**STANDARD OPERATING PROCEDURE:**

**Externally Sponsored Study Close-Down**

| | |
|---|---|
| **SOP REFERENCE NUMBER** | CLPG19 SOP 7 |
| **VERSION NUMBER** | Version 1 |
| **REPLACES SEPT DOCUMENT** | SOP 16 - Study Close Down (V1.0; 4 August 2014) |
| **REPLACES NEP DOCUMENT** | STANDARD OPERATING PROCEDURE: Externally Sponsored Study Close-Down v2 |
| **KEY CHANGES FROM PREVIOUS VERSION** | Update for EPUT |
| **AUTHOR** | Research & Development Manager |
| **CONSULTATION GROUPS** | R&D staff, R&D group |
| **IMPLEMENTATION DATE** | |
| **AMENDMENT DATE(S)** | |
| **LAST REVIEW DATE** | |
| **NEXT REVIEW DATE** | |
| **APPROVAL BY CLINICAL GOVERNANCE & QUALITY SUB-COMMITTEE** | March 2018 |
| **RATIFICATION BY QUALITY COMMITTEE** | April 2018 |
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**SOP SUMMARY**

The aim of this Standard Operating Procedure is to describe to research staff the procedure for study close-down, detailing the process and essential documentation required. According to ICH GCP the close-down of a clinical trial can only be done when both investigator/institution and sponsor files have been reviewed and it has been confirmed that all necessary documentation pertaining to the trial have been completed. ICH Good Clinical Practice guidelines define the study documents to be filed after completion or termination of the trial. This is an essential part of the trial process.

**The Trust monitors the implementation of and compliance with this policy in the following ways:**

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

| Services | Applicable | Comments |
|---|---|---|
| Trustwide | ✓ | |
| Essex MH&LD | | |
| CHS | | |

**ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST**

# STANDARD OPERATING PROCEDURE: Externally Sponsored Study Close-Down

**CONTENTS**

## 1. BACKGROUND

According to ICH GCP the close-down of a clinical trial can only be done when both investigator/institution and sponsor files have been reviewed and it has been confirmed that all necessary documentation pertaining to the trial have been completed. ICH Good Clinical Practice guidelines define the study documents to be filed after completion or termination of the trial. This is an essential part of the trial process.

## 2. PURPOSE

To describe the procedure for study close-down, detailing the process and essential documentation required.

## 3. RESPONSIBILITIES

This SOP is applicable to all investigative site personnel who are members of the study teams. The PI is responsible for informing all members of the study team and all applicable review bodies of the study closure.

The Principal Investigator or delegate is responsible for the closure of the trial according to regulatory and sponsor requirements.

## 4. PROCEDURE

As soon as the Principal Investigator or any study personnel are informed of study closure, the study team, to include the local Investigator, research practitioners (e.g. research nurses/practitioners/officers/coordinators/data managers) will ensure that all data required by the protocol are recorded and that all essential documents are filed (see list of essential documents Appendix 1). The study team will meet to finalise the closure of the study and to confirm that all study-related activities have stopped.

The study team need to notify the R&D Office who will update the study status.

The essential documents will be retained in accordance with SOP for Archiving and Destroying Documents.

The sponsor will inform the Local Ethics Committee within 90 days of study closure and within 15 days if the study was terminated early.

A member of the study team will inform Pharmacy and other support departments of the study closure.

The Research team should send a copy of the formal notification of study closure received from the sponsor to the R&D office.

The Sponsor will liaise with the pharmacy department to ensure that they are closed in accordance with regulatory and protocol requirements.

Once R&D has received the Sponsor's notification of study closure and the Trial Status Notification form they will close the study on the R&D database.

## 5. OTHER RELATED PROCEDURES

CLPG19 SOP 2 - Archiving and Destroying Documents

## 6. REFERENCES

ICH-GCP, Section 8.4

## 7. APPENDICES

Appendix 1: Close-down study file contents list

## APPENDIX 1: Close-down study file contents list

This guide describes the essential documentation that is required under ICH Good Clinical Practice (ICH GCP). The Clinical Trials Regulations do not require the adoption of ICH GCP but the checklist provides a useful reference. This section will be updated in line with changing regulatory requirements.

### Before the clinical conduct of the trial

| | **Title of Document** | **Located in Files of** | |
|---|---|---|---|
| | | **Investigator/ Institution** | **Sponsor** |
| **8.2.1** | **INVESTIGATOR'S BROCHURE** | X | X |
| **8.2.2** | **SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)** | X | X |
| **8.2.3** | **INFORMATION GIVEN TO TRIAL SUBJECT** | X | X |
| | - INFORMED CONSENT FORM | | |
| | - ANY OTHER WRITTEN INFORMATION | X | X |
| | - ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used) | X | |
| **8.2.4** | **FINANCIAL ASPECTS OF THE TRIAL** | X | X |
| **8.2.5** | **INSURANCE STATEMENT**<br><br>(where required) | X | X |
| **8.2.6** | **SIGNED AGREEMENT BETWEEN INVOLVED PARTIES,** e.g.: | | |
| | - investigator/institution and sponsor | X | X |
| | - investigator/institution and CRO | X | X (where required) |
| | - sponsor and CRO | | X |
| | - investigator/institution and authority(ies) (where required) | X | X |
| **8.2.7** | **DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:**<br><br>- protocol and any amendments<br>- CRF (if applicable)<br>- informed consent form(s)<br>- any other written information to be provided to the subject(s)<br>- advertisement for subject recruitment<br>(if used)<br>- subject compensation (if any)<br>- any other documents given approval/ favourable opinion | X | X |
| **8.2.8** | **INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION** | X | X (where required) |
| **8.2.9** | **REGULATORY AUTHORITY(IES) AUTHORISATION/APPROVAL/ NOTIFICATION OF PROTOCOL**<br>(where required) | X (where required) | X (where required) |

| | | | |
|---|---|---|---|
| **8.2.10** | **CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)** | X | X |
| **8.2.11** | **NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL** | X | X |
| **8.2.12** | **MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS**<br><br>- certification or<br>- accreditation or<br>- established quality control and/or external quality assessment or<br>- other validation (where required) | X<br>(where required) | X |
| **8.2.13** | **SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)** | | X |
| **8.2.14** | **INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS**<br><br>(if not included in protocol or Investigator's Brochure) | X | X |
| **8.2.15** | **SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS** | X | X |
| **8.2.16** | **CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED** | | X |
| **8.2.17** | **DECODING PROCEDURES FOR BLINDED TRIALS** | X | X<br>(third party if applicable) |
| **8.2.18** | **MASTER RANDOMISATION LIST** | | X<br>(third party if applicable) |
| **8.2.19** | **PRE-TRIAL MONITORING REPORT** | | X |
| **8.2.20** | **TRIAL INITIATION MONITORING REPORT** | X | X |

**During the clinical conduct of the trial**

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

| | **Title of Document** | **Located in Files of** | |
|---|---|---|---|
| | | **Investigator/ Institution** | **Sponsor** |
| **8.3.1** | **INVESTIGATOR'S BROCHURE UPDATES** | X | X |
| **8.3.2** | **ANY REVISION TO:**<br><br>- protocol/amendment(s) and CRF<br>- informed consent form<br>- any other written information provided to subjects<br>- advertisement for subject recruitment<br>(if used) | X | X |
| **8.3.3** | **DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:**<br><br>- protocol amendment(s)<br>- revision(s) of:<br>- informed consent form<br>- any other written information to be provided to the subject<br>- advertisement for subject recruitment<br>(if used)<br>- any other documents given approval/favourable opinion<br>- continuing review of trial (where required) | X | X |
| **8.3.4** | **REGULATORY AUTHORITY(IES) AUTHORISATIONS/APPROVALS/NOTIFICATIONS WHERE REQUIRED FOR:**<br>- protocol amendment(s) and other documents | X<br>(where required) | X |
| **8.3.5** | **CURRICULUM VITAE FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S)** | X | X |
| **8.3.6** | **UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL** | X | X |
| **8.3.7** | **UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS**<br><br>- certification or<br>- accreditation or<br>- established quality control and/or external quality assessment or<br>- other validation (where required) | X<br>(where required) | X |
| **8.3.8** | **DOCUMENTATION OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS SHIPMENT** | X | X |
| **8.3.9** | **CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS** | | X |
| **8.3.10** | **MONITORING VISIT REPORTS** | | X |
| **8.3.11** | **RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS**<br><br>- letters<br>- meeting notes<br>- notes of telephone calls | X | X |
| **8.3.12** | **SIGNED INFORMED CONSENT FORMS** | X | |
| **8.3.13** | **SOURCE DOCUMENTS** | X | |
| **8.3.14** | **SIGNED, DATED AND COMPLETED CASE REPORT FORMS (CRF)** | X<br>(copy) | X<br>(original) |
| **8.3.15** | **DOCUMENTATION OF CRF CORRECTIONS** | X<br>(copy) | X<br>(original) |
| **8.3.16** | **NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS** | X | X |

| | | | |
|---|---|---|---|
| **8.3.17** | **NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, WHERE APPLICABLE, TO REGULATORY AUTHORITY(IES) AND IRB(S)/IEC(S) OF UNEXPECTED SERIOUS ADVERSE DRUG REACTIONS AND OF OTHER SAFETY INFORMATION** | X (where required) | X |
| **8.3.18** | **NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION** | X | X |
| **8.3.19** | **INTERIM OR ANNUAL REPORTS TO IRB/IEC AND AUTHORITY(IES)** | X | X (where required) |
| **8.3.20** | **SUBJECT SCREENING LOG** | X | X (where required) |
| **8.3.21** | **SUBJECT IDENTIFICATION CODE LIST** | X | |
| **8.3.22** | **SUBJECT ENROLMENT LOG** | X | |
| **8.3.23** | **INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE** | X | X |
| **8.3.24** | **SIGNATURE SHEET** | X | X |
| **8.3.25** | **RECORD OF RETAINED BODY FLUIDS/ TISSUE SAMPLES (IF ANY)** | X | X |

### After completion or termination of trial

After completion or termination of the trial, all of the documents identified in sections 8.2 and 8.3 should be in the file together with the following:

| | **Title of Document** | **Located in Files of** | |
|---|---|---|---|
| | | **Investigator/ Institution** | **Sponsor** |
| **8.4.1** | **INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE** | X | X |
| **8.4.2** | **DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION** | X<br>(if destroyed at site) | X |
| **8.4.3** | **COMPLETED SUBJECT IDENTIFICATION CODE LIST** | X | |
| **8.4.4** | **AUDIT CERTIFICATE** (if available) | | X |
| **8.4.5** | **FINAL TRIAL CLOSE-OUT MONITORING REPORT** | | X |
| **8.4.6** | **TREATMENT ALLOCATION AND DECODING DOCUMENTATION** | | X |
| **8.4.7** | **FINAL REPORT BY INVESTIGATOR TO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES)** | X | |
| **8.4.8** | **CLINICAL STUDY REPORT** | X<br>(if applicable) | X |