**This protocol template is intended as a suggestion for the protocol layout to be used for Global Health non-CTIMP studies that taking place outside of the UK and which are sponsored by The University of Edinburgh.**

**This is minimum criteria so extra information can be added in as necessary. Some sections may not be applicable, depending on the nature of the study. Please ensure that you remove any sections which are not relevant to your study.**

**You should include a header/footer with short study title, version number and date.**

**The header should include appropriate logos i.e. (University of Edinburgh and any funders or partnering institutions/collaborators if applicable)**

**Text in blue is for guidance only and should be removed prior to submission**

Text in black is mandatory and should not be removed.

Text highlighted is for additional details where applicable.

Global Health Research

Non-CTIMP Study Protocol

*Insert study title*

|  |  |
| --- | --- |
| Sponsor | The University of Edinburgh  Usher BuildingEdinburgh Bioquarter5-7 Little France RoadEdinburghEH16 4UX |
| Protocol authors | **Insert name of protocol authors** |
| Funder | **Insert name of Funder (if applicable)** |
| Funding Reference Number | **Insert funding reference before finalisation** |
| Chief Investigator | **Insert name and title of CI** |
| Sponsor number | AC**xxxxx****This number will be provided by ACCORD during the sponsor review.** |
| Ethics Number | **Insert Ethics number before finalisation (include both the local country ethics number and the UoE/UK-based ethics number where applicable)** |
| Project registration | **All health and social care research studies should be registered on a publicly accessible register. It is mandatory for certain types of studies, and strongly recommended for others. Recommended registries are Clinicaltrials.gov (free registration) and ISRCTN (registration involves a fee). Please refer to POL13 for more details and email** resgov@accord.scot **for advice.**  |
| Version Number and Date | **Version number and date should be entered here (and should correspond with header). Please refer to SOP** **QA008 Document Version Control** **for more details.** **Ensure the title, version and date here aligns with that in the header.** |

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LIST OF ABBREVIATIONS

Insert abbreviations as required

This is not an exhaustive list.

Any additional abbreviations used within the protocol should also be added here. Delete as required.

|  |  |
| --- | --- |
| **ACCORD** | Academic and Clinical Central Office for Research & Development  |
| **CI** | Chief Investigator |
| **CRF** | Case Report Form |
| **GCP** | Good Clinical Practice |
| **ICH** | International Conference on Harmonisation |
| **PI** | Principal Investigator |
| **QA** | Quality Assurance |
| **SOP** | Standard Operating Procedure |

INTRODUCTION

## BACKGROUND

Should include:

* Reviews of previous studies
* Disease particulars
* Disease incidence
* The problem to be addressed
* Current treatment options
* Risks and benefits

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 complex medical and/or scientific terms and concepts is likely to be beneficial.

## RATIONALE FOR STUDY

Should include a clear explanation of the research question/aim(s) and hypothesis, justification for the study, including

* An explanation of why the study is appropriate, benefits to participants in the local country, health services, relevance to current policies etc.
* Description of the indication, its diagnosis, incidence, current treatments, their limitations etc.
* Description of the treatment/procedure under investigation.
* Statement of what would be a worthwhile improvement in study outcomes and what evidence there is that the treatment/procedure under investigation may achieve this.

## STUDY TEAM AND PARTNERSHIPS

Include Chief and/or local Principal Investigator(s), associate researchers, students, and research assistants. Include a brief description of their role, and their affiliation. Add any collaborating institutions/partnerships involved in the study and what their role is.

STUDY OBJECTIVES

## OBJECTIVES

### Primary Objective

Detail the primary objective(s)

### Secondary Objective

Detail all other secondary objective(s)

## ENDPOINTS

### Primary Endpoint

Detail the one primary endpoint

### Secondary Endpoint

Detail all other secondary endpoint(s)

STUDY DESIGN

Detail:

* Type of study
* Consider a schematic diagram of the study design
* Duration of participant involvement
* Study setting
* Consider including a study timeline (e.g. Gantt chart)

Consider equality, diversity and inclusion within the study design:

* Look at broadening eligibility criteria to include a diverse range of participants.
* Will your recruitment strategy reflect the population who have this condition?
* Consider any barriers to recruitment that your target population may have. Do this at an early stage to improve retention within the study.
* Consider where you recruit from. Can you reach a more diverse population by conducting outreach activities such as advertising on social media or building and sustaining trusting relationships through community engagement?
* Could travel expenses be offered to assist with additional costs of attending research appointments? Could childcare costs be offered?
* Can remote visits be offered to ensure participants can attend?
* Consider communication needs, for example you could provide:
	1. information sheets in larger font,
	2. ensure that the information sheet is in lay language
	3. translate information sheets if required
* Consider how you will report your results. Can analysis include reports on ethnicity, age and sex/gender?
* Publish a summary and the results of your study to ensure transparency and to build trust with participants.

STUDY POPULATION

## STUDY LOCATION

Detail:

* Location (country and the region/district) where study will be conducted, number of sites involved and the names of the sites.
* Name of institutions/partners involved in the study and their location.
* How the research setting is appropriate to address the research question/aim(s)?
* It is a multi-centre or single-centre study?
* Are there any specific local site requirements to run the study?

## SAMPLE SIZE

Detail the sample size, relevant assumptions and justifications. Comment on the number of participants/volunteers, participant population, length of recruitment period.

Explain the rationale behind the size of the sample (it may not always be possible to estimate the size of a sample e.g. if you continue sampling until you reach saturation. This section should describe and justify how your sampling strategy answers your research question/aim(s)).

Sampling technique

* At random, snowball, convenience sampling, purposive sampling?
	+ Where has the sample been derived from?
	+ What is the rationale for this sampling strategy? The rationale should reflect the methodological and theoretical framework for the study.

## INCLUSION CRITERIA

Detail participant inclusion criteria, including:

1. Willing and able to provide written informed consent.

## EXCLUSION CRITERIA

Detail participant exclusion criteria, including:

1. Unwilling or unable to provide written informed consent.

## JUSTIFICATION FOR INCLUSION OF VULNERABLE POPULATIONS

Detail:

If any vulnerable populations will be involved (e.g. children, refugees, prisoners, individuals who are politically powerless) please provide justification for their involvement. Ethics committees should be assured that these populations will not be exposed to excess risk and that they will benefit from the research findings as a participant group or individually.

## CO-ENROLMENT

Please refer to ACCORD Co-enrolment Policy ([POL008 Co-enrolment Policy](http://accord.scot/sites/default/files/POL008%20Co-enrolment%20v1.0.pdf)).

Detail the policy towards co-enrolment. If co-enrolment will not be allowed in any circumstances, this should be stated. If co-enrolment will be allowed, details of the nature of studies to which co-enrolment will be permitted will be given. Typical details include: interventional/non-interventional studies; nature of any intervention and; study population. Furthermore, details of how co-enrolment will be managed and recorded will be provided.

In addition, when considering permitting co-enrolment, investigators should be mindful of the potential burden upon participants, their families and research staff.

PARTICIPANT SELECTION AND ENROLMENT

## IDENTIFYING PARTICIPANTS

The aim of this section is to describe how participants are identified. Include:

* Details of first approach. Normally only a member of the potential participants existing care team should have access to medical records before consent is given (to check whether they meet inclusion criteria). If the trial proposes to use individuals outside of the usual clinical care team to identify potential participants or make the first approach, the reason for this should be documented.
* Who will identify potential participants and what method will be used? What resources will be used?
* Will any participants be recruited by publicity; posters, leaflets, adverts or websites?
* The arrangements for referral if the participants are to be identified by a separate research team.
* Provide any recruitment documents as part of the study document package for sponsorship review (e.g. social media advert or indicative text).
* The protocol should also detail any intended payments to participants for their participation in the study (e.g. reasonable travel expenses).
* Consider where participants will be recruited from, refer to POL011 – promoting diversity and inclusion in health-related research studies.

## CONSENTING PARTICIPANTS

The protocol should fully describe the process of gaining informed consent which could involve:

* Details of any limitations regarding who will be designated to take informed consent from participants. Any limitations stated must be adhered to unless the protocol is amended accordingly and approved by the relevant organisations.
* How long participants will be permitted to consider the information sheet before consenting (anything less than 24 hours should be justified for ethics review)
* discussion between the potential participant or their 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., information sheet and consent documents) which must be approved by the ethics committee(s), local regulatory body (where applicable) 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 particular 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).

For participants who cannot read:

* + Participants must be able to understand the concepts of the study and understand the risks and benefits of participating in the study when it is explained to them verbally.
	+ Participants must be able to verbally indicate agreement or non-agreement to study entry (note that verbal agreement/consent alone is not considered sufficient for participation in the study). Verbal consent must be audio recorded to provide evidence of consent.
	+ **ACCORD’s Verbal Information Sheet and Verbal Consent Form are available to download from the website under section** [**GH001**.](https://www.accord.scot/research-access/resources-researchers/sop?field_sop_categories_tid=9)
	+ Participants must be able to indicate their written agreement to participate in the study by making a mark on the signature line of the consent form. A common way to make one’s mark is a thumbprint. Some participants may also be able to sign their name or write their initials.
	+ An impartial Witness must be present. The Witness cannot be a member of the study team. Ideally, the Witness will not be a family member of the participant, but if only family members are available, a family member can be the Witness.
	+ The Witness must sign and date the consent form confirming that the requirements for informed consent have been satisfied and that consent is voluntarily given by the participant, without any element of force, fraud, deceit, duress, coercion, or undue influence.

Specific cultural considerations:

In some cultures, it is not appropriate for the PI or research team to seek consent directly from the participants without obtaining permission from the community leader or equivalent. Such customs should be respected, however individual consent from the participants is considered best practice and the permission from the community leader should not be a substitute for this.

Proxy consent and assent for minors:

* The legal age for consent in research conducted in Low-to-middle-income countries can be different to high-income countries. PI’s should be aware of any relevant issues regarding consent and confidentiality for ‘mature’ or ‘emancipated minors’ who may be able to freely consent to participate in research.
* Consideration must also be given to children’s wishes to take part in the study. This involves drafting age-appropriate child information sheets and a child assent form. As a general guide, it is recommended that these documents are provided in language appropriate to the following age groups (unless local country ethics guidance specifies their own criteria for age-appropriate materials for children in research): < 5 years, 6-11 years, 12-17 years
* The parent/guardian PIS/CF must always be provided for parents to consent on behalf of the child, in addition to child assent form.

### WITHDRAWAL OF STUDY PARTICIPANTS

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Principal Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant’s case report form, if possible. The participant will have the option of withdrawal from:

1. all aspects of the trial but continued use of data (and samples) collected up to that point.
2. all aspects of the trial including data collected up to that point where it is possible to delete this data e.g., this data will not be used in the final data analysis. To safeguard rights, the minimum personally identifiable information possible will be retained e.g., consent form.

To safeguard rights, the minimum personally-identifiable information possible will be collected.

Detail reasons and procedures for a study participant stopping early i.e. “stopping rules” and “discontinuation criteria” Detail how a participant can withdraw, e.g., by notifying the Principal Investigator or by completing a form.

##

STUDY ASSESSMENTS

## STUDY ASSESSMENTS

Describe the study procedures and assessments. Indicate the time points of all assessments and ensure that they are broken down as per visit if appropriate for clarity. A table of study assessments should be added. The table below is an example to be tailored to your study:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Assessment**  | **Screening**  | **Day 1****baseline**  | **Day 2** | **Day 3** | **30 days**  | **90 days**  | **1 year**  |
| Assessment of Eligibility Criteria  |  |    |    |    |   |   |   |
| Written informed consent  |  |    |    |    |   |   |   |
| Demographic data, contact details  |  |   |   |   |   |   |   |
| Weight |  |    |    |    |   |   |   |
| Blood sample |  |    |      |       |     |     |     |
|  |  |   |   |   |   |   |   |
|  |  |    |    |    |   |   |   |
|  |  |  |   |   |   |   |   |

Study Flow Chart

 Include a flow chart in this section to demonstrate what is happening in the study at each stage.

**In-depth-Interviews (IDIs)**

If the study plans to conduct interviews with participants, please provide details of the interview here (e.g who will conduct the interview, where the interview will take place, will the interview be conducted face-to-face/online/telephone, will the interview be recorded) and provide an Interview Topic Guide as part of the study document package for sponsorship review. The interview Topic Guide should contain (as a minimum) the introduction, the questions the participants will be asked, and the interview closing remarks.

**Focus Groups**

If the study plans to include focus groups, please provide details here (e.g. who is leading the focus group, how often do the focus groups plan to meet and where, will the focus groups be conducted face-to-face/online/telephone, will the focus group be recorded?). Provide a Topic Guide as part of the study document package for Sponsorship review.

**Questionnaires/Scales**

If the study plans to include questionnaires/surveys (e.g. participant questionnaires, health measurement scales), please include details here and provide these questionnaires/surveys/scales as separate documents from the protocol for sponsorship review.

## LONG TERM FOLLOW UP ASSESSMENTS

The protocol should describe the long term follow up period including the frequency of follow up visits, duration of follow up period and any assessments that will be carried out.

Include any details of long term data linkage if possible.

## STORAGE AND ANALYSIS OF SAMPLES

This section should describe the procedure for dealing with biological samples, if applicable to the study. The section should include:

* Sample types
* Volume of samples
* Arrangements for storage (including location) and analysis (e.g. where are samples going to be analysed)
* Will samples be shipped from research site to a 3rd party/other institution/a UK-based institution/lab/company?
* Will samples be destroyed at the end of the trial?
* Will consent be sought for long-term storage of samples?
* Whether the sample analysis is critical to the conduct of the trial, i.e. is necessary to determine eligibility and/or relates to primary/secondary endpoint data and objectives (e.g. specific mutations associated with eligibility assessments);
* whether the sample analysis is not critical to the conduct of the trial, i.e. relates to tertiary/exploratory endpoint data and objectives.

This information must also be detailed within the PIS/Consent form.

DNA / genome / exome wide analysis must be explicitly consented for by participants.

## TRANSCRIPTION AND TRANSLATION

### TRANSCRIPTION SERVICES

If the study plans to use a 3rd party provider for transcription service to provide transcripts of the interviews, please include details of this service here. Otherwise, please specify who will provide the transcripts for the interviews.

### TRANSLATION SERVICES

If the study plans to use a 3rd party provider for translating the study documents, please include details of this service here. Otherwise, please specify who will provide the study document translations.

DATA COLLECTION

As a sponsor based in the UK, the University of Edinburgh must comply with The UK General Data Protection Regulation (GDPR). GDPR requires you to put in place appropriate technical and organisational measures to implement the data protection principles effectively and safeguard individual rights. This is ‘data protection by design and by default’. In essence, this means you have to integrate or ‘bake in’ data protection into your processing activities and business practices, from the design stage right through the lifecycle.

Detail data to be collected, including:

* Time points for collection (e.g. baseline, during treatment, during follow up)
* Who will collect the data
* Details of standardised tools (e.g. pain scores)
* How will data be recorded?
* Describe any methods to maximise completeness of data collection (e.g. telephoning participants who have not returned questionnaires).
* Describe any audio/video recordings and where these will be stored.
* If using online methods of collecting data (e.g. online survey) detail what platform will be used.

Include details of any online services used, online methods of data collection.

Our recommendation is to use previously approved (by UoE) providers (such as [**Online Surveys**](https://information-services.ed.ac.uk/computing/comms-and-collab/jisc-online-surveys)

## SOURCE DATA DOCUMENTATION

Source data is defined as all information in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents

Source documents are original documents, data and records where source data are recorded for the first time.

* The source must be detailed here e.g., consent form, questionnaire, medical notes, electronic data collection procedures.
* Where the case report form is a source document, source data captured in the CRF must be detailed within this section.
* Where external data is supplied by a third-party, and the third-party stipulate conditions for the security and management of data on the infrastructure to be used, confirmation of the infrastructure to be used and how it meets the third-party conditions should be detailed here and detailed in a contract as appropriate.

## CASE REPORT FORMS

This section should provide information regarding the case report forms to be used, including the type of case report forms (i.e., paper and/or electronic). If electronic case report forms are to be used with personal data, this section must show how the eCRF will provide data protection by design and default, including encryption of data while it is being stored (at rest) and encryption while it is being entered or transferred into the eCRF.

DATA MANAGEMENT

## PERSONAL DATA

The following personal data will be collected as part of the research:

Here you should detail what personal data you are collecting (e.g. name, contact details, village name, participant/household address, household roster, marital status, gender, age, date of birth, ethnicity, educational level, occupation, audio recordings for participation in interviews and other unique numeric identifiers, location data, online identifiers (including IP address, cookies), one or more specific identifiers relating to the physical, physiological, genetic, biometric, mental, economic, cultural or social identity of a participant).

Please contact the [University of Edinburgh’s Data Support Team](https://digitalresearchservices.ed.ac.uk/resources/research-data-support) for assistance with setting up the appropriate remote Data Storage facility for active research data and for long-term retention of your research data.

Consider where the data will be stored.

Refer to [**guidance**](https://www.ed.ac.uk/information-services/research-support/research-data-service/guidance) from the UoE Research Data Service**, in particular** [**Quick Guide 3: Data Storage**](https://libraryblogs.is.ed.ac.uk/datablog/files/2019/10/Quick-Guide-3-DATA-STORAGE-OPTIONS-v1.4.pdf)and the [**flowchart**](https://www.ed.ac.uk/files/atoms/files/rds_flowchart_-_20170608_-_dmd_-_v7.pdf) for data management before, during and after your research.

Personal data will be physically stored by the research team at [detail location of data storage, who will have access to personal data and where the code break / key will be kept].

Personal data will be digitally stored by the research team using [detail location of all systems involved in the collection, transfer and storage of personal data, and who will have access to it for which purposes.]

Outline the retention period and the reason for the length of time. How will the data be deleted or made anonymous once the retention period is over?

Personal data will be stored for [detail duration or personal data retention].

## DATA INFORMATION FLOW

Describe the collection, use and deletion of personal data here. It could be useful to insert a data flow diagram here.

## TRANSFER OF DATA

[Please detail here if there is an intention for the data to be transferred out with University of Edinburgh] e.g. Data collected or generated by the study to be transferred to any relevant third party to manage on behalf of the sponsor, or data transferred to any other country and detail how this data transfer will be managed.

## DATA CONTROLLER

A data controller is an organisation that determines the purposes for which, and the manner in which, any personal data are processed. The Data Controller for this study is X

The University of Edinburgh is the data controller along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the research site or partnering institution in the local country where the study is being conducted)

## DATA BREACHES

Please ensure you have read the [minimum and required reading](https://www.ed.ac.uk/infosec/information-protection-policies/information-security-required-reading) setting out ground rules to be complied with for incident management.

Any data breaches will be reported to the University of Edinburgh Data Protection Officer who will onward report to the relevant authority according to the appropriate timelines if required. Please insert here details of any relevant Data Protection Officer/Committee in the LMIC who must also be notified of data breaches.

STATISTICS AND DATA ANALYSIS

## SAMPLE SIZE CALCULATION

Detail the sample size, precision or power calculation, dropout rates, relevant assumptions and justifications. Comment on an estimate of the recruitment period and justification that the required sample size will be achievable.

## PROPOSED ANALYSES

Detail the variables to be used for assessment and how these will be reported (e.g. means, standard deviations, medians etc.) Write detailed plans for analyses of primary and secondary outcome measures including:

* Summary measures to be reported
* Method of analysis
* Plans for handling missing, unused and spurious data, non-compliers and withdrawals
* Plans for pre-defined subgroup analyses
* Statement regarding use of intention to treat analysis
* Details of any interim analysis

ADVERSE EVENTS

Consider risk level for this study: even if a non-CTIMP, should the protocol still provide details of how adverse events, etc., will be dealt with / reported? Please contact ACCORD for further advice.

OVERSIGHT ARRANGEMENTS

This section is standard text and should remain unchanged.

## INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, ethics committees review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

## STUDY MONITORING AND AUDIT

The Sponsorwill assess the study to determine if an independent risk assessment is required.  If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Principal Investigator research sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

## STEERING COMMITTEE/DATA MONITORING COMMITTEE

Although not mandatory for Non-CTIMP Global Health research, some studies may wish to convene a Steering Committee and/or Data Monitoring Committee to provide overall supervision for the study and to monitor the data emerging from the study. For studies wishing to include these committees, the ACCORD Trial Steering Committee and Data Monitoring Committee Charter templates can be used for guidance.

GOOD CLINICAL PRACTICE

## ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP) in additional to the principles of the ethics committee(s)/Institutional Review Boards (IRBs) who have reviewed and approved this study.

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

## PRINCIPAL INVESTIGATOR RESPONSIBILITIES

The Principal Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Principal Investigator. Responsibilities may be delegated to an appropriate member of study site staff. *Delegated tasks must be documented on a Delegation Log and signed by all those named on the list prior to undertaking applicable study-related procedures.*

###

### Informed Consent

The Principal Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the Principal Investigator or qualified delegated person and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor.

*Inspection by regulatory authorities can be deleted for non-CTIMP studies.*The Principal Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Principal Investigator Site File (ISF) and participant’s medical notes (if applicable).

### Study Site Staff

The Principal Investigator must be familiar with the protocol and the study requirements. It is the Principal Investigator’s responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

### Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the Case Report Form (CRF) at each Principal Investigator Site.

### Principal Investigator Documentation

The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

### GCP Training

For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory requirement unless deemed so by the sponsor.  GCP training status for all investigators should be indicated in their respective CVs.

## DATA PROTECTION TRAINING

All University of Edinburgh employed researchers, students and study staff will complete the [Data Protection Training](https://www.ed.ac.uk/data-protection/training-events) through Learn.

## INFORMATION SECURITY TRAINING

All University of Edinburgh employed researchers, students and study staff will complete the [Information Security Essentials modules](https://www.ed.ac.uk/information-services/help-consultancy/is-skills/catalogue/capability-wellbeing/info-security-essentials) through Learn and will have read the [minimum and required reading](https://www.ed.ac.uk/infosec/information-protection-policies/information-security-required-reading) setting out ground rules to be complied with.

### GCP Confidentiality

All laboratory specimens, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Principal Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

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### Data Protection

All Principal Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the European Union General Data Protection Regulation, the Data Protection Act 2018 in the UK and any relevant Data Protection laws in the country where the study is being conducted (please insert any applicable local laws here) with regard to the collection, storage, processing and disclosure of personal information.

Computers used to collate the data will have limited access measures via usernames and passwords.

Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place

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# STUDY CONDUCT RESPONSIBILITIES

This section is standard text and should remain unchanged.

## PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to the sponsor for review and authorisation before being submitted in writing to the appropriate ethics committees/IRBs, for approval prior to participants being enrolled into an amended protocol.

## MANAGEMENT OF PROTOCOL NON-COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsor and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the appropriate ethics committees/IRBs for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsor every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to the sponsor at: QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

## SERIOUS BREACH REQUIREMENTS

A serious breach 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 trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the sponsor (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the sponsor to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

## STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

## END OF STUDY

The end of study is defined as the last participant’s last visit.

The Investigators or the sponsor has the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the appropriate ethics committees/IRBs and sponsor within 90 days, (or within the specific timelines specified by the individual ethics committees/IRBs). If the study is terminated prematurely, the end of study will be reported to the relevant ethics committees/IRBs and sponsor within 15 days. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved.

End of study notification will be reported to the sponsor via email to resgov@accord.scot

A summary report of the study will be provided to the appropriate ethics committee(s)/IRBs within 1 year of the end of the study (or within the specific timelines specified by the individual ethics committees/IRBs).

## CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

Detail if intervention will be continued to be provided following the end of the study. If not provide justification.

## INSURANCE AND INDEMNITY

The sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the sponsor responsibilities:

* The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
* Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The sponsor requires individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
* Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

## REPORTING OF RESULTS

Results should be made available in the public register where the study was initially registered within 12 months of the end of study. Further details on this requirement are detailed in [POL013](https://accord.scot/research-access-resources-researchers/policies) (Transparency: Registering and reporting research studies on a publicly accessible database) and [CR011](https://accord.scot/research-access/resources-researchers/sop) (Research Study Reports and Publication of Results). Detail any plans for reporting and dissemination of results to relevant stakeholders.

## AUTHORSHIP POLICY

Suggested text only - amend as appropriate.

*Suggested text only - amend as appropriate.*

Ownership of the data arising from this study resides with the study team.

REFERENCES

Insert all references and additional appendices (if applicable) or delete.