RDSOP20 End of Study Notification

Greater Manchester Mental Health NHS Foundation Trust
Title of Standard Operating Procedure: RDSOP20 End of Study Notification

Document Summary: To describe the procedures for notifying the main REC, the MHRA and the Trust of the completion or suspension of a research study in compliance with the guidelines and regulatory requirements.

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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 SOP’s

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1. Introduction

In accordance with Good Clinical Practice (GCP) guidelines and regulatory requirements, the closure of a research study must be notified to all organisations that approved the project.

The Research Ethics Committee that provided a favourable opinion of the research (the 'main REC') requires written notification of the end of a study within 90 days of the end of project, or within 15 days if the project is terminated early.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) falling under the Medicines for Human Use (Clinical Trials) Regulations (2004), the Medicines and Healthcare products Regulatory Agency (MHRA) must also be informed within the same timeframes.

Where the Trust is hosting and/or sponsoring the research, the GMMH Research Office must also be informed.

2. Purpose

To describe the procedures for notifying the main REC, the MHRA and the Trust of the completion or suspension of a research study in compliance with the guidelines and regulatory requirements.

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

For CTIMPs, the sponsor is responsible for notifying the MHRA and the main REC of the completion or suspension of the clinical trial. This responsibility may be delegated to the Chief/Principal Investigator (CI/ PI) by the sponsor. When the Trust sponsors a clinical trial, this responsibility is delegated to the PI at the Trust (see Trust RDSOP3: Definition of responsibilities).

For all other research, the CI is responsible for notifying the main REC of the completion or suspension of the study.

For both CTIMPs and other research, the local PI, or his/her delegate is responsible for notifying the Trust of the completion or suspension of the research.

### 4. Operating Procedures

The definition of the conclusion of the research should be provided in the application form to the main REC and in the protocol, and any change to this definition must be notified to the main REC - and the MHRA where applicable - as a substantial amendment. In most cases it will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol.

Final analysis of the data (following 'lock' of the study database) and report writing is normally considered to occur after formal declaration of the end of the project.

For CTIMPs, the sponsor (or CI, if the task has been delegated) must complete a EudraCT ‘Declaration of the end of a trial form’, which can be downloaded [here](#). Copies of the form must be provided to the MHRA, the main REC and the Trust Research Office. Where the form is completed by the CI, the sponsor must also receive a copy.

For all other research, the CI must complete a REC ‘End of study form’, which can be downloaded from [here](#). Copies of the form must be provided to the main REC, the sponsor and the Trust Research Office.
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The appropriate form must be sent within 90 days of the end of the project, or within 15 days if the project is terminated early. Where the project is terminated early, or halted temporarily, reasons must be given.

If a trial is suspended or prematurely terminated then it is the duty of the PI to promptly inform the trial subjects and ensure that they receive appropriate treatment and follow-up.

A summary of the final report of the research must be sent to the main REC within 12 months of the end of the project. This may be enclosed with the end of study declaration, or sent to the REC subsequently.

There is no standard format for final reports. As a minimum, the main REC should receive information on whether the project achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.
5. References

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/