# Standard Operating Procedure

| Title: | **End of Study Declaration, Early Termination and Final Report** | | |
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| | **Name and Position** | **Signature** | **Date** |
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Revision Log

| Previous Version number | Date of Review/Modification | Reason for Review/Modification | New Version Number |
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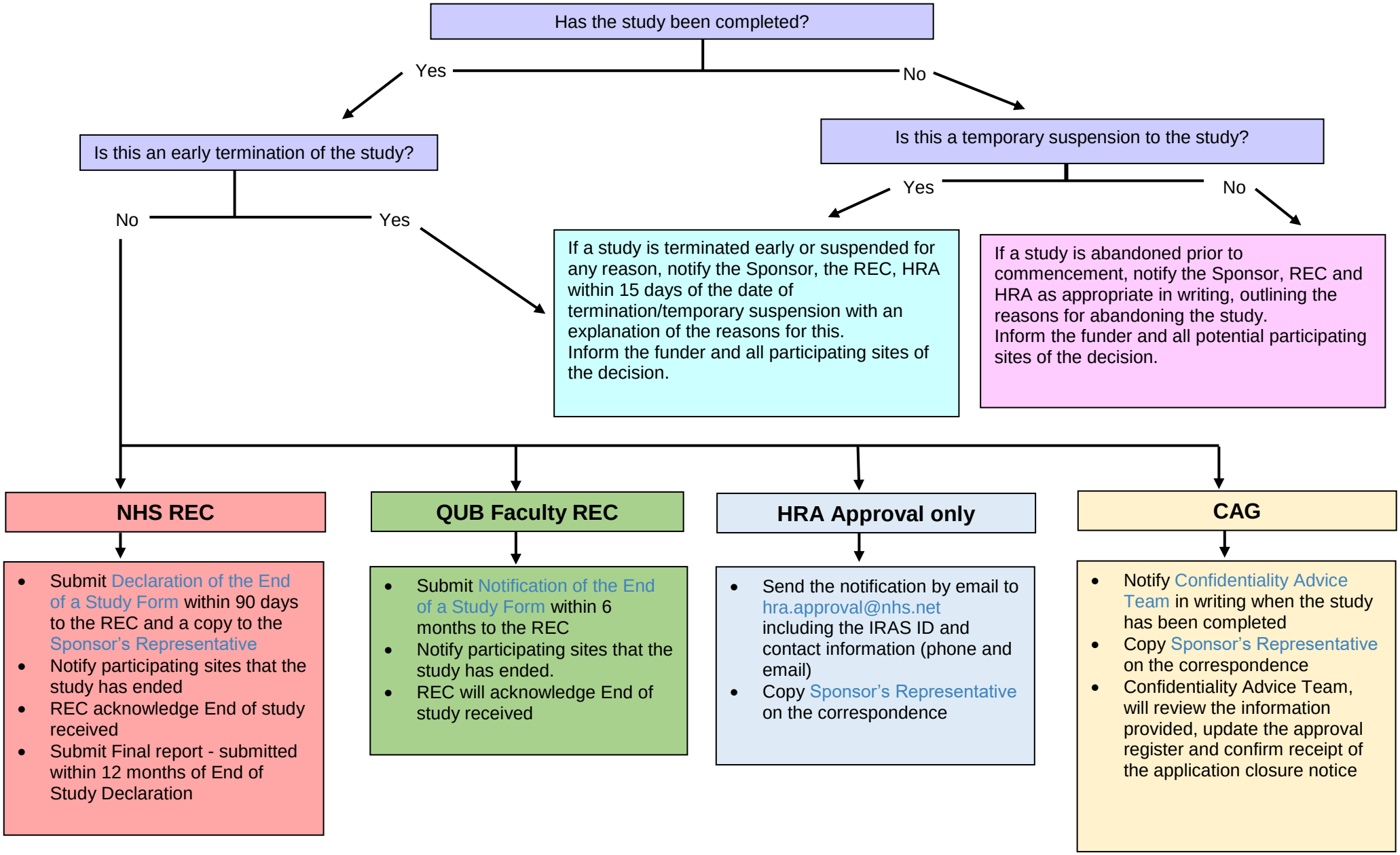
## 1. Purpose

This Standard Operating Procedure (SOP) describes the process for notifying an NHS/HSC Research Ethics Committee (REC) or QUB Faculty REC and the Sponsor that a research study has ended.

## 2. Procedure

The definition of the end of the study should be documented in the protocol or ethics application. In most cases, this will be the completion of data collection or for studies involving human tissue, the completion of the analysis of the samples.


Has the study been completed?
Yes
No
Is this an early termination of the study?
No
Yes
Is this a temporary suspension to the study?
Yes
No
If a study is terminated early or suspended for any reason, notify the Sponsor, the REC, HRA within 15 days of the date of termination/temporary suspension with an explanation of the reasons for this.
Inform the funder and all participating sites of the decision.
If a study is abandoned prior to commencement, notify the Sponsor, REC and HRA as appropriate in writing, outlining the reasons for abandoning the study.
Inform the funder and all potential participating sites of the decision.
NHS REC
Submit Declaration of the End of a Study Form within 90 days to the REC and a copy to the Sponsor's Representative
Notify participating sites that the study has ended
REC acknowledge End of study received
Submit Final report - submitted within 12 months of End of Study Declaration
QUB Faculty REC
Submit Notification of the End of a Study Form within 6 months to the REC
Notify participating sites that the study has ended.
REC will acknowledge End of study received
HRA Approval only
Send the notification by email to hra.approval@nhs.net including the IRAS ID and contact information (phone and email)
Copy Sponsor's Representative on the correspondence
CAG
Notify Confidentiality Advice Team in writing when the study has been completed
Copy Sponsor's Representative on the correspondence
Confidentiality Advice Team, will review the information provided, update the approval register and confirm receipt of the application closure notice

## 2.1 Notification of an End of Study

The REC which gave a favourable opinion of the research must be notified of its conclusion using the Declaration of the End of a Study Form within 90 days of the end of the study. Once completed and signed by the Chief Investigator (CI) the Declaration of the End of Study form should be sent to the REC and a copy to the Sponsor's Representative. The CI should also notify participating sites that the study has ended. The end of study declaration and all related correspondence should be retained in the Research File/Study Master File.

Before submitting the Seclaration of the end of the study, the plans approved by the REC for use of tissue and data collected in the course of the study, providing information to participants, and dissemination of results should be reviewed. If changes to the approved arrangements are required, an amendment may be made before submitting the end of study notification. Once the Declaration of the End of a Study Form has been received by the REC it is not possible to submit any further amendments to the study.

## 2.2 Final Report on the Research

The Chief Investigator should submit a summary study report to the sponsor and REC within 12 months of the declaration of end of the study. The Final Report Form should be completed and submitted via the webform on the HRA website. Once the information has been submitted an email confirming that the Final Report has been received will be generated and sent to the Chief Investigator. The email will contain a copy of the information submitted, which can be saved for inclusion in the Research File/Study Master File. A copy of the email should be forwarded to researchgovernance@qub.ac.uk.

## 2.3 Studies with HRA Approval only

Where a project has HRA Approval but was not reviewed by an NHS/HSC REC, the HRA must be informed when the project has ended. The Chief Investigator should send the notification by email to hra.approval@nhs.net including the IRAS ID contact information (phone and email). The Sponsor's Representative should be copied on the correspondence.

## 2.4 Notification of end of study to Confidentiality Advisory Group

If the study has received approval from Confidentiality Advisory Group, the Confidentiality Advice Team should be notified in writing when the study has been completed. Once received the Confidentiality Advice Team, will review the information provided, update the approval register and write to confirm receipt of the application closure notice. The Sponsor's representative should be copied on the correspondence.

## 2.5 Early Termination

If a study is terminated early or suspended for any reason, including lack of recruitment or lack of funding, the CI must discuss with the Sponsor the rationale for this and how this will be managed. The CI must notify the REC and HRA within 15 days of the date of termination/temporary suspension with an explanation of the reasons for this. The CI should inform the funder and all participating sites of the decision.

Where a project has HRA Approval and has been reviewed by a REC, only the REC needs to be informed when the study has ended. Where a project has HRA Approval and was not reviewed by an NHS/HSC REC, notification by email should be sent to

approvals@hra.nhs.uk including the IRAS ID and contact information (phone and email).

When a study is terminated early, the Declaration of the End of a Study Form should also provide the following information:

- Justification of the premature ending of the study;
- If applicable, number of patients still receiving treatment at the time of study's termination;
- If applicable, proposed management of the patient receiving treatment at the time of the study termination;
- Consequences for the evaluation of results.

### 2.5.1 Research Participants

Where required, the CI should ensure trial participants are promptly informed of the suspension/termination of the trial and provide assurances to them regarding their therapy and follow-up. The need for this should be discussed and agreed by the Trial Steering/Management Group, if applicable.

The CI should inform other investigators involved in the study of the suspension/termination. In the event of the termination the letter should:

- Thank the investigator for their participation;
- Summarise patient status;
- Remind the investigator(s) of their continuing trial obligations e.g. archiving;
- Arrange the return of trial supplies, if applicable;
- Advise the possibility of audit or inspection, if applicable;
- Outline the results of the trial or provide a copy of the trial report;
- Inform the investigators, if possible, of the expected timing of publication.

Any change to the definition of end of study after approval has been given for the research should be notified as an amendment to the appropriate review body(ies). Where it is necessary to seek ethical review of related actions such as informing subjects and arranging continuing care and follow up outside the study that has terminated early, a notice of substantial amendment can be submitted alongside the declaration of early termination.

A record of the decision to terminate the trial early, the end of study notification form and all related correspondence should be retained in the Research File/Study Master File.

### 2.5.2 Suspension/Termination by Sponsor

Where a Sponsor/co-sponsor raises concerns regarding the conduct of a study, the Sponsor may suspend the recruitment to the study until the concerns raised have been satisfactorily addressed. If the Sponsor suspends/terminates a trial, the CI must promptly inform the institution(s)/sites(s) where the trial is being conducted. The CI must also inform the relevant review bodies, including the main REC and HRA, as appropriate within 15 days of the date of the termination and provide them a detailed written explanation of the termination/suspension.

### 2.5.3 Suspension/Termination by REC

The main Research Ethics Committee (REC) may terminate or suspend its approval/favourable opinion of a trial. If the main REC suspends/terminates its

favourable opinion of a trial, the CI must inform the institution(s) where the trial is being conducted and notify the Sponsor as outlined in 2.5.2 above.

#### 2.5.4 Non-Commencement

If a study is abandoned prior to commencement, the CI should notify the Sponsor, REC and HRA as appropriate in writing, outlining the reasons for abandoning the study.

### 2.6 Faculty REC processes

For Faculty REC approved projects, the Chief Investigator/ Supervisor must inform the Research Ethics Officer that the study is completed and the Faculty REC file can be closed. The Notification of End of Study should be submitted to the Faculty REC within 6 months of study completion. The Research Ethics Officer should acknowledge receipt of the Notification of End of Study and close the Faculty REC file for archiving. Notification of End of Study forms for Faculty REC can be found here: https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Ethics/FacultyResearchEthicsCommittees/

## 3. References

HRA Ending your Project, last accessed September 2021. https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

QUB Faculty REC, last accessed August 2021 https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Ethics/FacultyResearchEthicsCommittees/