# SOP11 Study Pause, Termination and Close Down for NHS Research Sponsored by De Montfort University

1. **Introduction**

This Standard Operating Procedure (SOP) describes the procedures for reporting and documentation requirements for the closure of sponsored research. The document covers closure as defined in the protocol, along with early termination for safety, ethical or logistical reasons and closure of individual sites in Multi-centre studies.

The outcome is that the Sponsor is able to confirm study closure.

1. **Procedure**

The objective of trial closure is to ensure that:

* The rights and wellbeing of all participants have been protected
* All essential documents have been stored appropriately in the Trial Master File (TMF) / Investigator Site Files (ISF)
* The correct approved version of the protocol was used and adhered to
* Any SAEs (Serious Adverse Event), and SUSARs (Suspected Unexpected Serious Adverse Reaction) have been reported appropriately
* Source Data Verification (SDV) has been undertaken
* Monitoring has been performed as described in the study monitoring plan
* All contractual requirements have been met
* Any outstanding queries between the Sponsor and sites are resolved
* A study closure report has been produced

Plans for close down should be included in the monitoring plan and discussed during the Sponsor Risk Assessment and Approval Process.

1. **Planned closure**

Plans for closing the study should be discussed during the Sponsor Risk Assessment and Approval Process, and included in the monitoring plan. The definition of the end of the study should be included in the study protocol.

It is the responsibility of the Sponsor to ensure that study closure tracking and study end dates are maintained on the database. The aim is to support the production of an accurate overview and reporting of research activity sponsored by DMU.

It is the responsibility of the Chief Investigator to discuss study closure with the Sponsor and to complete relevant required documentation. The Sponsor will ensure that the regulatory authorities and REC receive completed documentation within 90 days in accordance with required timelines.

1. **Premature Termination / Early Closure**

As Sponsor, DMU has a legal responsibility to notify the Research Ethics Committee (REC) as relevant that a study has terminated early at a site within 15 days of the termination, irrelevant of reason. It may also be necessary to notify the following:

* Funding body / study finance staff
* All site investigators for multi centre studies

Research can be terminated prior to the planned closure date or event because of:

* Adverse Events
* Slow recruitment
* Sponsor decision
* Investigator decision
* Regulatory decision

It is essential that the CI discuss the process with the Sponsor to ensure that appropriate documentation is completed and submitted within the required timelines.

If a study is terminated early for any reason, including lack of recruitment or lack of funding, the CI (or Sponsor) must notify the REC within 15 days of the date of termination with an explanation of the reasons for the early termination, with a copy to the Sponsor. 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, a notice of substantial amendment could be submitted alongside the declaration of early termination.

If a study is abandoned prior to commencement the CI or Sponsor should notify the main REC in writing, outlining the reasons for abandoning the study.

1. **End of Study Notification and Final Report**

It is the responsibility of the CI to complete the appropriate forms at the end of the study and submit these to the REC which gave a favourable opinion of the research as appropriate. A copy should also be sent to the Sponsor. The appropriate form should be sent within 90 days of the end of the study. The Sponsor does not have a separate form to complete. The forms published on the HRA website should be used.

A summary of the final research report should be sent to the REC within 12 months of the end of the study. Production of the report is the responsibility of the CI who should submit it on completion to the Sponsor who will then forward it to the REC. There is no standard format for final reports. As a minimum, it should include information about whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

DMU as Sponsor will track all required notifications.

1. **Archiving**

Essential Documents must be archived for the relevant period specified in the study protocol. Responsibility lies with the Chief Investigator and if they become unable to be responsible for their essential documents (for example due to retirement) the Sponsor should be notified in writing and informed to whom the responsibility has been transferred.

Details of what documents are regarded as ‘essential’ are detailed in the SOP13 Trial Master Files.

1. **Participants at the End of Study**

At the end of the research study it is expected that all commitments made to the participants as described in the IRAS application, the protocol and the Patient Information Leaflet will be fulfilled. This may include care after research and/or providing information about the outcome of a study.

1. **Publication and Dissemination**

Researchers and Sponsors are expected to ensure, as a minimum that research is registered and summary results are published on a suitable publicly-accessible register. Reference to the IRAS ID number should be made in publications and reports to allow tracking of transparency commitments made to the funder and REC.

The requirements of the Health Research Authority (HRA) to ensure transparency are in development at the time of publication of this SOP and it is advised that their website is consulted to ensure Sponsor obligations are fulfilled.

<http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/transparency/>

1. **Doccument Control**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT** | | | | | | |
| **Author:** Douglas Gray | | | | | **Job Title:** Faculty Head of Research Ethics (HLS) | |
| **Approved by:** University Research Ethics Committee | | | | | **Date Approved:** 14/04/2021 | |
| **REVIEW RECORD** | | | | | | |
| **Date** | **Issue**  **Number** | | **Reviewed By** | **Description of Changes (If Any)** | | |
|  |  | |  |  | | |
|  |  | |  |  | | |
|  |  | |  |  | | |
| **DISTRIBUTION RECORD:** | | | | | | |
| **Date** | | **Name** | | **Dept** | | **Received** |
|  | |  | |  | |  |
|  | |  | |  | |  |
|  | |  | |  | |  |
|  | |  | |  | |  |

**Sponsor End of Study / Close-down Proforma**

|  |  |
| --- | --- |
| **Study Title (in full):** |  |
| **Reference No:** |  |
| **Sites:** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **In progress** | **Date Completed** |
| Has an appropriate public database been identified for  registration of the study? | ☐ | ☐ | ☐ |  |
| Is the end of study defined in the Protocol? | ☐ | ☐ | ☐ |  |
| Are the plans for archiving study documentation from all sites clear? | ☐ | ☐ | ☐ |  |
| Is there adequate funding available for archiving for all sites  or centrally? | ☐ | ☐ | ☐ |  |
| Is there a named individual responsible for study close down at each site? | ☐ | ☐ | ☐ |  |
| Has the individual responsible for  authoring the end of trial reports been identified? | ☐ | ☐ | ☐ |  |
| Has the individual responsible for  ensuring publication been identified? | ☐ | ☐ | ☐ |  |
| Has individual responsible for  database ‘lock’ at each site been identified? | ☐ | ☐ | ☐ |  |
| Has appropriate electronic  storage been identified at each site or centrally? | ☐ | ☐ | ☐ |  |
| Has study close out been included in the Monitoring Plan? | ☐ | ☐ | ☐ |  |

**Study Status**

|  |  |
| --- | --- |
| Planned participant number |  |
| Number of participants recruited |  |
|  | Comments: |

**Protocol**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Version/comment** |
| Is the current approved protocol on file? |  |  |  |
| Are superseded protocols on file? |  |  |  |
| **Comments/Findings** | | | |

**Ethics**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **Comments** |
| Are all original applications/submissions/approvals on file? |  |  |  |
| Are all substantial amendments complete and on  file? |  |  |  |
| Are all non substantial amendments complete  and on file? |  |  |  |
| Ethics correspondence on file? |  |  |  |
| Notification of trial completion on file? |  |  |  |
| **Comments/Findings** | | | |

**Study Documentation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Versions/Comments** |
| Is the current approved documentation  on file (including PIS and consent forms)? |  |  |  |
| Are all superseded documents on file? |  |  |  |
| Are previous versions of study documentation  marked as superseded? |  |  |  |
| **Comments/Findings** | | | |

**Informed Consent**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Are all consent forms present and correctly  completed? |  |  |  |
| Has 100% consent audit been undertaken and  documentation of the audit on file? |  |  |  |
| Is informed consent process properly documented in the medical/trial records |  |  |  |
| **Comments/Findings** | | | |

**Financial/Legal agreements**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all completed documents relating to contracts, finance, funding, indemnity and  sponsorship on file? |  |  |  |  |
| Reporting requirements for funder? |  |  |  |  |
| **Comments/Findings** | | | | |

**Annual/Final Reports**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** |  |
| Are annual progress and where applicable safety  reports to the Ethics Committee on file? |  |  |  |
| Are R&D confirmations of annual report receipt  on file? |  |  |  |
| **Comments/Findings** | | | |

**Publication**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** |  |
| Are copies of all study analysis publications on file? |  |  |  |
| Have any commitments to provide results to participants, or make publicly available, been met? |  |  |  |
| **Comments/Findings** | | | |

**Data Protection**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **Comments** |
| Are computer records and files containing identifiable data stored on a remote and secure  server? |  |  |  |
| Is access to electronic study records and files  password protected? |  |  |  |
| Are electronic data files for analysis anonymised? |  |  |  |
| Is there provision in place for suitable archiving? |  |  |  |

**Other – if not covered above**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** |  | |
|  |  |  |  | |
| **Comments/Findings** | | | | **Category** |
|  | | | |  |

**Additional Comments/Overview**

**Confirmation by Sponsor/Sponsors delegate that the study is ready for closure. Name (Print) …………………………………………………………..**

**Signature …………………………………………………………..**

**Role ………………………………………………………….**