SOP number	**57.005**	Version	**4.0**
Title	**GCRF Hosted Study Documentation and Data Management**		

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SOP category	57 NHS GG&C Clinical Research Facility – Administration

Staff category

Staff Category	**R**	**A**	**C**	**I**
Nursing	X			
Administration	X			
Principal Investigator	X			
Clinical Research Fellow	X			
GCRF Manager		X		
Site Clinical Trials Pharmacy				X
Clinical Research Imaging Facility (CRIF)				X
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Facility (GCRF).

2. Purpose

The purpose of this SOP is to describe the procedures for the collection, recording and management of clinical research data and documentation, providing guidance on managing source data to ensure correct and consistent recording of all clinical research participant data.

3. Procedures

Clinical research data is collected, recorded and stored in a variety of formats and must be of the highest quality, handled appropriately and managed in accordance with information governance.

The transfer of data should be in accordance with Code of Practice: Protecting Patient Confidentiality, General Data Protection Regulation (GDPR), Data Protection Act 2018 and NHS Greater Glasgow & Clyde (NHS GG&C) Information Governance Policies, following GUI 57.005A, GCRF Data Transfer.

3.1. Source data

Source data is the original record of clinical findings, observations or other activities in clinical research necessary for the reconstruction and evaluation of the study. Source data must be attributable, legible, contemporaneous, original, accurate and complete (ALCOA-C).

Clinical research source data should be documented by trained and delegated personnel. It is important that all source data is appropriately managed. The study team must agree the source data plan with Sponsor at study planning stage, if not provided by sponsor Source Data Plan template Form 56.002M should be used. This source data plan should be stored in the Investigator Site File (ISF) and revised where necessary, for instance when a study amendment adds a new investigation to the schedule of events.

Data is entered to paper or electronic Case Report Forms (CRFs) from source documentation. Entered data should be consistent with the source data and any discrepancies or missing information should be clearly explained following SOP 17.045, Case Report Form Completion.

Source documentation includes the original documents, data and records such as hospital records, clinical and laboratory notes, participant diaries, questionnaires, pharmacy dispensing records and x-rays.

NHS GG&C has an electronic health record system, Clinical Portal and all clinical source data is recorded and stored on the information system. There are other disease specialty systems that store source data including SERPA (renal), BADGERNET, EMIS (mental health), TrakCare, ICIP (Intellivue Clinical Information Programme - CareVue™ - critical care), Metavision (PICU) and paper case notes.

3.2. Recording of research data on Clinical Portal

3.2.1. Providing Information to Potential Participants

Following SOP 17.012 or SOP 17.055 potential participants must be given information regarding a study within a reasonable timeframe. Discussions must be documented in the participants electronic health record (EHR):

- Title of research study, R&I number.
- Date and time information provided.
- Discussions by whom.

3.2.2. Consent and Assent visit

Each research participant with a CHI number will have a Clinical Portal record. Once a participant has consented to take part in clinical research following SOP 17.012 or SOP 17.055, the following must be documented on Clinical Portal and any associated electronic health record.

Research Nurse:

- Title of research study, R&I number.
- Date and time of consent/assent.
- Confirmation that the participant meets eligibility criteria – CTIMP eligibility must be confirmed by a clinician.

- Name of consenting clinician or nurse.
- Evidence of consent/assent discussion, including any questions the participant may have asked.
- Version number and date of Patient Information Sheet (PIS) and Consent Form.
- If appropriate, confirmation GP informed of participation.

Where required by sponsor/protocol the Principal Investigator/delegated clinician must document the following:

- Title of research study, R&I number.
- Date and time of consent.
- Confirmation that the participant meets eligibility criteria
- Name of consenting clinician
- Evidence of consent discussion, including any questions the participant may have asked.
- Version number and date of Patient Information Sheet (PIS) and Consent Form.
- If appropriate, confirmation GP informed of participation.

A Clinical Alert must be added to a participant record when taking part in a Clinical Trial of Investigational Medicinal Product (CTIMP) or Medical Device Investigation.

A copy of the consent form and PIS must be scanned and uploaded to Clinical Portal following this table:

Document	**Area on Clinical Portal**
Consent form	• Legal documents & Research\Consent Forms
Participant Information Sheet	• Legal documents & Research\Consent Forms

3.2.3. Subsequent Study Visits

For each participant research visit the following must be recorded in Clinical Portal and or associated health record as defined by the Source Data Agreement, by the Research Nurse and Principal Investigator and Clinical Fellow :

- Title of research study, R&I number.
- Date, time and visit number.
- The participant must confirm their consent to continue their participation in the research study, unless the participant falls within Adults with Incapacity (Scotland) Act 2000.
- Eligibility to continue on the study.
- Procedures listed in research protocol conducted at visit, by whom and the results.
- Any procedures that were not performed must be documented along with an explanation.
- If appropriate, IMP details – date and time of dose, regimen.
- Details of any adverse events since the previous visit. The investigator must assess adverse events for seriousness as defined in the research protocol.
- Changes to current medication.
- Withdrawal from study and reasoning.

3.2.4. Telephone calls

Telephone calls with a participant should be recorded in the participant health record. For instance, where providing instruction for treatment compliance, self-care or information about referrals. Telephone calls to multidisciplinary colleagues regarding the participant's care while in the study must be recorded in participant health record.

3.2.5. Scanning Documents to Clinical Portal

The following must be completed when scanning documents to participant health record:

- Pages must be checked for double sides before scanning.
- Quality of the scan must be checked. When scanning large amounts first document scanned to be checked, then periodically.

3.3. Source Data Review and Verification

Source data review (SDR) is the review of source to check quality, protocol, Good Clinical Practice (GCP) and regulatory compliance ensuring the source documentation is adequate. Research Nurse Managers must regularly spot-check SDR on studies within their specialty, this must be documented in study worksheets or electronic health records.

Source data verification (SDV) is an evaluation of the data recorded in the data collection tool e.g. paper/electronic Case Report Form (CRF) against source documentation (Clinical Portal). SDV is conducted to ensure accuracy and reliability of data collected. It is essential that transcription from Clinical Portal to a CRF is completed in a timely manner. It is recommended that study staff periodically conduct QC checks from transcription of source to study systems, this should be documented in study worksheets or electronic health records.

Any concerns with SDR/SDV must be escalated to GCRF Manager, Lead Nurse and GCRF QA Lead.

3.4. Essential Documents and Investigator Site File

Essentials study documents demonstrate the compliance of the research team, sponsor, monitor/auditor in accordance with regulatory requirements, GCP and SOPs. The documents provide monitors/auditors/regulatory inspectors with the essential information required confirming validity of the study and the integrity of the data collected.

All documentation throughout a study lifetime must be stored within an Investigator Site File. The sponsor may provide participating sites with an Investigator Site File including index and necessary templates. If this is not provided guide GUI 57.011A should be followed.

The study team must ensure:

- ISF is maintained throughout the study lifetime.
- Previous versions of documents are retained but scored through with date superseded (R&I Permission date) to indicate document is no longer in use.
- Documents are filed chronologically within each section.
- Documents are complete, accurate, legible and signed/dated as appropriate.
- File notes document if ISF documents are stored in a separate location.
- ISF is retained within a secure place with restricted access to authorised persons only.

- ISF is available for monitoring, audit and regulatory visits.

3.5. Retention

The study will end as defined in the research protocol. Once the close-out visit has been complete the ISF may be stored off-site following GUI 57.005B. The retention period will be defined in the study protocol or GUI 57.005B.

4. Referenced documents

- GUI 57.005A – GCRF Data Transfer
- GUI 57.005B – GCRF archiving
- GUI 57.005C – Redaction Process
- GUI 57.011A – Investigator Site File (ISF)
- Form 57.005A – GCRF Archiving Box Contents
- Form 56.002M – Source Data Plan
- SOP 17.012 – Obtaining Informed Consent
- SOP 17.055 – Obtaining Informed Consent and Assent (Children)

5. Related documents

None

6. Document history

Version	Date	Description
1.0	11/12/2017	First release
2.0	26/08/2019	Minor changes to process, addition of electronic health record systems CareVue and Metavision, inclusion of Source Data Agreement, inclusion of AWI exception for continuing consent.
3.0	03/02/2020	Addition of Clinical Fellows; telephone calls; QC of data; Scanning to Portal; remove reference to chapter 53 and 56; inclusion of GUI 57.011A and Form 56.002.
4.0	03/08/2023	Update to GCTU SOP template v2.0 Addition of RACI matrix Reference to SOP 17.012 Minor changes to wording Addition of Source Data Review (SDR)