This protocol template is intended as a suggestion for the protocol layout to be used for non-CTIMP data only studies that are sponsored or co-sponsored by the 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.

Data Study Protocol

Insert study title

|  |  |
| --- | --- |
| Co-Sponsors | The University of Edinburgh and Lothian Health BoardACCORDUsher Building5-7 Little France CrescentEdinburgh Bioquarter-Gate 3Edinburgh, EH16 4UX |
| 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 |
| **CRF** | Case Report Form |
| **GCP** | Good Clinical Practice |
| **ICH** | International Conference on Harmonisation |
| **PI** | Principal Investigator |
| **QA** | Quality Assurance |
| **REC** | Research Ethics Committee |

# INTRODUCTION

## BACKGROUND

## RATIONALE FOR STUDY

# STUDY OBJECTIVES

## OBJECTIVES

### Primary Objective

Detail primary objective(s).

### Secondary Objectives

Detail secondary objectives(s).

## ENDPOINTS

### Primary Endpoint

Detail primary endpoint(s)

### Secondary Endpoints

Detail secondary endpoint(s)

# STUDY DESIGN

Consider:

* Include a data flow diagram
* Duration of study
* Study setting

## DATASET

Consider:

* Describe the dataset in use.
* What data (including how many records) are being collected?
* Detail all of the organisations that are involved in the study and what that involvement entails.
* How will the data be accessed and collected and by whom?
* Describe the use of any existing data and how any ongoing data collection will be carried out, maintained etc.
* Are there any particular methods employed to maximise data collection?
* Provide the time points for collection (e.g. baseline, during treatment, during follow up). Will it be a one off collection, or at fixed time points (e.g. every x months)
* How, where and by whom will the data be analysed?
* What data transfers are needed and how are these secured?

## SOURCE

Consider:

* What is the source? If multiple break up into sections to clearly.
* Is the data anonymised, can you describe how it has been anonymised and by whom, where is the link kept?
* Provide a description of who will have access to the data at each stage of the process (anonymisation, analysis etc.)
* Include a flowchart which outlines what is happening with the data
* Describe and existing datasets that you hold, will these be linked at all.
* Detail any potential onward sharing of the data (collaborators/regulators etc.)

## INCLUSION CRITERIA

Detail data inclusion criteria

## EXCLUSION CRITERIA

Detail data exclusion criteria

## CONFIDENTIALITY

Consider:

* Does the project involve any confidential information e.g. NHS data?
* What are the legal avenues for accessing this information e.g. care team / consent / Caldicott / CAG / PBPP / other.
* Is patient consent in place for the use of the data?
* Do you need/have PBPP/CAG approval or approval(s) from equivalent overseas bodies?

<https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/>

<https://www.informationgovernance.scot.nhs.uk/pbpphsc/>

## DATA PROTECTION TRANSPARENCY

Consider:

* Does the project involve personal data?
* What information has / will be provided to the data subjects about how their data will be used?
* Include details of any privacy notices being used
* 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.

## DATA STATUS – APPROVALS/CONSENT

Consider:

* Is there any data transfer between NHS and UoE – what is in place to cover this, what approvals, security measures etc?
* What approvals exist for its use in research, including any generic ethics approvals associated with the data?
* Describe the data sharing agreements that have been drafted or are being used in the study.
* Describe the use of any safe havens.

## 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 (pseudonymised) 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.

If not using a UoE supported service then details for backup and security should be included.

## 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

## SAMPLE SIZE CALCULATION

* Add in details of sample size calculation

Detail the sample size, precision or power calculation, dropout rates, relevant assumptions and justifications. Comment on and provide a 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
* Details of any interim analysis

# 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, 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.

### 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.

### Training

#### GCP Training

For data 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) and Data Protection for Research 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)  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.

### 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, confidential information 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.

Access to collated participant data will be restricted to individuals from the research team treating the participants, representatives of the Sponsor and representatives of regulatory authorities.

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.

Confirm that relevant information security policies and standards will be adhered to and the investigator should consider further protective measures in consultation with IS and with due consideration of IS policies and standards.

# 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.

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. An alternative frequency of deviation log submission to the Sponsor may be agreed with the Sponsor in writing.

## 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/last datapoint analysed

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 and Sponsor 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.

# REFERENCES

Insert additional appendix and details or delete.