1. Introduction

This Standard Operating Procedure (SOP) describes the process required to satisfy legislative requirements for Privacy and Data Protection at University Hospitals of Leicester NHS Trust (UHL). It details the steps required to confirm that all research activity hosted by UHL complies with the Data Protection Act 2018 and provides appropriate assurance to the Privacy and Data Governance Committees within the Trust.

2. Scope

This SOP applies to all research activity that is hosted by the University Hospitals of Leicester NHS Trust (UHL).

3. Data Protection & Privacy

The Data Protection Act 2018 sits alongside the General Data Protection Regulations (GDPR) adopted into Europe in 2018. The Act has EIGHT (8) principles:

That data collected is:

- Fair and lawful.
- Specific for its **purpose**.
- Be adequate and only for what is needed.
- Accurate and up to date.
- Not kept longer than needed.
- Take into account people's rights.
- Kept safe and secure.
- Not be transferred outside the EEA.

UHL as an organisation has an obligation to ensure that all data collected, for any purpose adheres to these principles.

4. Data Flows

UHL has a legal obligation to know what data are being collected. Where that data is stored, how long it's being stored for, where it's being stored and if it's stored appropriately. Additionally information is required about whether or not the data is being transferred out of the organisation and if so the method of transfer, the security of the data during transfer and the receiving organisations have appropriate processes and systems to retain it securely.

This SOP deals only with the details for research studies and does not go into detail about the Data Protection Act 2018 or GDPR specifically. When the processes are followed within this SOP, assurance can be provided to Privacy and Information Governance Committees at UHL that all necessary questions have been answered, and all relevant information has been collected for flows of data and issues of data security.

In addition and in most cases, research is subjected to external scrutiny by the Health Research Authority (HRA). Additional guidance is provided https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/.

5. Data Privacy Impact Assessment (DPIA)

A DPIA has been developed by the UHL Privacy Team. This document must be completed where data is collected. Further guidance on the completion of the document and when it is required is detailed on the INSITE pages. It is important to note that a completion of a DPIA document is not usually required for individual research studies. This is because we've agreed an alternative approach.

5.1 Completing a DPIA for research

Agreement has been reached with the UHL Privacy Team that a separate DPIA document is not required for research. Instead the questions that are relevant to research have been added as a list of attributes in the EDGE Research management database. These attributes are contained within an Entity named 'Data Flows / GDPR'. This Entity has been added to and is being completed for every research study active at UHL from 1st April 2018 onwards. The research teams are asked to complete a Google Form which details all the questions required for the Entity. Once completed the Google Form is sent to Research and Innovation and the data is used to populate the questions listed in the Entity. The process is detailed in a Flow Chart at Appendix 1.

On occasion there is a requirement for data to be transferred from UHL to an external organisation. These external organisations are categorised as 'Third Party'. Following feedback from the research community it was agreed to separate out the information required for ALL research activity from the additional information required where the Third Party transfers were required.

The new Entity lists are to be used with effect from 1st October 2020. They can be identified as:

- Data Flows / GDPR v2 W.E.F 01/10/2020
- External / 3rd Party Data Transfers W.E.F. 01/10/20

5.2 Completing DPIA for third party transfer

Not all research studies require that data is shared with a third party. Where a third party has been identified, additional question are required and this is represented by a second Google Form and Entity list named 'External / 3rd Party Data Transfers W.E.F 01-10-20'. Once added, the entity must be completed and the UHL Privacy Team notified of the study name and EDGE ID by email. In addition a Workflow named 'Privacy Team Workflow – EXTERNAL DATA FLOWS' must be added to the project on the 'SITE' or 'RED' level. This workflow enacts as confirmation that all Privacy checks have been completed and that the study is ok to start.

6. Reporting to Privacy

A regular report on all data flows is produced by UHL R&I and sent to the UHL Privacy Team.

7. Responsibilities

	Responsibility	Undertaken by	Activity
1	R&I	Research Personnel working study up for Capacity and Capability	Add 'Data / GDPR' attribute and send Google Form link to research team
2	R&I	Research Personnel working study up for Capacity and Capability	Populate 'Data / GDPR' attribute list from Google Form. If Third Party identified, send additional Google Form to research team, add External / 3rd Party Data Transfers W.E.F. 01/10/20 to the study along with the 'Privacy Team Workflow – EXTERNAL DATA FLOWS' and adding the UHL Privacy Team to both the GREEN and RED levels of EDGE
3	R&I	Research Personnel working study up for Capacity and Capability	Notify UHL Privacy Team of the study by email and that the External / 3rd Party Data Transfers W.E.F. 01/10/20 is being or has been completed.
4	R&I	Research Personnel working study up for Capacity and Capability	Notify UHL Privacy Team when External / 3rd Party Data Transfers W.E.F. 01/10/20 has been fully completed
5	UHL Privacy Team	UHL Privacy Team	Review External / 3rd Party Data Transfers W.E.F. 01/10/20. Complete relevant internal process. Once finalised, complete 'Privacy Team Workflow – EXTERNAL DATA FLOWS' to confirm that all relevant checks have been completed and that UHL Privacy are in agreement for the study to commence.

7. Supporting Documents and Key References

SOP C-2029 - Appendix 1

8. Key Words

Research, Innovation, Volunteers, Participants, Trials, Privacy, GDPR, DPIA, Data Protection Act

This line signifies the end of the document

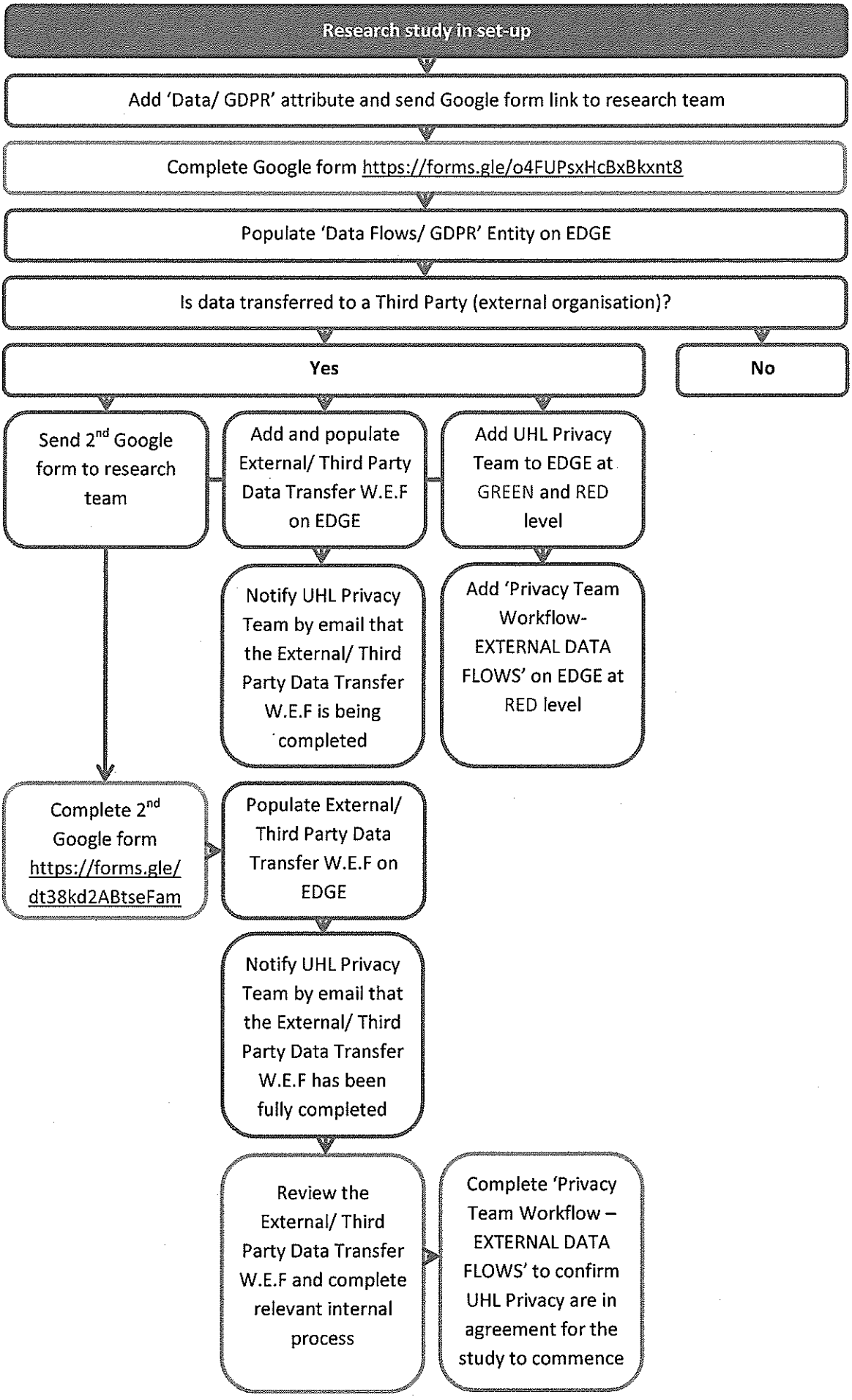
This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	UHL Research Management Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved:** 16/2/21

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

DISTRIBUTION RECORD:			
Date	**Name**	**Dept.**	**Received**

Appendix 1 - SOP-C-2029: Compliance with GDPR and Privacy in Research Flowchart



LEICESTER'S RESEARCH

NHS
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UHL Site Initiation Checklist for CTIMP Studies

1. Site Information

Site	Initiation Visit Method
Sponsor Reference Number:	On Site ☐
Study Name:	Teleconference ☐
Investigator:	Other (specify) ☐
Study Site:	
Date of Initiation:	
Conducted by:	

2. Personnel in Attendance

Name	Title

3. Study Overview/Protocol Overview

Items discussed/verified	Comments
Background and purpose of study	
Study IMP(s)	

4. GCP and Regulatory Compliance

Items Discussed/verified	Yes	No	Comments
Investigator obligations	☐	☐	
Sponsor obligations	☐	☐	
Standard Operating Procedures	☐	☐	
Ethics reporting requirements	☐	☐	
MHRA reporting requirements	☐	☐	
Sponsor reporting requirements	☐	☐	
Amendments	☐	☐	
Annual reports	☐	☐	
DSUR/ Annual Safety Report	☐	☐	
Data Protection/ GDPR	☐	☐	
Study record storage requirements	☐	☐	
Archiving arrangements	☐	☐	

5. Trial Master File/Investigator Site File

Items Discussed/verified	Yes	No	Comments
TMF/ISF created and complete	☐	☐	
Delegated individual for TMF/ISF maintenance	☐	☐	
Secure location/limited access	☐	☐	

6. Study Approval Status/Essential Documents

Items Discussed/verified	Yes	No	Version/ Comments
MHRA approval	☐	☐	
REC favourable opinion/HRA approval	☐	☐	
Composite of REC committee	☐	☐	
R&D/R&I Capacity & Capability	☐	☐	
Signed Sponsor/CI agreement	☐	☐	
Signed financial agreement/ contract	☐	☐	
Indemnity/Insurance	☐	☐	
Approved reference safety information: Investigator Brochure/SmPC	☐	☐	
Protocol (+ protocol signed by CI/PI/Sponsor)	☐	☐	
Protocol deviation/Serious breach reporting	☐	☐	
Patient information leaflet/ sheet (document version no. and date)	☐	☐	
Contact numbers on patient information leaflet/ sheet been checked?	☐	☐	
Consent (document version no. and date)	☐	☐	
Patient invitation (document version no. and date)	☐	☐	
GP letter (document version no. and date)	☐	☐	
Advertisement	☐	☐	

(document version no. and date)			
CRF (document version no. and date)	☐	☐	
ARSAC License	☐	☐	
Other	☐	☐	
Schedule of Source Data (SOP S-1007) completed	☐	☐	

7. Investigator Site Personnel

Items Discussed/verified	Yes	No	Comments
Adequate site staff to conduct the study	☐	☐	
Signed and dated CV for all study team members	☐	☐	
Documented evidence of GCP training/study specific training for all study team members	☐	☐	
All study team members listed on delegation of authority & signature log; all entries signed and dated by PI	☐	☐	

8. Recruitment

Items discussed/verified	Yes	No	Comments
Planned number of trial subjects	☐	☐	
Methods for identifying subjects	☐	☐	
Requirement to complete subject screening logs	☐	☐	
Requirement to complete subject enrolment logs	☐	☐	
Procedure for withdrawn subjects/lost to follow-up	☐	☐	

9. Informed Consent/Enrolment/Randomisation

Items Discussed/verified	Yes	No	Comments
Informed consent procedures/documentation requirements	☐	☐	
Eligibility criteria	☐	☐	
Consent audit requirements, per study risk strategy	☐	☐	
Randomisation procedures	☐	☐	
Unblinding procedure/ code break envelopes	☐	☐	
Which team members are blinded/ unblinded	☐	☐	

10. Investigational Medicinal Products

Items discussed/verified	Yes	No	Comments
QP release document	☐	☐	
Certificate of analysis	☐	☐	
Receipt	☐	☐	
Labelling and packaging	☐	☐	
Storage requirements	☐	☐	
Dispensing procedures	☐	☐	
IMP accountability	☐	☐	
Return of IMP procedures	☐	☐	
Reordering procedures	☐	☐	
Drug destruction	☐	☐	

11. Safety Reporting/Pharmacovigilance

Items Discussed/verified	Yes	No	Comments
AE / SAE reporting procedures	☐	☐	
SUSAR reporting procedures	☐	☐	
eSUSAR access	☐	☐	
Notification process	☐	☐	
Urgent Safety Measures	☐	☐	
DSUR /Short format DSUR	☐	☐	
Data safety monitoring board/ committee meeting and reporting requirements	☐	☐	

12. Data Management

Items Discussed/verified	Yes	No	Comments
Format and timelines	☐	☐	
CRF completion guidelines	☐	☐	
Are all study related documentation designed to ensure that they are anonymised by the use of study patient identifier	☐	☐	
Is all study hard copy documentation stored in a restricted access area	☐	☐	
Is access to electronic study records and files password protected?	☐	☐	
Are computer records and files containing identifiable data stored on a remote and secure server? Are emergency recovery processes in place?	☐	☐	
Requirements for Queries and corrections resolution	☐	☐	
eDC training (for electronic case report forms)	☐	☐	
Are electronic data files for analysis anonymised?	☐	☐	
Data Management plan in place (If applicable)	☐	☐	

Statistical analysis plan requirements	☐	☐	

13. Source Documentation

Items Discussed/verified	Yes	No	Comments
Source data agreement/ schedule	☐	☐	
CRFs as source	☐	☐	
Document retention period	☐	☐	
Archiving responsibilities at end of study	☐	☐	

14. Equipment List

Items Discussed/verified	Yes	No	Comments
Equipment list	☐	☐	
Calibration of equipment	☐	☐	
Maintenance/service record requirements	☐	☐	

15. Specimen collection

Items Discussed/verified	Yes	No	Comments
Specimen collection	☐	☐	
Sample result verification. CS/NCS status and required actions	☐	☐	
Specimens to be obtained	☐	☐	
Specimen storage	☐	☐	
Specimen storage and tracking logs	☐	☐	
Temperature monitoring	☐	☐	
Sample shipment	☐	☐	
Laboratory training/manual/SOPs	☐	☐	
Lab kits	☐	☐	
Lab accreditation	☐	☐	
Lab reference ranges	☐	☐	

16. Communications

Items discussed/verified	Yes	No	Comments
Format and frequency	☐	☐	
Site contacts	☐	☐	
Recruitment updates to Sponsor/ EDGE/ CPMS	☐	☐	

17. Monitoring

Items discussed/verified	Yes	No	Comments
Site monitoring plan	☐	☐	
Site monitoring response requirements	☐	☐	

18. SOP

Items discussed/verified	Yes	No	Comments
Are the most current SOPs on file or do the study team know how to access the Sponsor SOPs via	☐	☐	

the webpages?			
SOP read list completed for all study team members?	☐	☐	

Additional Comments/ Visit Overview

Study commencement must not occur until Sponsor Green Light process has been completed

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UHL Site Initiation Outstanding Issues Report

Sponsor Reference and Short Title:

Date of Visit: **Date of Report:** **Date Responses Due Back:**

No	Outstanding Issue	Action required	Action Taken	Signature & Date

SIV Completed By:

Name:
Role:
Telephone:
e-mail:
Signature:
Date:

Report Responses Completed By:

Name:
Telephone:
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed SIV Report Approved/ Closed By:

Name:
Role:
Signature:
Date:

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UHL Pharmacy Initial Visit Checklist

Site Information

Site	Initiation Visit Method	
Sponsor Reference Number:	On Site	☐
Study Name:	Teleconference	☐
Study Phase:	Other (specify)	☐
Investigator:		
Study Site:		
Date of Initiation:		
Conducted by:		

Personnel in Attendance

Name	Title

Study Overview

Items discussed/verified	Comment
Study IMP(s)	

Training Log

Items Discussed/verified	Yes	No	Comment
Signature log	☐	☐	

Contact Details

Items Discussed/verified	Yes	No	Comment
Contact details	☐	☐	

1. Synopsis

Items Discussed/verified	Yes	No	Comment
Study synopsis	☐	☐	
Document version control history	☐	☐	

2. Dispensing

Items Discussed/verified	Yes	No	Comment
Dispensing procedure	☐	☐	
Labelling/ over-labelling	☐	☐	
Master label			

3. Drug Accountability

Items Discussed/verified	Yes	No	Comment
Master inventory log	☐	☐	
Master patient specific log	☐	☐	

4. Prescriptions/Worksheets

Items Discussed/verified	Yes	No	Comment
Master	☐	☐	

5. Order and Receipt

Items Discussed/verified	Yes	No	Comment
Procedure	☐	☐	
Order	☐	☐	
Receipt	☐	☐	
C of A/QP release certificates	☐	☐	
Re-labelling	☐	☐	

6. Returns/Destruction

Items Discussed/verified	Yes	No	Comment
Procedure	☐	☐	
Documentation	☐	☐	

7. Code Break Information

Items discussed/verified	Yes	No	Comment
Unblinding procedure and paperwork	☐	☐	

8. Pharmacy Personnel

Items Discussed/verified	Yes	No	Comment
Location of CVs and GCP certificates	☐	☐	
Trial specific training documentation	☐	☐	

9. Temperature Monitoring

Items Discussed/verified	Yes	No	N/A	Comment
Temperature monitoring file note	☐	☐		
Temperature deviation information	☐	☐		
Remote storage monitoring information	☐	☐		

10. Correspondence

Items Discussed/verified	Yes	No	Comment
Monitoring log and reports	☐	☐	
Correspondence	☐	☐	

11. Regulatory Documentation

Items Discussed/verified	Yes	No	Comment
Amendment documentation	☐	☐	
Original approvals	☐	☐	
Completed pharmacy risk assessment	☐	☐	
Remote storage risk assessment documentation	☐	☐	
Completed clinical trials review form	☐	☐	
Completed folder audit forms	☐	☐	

12. Finance

Items Discussed/verified	Yes	No	Comment
Information	☐	☐	
Fee structure and finance contract	☐	☐	

13. Protocol

Items discussed/verified	Yes	No	N/A	Comment
Protocol	☐	☐		
Pharmacy manual	☐	☐		

14. Investigator Brochure/SmPCs

Items discussed/verified	Yes	No	N/A	Comment
Investigator Brochure	☐	☐		
SmPCs	☐	☐		

15. Superseded Pharmacy Documents

Items discussed/verified	Yes	No	Comment
Superseded documents	☐	☐	

Additional Comments/ Visit Overview

SIV Completed By:

Name:
Role:
Telephone:
e-mail:
Signature:
Date:

Report Responses Completed By:

Name:
Telephone:
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed SIV Report Approved/ Closed By:

Name:
Role:
Signature:
Date:

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UHL Site Initiation Final Outstanding Issue Sign Off

Sponsor Reference and Short Title:

Date of Visit: **Date of Report:** **Date Responses Due Back:**

No.	Outstanding Issue	Action required	Action Taken	Signature & Date

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Name:	Role:
Sponsor Number	Study Title

Standard Operation Procedures Read Log
For UHL Sponsored Studies

Researchers must read all UHL Standard Operating procedures (SOPs) that are relevant to the studies undertaken. A full list of all available Standard Operating Procedures is available on the R&I Website

The Documents **listed in bold are ESSENTIAL** reading for all members of the Research team. They must be read prior to or at Study Initiation or within 1 month of the researcher/team members joining the study. Review of all SOPS should be undertaken on a yearly basis or when made aware by the Sponsor that new documentation has been issued.

CI/PI Specific

Document	Document Title	Document Version	Document Date	Staff Signature	Date Read

Research Team Specific

Document	Document Title	Document Version	Document date	Staff Signature	Date Read

Study specific Instructions/SOPs

Document	Document Title	Document Version	Document Date	Staff Signature	Date Read

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SUBJECT SCREENING LOG

This screening log MUST NOT contain patient identifiable date. Only the patients initials and date of birth

Study Title

Sponsor Number:

Investigator:

Hospital/Site:

Date First Approached/ Screened	Patients Initials	Year of Birth	Enrolled Yes or No	Subject Study Number (if recruited) or Reason for Exclusion

This form MUST be updated and retained in the Trial Master File/Investigator Site File

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SUBJECT ENROLMENT LOG

Study Title:

Sponsor Number:

Investigator:

Hospital/Site:

Subject Study Number	Enrolment/ Consent Date	Subject Details (e.g. Name DoB, Hospital/NHS Number. Alternative third identifier e.g. address for subjects where medical records do not exist)	Randomisation No (if different from study number)	Date of completion or withdrawal

<u>This form MUST be completed and retained in the Trial Master File/Investigation/Investigator Site File</u>

LEICESTER'S RESEARCH

NHS
University Hospitals of Leicester
NHS Trust

UHL Site Initiation Checklist

for studies NOT involving Investigational Medicinal Products

Site Information

Site	Initiation Visit Method	
Sponsor Reference Number:	On Site	☐
Study Name:	Teleconference	☐
Investigator:	Other (specify)	☐
Study Site:		
Date of Initiation		
Conducted by:		

Personnel in Attendance/Completing Report

Name	Title

Study Overview/Protocol Overview

Items discussed/verified	Comments
Background and purpose of study	

1. Training and Regulatory Compliance

Items Discussed/verified	Yes	No	Comments
Investigator obligations	☐	☐	
Sponsor obligations	☐	☐	
Standard Operating Procedures	☐	☐	
Regulatory Authority reporting requirements	☐	☐	
Sponsor reporting requirements	☐	☐	
Amendments	☐	☐	
Annual progress reports	☐	☐	

Data Protection/ GDPR	☐	☐	
Study record storage requirements	☐	☐	

2. Trial Master File/Investigator Site File

Items Discussed/verified	Yes	No	Comments
TMF/ISF created and complete	☐	☐	
Delegated individual for TMF/ISF maintenance	☐	☐	
Secure location/limited access	☐	☐	

3. Study Approval Status/Essential Documents

Items Discussed/verified	Yes	No	Version/ Comments
REC Favourable opinion/HRA approval	☐	☐	
R&D/R&I/Host organisation approval/authorisation/ Capability & Capacity	☐	☐	
Signed Sponsor/CI agreement	☐	☐	
Signed financial agreement/ contract	☐	☐	
Protocol - Confirm protocol signed and dated by the PI	☐	☐	
Protocol deviation/Serious breach reporting	☐	☐	
Patient Information Leaflet (document version no and date)	☐	☐	
Are the contact numbers on the PIS correct/ been checked?			
Consent (document version no and date)	☐	☐	
Patient Invitation (document version and date)	☐	☐	
GP Letter (document version and date)	☐	☐	
Advertisement (document version and date)	☐	☐	
CRF (document version and date)	☐	☐	
Other	☐	☐	

4. Investigator Site Personnel

Items Discussed/verified	Yes	No	Comments
Adequate site staff to conduct the study	☐	☐	
All study team members listed on delegation of authorities log/ all entries signed and dated by PI	☐	☐	
Signed and dated CVs for all study team members	☐	☐	
Documented evidence of research training / consent/study specific training	☐	☐	

5. Recruitment

Items discussed/verified	Yes	No	Comments
Planned number of trial subjects	☐	☐	
Methods for identifying subjects	☐	☐	
Requirement to complete subject logs	☐	☐	
Requirement to complete subject enrolment logs			
Procedure for withdrawn subjects/Lost to follow-up	☐	☐	

6. Informed Consent/Enrolment

Items Discussed/verified	Yes	No	Comments
Informed consent/ procedures/documentation requirements	☐	☐	
Eligibility criteria confirmed	☐	☐	

7. Randomisation/Blinding

Items discussed/verified	Yes	No	Comments
Unblinding procedure/code break envelopes	☐	☐	
Randomisation procedures	☐	☐	
Blinded/ unblinded team members			

8. Safety Reporting (Check box if N/A ☐)

Items Discussed/verified	Yes	No	Comments
AE / SAE reporting procedures	☐	☐	
Sponsor notification process	☐	☐	

9. Data Management

Items Discussed/verified	Yes	No	Comments
Format and timelines	☐	☐	
CRF completion guidelines	☐	☐	
Are all study related documentation designed to ensure that they are anonymised by the use of	☐	☐	

study patient identifier			
Is all study hard copy documentation stored in a restricted access area	☐	☐	
Is access to electronic study records and files password protected?	☐	☐	
Are computer records and files containing identifiable data stored on a remote and secure server? Are emergency recovery processes in place?	☐	☐	
Requirements for Queries and corrections resolution	☐	☐	
eDC training (for electronic case report forms)	☐	☐	
Are electronic data files for analysis anonymised?	☐	☐	
Data Management plan in place (If applicable)	☐	☐	
Statistical analysis plan requirements	☐	☐	

10. Source Documentation

Items Discussed/verified	Yes	No	Comments
Source Data agreement/ schedule in place?	☐	☐	
CRFs as source	☐	☐	
Document retention requirements	☐	☐	
Archiving requirements/ responsibilities	☐	☐	

11. Equipment List (Check box if N/A ☐)

Items Discussed/verified	Yes	No	Comments
Equipment list	☐	☐	
Calibration of equipment	☐	☐	
Maintenance/service record requirements	☐	☐	

12. Specimen collection (Check box if all N/A ☐)

Items Discussed/verified	Yes	No	Comments
Specimen collection	☐	☐	
Sample result verification. CS/NCS status and required actions	☐	☐	
Specimens to be obtained	☐	☐	
Specimen storage	☐	☐	
Specimen storage and tracking logs	☐	☐	
Temperature monitoring	☐	☐	
Sample shipment	☐	☐	

Laboratory training/manual/SOPs	☐	☐	
Lab kits	☐	☐	
Lab accreditation	☐	☐	
Lab reference ranges	☐	☐	

13. Communication

Items discussed/verified	Yes	No	Comments
Format and frequency	☐	☐	
Site contacts	☐	☐	
Recruitment updates to Sponsor	☐	☐	

14. Monitoring/Audit

Items discussed/verified	Yes	No	Comments
Site Monitoring/Audit/ response requirements	☐	☐	

15. SOP

Items discussed/verified	Yes	No	Comments
Do all members of the study team know how to access the Sponsor SOPs via the webpages?	☐	☐	
CI/PI confirmation of review and compliance with all Sponsor Standard Operating Procedures.	☐	☐	
UHL Sponsor SOPs: http://www.leicestersresearch.nhs.uk/sops/sop-downloads-sponsor/			

Additional Comments/ Visit Overview

Study commencement must not occur until Sponsor Green Light process has been completed

UHL Site Initiation Outstanding Issues Report

Sponsor Reference and Short Title:

Date of Visit: **Date of Report:** **Date Responses Due Back:**

No	Outstanding Issue	Action required	Action Taken	Signature & Date

SIV Report Completed By:

Name::
Role:
Telephone:
e-mail:
Signature:
Date:

Report Responses Completed By:

Name:
Telephone:
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed SIV Report Approved By:

Name:
Role:
Signature:
Date:

UHL Site Initiation Checklist
For CE Marked or Proof of Concept Medical Device Studies

Site Information

Site	**Initiation Visit Method**
Sponsor Reference Number:	On Site ☐
Study Name:	Teleconference ☐
Investigator:	Other (specify) ☐
Study Site:	
Date of Initiation:	
Conducted by:	

Personnel in Attendance/Completing Report

Name	Title

Study Overview/Protocol Overview

Items discussed/verified	Comments
Background and purpose of study	
Investigational Medicinal Device/Software	

1. GCP and Regulatory Compliance

Items Discussed/verified	Yes	No	Comments
Investigator obligations	☐	☐	
Sponsor obligations	☐	☐	
Standard Operating Procedures	☐	☐	
Regulatory Authority reporting requirements	☐	☐	
Sponsor reporting requirements	☐	☐	
Amendments	☐	☐	
Annual reports/DSUR requirements	☐	☐	
Data Protection	☐	☐	
Study record storage requirements	☐	☐	
Archiving arrangements	☐	☐	

2. Trial Master File/Investigator Site File

Items Discussed/verified	Yes	No	Comments
TMF/ISF created and complete	☐	☐	
Delegated individual for TMF/ISF maintenance	☐	☐	
Secure location/limited access	☐	☐	

3. Study Approval Status/Essential Documents

Items Discussed/verified	Yes	No	Version/ Comments
EC Favourable opinion/HRA approval	☐	☐	
R&D/R&I/Host organisation approval/authorisation	☐	☐	
Signed Sponsor/CI agreement	☐	☐	
Signed financial agreement	☐	☐	
Protocol/CIP - Confirm protocol/CIP signed and dated by the CI/PI	☐	☐	
Protocol deviation/Serious breach reporting	☐	☐	
Patient Information Leaflet (document version no and date)	☐	☐	
Are the contact numbers on the PIS correct/ been checked?	☐	☐	
Consent (document version no and date)	☐	☐	
Patient Invitation	☐	☐	

(document version and date)			
GP Letter (document version and date)	☐	☐	
Advertisement (document version and date)	☐	☐	
CRF (document version and date)	☐	☐	
Other:	☐	☐	

4. Investigator Site Personnel

Items Discussed/verified	Yes	No	Comments
Adequate site staff to conduct the study	☐	☐	
All study team members listed on delegation of authority log/ all entries signed and dated by PI	☐	☐	
Signed and dated CVs for all study team members	☐	☐	
Documented evidence of GCP/ consent/device/study specific training	☐	☐	

5. Recruitment

Items discussed/verified	Yes	No	Comments
Planned number of trial subjects	☐	☐	
Methods for identifying subjects	☐	☐	
Research team aware of inclusion/exclusion criteria?	☐	☐	
Requirement to complete subject screening and enrolment logs	☐	☐	
Procedure for withdrawn subjects/Lost to follow-up	☐	☐	

6. Informed Consent/Enrolment

Items Discussed/verified	Yes	No	Comments
Informed consent procedures/documentation requirements	☐	☐	
Eligibility criteria confirmed	☐	☐	

7. Medical Device/Software

Items discussed/verified	Yes	No	Comments
Medical Device Investigation Brochure/ Manufacturer Instructions on file	☐	☐	
Electrical safety testing completed	☐	☐	

Equipment List: Batch No/Lot No/Device No are entered on device accountability log	☐	☐	
Calibration of equipment has occurred/processes are in place.	☐	☐	
Sterilisation process(s) if applicable	☐	☐	
Software use/licensing (If applicable)	☐	☐	
Maintenance/service record requirements	☐	☐	

8. Labelling (Check box if N/A ☐)

Items discussed/verified	Yes	No	Comments
Does the label include the name or trade name and address of the manufacturer?	☐	☐	
Does the label indicate exclusively for clinical investigation?	☐	☐	
Does packaging identify the device and the contents of the packaging?	☐	☐	
Where appropriate is the product marked as sterile?	☐	☐	
Is the batch No/Lot No or serial number on the label	☐	☐	
Where appropriate does the label indicate the date by which the device should be used?	☐	☐	
Where appropriate is there an indication that the device is for single use only?	☐	☐	
Does the label contain special operating instructions/warnings and/or precautions to take?	☐	☐	

9. Randomisation/Blinding (check box if N/A ☐)

Items discussed/verified	Yes	No	Comments
Is a blinded evaluator being utilised	☐	☐	
Randomisation procedures	☐	☐	
Decoding procedure/code break envelopes where applicable	☐	☐	

10. Safety Reporting

Items Discussed/verified	Yes	No	Comments
AE / SAE reporting procedures	☐	☐	

Device deficiency reporting/ quarantine procedures	☐	☐	
ADE/SADE reporting procedures	☐	☐	
USADE reporting procedures	☐	☐	
Notification process	☐	☐	
Data safety monitoring board/committee reporting requirements	☐	☐	

11. Data Collection

Items Discussed/verified	Yes	No	Comments
Format and timelines	☐	☐	
CRF completion guidelines	☐	☐	
Are all study related documentation designed to ensure that they are anonymised by the use of study patient identifier	☐	☐	
Is all study hard copy documentation stored in a restricted access area	☐	☐	
Is access to electronic study records and files password protected?	☐	☐	
Are computer records and files containing identifiable data stored on a remote and secure server? Are emergency recovery processes in place?	☐	☐	
Requirements for queries and corrections resolution	☐	☐	
eDC training (for electronic case report forms)	☐	☐	
Are electronic data files for analysis anonymised?	☐	☐	
Data management plan in place (If applicable)	☐	☐	
Statistical analysis plan requirements	☐	☐	

12. Source Documentation

Items Discussed/verified	Yes	No	Comments
Source data agreement in place?	☐	☐	
CRFs as source	☐	☐	
Document retention requirements/procedures	☐	☐	

13. Specimen collection (Check box if N/A ☐)

Items Discussed/verified	Yes	No	Comments

Specimen collection	☐	☐	
Sample result verification/CS/NCS status and required actions	☐	☐	
Specimens to be obtained	☐	☐	
Specimen storage	☐	☐	
Specimen storage and tracking logs	☐	☐	
Temperature monitoring	☐	☐	
Sample shipment	☐	☐	
Laboratory training/manual/SOPs	☐	☐	
Lab kits	☐	☐	
Lab accreditation	☐	☐	
Lab reference ranges	☐	☐	

14. Communication

Items discussed/verified	Yes	No	Comments
Format and frequency	☐	☐	
Site contacts	☐	☐	
Recruitment updates to Sponsor	☐	☐	

15. Monitoring/Audit

Items discussed/verified	Yes	No	Comments
Site Monitoring/ Audit and response requirements	☐	☐	

16. SOP

Items discussed/verified	Yes	No	Comments
Do all members of the study team know how to access the Sponsor SOPs via the webpages?	☐	☐	
CI/PI confirmation of review and compliance with all Sponsor Standard Operating Procedures.	☐	☐	

17. Archiving

Items Discussed/verified	Yes	No	

Site Archiving at end of study discussed?	☐	☐	
Will any documentation be archived off site? If yes, Sponsor archiving requirements discussed.	☐	☐	

Additional Comments/ Visit Overview

Study commencement must not occur until Sponsor Green Light process has been completed

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UHL Site Initiation Outstanding Issues Report

Sponsor Reference and Short Title: **Site:**

Date of Visit: **Date of Report:** **Date Responses Due Back:**

No	Outstanding Issue	Action required	Action Taken	Signature & Date

SIV Report Completed By:

Name:
Role:
Telephone:
e-mail:
Signature:
Date:

Report Responses Completed By:

Name:
Telephone:
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed SIV Report Approved By:

Name:
Role:
Signature:
Date:

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NHS
University Hospitals of Leicester
NHS Trust

Site Initiation Checklist Guidance

for Non CTIMP Studies

This document was designed for use at onsite or remote application for either single site or multisite studies not involving Investigational Medicinal Products as per Sponsor Site Initiation Standard Operating Procedure S-1011 UHL. The form is in the format of a checklist to ensure that all aspects of trial set up and research team requirements have been discussed/completed. Selected aspects, where indicated i.e. randomisation/blinding/labs may not be applicable for all studies and should be marked as not applicable.

Addition of other study specific aspects can be added to the checklist by the investigator if applicable.

The aim is to provide the CI/PI with relevant documentation to ensure that all aspects of site set up have been completed at either single or multiple sites prior to commencement of recruitment as per the relevant Sponsor Standard Operating Procedures.

The report when complete, following resolution of any outstanding issues, should be signed by the person completing the checklist and approved by the CI/PI and where required the Sponsor monitoring lead.

Completion of form

- Complete full study details and document the method of site initiation. Please ensure the Sponsor reference number is that supplied by the Sponsor and not the REC or Protocol number.
- List personnel in attendance at the initiation meeting. This should always include the Principal Investigator/ delegate and relevant members of the research team.
- Provide overview of the study and adherence to the protocol
- Review the CI/PI and Sponsor responsibilities and obligations. Review Sponsor reporting requirements.
- Confirmation that TMF/ISF has been created and is complete prior to study commencement.
- Review all patient facing documents to be utilised within the study and record the version and date of all approved documents that will be in use, at the commencement of the study. This is particularly important with multisite studies, where site commencement may occur at different time points in the study and potentially amendments may have been made to original versions of patient documentation.
- Confirmation that the delegation of authority log has been completed for all members of the research team and that the relevant evidence of experience signed and dated CVs, GCP

certificates, consent certificates(if applicable) and study specific training are on file. All members of the research team must have received training on the protocol.

- Review of the recruitment method and time that participants will have to consider taking part in the study/ completion of screening and enrolment logs. Recording of withdrawal/completion of study.
- Review eligibility criteria and informed consent/reconsent process.
- Ensure all members of staff are aware of the randomisation, and where applicable, blinding processes and requirements. Where appropriate unblinding/code break processes.
- Review of safety reporting and Sponsor notification requirements. Detail any exemptions as recorded on REC application.
- Review data collection process and response requirements to queries and corrections.
- Any deviations from the protocol should be recorded utilising the protocol deviation log.
- Review the requirements for utilisation of equipment specifically utilised for study purposes and the calibration/maintenance requirements.
- Review the process for collection/preparation and analysis of study samples. Samples result verification, signed and dated and marked CS or NCS if out of normal reference ranges.
- Ensure that all study related communication i.e. emails, Investigator/steering committee meeting agendas and minutes are on file.
- Discuss study audit/monitoring requirements. Sponsor response requirements.
- Ensure all members of the study team whether single or multicentre are aware of and adhere to the Sponsor standard operating procedures. Ensure that all team members are aware of where to access the most current versions of standard operating procedures and associated documents.
- Ensure relevant arrangements are in place for the archiving of the study as per Sponsor SOP S-1029 UHL.

Please be aware that Sponsor documentations should be utilised for all centres, unless agreed otherwise with the Sponsor i.e. Delegation of authority log, screening/enrolment logs, protocol deviation log, SAE reporting forms.

If all aspects of study set up have not been completed at initiation visit then an outstanding issues report should be sent to the site for completion and Principal Investigator signature/date. A review and confirmation that all outstanding issues have been resolved should be obtained before site recruitment is commenced.

Sponsor Green light

For individual studies this will be in the format of the R&I approval/authorisation. For multicentre studies, the Sponsor will require confirmation that site initiation has taken place and all outstanding findings addressed prior to Sponsor green light being given for recruitment to start.

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Site Initiation Checklist Guidance

for CE Marked or Proof of Concept Medical Device Studies

This document was designed for use at onsite or remote application for either single site or multisite studies not involving Investigational Medicinal Products as per Sponsor Site Initiation Standard Operating Procedure S-1011 UHL. The form is in the format of a checklist to ensure that all aspects of trial set up and research team requirements have been discussed/completed. Selected aspects, where indicated i.e. randomisation/blinding/labs may not be applicable for all studies and should be marked as not applicable.

Addition of other study specific aspects can be added to the checklist by the investigator if applicable.

The aim is to provide the CI/PI with relevant documentation to ensure that all aspects of site set up have been completed at either single or multiple sites prior to commencement of recruitment as per the relevant Sponsor Standard Operating Procedures.

The report when complete, following resolution of any outstanding issues, should be signed by the person completing the checklist and approved by the CI/PI and where required the Sponsor monitoring lead.

Completion of form

- Complete full study details and document the method of site initiation. Please ensure the Sponsor reference number is that supplied by the Sponsor and not the REC or Protocol number.
- List personnel in attendance at the initiation meeting. This should always include the Principal Investigator/ delegate and relevant members of the research team.
- Provide overview of the study and adherence to the protocol
- Review the CI/PI and Sponsor responsibilities and obligations. Review Sponsor reporting requirements.
- Confirmation that TMF/ISF has been created and is complete prior to study commencement.
- Review all patient facing documents to be utilised within the study and record the version and date of all approved documents that will be in use, at the commencement of the study. This is particularly important with multisite studies, where site commencement may occur at different time points in the study and potentially amendments may have been made to original versions of patient documentation.
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certificates, consent certificates(if applicable) and study specific training are on file. All members of the research team must have received training on the protocol.

- Review of the recruitment method and time that participants will have to consider taking part in the study/ completion of screening and enrolment logs. Recording of withdrawal/completion of study.
- Review eligibility criteria and informed consent/reconsent process.
- Ensure all members of staff are aware of the randomisation, and where applicable, blinding processes and requirements. Where appropriate unblinding/code break processes.
- Ensure all members of the team are aware of the requirements for utilisation of Device/softwarespecifically utilised for study purposes and the calibration/maintenance requirements.
- Review of safety reporting and Sponsor notification requirements. Detail any exemptions as recorded on REC application.
- Review data collection process and response requirements to queries and corrections.
- Any deviations from the protocol should be recorded utilising the protocol deviation log.
- Review the process for collection/preparation and analysis of study samples. Samples result verification, signed and dated and marked CS or NCS if out of normal reference ranges.
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- Discuss study audit/monitoring requirements. Sponsor response requirements.
- Ensure all members of the study team whether single or multicentre are aware of and adhere to the Sponsor standard operating procedures. Ensure that all team members are aware of where to access the most current versions of standard operating procedures and associated documents.
- Ensure relevant arrangements are in place for the archiving of the study as per Sponsor SOP S-1029 UHL.

Please be aware that Sponsor documentations should be utilised for all centres, unless agreed otherwise with the Sponsor i.e. Delegation of authority log, screening/enrolment logs, protocol deviation log, SAE reporting forms.

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Investigational Medical Device Accountability Log

Receipt of Device	Use of Device	Disposition (Return/Repair/Destruction)	
		*Status RET = Returned DES = Destroyed REP = Repaired LOS = Lost OTH = Other(must comment)	** Reasons 1 = Subject completed study 2 = Subject Withdrew 3 = Lost to follow-up 4 = Expired 5 = Device damaged. not functioning or recalled

Date Rec'd	Initials of receiver	Lot/serial or Model Number	Device Type/Batch	Date Used	Initials of device dispenser	Subject ID	Status*	Date	Initials	Number of units	Reason**	Comments