Wellcome - HRB
Clinical Research Facility
at St. James's Hospital

INFORM CONSENT FORM

Protocol no:	Participant ID:	Participant name:

Type of consent: Initial consent ☐ Re-consent ☐

Initial Contact Date: __ / ___ / ____

Contact Method: Phone ☐ In-person ☐

Date of PIL/ICF given: __ / ___ / ____

Patient Information Leaflet given to Patient: Yes ☐ No ☐ Version no:

ICF Version/Date consented: __ /___ /____

Time of Consent: __ : __ 24 hrs

Was Sufficient Time allowed to Review and to ask/ Answer Questions before consenting: Yes ☐ No ☐

If no, please explain:

For Re-consent, was tracked changes explained to patients : Yes ☐ No ☐

Was Informed Consent Signed Prior to Initiation of any Study Procedure: Yes ☐ No ☐

The subject reminded they could withdraw consent at any time: Yes ☐ No ☐

Fully Signed PIL/ICF given to patient: Yes ☐ No ☐

Fully Signed PIL/ICF filed in the ISF/ Shadow file: Yes ☐ No ☐

Copy of Fully Signed PIL/ICF Filed in Patient Chart and uploaded in EPR: Yes ☐ No ☐

Additional comments:

Written Consent Taken By: .....

Signature: .....

Date: __ /___ /____

Site Initiation Visit Investigator Site File Checklist

Wellcome - HRB Clinical Research Facility at St. James's Hospital

Trial Information

Protocol Number:	
Trial Site:	
Sponsor:	
Principal Investigator:	

The below form is to be completed by assigned monitor at the Site Initiation Visit or the first monitoring visit thereafter. At the beginning of the study the monitor is responsible for ensuring that the Site file is complete, any missing documents must be supplied and filed by Monitor.

Sections as they appear in the ISF	Documents	On File* (Yes, No, N/A)	Notes/ Location
0.0	**Index**		
1.0	**Contacts List** *(including out of hours contact for CRA and Sponsor)*		
2.0	**Protocol**		
2.1	Current, Approved Protocol *(include investigator signature page)*		
2.2	Signed Protocol Page		
2.3	Superseded Protocols/ amendments		
3.0	**Participant Documentation (Local Versions)** *All documents must be on appropriate institution letterhead.*		
3.1	Current Patient Information Sheet and Informed Consent Form (PIL/ICF) on SJH Headed paper		
3.2	Advertisement and other documents provided to participants		
3.3	Current, approved GP letter on SJH headed paper		
3.5	Participant Screening and Enrolment Log (Template)		
3.6	Participant Identification Log (Template)		
4.0	**Research Ethics/ HRCDC Committee**		
4.1	Application to ethics/ HRCDC- Where applicable (including supporting documentation)		
4.2	Ethics/ HRCDC Approval(s) (including amendments)		
4.3	Correspondence ***(please file chronologically, most recent at the front, and include all email correspondence)***		
5.0	**Regulatory Authorisation**		
5.1	Application to HPRA (If Applicable)		
5.2	HPRA amendment submissions (If Applicable)		
5.3	HPRA Approval(s) (If Applicable)		
5.4	CTA Application Through CTIS- Part I and II (If Applicable)		
5.5	ICTA- Ireland Part 1 and II Approval (If Applicable)		
5.6	ICTA- Amendment Submissions through CTIS (If Applicable)		
5.7	Correspondence ***(please file chronologically, most recent at the front, and include email correspondence)***		

Site Initiation Visit Investigator Site File Checklist

Sections as they appear in the ISF	Documents	On File* (Yes, No, N/A)	Notes/ Location
5.8	Developmental Safety Update Report		
6.0	**Financial / Legal**		
6.1	Insurance		
6.2	Clinical Trial Agreement (CTA) Indemnity Statement		
6.3	Confidentiality Agreements		
7.0	**Site Study Team**		
7.1	Delegation of Responsibility and Signature Log (completed and signed off by PI)		
7.2	Signed and dated CVs and GCP certificates (including superseded versions)		
7.3	Study Team Training Records		
8.0	**Safety Reporting**		
8.1	Safety Reporting Procedures		
8.2	Adverse Events/ Serious Adverse Event (SAE) Forms/ Templates		
8.3	SAE Report Template and SAE Report Log*		
8.4	SUSAR Reporting Template/Forms		
8.5	Safety Updates/ correspondence		
9.0	**Investigational Medicinal Product (IMP)** *(If documents are retained in separate file – please include in ISF prior to archiving)*		
9.1	Investigator Brochure (IB)/ Summary of Product Characteristics (SPC) with acknowledgement of receipt		
9.2	Signed IB/ SPC Amendments		
9.3	Pharmacy Study Specific Procedures		
9.4	Sample Labels		
9.5	Instructions for Handling IMP		
9.6	QP release		
9.7	Correspondence		
9.8	Other Forms/Templates		
9.9	Emergency Unblinding Procedure		
10.0	**Study Management and Monitoring**		
10.1	Monitoring Visit Log		
10.2	Site Initiation Meeting Documentation		
11.0	**Clinical Laboratory *(If documents are retained in separate file – please include in ISF prior to archiving)***		
11.1	Local Certificate(s) of accreditation and C.V. of Laboratory Director (If applicable)		
11.2	Local Normal Reference Ranges (If applicable)		

Site Initiation Visit Investigator Site File Checklist

Sections as they appear in the ISF	Documents	On File* (Yes, No, N/A)	Notes/ Location
11.3	Laboratory Manual		
11.4	Sample Labels		
11.5	Sample Shipment/Receipt Tracking		
12.0	**Case Report Forms and Data Collection Tools***		
12.1	Blank CRF and CRF Completion Guidelines		
12.2	Participant Questionnaires		
12.3	Study Specific Report Forms		
13.0	**Study Related Supplies and Equipment** *For study materials and supplies*		
13.1	Contact details for supplies		
13.2	Completed supplies re-order forms		
13.3	Other Forms/Templates		
13.4	Equipment Documentation		

General Notes

- Not all sections will be applicable: Mark such sections as "N/A" in the "On File" Column

The below form is to be completed by assigned monitor at the Site Initiation Visit. At the beginning of the study the monitor is responsible for ensuring that the Site file is complete, any missing documents must be supplied and filed by Monitor.

Name of Monitor completing Site file review:	
Signature of Monitor Completing Site File Review:	
Date ISF file review complete:	
Checked By CRF Quality Dept:	
Signature of CRF Quality Dept:	
Date Checked by CRF Quality Dept:	

Protocol Amendment Checklist for Clinical Trials	
Principal Investigator	
CRF Study Number	
Protocol Number/ Short Protocol Title	
Type of Document amended	☐ Protocol ☐ IB ☐ Others ……..
Amendment Version	
Initial Notification date of the amendment to the site	
Amendment site implementation date	

1. Regulatory	**Yes**	**No**	**N/A**
a. Central EU approval in place through CTIS for new clinical trials registered after 31 January 2023?	☐	☐	☐
b. Ethics Approval in place for new amendment (NREC) for trials not submitted under new Clinical Trial Regulation through CTIS	☐	☐	☐
c. HPRA Approval in place for new amendment trials not submitted under new Clinical Trial Regulation through CTIS	☐	☐	☐
d. Has the IB been updated	☐	☐	☐
e. Has the PIL been updated?	☐	☐	☐
f. If YES does the patient need to be reconsented	☐	☐	☐
g. Does DPIA need to be updated? Note: This is required only if there are updates to Data handling, storage, Data Transfer, or any other updates impacting data integrity	☐	☐	☐
h. If yes, has the DPO been informed of the amendment and has the DPIA been approved?	☐	☐	☐
i. Has the site received greenlight from the sponsor to implement the amendment?	☐	☐	☐
j. If you have answered "NO" to "a" "b" "c" "g" or "h" for the above, please do not proceed.			
Has the study team (all on delegation log) been retrained on new protocol Amendment (documented on training log) etc			
PI and Sub-Investigators	☐	☐	☐
Nursing	☐	☐	☐
Pharmacy	☐	☐	☐
Laboratory	☐	☐	☐
Study Co-ordinators	☐	☐	☐
Other roles as per delegation log and individual trial requirements	☐	☐	☐
If all Staffs mentioned above could not be trained prior to implementation of updated protocol, where all staffs in the delegation log as mentioned above been trained before performing any trial tasks related to the updates.	☐	☐	☐

2. Protocol Changes	Yes	No	N/A
a. Has the Protocol been updated	☐	☐	☐
b. Has the Protocol Schedule of Events changed?	☐	☐	☐
c. If YES has there been an increase in study visits?	☐	☐	☐
d. Is there a new Budget or CTA to be reviewed?	☐	☐	☐
e. Does CRF manager form need to be updated to reflect new study visits? Or Conditional Procedures?	☐	☐	☐
f. Does the Agreement letter need to be updated?	☐	☐	☐
g. Does the Risk Assessment need to be updated?	☐	☐	☐
h. Have R&I been informed of Amendment by email?	☐	☐	☐
i. If yes, has the approval letter been sent to R and I?	☐	☐	☐
j. Is there an Up-dated IB? Has PI signed for Acknowledgement Log?	☐	☐	☐
3. Documentation	**Yes**	**No**	**N/A**
a. Has older version of protocol been superseded?	☐	☐	☐
b. Has new protocol been filed on both shared drive and site file?	☐	☐	☐
c. Have older protocol versions been removed from circulation?	☐	☐	☐
d. If PIL has been updated, have older versions been superseded and taken out of circulation?	☐	☐	☐
e. Has the site file and shared drive been updated with the PIL?	☐	☐	☐
f. Has the PI signed the new updated version of the protocol under protocol signature page?	☐	☐	☐
g. If there are any worksheets in place for the stud do they require any update?	☐	☐	☐
h. If there are study specific procedures SSPs in place, do they require any update?	☐	☐	☐
4. Finances and Contract	**Yes**	**No**	**N/A**
a. If there are additional visits – have these been costed and approved?	☐	☐	☐
b. Is there a new Clinical Trial Agreement CTA in place?	☐	☐	☐
5. Pharmacy – completed by pharmacist	**Yes**	**No**	**N/A**
a. Has the required training been completed and documented accordingly?	☐	☐	☐
b. Does Amendment require a change to pharmacy procedures for drug handling, storage, dispensing, preparations, returns etc?	☐	☐	☐
IF YES:			
c. Has the Trial Summary/Prescribing & Dispensing Guide been updated if required?	☐	☐	☐
d. Has Trial summary/ Prescribing and Dispensing Guide been uploaded, and old version removed and superseded?	☐	☐	☐
e. Have all superseded paper copies of the Trial Summary/Prescribing and Dispensing Guide been removed and new versions filed?	☐	☐	☐
f. Has the new Amendment been filed in the Pharmacy Site File and the old version superseded?	☐	☐	☐

g. Are there any additional pharmacy costs to be considered?	☐	☐	☐
h. Are there any changes required to the pharmacy section of the Risk Assessment (CRF only)?	☐	☐	☐
6. Laboratory	**Yes**	**No**	**N/A**
a. Has the lab manual been updated?	☐	☐	☐
b. Is there any change in the processing of lab samples?	☐	☐	☐

Checklist Reviewed by:

Reviewed by	☐ Clinical Trial Coordinator/ Study Start-Up specialist	☐ Lead Nurse (Includes CCTU)	☐ Trial/Study Pharmacist	☐ Laboratory Manager/Coordinator	☐ Quality and Regulatory Affairs Manager	☐ Programme Manager
Initials and Date						

Checklist completed by:

Name:			
Signature:		**Date:**	