GUIDANCE

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.

This protocol template is intended as a suggestion for the protocol layout to be used for Global Health non-CTIMP data only studies that are taking place outside of the UK and which are sponsored by the University of Edinburgh. For example, this could be for a data involving only retrospective data analysis. Studies involving prospective data collection should use GH001-T01 Global Health Non-CTIMP Protocol Template. 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. The header should include appropriate logos i.e., (University of Edinburgh and any funders or partnering institutions/collaborators if applicable).

Global Health Data Study Protocol

*Insert study title*

|  |  |
| --- | --- |
| Sponsor | The University of Edinburgh  ACCORD Usher Building, Edinburgh BioQuarter  Gate 3, 5-7 Little France Road Edinburgh EH16 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 | ACXXXXX  This number will be provided by ACCORD during the sponsor review. |
| Ethics ID 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](mailto:resgov@accord.scot) for advice.  Enter N/A if not registering the study. |
| 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 |
| **REC** | Research Ethics Committee |

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 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 data under investigation.
* Statement of what would be a worthwhile improvement in study outcomes and what evidence there is that the data 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 partnerships involved in the study and what their role is.

STUDY OBJECTIVES

## OBJECTIVES

### Primary Objective

Detail the primary objective(s)

### Secondary Objectives

Detail all other secondary objective(s)

## ENDPOINTS

### Primary Endpoint

Detail the one primary endpoint

### Secondary Endpoints

Detail all other secondary endpoint(s)

STUDY DESIGN

Detail:

* Include a data flow diagram
* Timeline 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?
* What permissions/approvals are required to access the dataset?
* 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 of the data? If there are multiple, break up these into sections.
* Is the data anonymised? Describe how it has been anonymised and by whom, where the link is 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 at each stage. Include its level of identifiability at each stage, and who has access to it.
* Describe any existing datasets that you hold, and whether 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 participant exclusion criteria.

## CONFIDENTIALITY

Consider:

* Does the project involve any confidential information e.g., participant medical records?
* What are the legal avenues for accessing this information e.g., local permission or approvals?
* Is participant consent in place for the use of the data?

## DATA PROTECTION TRANSPARENCY

Consider:

* Does the project involve personal data? Include a list e.g., name, contact details, village name, participant/household address, household roster, marital status, gender, age, date of birth, ethnicity, educational level, occupation, and any 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.
* 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 Information Flow

Describe the collection, use, retention, transfer, and deletion of personal data here. It is recommended that you insert a data flow diagram here to illustrate the movement of data from the point of collection through to archiving.

### Transfer of Data

Please detail here if there is an intention for any data (identifiable or de-identified) to be transferred outside the local country and for what purpose (e.g., transferring to and storing on a secure server at The University of Edinburgh; data to be transferred to any relevant third party or transferred to any other country. Provide details on 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 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). The joint Data Controller for this study is <insert name of local collaborating institution who will handle personal data>.

### 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 and adhere to the [Information Security Standard for Incident Management](https://www.ed.ac.uk/infosec/information-protection-policies/information-security-required-reading).

Any data breaches will be reported to the University of Edinburgh Data Protection Officer ([dpo@ed.ac.uk](mailto:dpo@ed.ac.uk)) who will onward report to the relevant authority according to the appropriate timelines if required

Please insert here contact details of any relevant Data Protection Officer/Committee in the local country who must also be notified of data breaches.

## DATA STATUS – APPROVALS/CONSENT

Consider:

* Will there be any transfer of data from the LMIC (where the study is being conducted) to a UoE data storage server or to another institution/third party?
* What approvals exist or are required for using the data in research? (e.g., local hospital approval, local ethics approvals associated with the data?)

## DATA STORAGE

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.

If data is pseudonymised where will the link to the identifiable data be held?

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

Data will be stored by the research team using <detail location of all systems involved in the collection, transfer and storage of electronic personal data, and who will have access to it for which purposes>.

## DATA RETENTION

Outline the retention period and the reason for the length of time.

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.

## 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.

STATISTICS AND DATA ANALYSIS

## 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
* Statement regarding use of intention to treat analysis
* Details of any interim analysis

OVERSIGHT ARRANGEMENTS

This section is standard text and should remain unchanged unless where indicated.

## INSPECTION OF RECORDS

Principal Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the Sponsor, ethics committee review, and regulatory inspection(s). In the event of audit or monitoring, the Principal 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 Principal 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) in addition to the principles of the ethics committee/ 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.

This study will receive favourable ethical approval from both the University of Edinburgh <insert university ethics group or EMREC> and from <insert local ethics board detail>.

## 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.

### 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 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, students 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) 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.

### 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 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, 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 Data Protection Act 2018 and any relevant Data Protection laws in the country where the study is being conducted <insert any applicable local laws here> with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles. 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 the Global Health Clinical Research Facilitator 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 [QA@accord.scot](mailto: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:

1. the safety or physical or mental integrity of the participants of the trial; or
2. 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](mailto: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 three 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 data point 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 appropriate ethics committees/IRBs 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](mailto:resgov@accord.scot).

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

## 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 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.

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

REFERENCES

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