RDSOP31 Study Close-Out

Greater Manchester Mental Health NHS Foundation Trust
## Title of Standard Operating Procedure:
RDSOP31 Study Close-Out

### Document Summary:
To establish a procedure for closing down clinical trials in the Trust to support compliance with the UK Clinical Trial Regulations.

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### Target Audience:
Trust-wide, Research Community, Internal and External Researchers

### Consultation:
R&I Office, research community and R&I Committee members

### Approval Committee:
R&I Committee

### Cross Reference Document(s):
Research Approval Policy
All Trust R&I SOPs

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1. Introduction

Trial close-out is the act of ensuring that all clinical trial related activities have been appropriately reconciled. Close-out is integral to the quality of a trial and is designed to ensure that all necessary documents are in place should the trial data need to be queried or inspected in the future.

2. Purpose

This SOP establishes a procedure for closing down clinical trials in the Trust to support compliance with the UK Clinical Trial Regulations.

3. Roles and Responsibilities

3.1 Duties within the Organisation

It is the responsibility of the Research & Innovation Office to make Trust R&I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R&I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R&I SOP it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R&I SOPs including their approval, dissemination and archiving. All Trust R&I SOPs must be made available via Q-Pulse and published on the Trust website.
3.2 Specific to this SOP

Chief Investigator (CI) Responsibilities – Trust-Sponsored Studies

It is the responsibility of the CI, acting on behalf of the Sponsor, to organise the Trial Master File (TMF) ensuring all necessary documents are present, and to complete and distribute the Declaration of End of Trial Form and end of study report, as detailed in section 4.3 Notification and Reporting, and RDSOP20 End of Study Notification.

The CI must instigate archiving procedures in line with RDSOP21 ensuring that files are retrieved from support departments (e.g. Pharmacy) so that all essential documents relating to a particular trial are archived together.

R&I Responsibilities

The R&I Office will update internal databases and communicate with the CI regarding study closure as detailed in section 4.3 Notification and Reporting.

The R&I Office will prepare the R&D files (and Sponsor files where applicable) for archiving. When ready for archiving, the Named Archivist will prepare archive boxes in line with RDSOP21.

4. Procedure

Deeming a Site “Closed”

A site must be closed as soon as is practicable to do so. A site may be deemed “closed” once all study-related activities at a particular site are reconciled and/or complete. This includes ensuring:

- Investigator/institution and sponsor files are reviewed and all essential documentation for a particular site are confirmed in the appropriate files, providing a clear audit trail of study conduct at the site.
- All site data is collected, entered, validated and all data queries resolved where feasible. This includes queries resulting from reconciliation of the clinical and safety database.
- All issues from previous study monitoring procedures are resolved and documented.
- All financial matters are resolved and all site payments are complete as agreed and documented in study contracts/agreements/approvals.
- All unused trial supplies are returned or destroyed according to study and/or sponsor requirements.
For CTIMPs - final drug accountability is complete and return (if returned) or destruction of unused study drug is documented in the site file (if destroyed locally at site). See 4.1 Pharmacy below for further details.

Investigator(s) are aware of the study publication policy, as documented in the study protocol and/or study contracts/agreements.

Investigator(s) are aware of, and have implemented, relevant ongoing requirements such as site archiving, subsequent audit/inspection procedures and any ongoing reporting requirements. The Chief Investigator (CI) site should not be closed until all the participating sites have been closed-out. Consideration must also be given to those trials that can be ‘closed’ but where the patients are placed into long-term follow-up (e.g. Oncology trials).

Pharmacy

For CTIMPs, all Investigational Medicinal Product (IMP) must be accounted for, including a check that all IMP has been returned by trial subjects and that all IMP not used for the study is present and unopened. All IMP logs must be checked for accuracy and any discrepancies must be accounted for. Serious breaches in IMP accountability must be brought to the attention of the CI and Sponsor.

Return and destruction of IMPs must be carried out according to protocol and legal requirements. IMPs must not be destroyed until permission to do so is given by the Sponsor. A Certificate of Destruction should be obtained when the IMP is destroyed, this should be filed in the Trial Pharmacy File.

Clinical Samples

Storage and destruction of clinical samples must be carried out according to Protocol and Sponsor requirements.

Notification and Reporting

Chief Investigator

It is the responsibility of the CI, acting on behalf of the Sponsor, to notify the main REC, the MHRA (CTIMPs only) and the R&I Office of the end of the trial for every participating site and CI site using the Declaration of End of Trial Form (see RDSOP20 End of Study Notification).

The CI must send notification of the end of the trial within 90 days of the trial ending (trial end as defined in the Protocol) or within 15 days if terminated early.
Once notified of the end of trial, the CI will contact the Monitor in order to arrange a close-out monitoring visit for each site. Support departments (e.g. Pharmacy) should also be notified in order that they can prepare for close-out.

The CI must submit an end of study report to the R&I Office within 10 months of the date of the end of trial. This report will be submitted to the GMMH Research & Innovation Committee for information. The R&I Office will subsequently be responsible for submitting the end of study report to the MHRA (CTIMPs only) and Main Ethics Committee to arrive within 12 months of the date of the end of the study, unless otherwise delegated by the R&I Office.

**R&I Office**

Upon receipt of notification of study closure from the CI the R&I Office will update the end date on the R&I database and change the study status to completed/closed.

Once the close-out procedures have been completed the R&I Office will notify the CI that the study is closed.

The R&I Office will prepare the R&D files (and Sponsor files where applicable) for archiving. When ready for archiving, the Named Archivist will prepare archive boxes in line with RDSOP21.
1. References

Terms of Reference for the GMMH R&I Committee

UK Policy Framework for Health and Social Care Research v3.3 07/11/17

The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031)

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (Statutory Instrument 2006/1928)

The Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations 2006 (Statutory Instrument 2006:2984)

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (Statutory Instrument 2008/941)

The Medicines for Human Use (Miscellaneous Amendments) Regulations 2009

The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010

Health Research Authority
http://www.hra.nhs.uk/