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

**UCLH/UCL Research Office**

**(*Version 2.0, 06/01/2021)***

**Guidance**

***Please check the Joint Research Office website*** [***https://www.ucl.ac.uk/joint-research-office/sops-and-templates***](https://www.ucl.ac.uk/joint-research-office/sops-and-templates) ***to ensure you have the most up to date version of this template.***

This protocol template is for use by UCL/**UCLH Chief Investigators to submit observational studies for UCL or UCLH Sponsorship** via the UCLH/UCL Joint Research Office (JRO).

***Observational studies:***

*A study in which participants may undergo procedures or tests using various methods in order to investigate a research question, but there is no intervention or treatment altering clinical/standard care involved. Examples of observational research:*

* *a basic science study involving procedures with human participants*
* *a study administering questionnaires/interviews for quantitative analysis, or using mixed qualitative/quantitative methodology*
* *a study involving qualitative methods only*
* *a study limited to working with human tissue samples (or other human biological samples) and data (specific project only).*

Further information on which studies UCL or UCLH will sponsor can be obtained from a JRO Sponsorship Officer.

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)
* using interventional methodology
* data only studies

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

**Instructions for use**

**Please ensure the protocol is written in third person.**

**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 **blue** and should be removed or replaced in your protocol with the appropriate text.

**Post sponsorship approval;** any modification to the protocol should be written in the protocol version history table, 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 CI/committee/parties, and the date it became effective.

The protocol must be consistent with the participant information sheet, consent form, IRAS form, and any other relevant study documentation, and should be cross checked prior to finalisation. The JRO will carry out a review of the draft protocol and provide advice and guidance prior to approval.

**Guidance notes on Style and Formatting:**

1. Abbreviations should be written in full on first appearance and a list of abbreviations should be included in the protocol.
2. Ensure consistency: refer to study ‘participants’ throughout the protocol (not patients, subjects or volunteers), refer to ‘study’ throughout the protocol, refer to study ‘sites’, not ‘centres’, for a participating institution.
3. Use bullet point lists or tables where appropriate rather than long passages of prose.
4. Logos: ensure all appropriate and relevant logos are added to the front page, and that bodies represented have agreed to the use of their logo.

**This covering page and JRO template header should be deleted once the protocol has been drafted**





**[If UCL sponsored, insert UCL header here] [If UCLH sponsored, enter UCLH header here]**

Include other logos as appropriate – study specific logo, funders, collaborators, research networks

**Study Protocol Front Page**

|  |  |
| --- | --- |
| **Full/long title of study**  If this is a student project, ensure it is clearly identified as such here, and which UCL academic qualification it relates to. | [Type full descriptive study title] |
| **Short title**  The full and short title must be the same on the IRAS form and all study documents e.g. participant information sheet. A study acronym is a useful short title. | [Type short title/acronym] |
| **Version and date of protocol**  The protocol should be labelled **draft** until approved for submission to the REC when draft should be deleted, and it should become Version 1 | Version [insert version number], [insert date DD/MM/YYYY] |
| **Sponsor:** | University College London (UCL)/University College London NHS Foundation Trust (UCLH) (delete as applicable) |
| **Sponsor reference number:** | [Insert EDGE ID number] |
| **Funder (s):**  **IRAS Number:**  **ISRCTN / Clinicaltrials.gov no:** delete as applicable | [Insert names of ALL organisations providing funding for this study] [Type IRAS no]  [Insert ISRCTN or Clinicaltrials.gov reference no] |
| **UCL Data Protection Number:**  **Chief investigator/Academic Supervisor:**  Insert name, title, address and contact details. Include details of Academic Supervisor (where applicable) if different from CI. | [For **UCL sponsored studies** only using identifiable or pseudonymised data. Remove if using anonymised date, or UCLH sponsored]  **Sponsor Representative**:  [insert name] [insert email address]  UCLH/UCL Joint Research Office,  4th Floor, West  250 Euston Road  London  NW1 2PG |
|  |  |
|  |  |

**PROTOCOL VERSION HISTORY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version Stage** | **Versions Number** | **Version Date** | **Protocol updated & finalised by;** | **Reasons for Update** |
| Current | [insert Version]  [Note: all draft versions should be numbered 0.1, 0.2, etc. the ‘final’ version to be submitted to HRA/REC should be numbered version 1.0] | [insert date] | [full name(s) & title(s)] | [include appendix no., if applicable]  NB: Appendix is to be attached to current version of the protocol |
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|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**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 U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor 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 research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. 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) | (e.g. UCL Data Protection number) |
| 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 | [This should be dated at least 3 months after the study has been granted sponsorship authorisation, to allow for regulatory and NHS approvals (where applicable)] |
| 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 / DATA (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 | |
| Chief Investigator | Full contact details including phone and email |
| Study Coordinator | Full contact details including phone and email |
| Sponsor | Full contact details including phone and email |
| Funder(s) | Full contact details including phone and email |
| Committees | Name(s) of committees, full contact details including, phone and email. E.g. study steering groups. For each committee/group, the protocol should state their roles and responsibilities and degree of independence from the Sponsor and Investigators. |
| Sub-contractors |  |
| Other relevant study personnel | (e.g. Data Custodian and Data Processors) |

**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 must 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 he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability 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 REC and JRO of the end of the study (including the reasons for premature termination, where applicable). 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 and JRO.

**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, no more than 6 phrases.

**LIST OF ABBREVIATIONS**

Commonly used abbreviations – insert a table of commonly used abbreviations here

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***Ensure to click ‘update table’ prior to finalising the Protocol***

# INTRODUCTION

Overview of the study; it should be sufficient to guide the reader to the main purpose of the study, how it will be conducted, on which population(s) 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**: allows users of the document to follow the participant and study pathway with ease, e.g. via a Gantt chart or timeline of activity), and should detail whether this project is being conducted in relation to an academic qualification (a student project), or is related to any previous research sponsored by UCL/UCLH.

# 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 (i.e. why this research is worthwhile to participants or wider service delivery)
* A contextual framing of the research aims in relation to existing theoretical frameworks, relevant policy, etc.

It should be written so it is easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be beneficial.

# AIM(S) AND OBJECTIVES

Define the primary research question/aim(s), then list objective(s).

## Primary Objective

## Secondary Objectives

# STUDY DESIGN & METHODS OF DATA COLLECTION

Study design should include, where applicable;

* Type/design of study e.g. Case Control, cross-sectional, cohort, qualitative, observational etc.
* Study population and groups (how are participants being identified and recruited/data identified prior to collection?)
* How has the planned number of participants been derived?
* Methods used to determine the sample size (reference statistical software and any statistician support)
* What sampling technique will be used, e.g. random, snowball, convenience, purposive sampling? What is the rationale for this sampling strategy?
* What data will be collected, and how? For purely observational studies: what will be observed? What resources or equipment will be used when recording observations? Who will be observing? For qualitative studies, will interviews and/or focus groups be used? Has an interview schedule or prompt guide been developed? Who is conducting interviews, by telephone or in person? How are interviews being recorded? Focus groups: who is leading the focus group? How are focus groups being recorded?
* Where will data be collected, explain what activities will take place in each site, and justify the choice of site(s) and any special requirements
* Where and how are you accessing participants? How is the research setting appropriate to address research question/aims?
* Is this a single site or multi-site study?
* Are there any site-specific requirements to run the study?
* Outline if there are different ‘types’ of activity being undertaken at each site (e.g. identifying or recruiting) and what the specific arrangements are for each.
* Approximate duration of enrolment and follow-up

**Considerations for using electronic methods of consent and data collection should always be considered and documented, particularly in preparation for potential pandemics or lockdown measures.**

# STUDY SCHEDULE

Provide detailed information on:

* enrolment process (and screening if applicable)
* Follow up
* Participant withdrawal criteria and procedures for withdrawing participant, removing data (or including based on appropriate justification)
* End of study (definitions)

# ELIGIBILITY CRITERIA

This section should set out the precise definitions of which participants are eligible for the study, defining both inclusion and exclusion criteria. The choice of criteria can affect recruitment and attrition to the study.

## Inclusion Criteria

E.g. gender, age range, ethnicity, socio economic group, clinical condition, location, etc.

## Exclusion Criteria

E.g. outside of stated age range, outside of stated location, gender, etc.

If there are separate participant groups being used in the study, ensure separate inclusion and exclusion criteria are detailed (e.g. patients/staff).

Make sure this section is identical to A17-1 and A17-2 in your IRAS form.

# RECRUITMENT

The recruitment section may include:

* Recruitment schedule (where appropriate)
* Method for identifying and recruiting participants for the study: who in the study team will identify participants and approach participants for consent, and what methods will be used?
* What resources will be used? Will any participants be recruited through Patient Identification Centres (PICs)?
* Will any participants be recruited by publicity; posters, leaflets, adverts or websites?
* Details of the sources of identifiable personal information that will be used to identify potential participant. In the case of healthcare research on patients, usually only a member of the patient’s existing clinical care team should have access to patient records without explicit consent in order to identify potential participants, check whether they meet the inclusion criteria, or make the initial approach to patients. If the research proposes to use someone outside the clinical team to identify suitable participants or as first contact with the participant, the reason for this should be explained.
* The arrangements for referral if the participants are to be identified by a separate research team.
* If patient or disease registers are used to identify potential participants a brief description of the consent and confidentiality arrangements of the register should be included.
* The protocol should also detail all intended payments to participants e.g. reasonable travel expenses for any visits additional to normal care (please refer to HRA guidance on [www.hra.nhs.uk](http://www.hra.nhs.uk) for further information)
* Procedures for documentation of reasons for ineligibility and or non-participation of eligible candidates (e.g. Screening logs)

# CONSENT

Informed consent must be obtained prior to the participant undergoing any activities that are specifically for the purpose of the study. The protocol should fully describe the process of gaining and documenting informed consent which could involve:

• discussion between the potential participant or his/her legally acceptable representative and an individual knowledgeable about the research, about the nature and objectives of the study and possible risks associated with their participation

• the presentation of written material (e.g., participant information sheet and consent documents) which must be approved by the REC, local regulatory requirements and legal requirements

* the opportunity for potential participants to ask questions
* assessment of capacity. For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:
* understand the purpose and nature of the research
* understand what the research involves, its benefits (or lack of benefits), risks and burdens
* understand the alternatives to taking part
* be able to retain the information long enough to make an effective decision.
* be able to make a free choice
* be capable of making this decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
* where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected
* For a very limited range of activities – such as some ethnographic observations – individuals in a research setting may not be deemed to be research “participants” and it may not be possible to gain consent from each individual observed. In such instances, a full explanation should be given of how the rights and privacy will be protected for those observed or otherwise involved in some way in a research activity for which it is not proposed to gain individual consent.
* consent process must include provisions for specific populations’ e.g. non-English speakers, children, vulnerable populations. If there are different sample groups with different consent arrangements, ensure these are separately detailed (e.g. children, adults lacking capacity).
* for further details on the ethical considerations of informed consent for research see the guidance notes available on the HRA website.
* <http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>

**Electronic Consenting**

If consent will be taken **electronically**, refer to joint HRA & MHRA guidance on appropriate arrangements required: <https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/>.

* It is recommended that PPI groups are consulted to advise if electronic consenting/data collection is appropriate and feasible for your target population. Please ensure the rationale for including this method is documented in your protocol, and traditional means of consenting (paper, in person informed consenting) are available for participants as an alternative, and clarified in all patient documents.
* Considerations for using electronic methods of consent and data collection should always be considered and documented, particularly in preparation for potential pandemics or lockdown measures (e.g. COVID-19).

UCL sponsored studies or Chief Investigators with UCL contracts may use REDCAP free of charge, UCL’s Research Data Collection Service. This may be used for eConsent and data collection, either for collection of all source data, or as an alternative to paper methods. Refer here for further information: <https://www.ucl.ac.uk/isd/it-for-slms/redcap-research-data-collection-service>. The Safe Haven version should always be used for research projects.

If consent is not applicable, describe why, the type of data that is being collected and from where, and what regulatory approvals will be made. Decisions on whether an application to process patient information without consent should be made locally and ultimately decided by those who hold the requested data. If there are consent exemptions, justify here, and discuss with Sponsorship Officer if an application to CAG is also required to avoid a breach of the common law duty of confidentiality. Insert details here if applicable.

N.B. UK jurisdictions where data originates:

England and Wales – Confidentiality Advisory Group (CAG): <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/>

Scotland – Public Benefit and Privacy Panel For Health And Social Care (HSC-PBPP): <https://www.informationgovernance.scot.nhs.uk/pbpphsc/>

Northern Ireland – Privacy Advisory Committee (NI PAC): <http://www.privacyadvisorycommittee.hscni.net/PACrefdocs.html>

# DATA ANALYSIS

For quantitative studies using statistical analyses:

This section should include:

* reason for choice of study design statistical analysis plan
* summary of baseline data
* other statistical considerations
* any software to be used in assisting in the analysis should be specified.

For qualitative studies using qualitative data analysis methods:

* Data analysis methods may include content analysis, the constant comparative method, framework analysis, interpretative phenomenological analysis, etc.
* Protocol should clearly describe how and by whom data will be transcribed, coded, de-identified, stored/transferred, accessed, archived.
* Any software to be used in assisting the analysis should be specified.

# 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:

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

# FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Joint Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via [insert site name e.g. 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.

If external collaborators are being used, e.g. the study will be managed by an external Clinical Trial Unit (hosted by another university/NHS Trust), detail what the arrangements are, what will they be responsible for and how this will be different from Sponsor responsibilities (and consequently detail in relevant sections in the protocol). Discuss with Sponsor Officer for guidance if required.

Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, shareholding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest, and must be detailed.

# DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act’s core principles. UCL/UCLH is the data controller; the UCL/UCLH Data Protection Officer is [insert DPO generic email address/name and contact details of UCLH DPO]. The data processors are [insert details]. The study will be collecting the following personal data:

This section may include:

* Where data is coming from (e.g. directly from participants, medical records, NHS Digital, etc.)
* Data collection procedures: What personal data is being collected, and whether it’s identifiable, pseudo-anonymised, or anonymised (and whether the extent to which it can be identified changes throughout duration of study). If data will be depersonalised, what will participant’s personal data be replaced with?
* Where data will be recorded (source data, e.g. medical notes)
* Where electronic and hard copy data will be stored
* Who is the data custodian?
* Who in the research team will have access to data? Mention if you will be limiting access to the minimum number of individuals necessary for quality control, audit and analysis.
* Data security: E.g. secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media.
* Details of where, how and to who the data will be transferred to, and how confidentiality of data will be preserved during this process (what are the issues and arrangements in place to maintain participant confidentiality?).
* 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
* Data monitoring committees (if applicable)
* How long will data be stored for, and what are the destruction arrangements (if applicable)?

Include Data Flow Diagram here to map out the organisational relationship and flow of anonymised, pseudonymised and identifiable data between the different organisations and collaborators.

# MATERIAL/SAMPLE STORAGE (delete if not applicable)

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, and the applicable HTA Codes of Practice Departmental SOPs will be followed/developed to facilitate regulatory compliance.

# PEER AND REGULATORY REVIEW

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

Choose either (having discussed with the UCLH/UCL Joint 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 here, e.g. NHS REC Favourable Opinion/UCL Ethics approval and HRA Approval). **Before any site can enrol patients into the study,** the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place (delete if there are no NHS sites involved).

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator’s responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

# ASSESSMENT AND MANAGEMENT OF RISK

Provide details of any potential risks to participants (physical, psychological, social, legal or other), particularly expected events. 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.

Describe risk analysis plus risk management if the researcher were to come into information which had safeguarding implications.

* A clear explanation of any risk/potential risks of the study.
* A risk management plan for dealing with any potential risk/harm to the participant. For example whilst undertaking an interview the researchers obtain information that the participant is suicidal. What mechanisms for safeguarding the participant would be put in place? Who should the information be shared with to mitigate harm to the participant?
* A management plan for dealing with safeguarding issues for potential harm to others. For example if the participant discloses information about intention to harm others. What mechanisms for safeguarding others outside of the research would be put in place? Who should the information be shared with to mitigate harm to others?

# RECORDING AND REPORTING OF EVENTS AND INCIDENTS

Research related events and incidents can encompass incidents that involve participants, staff or a carer/visitor during the course of the research study (e.g. a member of staff may be injured whilst administering an intervention, participants may not have been consented properly, collected data may be misplaced or stolen, data losses or breaches in confidentiality may occur, protocol violations or non-compliances with regulatory requirements or Sponsor conditions of approval, etc.). For any doubts or queries as to whether an incident is reportable or not, contact the JRO Quality Assurance team/refer to the *JRO non-CTIMP Research Incident Reporting SOP*. List here the types of incidents that may occur in this study, or whether incident reporting is not applicable.

Research related incidents are all unintended or unexpected events that could have led, or did lead to harm for participants, staff or members of the public receiving care, delivering services or visiting any UCLH site for the duration of the research study. A reportable incident may significantly affect:

a) the rights or wellbeing of a research participant

b) the scientific value of the study

c) the compliance of the study/research staff with relevant legislation, e.g. General Data Protection Regulation (2018), the U.K. Policy Framework for Health and Social Care Research, or the Human Tissue Act (2004), etc.

d) UCL/UCLH’s organizational reputation, and that of participating organisations.

All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor via [UCLH sponsored: Trust Datix; UCL: [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk) or [UCL REDCAP incident reporting form](https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo)) and host sites via their Trust reporting systems, and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

## Personal Data Breaches

In some instances, despite risk management and mitigations, personal data breaches may occur throughout the duration of the study. GDPR broadly defines personal data breaches as a security incident that has affected the confidentiality, integrity or availability of personal data. In short, there will be a personal data breach whenever any personal data is lost, destroyed, corrupted or disclosed; if someone accesses the data or passes it on without proper authorisation; or if the data is made unavailable, for example, when it has been encrypted by ransomware, or accidentally lost or destroyed.

* If there is a data breach/breach of confidentiality (as per GDPR definitions), how will this be handled by each site, and how will this be reported to Sponsor and Data Controller? Detail here.
* If there is a CTU involved in the management of this study, detail what their responsibilities are in investigating/managing data breaches, and reporting these to the Sponsor and Data Protection Officer.

Choose either:

* UCL sponsored studies: Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer [insert name and contact email], (as per form and guidance: <https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data>), and to the Sponsor via the UCL REDCAP incident reporting form (<https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo>). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their TMF/ISFs.
* UCLH sponsored studies: Personal data breaches will be immediately reported to the UCLH Information Governance team and the UCLH Data Protection Officer [insert name and contact email], and to the Sponsor via <https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo> or [Research-incidents@ucl.ac.uk](mailto:Research-incidents@ucl.ac.uk). Sites will additionally follow their Trust incident reporting mechanisms and will document this within their ISFs.

Also consider what arrangements have been made with UCLH Information Governance (e.g. via the Data Access Committee or Data Explorer)? Has guidance been sought?

## Adverse Events and Serious Adverse Events Sponsor Reporting Requirements (if applicable)

If there is absolutely no likelihood of AEs or SAEs occurring on the study (e.g. questionnaire only studies, interview only studies), delete this section. If, however this is a basic science study in which participants are undergoing standard care procedures, e.g. scans, tests, etc. that may give rise to **expected** AEs/SAEs, keep the below section for information, but adapt accordingly.

Adverse events are any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. These do not require reporting to the Sponsor, but the severity, causality and expectedness will be recorded in the participant’s medical records, CRF and AE log (if required: if a database will be used to collect data throughout study, AE log will not be required. Database must however facilitate extraction of list of SAEs for review), with a description of clinical symptoms and the event, including dates as appropriate.

SAEs (any event that results in death, is life-threatening, requires hospitalisation or prolongation of existing inpatient hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect) that have been determined to be **unrelated** to the research intervention by the CI/PI do not require reporting to the Sponsor, but will be recorded in the participant’s medical records, CRF and site file. Additionally, **expected** SAEs that are likely to occur on a regular basis and offer no further new information to the safety profile, or are related to the disease area of the participants, do not require reporting to the Sponsor, but must be recorded as previously stipulated. Sponsors will however be notified where the frequency and severity of unrelated SAEs are unusual; research sites will report as per Sponsor reporting requirements.

In some instances, **unexpected and related SAEs** may occur in observational research [provide the rationale for why this might be applicable to your research study]. All reportable SAEs will be recorded in the medical records and CRF, and reported to the Sponsor via the [JRO REDCAP research incident reporting form](https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo) or [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk), 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 [if the study is being managed by an external Clinical Trial Unit, describe their procedures for recording and reporting incidents to Sponsor].

## Incidental Findings in Research

Defined as a finding that has potential health or reproductive importance, which is discovered in the course of conducting research, but is unrelated to the aims of the study**.**

Insert details here regarding:

* Whether incidental findings are applicable to your study
* Ensure this is detailed in the Patient Information Sheet and Consent Form, and the process of notifying patients and timeline
* What types might occur during the study (e.g. abnormal results during research scans, blood tests, etc.)
* How they will be identified, reported and acknowledged by the site PI and patient’s clinical care team/GP within 48 hours, and updated to the CI
* How this will be reported to the Sponsor and documented in patient medical records and ISFs.

All research staff must follow participating sites’ incidental findings policies, and training must be provided as part of initiation to the research study (where applicable).

## Protocol deviations and notification of protocol violations

Protocol deviations are 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, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

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 via [UCLH sponsored: Trust Datix and [uclh.randd@nhs.net](mailto:uclh.randd@nhs.net); UCL: [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk) or UCL REDCAP incident reporting form].

If there is a CTU involved in the management of this trial, include details for how incidents will be managed, and how these will be notified to the Sponsor.

## Reporting incidents involving a medical device(s) (delete if not applicable)

Any adverse incident involving a medical device will 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. 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, details and responsibilities for reporting events to the MHRA should be included here.

Local trust reporting procedures for medical device events will 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.

## NHS Serious Incidents and near misses (delete if no NHS sites are involved)

A serious 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.

Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

## Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor [UCL sponsored: via [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk), following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy; for UCLH sponsored: via [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk) and the UCLH Complaints process]; for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

# 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/safety 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 and how this will be managed.

# INTELLECTUAL PROPERTY

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

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party’s rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL/UCLH (delete as applicable).  All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL/UCLH (delete as applicable) by the 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, effectively assigns all such intellectual property rights (“IPR”) to UCL/UCLH (delete as applicable) and discloses all such know-how to UCL/UCLH (delete as applicable).

Nothing in this section shall be construed so as to prevent or hinder the participating sites from using its own know how or clinical data gained during the performance of the study, as its own risk, in the furtherance of its normal activities or providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information of the infringement of an intellectual property rights of UCL/UCLH (delete as applicable), or their funder. This section does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the study.

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. Additionally, UCLH does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity. 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, as 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.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor’s Insurers, via the Sponsor’s office.

Hospitals selected to participate in this clinical study shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

To be inserted for either UCL or UCLH sponsored studies where equipment is being provided to sites for the purpose of the study:

If equipment is to be provided to site(s) for the purpose of the study, [please describe what arrangements will be made for insurance and/or indemnity to meet potential legal liability arising in relation to the equipment (e.g. loss, damage, maintenance responsibilities for the equipment itself, harm to participants or site staff arising from the use of equipment)].

# 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 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 in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL in accordance with the *JRO Standard Operating Procedure 10 Archiving of the UCLH Investigator Site File/Trial Master File*. It will be archived for a minimum of 5 years from the study end, and no longer than 20 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 in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule and Policy. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

**NB**: UCL do not archive student projects and therefore, the length of storage is not subject to the standard Sponsor requirements.

# PUBLICATION AND DISSEMINATION

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

* how authorship will be determined (in collaborative studies only)
* who owns the data arising from the study
* that on completion of the study, the data will be analysed and tabulated and a Final Study Report prepared
* where the full study report will be accessed
* if any of the participating investigators will have rights to publish any of the study data
* terms or conditions relating to the funding which may impact upon publication and dissemination
* whether any funding or supporting bodies need to be acknowledged within the publication and whether they have reviewed
* whether there are any plans to notify the participant of the outcome of the study, either by provision of the publication, or via a specifically designed newsletter, letter/email, etc.
* whether the study protocol, full study report, anonymised participant level dataset, and statistical code for generating the results will be made publicly available; and if so, describe where, the timeframe and any other conditions for access.
* **For Student projects**: plans for disseminating/publishing theses
* Resulting publications and/or abstracts will be emailed to the JRO.

# REFERENCES

List the literature and data that are relevant to the study, and that provide background for the study.

# APPENDICES

Include here **a list** of the 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.

It is not advisable to insert copies of documents such as the PIS and ICF due to version control and document management issues. You may wish to list the document titles here or delete if unnecessary.

## Associated Documents

Include here supplementary information and documents that will support the protocol and information contained therein.

E.g. data dictionary

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