This protocol template is intended as a suggestion for the protocol layout to be used for non-CTIMP qualitative studies that are sponsored or co-sponsored by University of Edinburgh and/or Lothian Health Board. This is minimum criteria and 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 unless there is an indication that the section is standard text and should remain unchanged.

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

Text in blue is for guidance only and should be deleted prior to submission.

Qualitative Study Protocol

Insert study title

|  |  |
| --- | --- |
| Co-Sponsors | The University of Edinburgh and Lothian Health BoardACCORDThe Queen’s Medical Research Institute47 Little France CrescentEdinburghEH16 4TJ |
| 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** |
| REC Number | **Insert REC number before finalisation** |
| Project registration | **Studies should be registered on a publicly accessible register where possible**  |
| 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.**  |

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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 - Joint office for The University of Edinburgh and Lothian Health Board |
| **CI** | Chief Investigator |
| **GCP** | Good Clinical Practice |
| **ICH** | International Conference on Harmonisation |
| **PI** | Principal Investigator |
| **QA** | Quality Assurance |
| **REC** | Research Ethics Committee |
| **SOP** | Standard Operating Procedure |

# INTRODUCTION

## BACKGROUND

Should include:

* Reviews of previous studies
* Area of interest particulars and incidence.
* Current treatment options

## RATIONALE FOR STUDY

Should include a clear explanation of the research question and hypothesis, and justification for the study.

# STUDY OBJECTIVES

## AIMS & OBJECTIVES

### Primary Objective

Detail primary objective(s)

### Secondary Objectives

Detail secondary objective(s)

# STUDY DESIGN AND METHODS

Detail:

* General approach
* Type and length of study
* Consider a schematic diagram of the study design
* Duration of participant involvement
* Describe any interviews/focus groups/questionnaires and how they will be conducted, managed etc. Note that an interview/topic guide/questionnaire will need to be included in the submission for Sponsor review and any other submissions for approvals (ethics/R&D etc).

Consider equality, diversity and inclusion within the study design:

* If possible engage with the Patient Public Involvement Team regarding how best to serve the needs of the demographic you are looking to involve in your study (thinking about who the research study will benefit in the future).
* 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 child care 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.

Consider how any distress will be dealt with that could arise post interviews etc. Think about providing contact details for relevant support groups or advising to contact GP within the information sheet.

# STUDY SETTING

Detail sites, number of sites, where the study is based, where interviews will take place etc.

* Will online methods of interviews/focus groups be used, if so what platform will be used.

# STUDY POPULATION

## NUMBER OF PARTICIPANTS

Detail:

* Number of participants/volunteers
* Participant population (e.g. condition/disease/trait/service used)
* Length of recruitment period

## INCLUSION CRITERIA

Detail participant inclusion criteria

## EXCLUSION CRITERIA

Detail participant exclusion criteria

## CO-ENROLMENT

Refer to ACCORD Co-enrolment Policy (POL008 Co-enrolment Policy).

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. The following should be included in this section:

* Who will identify potential participants?
* Details of first approach.
* Will online methods of interviews/focus groups be used, if so what platform will be used.
* Detail any registries to be used e.g. SHARE database
* Consider where participants will be recruited from, refer to POL011 – promoting diversity and inclusion in health-related research studies
* How will the PIS be given to potential participants e.g. at clinic appointment/post/email

## CONSENTING PARTICIPANTS

Describe the consent process:

* How long participants will be permitted to consider the information sheet before consenting.
* Who will take informed consent from the participants.
* Provide justification if including any vulnerable participants.
* Is e-consent intended to be used, if yes please specify the name of the system and vendor who manages it?

### Withdrawal of Study Participants

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

Is there is a point where participants cannot opt out (e.g. after interview data is transcribed)?

## LONG TERM FOLLOW UP ASSESSMENTS

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

# STUDY FLOWCHART

Consider Including a flowchart demonstrating what is happening in the study.

| **Assessment**  | **Day 1****baseline**  | **Month 6** | **1 year**  |
| --- | --- | --- | --- |
| Assessment of Eligibility Criteria  | ☒☐ | ☐ | ☐ |
| Written informed consent  | ☒☐ | ☐ | ☐ |
| Demographic data, contact details | ☒☐ | ☐ | ☐ |
| Interview  | ☐ | ☒ | ☒ |

# DATA COLLECTION

The UK General Data Protection Regulation (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 interview/questionnaire/other.
* Who will conduct the interview/questionnaire/other.
* Details of questionnaire, structured/semi-structured interviews and any other data collection methods. ) Describe recording methods, audio/visual encryption etc.
* Describe any methods to maximise completeness of data collection (e.g. telephoning participants who have not returned questionnaires).
* How will data be recorded?
* Describe the use of any transcription services.
* If there will be any lone working describe this and detail any risk assessments that will be used and carried out.
* Describe any audio / video recordings and where these will be stored
* If using online methods of collecting data e.g. online survey, what platform will be used
* Describe the use of any transcription services.

Our recommendation is to use previously approved (by UoE/NHSL) providers (such as Online Surveys
<https://www.ed.ac.uk/information-services/learning-technology/survey-tools>.

## SOURCE DATA DOCUMENTATION

Source documents are those in which information is recorded and documented for the first time. Detail the source (e.g. questionnaire, medical noted, interview script).

## CASE REPORT FORMS

If applicable, document the type of case report forms to be used, including any electronic data collection procedures. If electronic case report forms are to be used with personal data, then 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

Describe how the data will meet the ‘data protection by design and default’ principles of the UK GDPR legislation at every stage of the Data Information Flow. This may require explanation of the infrastructure and systems that will be used to manage the data, and how they are secured at each stage of the flow.

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

[Here you should detail what personal data (e.g. name, CHI number, 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.]

### Data Information Flow

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

### Data Storage

Describe where the data will be stored e.g. paper/electronic (if electronic, name organisation and country where data will be hosted). You should distinguish between personal identifiable data and pseudonymised data

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

Personal data (pseud anonymised) will be physically stored by the research team at detail location, organisation, country of data storage, who will have access to personal data and where the code break/key will be kept

Anonymised data will be physically stored by the research team at detail location.

### Data Retention

This section should describe the duration for which paper and electronic trial records will be retained following the end of the trial.

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 be destroyed with permission from the Sponsor.

Refer to [guidance](https://www.ed.ac.uk/information-services/research-support/research-data-service/guidance) from the UoE Research Data Service 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.

Typically, personal data should be stored in a suitable repository e.g. DataStore/[DataVault](https://www.ed.ac.uk/information-services/research-support/research-data-service/after/datavault/why-use-datavault).

Personal identifiable data will be stored for detail duration of personal data retention.

Personal data (pseudonymised will be stored for detail duration of personal data retention.

Anonymous data will be stored for detail duration of personal data retention

### Disposal of Data

How will the data be deleted or made anonymous once the retention period is over?

Refer to [guidance](https://www.ed.ac.uk/information-services/research-support/research-data-service/guidance) from the UoE Research Data Service.

### External Transfer of Data

Please detail here if there is an intention for any personal identifiable data to be transferred/stored out with NHS Lothian, e.g. for transcription services, eCRF/database. An NHS Lothian IT security risk assessment for securely transferring personal identifiable data outside of NHS Lothian will be required by NHS Lothian Information Governance. This may also be required if pseudonymised personal data is be shared with organisations out with the UK/EU depending on GDPR adequacy arrangements i.e. transfer of any personal data out with NHS Lothian should be described in the protocol and the PIS

Data collected or generated by the study (including personal data) will not be transferred to any external individuals or organisations outside the sponsoring organisation(s) without participant consent, appropriate approvals (where applicable) and a data sharing agreement.

Where it is known that data will be shared, this should be explicit in the PIS e.g. what data, with whom (organisation, country).

### 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 University of Edinburgh and Lothian Health Board are joint data controllers along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the site)

### Data Breaches

Any data breaches will be reported to the University of Edinburgh (dpo@ed.ac.uk) and NHS Lothian Data Protection Officers (Lothian.DPO@nhs.scot) who will onward report to the relevant authority according to the appropriate timelines if required.

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 and adhere to the Information Security Standard for Incident Management <https://www.ed.ac.uk/infosec/information-protection-policies/information-security-required-reading>.

# STATISTICS AND DATA ANALYSIS

## DETERMINING SAMPLE SIZE

* Add in details of sample size calculation

Detail the sample size, relevant assumptions and justifications. Comment on an estimate of the recruitment period and justification that the required sample size will be achievable. If any quantitative data are to be collected (e.g. in a survey) provide a power calculation).

# OVERSIGHT ARRANGEMENTS

This section is standard text and should remain unchanged.

## INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit study related monitoring and audits on behalf of the Sponsor, REC 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.

# 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).

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

## INVESTIGATOR RESPONSIBILITIES

The 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 Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

Delegated tasks should 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 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 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 (if relevant) and agree to their medical records being inspected by representatives of the Sponsor (s), if applicable.

The 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 Investigator Site File (ISF) and participant’s medical notes (if applicable).

### Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the 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 at each Investigator Site.

### 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 and study staff will complete the [Data Protection Training](https://www.ed.ac.uk/data-protection/training-events) through Learn.

NHS Lothian employed researchers and study staff will comply with NHS Lothian mandatory Information Governance Data Protection training.

Non-NHS Lothian staff that have access to NHS Lothian systems will familiarise themselves and abide by all NHS Lothian IT policies, as well as employer policies

### 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)  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.

NHS Lothian employed researchers and study staff will comply with NHS Lothian mandatory Information Governance IT Security training.

Non-NHS Lothian staff that have access to NHS Lothian systems will familiarise themselves and abide by all NHS Lothian IT policies, as well as employer policies.

### Confidentiality

All, 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 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.

### Data Protection

All Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the UK General Data Protection Regulation legislation and Data Protection Act) with regard to the collection, storage, processing and disclosure of personal information.

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

Published results will not contain any personal data that could allow identification of individual participants.

# 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.

Proposed amendments will be submitted to a Sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D 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 REC, and local R&D for review and approval if appropriate.

### Definitions

**Deviation** - Any change, divergence, or departure from the study design, procedures defined in the protocol or GCP that does not significantly affect a subjects rights, safety, or well-being, or study outcomes.

**Violation** - A deviation that may potentially significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject’s rights, safety, or well-being

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 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.

**SERIOUS BREACH REQUIREMENTS**

A serious breach is a breach which is likely to affect 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 (qa@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.

## END OF STUDY

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

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

The end of the study will be reported to the REC, and R&D Office(s) and Sponsor within 90 days, or 15 days if the study is terminated prematurely. 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 REC within 1 year of the end of the study.

## 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 which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.

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

## AUTHORSHIP POLICY

Suggested text only - amend as appropriate.

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

## Data Sharing

Detail procedures for data sharing (if any) – may be funder specific

# REFERENCES

Insert additional appendix and details or delete.