pharmacy staff prior to the start of the study. Pharmacy processes should be proportionate to the risks associated with the investigational product and should support the integrity of the randomisation, blinding and accountability systems. Pharmacy staff should ensure that any electronic systems used for IMP management comply with local data governance and security requirements.

Study documents

- The current approved version of the protocol
- Instructions for pharmacy (pharmacy manual)
- Instructions for randomisation (if applicable)
- Instructions for unblinding (if applicable)
- Summary/ies of Product Characteristics (link to website – electronic version to be used as expectedness reference)

CT Pharmacy Staff

- The delegation and signature log (completed by all site staff including pharmacy staff involved with the study)
- Pharmacy signature sheet (if applicable)
- The contact sheet with up-to-date contact details for study staff
- Signed and dated CVs of pharmacy staff on the delegation log.
- GCP training certificates of pharmacy staff on the delegation log.

Relevant regulatory information

PSF checklist

- The PSF checklist signed off by CT pharmacy. A suggested checklist is in Appendix 3.

4 Chief Investigator responsibilities

The Chief Investigator must ensure that trial-level processes reflect a quality-by-design approach, identifying critical-to-quality factors during study planning and ensuring that site-initiation activities

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address these factors. The CI should ensure that monitoring, data management and safety oversight plans are proportionate to the risks associated with the trial and the importance of the data collected.

- To ensure the following approvals and documents are in place in the **Trial Master File** prior to site initiation:

For the study:
- The original MHRA notice of acceptance (for the study and modifications)
- The original REC favourable opinion (for the study and modifications)
- The original HHP R&D approval as lead site (for the study and modifications)
- The current approved version of the protocol and superceded versions.
- The current approved version of the patient information sheet and superceded versions
- The current approved version of the informed consent form and superceded versions
- Any other REC approved study documents (and superceded versions)
- An example of the patient study card
- The current approved version of the GP/hospital consultant letter (as applicable) and superceded versions
- The current version of the CRF and superceded versions

From the participating site to be initiated:
- A copy of the SSI form (signed and dated by the Principal Investigator)
- A copy of the site R&D approval
- An original fully signed and dated site contract (model clinical trial agreement)
- An original fully signed and dated Principal Investigator Responsibilities
- A copy of the site delegation and signature log (fully completed and signed)
- A copy of the site staff contact sheet (up-to-date)
- Copies of CVs (signed and dated) of all site staff involved with the study
- Copies of GCP training certificates of all site staff involved with the study.
- A copy of the ISF checklist signed off by the Principal Investigator. Appendix 1 is a suggested ISF checklist.

5 Sponsor responsibilities

- Once the Sponsor (HHP R&D manager) receives a copy (electronic or paper) of the following documents from the Chief Investigator or trial co-ordinator then the Sponsor will email the 'green light' letter to the PI instructing the site to start the study. The Sponsor must ensure that site-initiation checks focus on factors critical to participant safety, data reliability and protocol compliance. Before sponsor greenlight, confirm the trial has been registered in a publicly accessible registry. The Sponsor should confirm that site processes, staffing and facilities are adequate and proportionate to the risks associated with the trial.
- Where electronic systems are used for document storage, communication, safety reporting or data capture, the Sponsor must ensure that appropriate data governance, access control and audit trail requirements are met.

- Clinical Trial Site Agreement (fully signed)
- Principal Investigator Delegation of Duties (fully signed, may be part of CTSA)
- Site initiation report (signed by trial co-ordinator/trained staff)
- ISF checklist signed off by the PI

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- PSF checklist signed off by pharmacy
- Local site R&D approval
- Local site pharmacy greenlight

- Appendix 3 is the template for the sponsor 'green light' letter allowing a research site to start. The original signed copy will be sent to the PI for filing in the ISF.

- All the above documents will be saved electronically in the Y: drive in GCP SOPs & forms in the Green Lights section of the study folder. Paper copies will be kept in the Sponsor Study File in the R&D office.

6 Implementation

- Implementation of this SOP will conform to the process outlined in **R&D SOP 01 Management of SOPs**

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Appendix 1

Study title:		R&D ref no:
Sponsor: Hull University Teaching Hospitals NHS Trust	IRAS Project ID:	Chief/Principal Investigator:

TRIAL MASTER FILE

LIST OF CONTENTS

This Trial Master File should be maintained in accordance with ICH GCP and should support the full data life-cycle, including data capture, review, correction, transfer, retention and destruction. Where electronic systems are used, appropriate validation, security, audit trails and access controls must be in place.

Key: **R** = Documents **required** at start of study
N = Documents absolutely **necessary** before study can start

This file will hold the original study documents.
At study end, this file will require secure archiving but will need to be readily available upon request.

*Available from the R&D clinical trials monitor

Section No.	Section	Contents	Document version	Monitor check date & initials Any comments
1	Communication	Study Staff Contact Sheet*	**R** □ copy	……
		Study Tracking Log*	□ copy	……
		Visit Record*	**R** □ original	……
		Monitoring plan (signed & dated)	**R** □ original	……
		Monitoring Action Sheets	□ originals	……
		File Note Template	□ copy	……
		Protocol Deviations Form*	□ copy	……
		General correspondence	□ copies	……

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2	Patients	Study Patient List* (screening, recruitment & identification)	**R** □ original	……
		Blank Informed Consent Form**	**R** □ copy	……
		Blank Patient Information Sheet**	**R** □ copy	……
		Patient study card example	**R** □ copy	……
		Blank GP letter (**on headed notepaper)	**R** □ copy	……
		Signed Informed Consent Forms	**R** □ original	……

Section No.	Section	Contents	Document version	Monitor check date & initials Any comments
3	Study Medication & Materials	Reference Safety Information (RSI) file note	**R** □ copy	……
		Study Medication Compliance Form*	**R** □ originals	……
		Sample Label attached to Medication container (pharmacy)	**R** □ copy	……
		Study prescription template	**R** □ copy	……
		Instructions for handling of Medication & Materials (if not in protocol, SPC or pharmacy file)	**R** □ copy	……
		Supply/Receipt/Return Forms (pharmacy)	**R** □ copies	……
		Certificate(s) of Analysis of Medication & New Batches (pharmacy)	**R** □ copies / originals	……
		Decoding procedures for blinded trials (if not in protocol or pharmacy file)	**R** □ copy	……
		Randomisation Code Envelopes/List (pharmacy)	**R** □ original	……
		Documentation of destruction of medication at study end (pharmacy)	□ copy	……
4	Medical/ laboratory/ technical	Laboratory agreement (if external lab being used).	**N** □ original	……
		Record of samples stored *	**R** □ copy	……

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	procedures and tests	Description of procedures/tests (if not in protocol) Normal Ranges & updates (file note) Name & Address of Head of Laboratory (file note) QC Certificates/QC assessments/ Accreditation Servicing/calibration/maintenance records of trial equipment (file note)	**R** □ copy **R** □ copy □ copy □ copy □ copy	…….. …….. …….. …….

Section No.	Section	Contents	Document version	Monitor check date & initials Any comments
5	Investigator Documents	Training and Delegation Log* Study Training Record* Formal agreement of investigator and sponsor* (signed & dated) Study Agreement (Research Sponsorship Agreement or Grant Agreement – signed & dated) Curriculum vitae of Study Personnel (signed & dated) GCP Training Certificates Honorary contracts (signed & dated)	**N** □ original **N** □ original **N** □ original **N** □ original / Copy **R** □ originals R □ copies R □ copies	…….. …….. …….. …….. …….. …….. ……
6	HEY R&D Department	Confirmation of R&D Capability and Capacity Confirmation of R&D Capability and Capacity for protocol modifications (if any)	**N** □ copy of email **N** □ copy of email	…….. ……
7	Research Ethics Committee	REC favourable opinion of study protocol with list of REC members.	**N** □ original	……

		REC application form (signed & dated), covering letter and REC/investigator response letters/emails	**R** □ copy/ original	……
		Annual progress reports to REC, covering letters and REC/investigator response letters/emails - copy to R& D	□ copy/ Original	
		Notification of any Safety Information	□ copy/ original	……

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Section No.	Section	Contents	Document version	Monitor check date & initials Any comments
8	Regulatory Affairs (MHRA)	MHRA clinical trial authorisation MHRA application form (signed & dated), covering letter and MHRA/investigator response letters/emails Development Safety Update Reports, covering letters and MHRA/investigator response letters/emails - copy to REC & R&D End of Trial Declaration Form, covering letter and MHRA/investigator response letters/emails - copy to REC & R&D	**N** □ original **R** □ copy / original □ copy/ original □ copy/ original	…….. …….. …….. ……..
9	Health Research Authority	HRA approval letter Notification of assessment arrangements email/ requests for information/investigator responses		
10	Substantial Modifications/ Modification of an Important Detail/ Minor Modification	Notification of substantial modification/Modification of an Important Detail/ Minor Modification forms (signed & dated) covering letter and MHRA/REC/HRA investigator response letters/emails	□ copy/ original	……
11	Indemnity/ Insurance	Indemnity/Insurance Arrangements Indemnity Form (if applicable)	**N** □ copy / original **N** □ copy / original	…… ……
12	Serious Adverse Events	SAE/SAR/SUSAR reports and related correspondence Any other safety information sent to MHRA, REC and R&D	□ original □ original	…… ……

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		SAE/SAR/SUSAR File Note* (includes definitions and link for report forms)	**R** □ copy	……

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Section No.	Section	Contents	Document version	Monitor check date & initials Any comments
13	Finances	Investigation costs, patient expenses, study funding etc.	□ copies	……..
14	Study Documents	Protocol (signed & dated) Protocol Modifications(signed & dated) Advertisement for recruitment (if one) GCP SOPs File Note* UK Clinical Trial Regulations File Note* Minutes of study meetings (team, department, TMG, TSC, DMC meetings) Final Clinical Study Report (summary) - including summary of all adverse events - copy to REC, MHRA & R&D Publications, posters, presentations	**N** □ original □ original **R** □ copy **R** □ copy **R** □ copy □ copy □ copy □ copies	…… …… …… …… …… …… …… ……
15	Case Report Forms	Sample CRF Completed CRFs(signed & dated by PI) May need to be filed separately Data Queries Log	**R** □ copy □ originals □ original	…… …… ……
16	Data Management	Data Management File Note	**R** □ original	……
17	Archiving of Trial Master File & CRFs.	Archiving File Note* (with address of archive, contact details of archivist, list of trial files and allowed date of destruction)	□ copy	…… Original to be kept by Chief/ Principal Investigator.

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Appendix 2

Study title:	**IRAS Project ID:**
Principal Investigator:	**Hospital/GP address:**
Chief Investigator:	**Sponsor: Hull University Teaching Hospitals NHS Trust**

Principal Investigator Delegation of Duties

The Chief Investigator (insert name) and Sponsor (Humber Health Partnership (HHP) R&D department) delegate the following duties to the Principal Investigator to ensure that the (insert acronym) trial is conducted according to the UK Clinical Trial Regulations and GCP.

Duties delegated to Principal Investigator

Site-specific Information Form

- To complete and submit the SSI form to the local site R&D department. HHP lead research site/CTU will provide guidance and a template SSI form.

Delegation

- To ensure the completion of the study *Delegation and Signature Log* prior to the start of the study to confirm all the research staff involved with the study and their delegated duties. The signature and initials of staff ensure they can then be identified on forms, medical records etc.
- To keep the *Delegation Log* up-to-date on an ongoing basis.
- To send the up-to-date *Delegation Log* to HHP lead site/CTU annually or upon request to allow central monitoring of the log.

Training

- To ensure all research site staff who are involved with the study are familiar with the protocol and have been trained in the study procedures (including informed consent procedure and safety reporting).
    - Risk-Based Conduct of Trial Activities - The PI must ensure that delegated staff understand the critical-to-quality factors for the trial and that site processes are proportionate to the risks associated with the investigational product and trial procedures. Staff should be trained in any risk-mitigation measures relevant to their delegated duties.
- To ensure GCP training of all site staff is up-to-date.

Investigator Site File

- To keep all study documents and correspondence in an *Investigator Site File (ISF)*. This file will be provided by the lead site/CTU.
- To sign off the ISF contents checklist and send to the lead research site to confirm the necessary study documents are in place prior to the start of the study.

Study medication

- To ensure all procedures regarding study medication are followed according to the protocol and pharmacy instructions.

Study equipment

- To ensure any equipment used during the course of the trial is maintained, serviced and calibrated according to local Trust policy.

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Study start

- To ensure that the following are in place prior to the *first patient being consented* and entered into the study and prior to any screening procedure being done:
  - **Local pharmacy greenlight**
  - Local site R&D approval (NHS permission)
  - Site Agreement (fully signed)
  - Investigator Site File
  - HHP **R&D sponsor letter – the green light for the study to start.**

Protocol

- To conduct the trial in compliance with the protocol approved by the MHRA, Research Ethics Committee (REC) and Trust (HHP and local).
- Not to deviate from or change the protocol without agreement from the Chief Investigator, CTU and HHP R&D.
- To notify lead HHP site/CTU promptly of any protocol deviations.
- To notify Chief Investigator/lead HHP site/CTU/HHP R&D of any serious breaches **within 24hrs** of knowledge of serious breach.

Consent

- To check that the *latest REC and R&D (local and* HHP*) approved versions* of the informed consent form (ICF), patient information sheet (PIS) and GP/hospital consultant letter are used when recruiting patients.
- To ensure that only the PI or Co-investigators (study doctors) on the study *Delegation Log* answer the final patients questions and countersign the consent form after the patient. (Insert research nurse if delegation approved by REC).
- To ensure that the ICF is signed and dated by the patient and study doctor (and insert research nurse if applicable) before any study related procedure is performed (including screening).
- To keep the fully signed and dated original ICF in the Investigator Site File.
- To give one copy of the signed ICF to the patient.
- To file one copy of the signed ICF in the patients casenotes/medical records together with a copy of the PIS, the letter sent to the patient's GP/hospital consultant and the signed inclusion/exclusion criteria checklist.

GP/hospital consultant letter

- To send out the GP/hospital consultant letter ideally on the day of consent or shortly after the date of consent.

Case report forms (CRFs) and data queries

- To ensure the accuracy and legibility of CRFs (patient data collection forms).
- To complete CRFs as fully as possible.
- To send CRFs to the HHP lead site/CTU promptly after each patient visit.
- To resolve and respond to any data queries generated by the lead HHP site/CTU **within one month** of receipt of queries. Insert < Payments will depend on return of outstanding data queries> if applicable.

Patients casenotes

- To ensure patient study visits are clearly recorded in patient's casenotes/medical records as visits occur.
- HHP lead site/CTU will provide guidance. The minimum details to record are*;*
- *Clearly written date of visit or contact, brief study title/acronym and visit number,*
- *Date patient given patient information sheet,*
- *Date consent form signed,*
- *Date of screening,*
- *Medical history, concomitant diseases and medication including study medication, and any changes in*

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concomitant diseases and medication at subsequent visits,
- *Anything which is relevant to the ongoing care of the subject;*
- *Relevant results and study medic's assessment of these results.*
- *Brief description of any AEs with start & stop times/dates and any significant test results or a medical summary of events if more appropriate.*
- *Any other relevant information.*

Samples
- To ensure that samples are taken, processed, stored and transferred to the central lab for analysis according to the Protocol and Trial Samples Guide produced by HHP lead site/CTU.

Modifications
- To implement any modifications to the protocol which have been notified to you by the Chief Investigator/lead HHP site/CTU after obtaining local R&D approval.

Safety reporting
- To ensure reporting and documenting of all adverse events (serious and non-serious) according to the protocol and as requested in the CRF or by the lead HHP site/CTU.
- Report **all** serious adverse events (SAEs) to the lead HHP site/CTU **within 24 hours** of becoming aware of the event according to instructions provided by lead HHP site/CTU.
- Report additional follow-up information to lead HHP site/CTU as available or upon request until the SAE has resolved or a decision has been taken for no further follow-up.
- To ensure that a study medic assesses the seriousness, intensity, relatedness and unexpectedness of SAEs.
- As PI to review and sign off all SAEs at site. The PI's decision on relatedness and unexpectedness will not be overruled by the CI or Sponsor.
- To file the original signed SAE report forms in the Investigator Site File.
- <Delete this section if not relevant> If a study patient falls pregnant during the course of the clinical trial, follow the instructions in the safety section in the protocol.

End of trial
- To notify the Chief Investigator/CTU and Sponsor immediately of any reason to stop the trial.
- To end recruitment for the trial when notified by the Chief Investigator/CTU.

Archiving
- To archive the Investigator Site File and CRFs in a secure location as stipulated in the site agreement until the allowed date of destruction.
- To obtain permission from the Chief Investigator before destruction of the Investigator Site File and CRFs.

As Principal Investigator, I confirm that I have read, acknowledge and understand the above duties. I acknowledge and understand that:
- **I take responsibility for the initiation and conduct of the study at my site. If I delegate some of the above duties, I still remain responsible for them.**
- **The Sponsor reserves the right to temporarily suspend or terminate the study at my site at any time for reasons including (but not limited to) safety or ethical issues, or severe GCP non-compliance.**
- **An on-site visit by the CI/Sponsor/CTU may be required for serious issues or non-compliance.**

	Name	Signature	Date
Principal Investigator			

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Chief Investigator			
HHP R&D Manager			

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Appendix 3

Study title:	
R&D ref no:	**IRAS Project ID:**
Principal investigator:	**Hospital/GP address:**
Sponsor: Hull University Teaching Hospitals NHS Trust	

PHARMACY STUDY FILE

CONTENTS CHECKLIST

Documents in bold type must be present in file before site initiation. Pharmacy to sign off and send this form to HHP lead site/CTU when all documents in bold are present.
Pharmacy staff should ensure that investigational product management processes are proportionate to the risks associated with the product and trial design. Where electronic systems are used for accountability, temperature monitoring or stock control, these must comply with data governance and audit trail requirements.

This file will contain original essential study documents, please keep in a secure location. At study end, this file will require secure archiving but will need to be readily available upon request.

Section No.	Section	Contents	Document version	Tick if documents present
1	Contacts	Study Staff Contact Sheet	Copy	☐
		Delegation and Signature Log	Copy	☐
		Pharmacy Signature list	Original	☐
		CVs (signed and dated) of CT pharmacy staff on Delegation Log	Originals	☐
		GCP training certificates of CT pharmacy staff on Delegation Log	Originals	☐
2	Dispensing	Dispensing procedure	Copy	☐
		Prescriptions	Originals	☐
		Study Medication Accountability Forms	Originals	☐
			Copy	☐

Docusign Envelope ID: 1B25761E-97DE-86F4-8335-7DE05D6CEA32

Section No.	Section	Contents	Document version	Tick if documents present
3	Study medication	Emergency code breaking procedure for blinded trials		
		Emergency code break forms	Copies	☐
		Randomisation instructions/ Randomisation Code Envelopes/List (as applicable)	Originals	☐
		Supply/Receipt/Return Forms	Copies / Originals	☐
3	Study medication contd.	Sample Labels	Copy	☐
		Summary of Product Characteristics (file note)	Copy	☐
		Certificate(s) of Analysis of Medication & New Batches	Copies / originals	☐ ☐
		Documentation of destruction of medication at study end	Original / copies	☐ ☐
4	Study Documents	Pharmacy manual/instructions	Copy	☐
		Pharmacy greenlight	Copy	☐
		Pharmacy financial arrangements	Original/copy	☐
		Study protocol and relevant modifications	Copies	☐ ☐
		Study document tracking log	Copy	
5	Regulatory information	Relevant pharmacy MHRA, REC, HRA and R&D information	Copies	☐

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Section No.	Section	Contents	Document version	Tick if documents present
6	Communication	Emails, study updates, letters, file notes etc.	Copy	☐

As Pharmacy CT representative,
I confirm that the documents in bold type are present in this Pharmacy Study File.

Name: _____ **Signature:** _____ **Date:** _____

(Insert sending instructions) Please sign and date when all documents in bold are present and email (insert email address) or fax (insert no.) on the same day, marked for the attention of (insert name).

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Appendix 4
Sponsor Greenlight Letter

Address of HHP R&D Department
R&D Office telephone numbers

Date of letter

Study title:	
Sponsor R&D ref no: **CSP no.**	**IRAS Project ID:** **REC ref no**:
Principal investigator:	**Hospital/GP address:**
Sponsor: Hull University Teaching Hospitals NHS Trust	**Participating site:**

Dear Principal Investigator

Regarding the above clinical trial for which you are a participating site, the R&D Office at Humber Health Parnership has received the following documents (amend list of documents as applicable):

- Confirmation of R&D C&C dated…
- Site initiation report signed…
- A fully signed model clinical trial site agreement dated…
- Principal Investigator Delegation of Duties signed …
- Pharmacy greenlight dated …
- PSF checklist signed…

We are satisfied that the trial co-ordinator/CTU have made the necessary checks to ensure the essential study documents are in place at your site and that research staff have been appropriately trained.

Please take this letter as confirmation from the Sponsor for you to commence recruitment to this study at your site.

Thank you for your participation in this trial.

Yours sincerely

R&D Manager
Humber Health Partnership