**Observational Protocol Template: UCLH/UCL Sponsored Studies**

**UCL/UCLH Research Office**

**Guidance**

This protocol template is for use by **UCLH investigators to submit studies for UCL or UCLH Sponsorship** via the UCL/UCLH Research Office (RO).

Further information on which studies UCL or UCLH will sponsor can be found on its website.

This template is **not applicable** for all studies:

* deemed to be Clinical Studies of Investigational Medicinal Products (CTIMP)
* involving new Devices or Devices being used for a new purpose
* managed via a UCL Clinical Trials Unit (CTU)

This template has been developed to include all relevant regulatory, ethics and local policy requirements. The template contains all sections recommended by the Health Research Authority (HRA) for regulatory review by the HRA and the Research Ethics Committees.

**Investigators may use other templates**, but must ensure the sufficient level of detail is presented. Investigators wishing to do so are encouraged to read through this template. Text marked in **black** must be inserted into these protocols.

The RO will review each protocol submitted to ensure key sections and details are included before Sponsorship is formally agreed.

**Instructions for use**

**Not all sections will be relevant for all studies**. Each section can be modified or deleted as applicable to your type of study.

Instructions and explanatory text are indicated in **red** and should be removed or replaced in your protocol with the appropriate text.

**Post sponsorship approval;** any modification to the protocol should be annotated on the coversheet or in an appendix. The annotation should note exact words that are changed, the location in the protocol, the date the modification was approved by the relevant committee/parties, and the date it became effective.

**Study Protocol Front Page**

**FULL PROTOCOL TITLE OF THE STUDY**

**SHORT STUDY TITLE / ACCRONYM**

**Chief Investigator:**

[List CI name, degree, position and affiliations]

**Supported by:**

[Include application or grant number(s) when available]

**Sponsored by:**

University College London Hospitals NHS Foundation Trust (UCLH)

OR

University College London (UCL)

(delete as applicable)

**Protocol version number and date:**

**R&D / Sponsor Reference Number(s):**

**Study Registration Number:**

**PROTOCOL VERSIONS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version Stage** | **Versions No** | **Version Date** | **Protocol updated & finalised by;** | **Appendix No detail the reason(s) for the protocol update** |
| Current | [insert Version] | [insert date] | [full name & title] | [appendix no]  NB: Appendix is to be attached to current version of the protocol |
| Previous |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**DECLARATIONS**

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the Research Governance Framework 2005 (as amended thereafter), the Trust Data & Information policy, Sponsor and other relevant SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I (investigator) also confirm that an honest accurate and transparent account of the study will be given; and that any deviations from the study as planned in this protocol will be explained and reported accordingly.

**Chief Investigator:**

**Signature:.................................................................................... Date....../....../.......**

**Print Name(in full):......................................................................**

**Position:.........................................................................................**

**On behalf of the Study Sponsor:**

**Signature:..................................................................................... Date....../....../.......**

**Print Name(in full):.......................................................................**

**Position:.......................................................................................**

**STUDY SUMMARY**

|  |  |
| --- | --- |
| **Identifiers** |  |
| IRAS Number |  |
| REC Reference No |  |
| Sponsor Reference No |  |
| Other research reference number(s) (if applicable) |  |
|  |  |
| Full (Scientific) title |  |
| Health condition(s) or problem(s) studied |  |
| Study Type i.e. Cohort etc |  |
| Target sample size |  |
|  |  |
| **STUDY TIMELINES** |  |
| Study Duration/length |  |
| Expected Start Date |  |
| End of Study definition and anticipated date |  |
| Key Study milestones | e.g. study submission, budget and contract to be finalised, first patient recruitment |
| **FUNDING & Other** |  |
| Funding | Insert names and contact details of ALL organisations providing funding for this study |
| Other support | Insert details of the non-financial support given, and the names & contact details of all organisation providing the non-financial support |
| **STORAGE of SAMPLES**  **(if applicable)** |  |
| Human tissue samples | Insert name and contact details for where samples will be transferred and/or analysed if external to the organisation. |
| Data collected / Storage | Insert name and contact details were the data will be transferred to for storage and analysis if external to the research group and institution. |
| **KEY STUDY CONTACTS** | Full contact details including phone, email and fax numbers |
| Chief Investigator |  |

**KEY ROLES AND RESPONSIBILITIES**

**SPONSOR:** The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also has to be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

**FUNDER:** The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work. If further arrangements have been agreed with the funder, please refer to the funding agreement and insert

**CHIEF INVESTIGATOR (CI):** The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether or not he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the RE of the end of the study, including the reasons for the premature termination. Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

**PRINCIPLE INVESTIGATOR (PI):** Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

**OTHER:**add other key personal/entity responsibilities where relevant to the study

**KEY WORDS**

Insert relevant key words to describe the study

**LIST OF ABBREVIATIONS**

Commonly used abbreviations – add or delete as applicable

|  |  |  |
| --- | --- | --- |
| AE | Adverse Event | |
| AR | Adverse Reaction | |
| CI | Chief Investigator | |
| CRF | Case Report Form | |
| CRO | Contract Research Organisation | |
| DMC | Data Monitoring Committee | |
| GAfREC | Governance Arrangement for NHS Research Ethics | |
| HTA | Human Tissue Authority | |
| IB | Investigator Brochure | |
| ICF | Informed Consent Form | |
| MD | Medical Device | |
| ISRCTN | International Standard Randomised Controlled Studies Number | |
| PI | Principle Investigator | |
| PIS | Participant Information Sheet | |
| QA | Quality Assurance | |
| QC | Quality Control | |
| RCT | Randomised Clinical Study | |
| REC | Research Ethics committee | |
| SAR | Serious Adverse Reaction | |
| SAE | Serious Adverse Event | |
| SDV | Source Data Verification | |
| SOP | Standard Operating Procedure | |
| SSI | Site Specific Information | |
| TMF | Trial Master File | |
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# INTRODUCTION

Brief overview of the study it should sufficient to guide the reader to the main purpose of the study, how it will be conducted and its expected benefits. It should say how the results of the study would benefit in terms of clinical practice, policy or the NHS as whole. The introduction may include a study flowchart (recommended)

# BACKGROUND AND RATIONALE

Brief background to the present proposal which may include;

* Evaluating existing knowledge, and gaps which the study is intends to fill
* Current literature and existing research carried out in the study area
* Pertinent studies supporting the proposed study
* The need, relevance and priority for the study

# OBJECTIVES

## Primary Objective

## Secondary Objectives

# STUDY DESIGN

Study design may include;

* Type/design of study e.g. Case Control, cross-sectional, cohort, qualitative, observational etc
* Study population and groups
* Approximate duration of enrolment and follow-up
* How has the planned number of participants been derived
* Methods used to determine the sample size (reference statistical software and any statistician support)
* Statistical analysis plan

# STUDY SCHEDULE

Provide detailed information on:

* enrolment process (and screening if applicable)
* Follow up
* Participant withdrawal criteria and procedures
* End of study (definitions)

# CONSENT

Describe the procedures for obtaining and documenting informed consent of study participants. Include provisions for specific populations e.g. non-English speakers, children, vulnerable populations.

# ELIGIBILITY CRITERIA

## 7.1 Inclusion Criteria

## 7.2 Exclusion Criteria

# RECRUITMENT

The recruitment section may include:

* Recruitment schedule (where appropriate)
* Method for identifying and recruiting participants for the study.
* Who will identify and approach participants for consent.
* Procedures for documentation of reasons for ineligibility and or non-participation of eligible candidates (e.g. Screening logs)

# STATISTICAL METHODS

This section should include:

* how the planned number of participants was derived
* methods used to determine the sample size and reference to tables or statistical support used to carry out the calculations
* reason for choice of study design statistical analysis plan
* summary of baseline data
* other statistical considerations

# PATIENT AND PUBLIC INVOLVEMENT (PPI)

This section of the protocol should detail which aspects of the research process have actively involved, or will involve, patients, service users, and/or their carers or members of the public. This may include how these groups will be involved in:

* design of the research
* management of the research
* analysis of results and dissemination of findings.

# FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCL/UCLH Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via UCLH and/or the Local Clinical Research Network.

The research costs for the study have been supported by (add funder, including funding amount and date of award).

This section should contain (where applicable) an outline of the funding arrangements to support external sub-contractors and additional sites. It should also provide details of excess treatment costs or the supply of equipment or other resource from third parties where this is applicable.

Also include the details of specific equipment to be used and their intended use, department where they will be used, and whether these are to be provide by an external body.

# DATA HANDLING AND MANAGEMENT

This section may include:

* Where data will be recorded (source data, e.g. medical notes)
* Where electronic and hard copy data will be stored
* Details of where and how the data will be transferred
* If data will be maintained outside the study unit/office/organisation,
* Which institution will maintain the data, specifically how the data will get there
* The purpose for its transfer over to other institutions, and who will view/custodian of the data at the other institution
* Issues and arrangements regarding confidentiality
* Data collection procedures
* Data monitoring committees and data controllers (if applicable)

# MATERIAL/SAMPLE STORAGE

This section should contain:

* Details of sample sharing
* Details of where material will be stored (or transferred)
* If samples will be stored for future use (and the details)
* Measures for the processing, control and safe storage of samples
* Sample disposal methods
* Whether samples will be coded or de-identified.
* Details of data controller/custodian
* Legal/contractual arrangements

In the study, [Description of tissue samples to be inserted] will be collected from patients in accordance with the patient consent form and patient information sheet and shall include all tissue samples or other biological materials and any derivatives, portions, progeny or improvements as well as all patient information and documentation supplied in relation to them. Samples will be processed, stored and disposed in accordance with all applicable legal and regulatory requirements, including the Human Tissue Act 2004 and any amendments thereafter.

# PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL/UCLH (delete as appropriate).

Choose either (having discussed with the UCL/UCLH Research Office):

* The Sponsor considers the procedure for obtaining funding from (insert funder name) to be of sufficient rigour and independence to be considered an adequate peer review.
* This study has been peer reviewed within UCL/UCLH (amend as required), by an independent and relevant peer reviewer/committee (amend as required) on (insert date). The Sponsor has accepted these reviews as adequate evidence of peer review.
* This study has been reviewed as part of an educational programme. The Sponsor has verified that the supervisor of the project has undertaken sufficient review of the protocol in line with the requirements of his/her department.

The study was deemed to require regulatory approval from the following bodies (list). Each approval will be obtained before the study commences.

# ASSESMENT AND MANAGEMENT OF RISK

Provide details of any potential risks to participants (physical, psychological, social, legal or other. List any mitigations and procedures for protecting against or minimising any potential risks, and why the risks to participants are reasonable in relation to the anticipated benefit.

# RECORDING AND REPORTING OF EVENTS AND INCIDENTS

## 16.1 Definitions of Adverse Events

|  |  |
| --- | --- |
| **Term** | **Definition** |
| Adverse Event (AE) | Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. |
| Serious Adverse Event (SAE). | Any adverse event that:   * results in death, * is life-threatening\*, * requires hospitalisation or prolongation of existing hospitalisation\*\*, * results in persistent or significant disability or incapacity, or * consists of a congenital anomaly or birth defect |
| \*A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.  \*\* Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE. | |

## Assessments of Adverse Events

Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below.

* + 1. **16.2.1 Severity**

The generic categories below are given for use as a guide. You may have a more specific scale that you want to use related to the disease (e.g. CTCAE criteria), (amend as required).

|  |  |
| --- | --- |
| **Category** | **Definition** |
| Mild | The adverse event does not interfere with the participant’s daily routine, and does not require further procedure; it causes slight discomfort |
| Moderate | The adverse event interferes with some aspects of the participant’s routine, or requires further procedure, but is not damaging to health; it causes moderate discomfort |
| Severe | The adverse event results in alteration, discomfort or disability which is clearly damaging to health |

* + 1. **16.2.2 Causality**

The assessment of relationship of adverse events to the procedure is a clinical decision based on all available information at the time of the completion of the case report form.

If a differentiated causality assessment which includes other factors in the study is deemed appropriate, please add/amend the following wording to specify:

It is of particular importance in this study to capture events related to the product application procedure (specify e.g. surgery) / product failure / mandatory concomitant medications (specify e.g. conditioning chemotherapy). The assessment of relationship of an adverse event to this/these additional safety issue(s) will also be carried out as part of the study.

The differentiated causality assessments will be captured in the study specific CRF/AE Log and/or SAE form (amend as required).

The following categories will be used to define the causality of the adverse event:

|  |  |
| --- | --- |
| **Category** | **Definition** |
| Definitely: | There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. |
| Probably: | There is evidence to suggest a causal relationship, and the influence of other factors is unlikely |
| Possibly | There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant’s clinical condition, other concomitant events). |
| Unlikely | There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant’s clinical condition). |
| Not related | There is no evidence of any causal relationship. |
| Not Assessable | Unable to assess on information available. |

* + 1. **16.2.3 Expectedness**

|  |  |
| --- | --- |
| Category | Definition |
| *Expected* | An adverse event which is consistent with the information about the procedure listed in the Investigator Brochure, SPC, manual of Operation (amend as appropriate) **or clearly defined in this protocol.** |
| *Unexpected* | An adverse event which is not consistent with the information about the procedure listed in the manual of operation (or other – amend as appropriate)\* **or clearly defined in this protocol.** |

\* this includes listed events that are more frequently reported or more severe than previously reported

## Recording adverse events

Choose most appropriate sentence(s):

All adverse events will be recorded in the medical records in the first instance.

AEs will not be collected in the CRFs for this study(provide justification. However, all SERIOUS adverse reactions must be recorded in the CRF) or;

All Adverse events will be recorded in the CRF following consent.

All adverse events will be recorded with clinical symptoms and accompanied with a simple, brief description of the event, including dates as appropriate.

All adverse events will be recorded in the CRF until (insert as appropriate e.g. the participant completes the study)

## Procedures for recording and reporting Serious Adverse Events

All serious adverse events will be recorded in the medical records and the CRF, and the sponsor’s AE log (the sponsors AE log is used to collate SAEs and AEs so that the CI can review all in one place for trend analysis. If this data will be collated on a database throughout the study, from which a line listing of the SAEs can be extracted for review, an AE log will not be required).

All SAEs (except those specified in section 16.5 as not requiring reporting to the Sponsor) must be recorded on a serious adverse event (SAE) form. The CI/PI or designated individual will complete an SAE form and the form will be preferably emailed to the Sponsor within 5 working days of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the procedure this must be reported by the Investigator to the Health Research Authority within 15 days.

Completed forms for unexpectedSAES must be sent within 5 working days of becoming aware of the event to the Sponsor

**Email forms to** [randd@uclh.nhs.uk](mailto:randd@uclh.nhs.uk) (if sponsored by UCLH)

[Research-incidents@ucl.ac.uk](mailto:Research-incidents@ucl.ac.uk) (if sponsored by UCL)

**Flow Chart for SAE reporting (this simple flow chart is for single site study, please amend in line with study specific requirements)**

**Was the event an Other Notifiable event?**

See section 16.5 for notifiable events which should also be reported as serious

**Submit SAE form to Sponsor within 5 working days**

Record in medical records, CRF (and AE Log if required)

**Complete an SAE report form**

No

Yes

Record in medical records,

And CRF in accordance with the protocol

**Is the event specified as an adverse event which does not require immediate reporting as an SAE?**

Yes

Yes

Record in medical records and CRF (if applicable)

No

No

**Was the event Serious?**

**AE occurs**

**Assign Severity Grade**

### 16.5 Serious Adverse Events that do not require reporting

You may choose not to report some particular SAEs to the sponsor, for example if they are expected to occur on a regular basis and offer no further new information to your safety profile or are related to the disease area of the participants. It should be specified that where the frequency or severity of these events is unusual they must be reported. These events must continue to be recorded in the medical records, CRF and the AE log (if required), however you may state that you will not complete an SAE form and forward it to the sponsor. Provide the rationale for doing so.

## Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

## Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The CI will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

The CI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

## 16.8 Reporting incidents involving a medical device(s) (if applicable)

Any adverse incident involving a medical device should be reported to the manufacturer of the device.

This is especially important where the incident has led to or, was it to occur again could lead to an event classified as serious (see section 9.1 for definition of SAE). Other minor safety or quality problems should be reported along with incidents that appear to be caused by human error.

For multisite studies detail the process for reporting to the manufacturer (e.g. sites to report to central study coordinator who submits reports to manufacturer).

All adverse incidents must be reported to [add contact details of the device manufacturer for reporting purposes].

Incidents should be reported as soon as possible (usually within 24 hours). Specify any additional timelines which have may have been agreed with the manufacturer for reporting.

Incidents should be reported to the manufacturer using the [Specify if a particular report format is required by the manufacturer] form provided.

It may be required for events to be reported directly to the MHRA as well as or instead of the manufacturer (this should be discussed with the manufacturer). In this case the following information can be included:

Adverse incidents related to a medical device can be reported directly to the MHRA via the online system ([www.mhra.gov.uk](http://www.mhra.gov.uk)). Alternative contact details: Medicines & Healthcare products Regulatory Agency Adverse Incident Centre (Tel: 020 7084 3080; Fax 020 7084 3109).

Local trust reporting procedures may also need to be followed. It is the responsibility of the PI and study site team to ensure they are aware of any specific local requirements for reporting device incidents.

## Trust incidents and near misses

An incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.

b. It is contrary to specified or expected standard of patient care or service.

c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.

d. It puts the Trust in an adverse position with potential loss of reputation.

e. It puts Trust property or assets in an adverse position or at risk.

Incidents and near misses must be reported to the Trust through DATIX as soon as the individual becomes aware of them.

A reportable incident is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

1. It is an accident or other incident which results in injury or ill health.
2. It is contrary to specified or expected standard of patient care or service.
3. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
4. It puts the Trust in an adverse position with potential loss of reputation.
5. It puts Trust property or assets in an adverse position or at risk of loss or damage.

# MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

Insert details of any additional monitoring support (if applicable), e.g., data monitoring committees

# TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files

The training section may also include:

* Specific training requirements for staff working on the project
* Specific qualifications and experience required of staff on the project
* Identifying if training may require a renewal at any point throughout the study

# INTELLECTUAL PROPERTY

If formal site agreements will not be used for the study, but after discussion with the study team, the RO has determined that there is sufficient need for intellectual property provisions to be covered in a sponsor-site document, insert this text:

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCL/UCLH (delete as applicable).  Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights (“IPR”) to UCL/UCLH (delete as applicable) and to disclose all such know-how to UCL/UCLH(delete as applicable). with the understanding that they may use know-know gained during the study in clinical services and teaching to the extent that such use does not result in disclosure of UCL/UCLH (delete as applicable) confidential information or infringement of UCL/UCLH (delete as applicable) IPR.

Otherwise, this section is not needed.

# INDEMNITY ARRANGEMENTS

Delete as applicable

UCLH sponsored:

UCLH will provide NHS indemnity cover for negligent harm, as appropriate and is not in the position to indemnify for non-negligent harm. NHS indemnity arrangements do not extend to non-negligent harm and NHS bodies cannot purchase commercial insurance for this purpose; it cannot give advance undertaking to pay compensation when there is no negligence attributable to their vicarious liability. The Trust will only extend NHS indemnity cover for negligent harm to its employees, both substantive and honorary, conducting research studies that have been approved by the R&D Department. The Trust cannot accept liability for any activity that has not been properly registered and Trust approved. Potential claims should be reported immediately to the Joint Research Office.

If UCL sponsored:

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital’s duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

# ARCHIVING

Delete as applicable

UCLH sponsored:

UCLH and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The study master file will be archived at UCL in accordance with the UCLH Standard Operating Procedure 10 Archiving of Investigator Site File (ISF) and Pharmacy Site File (PSF). It will be archived for a minimum of 5 years from the study end, and no longer than 30 years from study end.

UCL sponsored:

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at [insert site name] for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site’s study documents for [insert duration] and in line with all relevant legal and statutory requirements.

# PUBLICATION AND DISSEMINATION POLICY

Describe any plans for publication and dissemination. This may include:

* how authorship will be determined (in collaborative studies only)
* terms or conditions relating to the funding which may impact upon publication and dissemination
* plan for the dissemination of the results of the study

# REFERENCES

# APPENDICES

Include here supplementary information and documents that will support the protocol and information contained therein, e.g. PIS, ICF, schedule visit, assessment tools, delegation log, case report forms, questionnaires, scales, tables, charts, diagrams, manufacturer’s brochures.