***Protocol Template***

**This template for a study protocol and ethics approval form for health research involving human participants.**

**It is intended as a suggestion for studies that are sponsored by Edinburgh Napier University or co-sponsored by Edinburgh Napier University and other legal entities e.g. NHS Health Boards.**

**The template includes minimum criteria so extra information can be added as necessary. Some sections may not be applicable, depending on the nature of the study. Please not all questions must be answered, but state “Not applicable” if this section is not relevant to your study.**

**Please include a header/footer on your protocol which includes a short study title, the date and version number (e.g. ENU Study; 24 May 2017; v1.0]. The header should include appropriate logos i.e. (Edinburgh Napier University and/or NHS Board Sponsor and/or funders where appropriate).**

**The protocol should have page numbers inserted and formatted e.g. ‘1 of 10’**

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

Project Title

*Insert title of study here*

|  |  |
| --- | --- |
| Sponsor/School | Edinburgh Napier University  **Insert full address**  School of Health and Social Care  **or insert alternative sponsor/co-sponsor details as appropriate** |
| Name of Applicant | **Insert name of protocol authors** |
| Chief/Principal Investigator | **Insert name and title** |
| Co-investigators/Director of Studies | **Insert name of co-investigators**  **Director of Studies and/or Supervisory Team (if post graduate student)** |
| Applicant details (tick all applicable | **Staff**  **PGR**  **Postgraduate Taught**  **Undergraduate** |
| Funder | **Insert name of Funder (if applicable)** |
| Funding Reference Number | **Insert funder reference number (if applicable)** |
| Sponsor number | **Insert Sponsor reference number** |
| NHS REC Number | **Insert NHS REC number and/or School RIC number** |
| Project registration | **If applicable, studies classed as clinical trials should be registered on a publically accessible database.**  **Insert database/s where project is registered.** |
| Version Number and Date | **Version number and date should be entered here (and should correspond with header/footer).** |
| Project Start Date | **Insert project start date. Applicants should submit a minimum of 4-6 weeks of proposed start date bearing in mind that updates/amendments may be required** |
| Project End Date | **Insert project end date. Note any changes to duration of study, please notify the SHSC ethics.** |

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# INTRODUCTION

## BACKGROUND

Should include:

* Topic details/importance of study topic
* Epidemiology (prevalence/incidence etc)
* Review of literature/previous studies (and their limitations)
* Current policy/standards/options for treatment/care (where appropriate)
* Risks of study
* Benefits of study

## RATIONALE FOR STUDY

Should include: a clear explanation of the research hypothesis/research questions, and justification for the study, including why the study is appropriate, potential benefits to participants, health/social care, policy, practice etc.

If study involves an intervention/treatment/new procedure, provide a description of the intervention/procedure under investigation and include a 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 AIM and OBJECTIVES

## Aim/Primary Objective

### Secondary Objectives

Detail secondary objective/s (where appropriate)

## Primary Endpoint/Outcome Measure

### Secondary Endpoints/Outcome Measures

Detail secondary endpoint/s (where appropriate)

# STUDY DESIGN

Detail:

* type of study and length of study
* duration of participant involvement in study
* study setting
* consider including a schematic diagram (flowchart) of the study design

# STUDY POPULATION

## NUMBER OF PARTICIPANTS

Detail number of participants/volunteers, participant population/s, number of sites involved, length of recruitment period. It is important to consider this in terms of the validity and viability of your study

## INCLUSION CRITERIA

Detail participant inclusion criteria

## EXCLUSION CRITERIA

Detail participant exclusion criteria

# PARTICIPANT SELECTION AND ENROLMENT

## IDENTIFYING AND RECRUITMENT OF PARTICIPANTS

Describe how participants will be identified and include who will identify potential participants and details of first approach. Researchers should give thought to why they are carrying out their research in a particular context and with a specific group of people and how they intend to contact potential participants. They may be recruiting participants via contact with a school, a particular establishment or workplace. Or they may be planning to contact a specific group of students through online methods or posters etc

If study will be advertised, provide details.

## CONSENTING PARTICIPANTS

Describe the consent process:

* Include who will consent participants, where and how.
* State how long participants will be permitted to consider the participant information sheet (PIS) before consenting.

### Withdrawal of Study Participants

Detail withdrawal process.

Participants are free to withdraw from the study at any point, without giving any reason. A participant can be withdrawn by the Investigator as well.

If withdrawal occurs, it should be clear that the participant has the option to:

1. withdraw from all aspects of the study but continued use of data collected up to that point
2. withdraw from all aspects of the study with removal of all previously collected data (and any stored participant samples, where appropriate).

For intervention studies, detail reasons and procedures for a study participant stopping early i.e. “stopping rules” and “discontinuation criteria”.

# STUDY PROCEDURE

## STUDY ASSESSMENTS

Describe the study procedures and interviews/assessments, as well as time points for all interviews/assessments. Ensure that they are broken down as per visit if appropriate for clarity. Include a table of interviews/assessments where appropriate.

## FOLLOW UP ASSESSMENTS

If participants will be monitored/assessed after the intervention/treatment phase has finished, the protocol should describe the follow up period including the frequency of follow up, duration of follow up period, and any interviews/assessments that will be carried out.

## STORAGE AND ANALYSIS OF SAMPLES

If study involves dealing with biological samples, this section should describe the procedure and include:

* Sample types and volume of samples
* Arrangements for storage and analysis
* Whether samples will be destroyed at the end of the study
* Whether consent will be sought for long-term storage of samples.

# DATA COLLECTION

Detail all data to be collected, including:

* Details of standardised tools/measures/interview schedules
* Time points for collection (e.g. baseline, during intervention/treatment, end of intervention/treatment, follow up)
* Who will collect the data
* How data will be obtained (including the source)
* Describe any methods to maximise completeness of data collection (e.g. telephoning participants who have not returned questionnaires, payment for participants who complete interviews etc).

## Case Report Forms (if appropriate)

Where appropriate, for intervention studies, detail the type of case report forms which will be used.

# DATA ANALYSIS

## SAMPLE SIZE CALCULATION (if appropriate)

Detail the sample size and include, where appropriate, power calculation, dropout/retention/completion rates, relevant assumptions and justifications. Estimate recruitment figures/period and justification that the required sample size will be achievable.

## PROPOSED ANALYSES

Detail the type of data analysis to be conducted.

Where appropriate include variables to be used for assessment and how these will be reported (e.g. means, standard deviations, medians etc.) and 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

For qualitative analysis, detail analytic strategy, handling of data/coping procedure, who will conduct analysis/checks etc

# ADVERSE EVENTS

Please refer to **Adverse Events** Standard Operating Procedure (SOP).

Consider the risk level for this study (for participants) and detail any known risks/potential adverse events and how these will be recorded and reported. This should include any procedures for breach of the study protocol. Even with non-intervention studies, the protocol should still provide details of how any adverse events, harms etc. will be dealt with and reported.

Consider risks to researcher and detail how these risks will be avoided or mitigated.

# OVERSIGHT ARRANGEMENTS

## INSPECTION OF RECORDS (where appropriate)

Investigators and institutions involved in studies (classed as ‘clinical trials’) will permit study monitoring and audits on behalf of the sponsor, NHS REC review, and regulatory inspection(s) where relevant. In the event of audit or monitoring, the Investigator shall agree to allow representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator shall agree to allow inspectors direct access to all study records and source documentation.

## RISK ASSESSMENT

A study specific risk assessment may be performed by representatives of the sponsor/s, in accordance with RIO governance and sponsorship arrangements. Input will be sought from the Chief/Principal Investigator. The risk assessment outcomes will form the basis of the monitoring and audit plans.

## STUDY MONITORING AND AUDIT

The Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the designated Health Research Governance Manager to determine if an audit should be performed before/during/after the study and, if so, at what frequency. Should audit be required, details will be captured in an audit plan.

# ETHICAL CONSIDERATIONS and GOOD CLINICAL PRACTICE

## ETHICAL CONDUCT

Where relevant, studies 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 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 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 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.

Where relevant, the participant will be informed and agree to their health/social care records being inspected by regulatory authorities and representatives of the sponsor(s).

*Inspection by regulatory authorities can be deleted for non-CTIMP studies.*The Investigator or delegated member of the study 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 should be filed in the Study File (SF) and participant’s medical notes (if applicable).

### Study Site Staff

It is the Investigator’s responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their study related duties.

### Data Recording

The Principal Investigator is responsible for the quality of the data recorded at each Investigator Site.

### 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.

### Confidentiality

Please detail procedures to ensure confidentiality.

All participant study records must be identified in a manner designed to maintain participant confidentiality (for example, through the use of a unique participant identifier codes). All records must be kept in a secure storage area with limited access. ‘Personal identifiable information’ (e.g. names, dates of birth, addresses) must not be stored on any University computer.

Participants must provide written permission for the release of, or access to, any confidential or clinical information. The Investigator and study site staff involved with the study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed for the purpose of the study (unless specifically stated otherwise – for example, for the purposes of child and/or adult protection). Prior written agreement from the sponsor must be obtained for the disclosure of any said confidential information to other parties.

### Data Protection

The study protocol should include a **data management plan** which details the collection, transfer, storage, processing and disclosure of personal information related to the study.

All Investigators and study site staff involved with this study must comply with the requirements of the Data Protection Act 1998 and will uphold the Act’s core principles. Access to collated participant data will be restricted to individuals from the research team, representatives of the sponsor(s) and representatives of regulatory authorities.

Computers used to collate data will have encryption or 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

## PROTOCOL AMENDMENTS

Any changes in research activity, which involve a change in the study protocol (except those required to manage an urgent safety issue), must be reviewed and approved by the Chief Investigator. All study 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.

## SERIOUS BREACH OF PROTOCOL REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental wellbeing of the participants in the study; or

(b) the scientific value of the study.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the Sponsor 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 study, to determine whether the incident constitutes a serious breach and report to the relevant research ethics committee/s as necessary.

## STUDY RECORD RETENTION

All study documentation (excluding audio and media files) will be kept for a minimum of 3 years from the protocol defined end of study point. For studies classed as ‘clinical trials’, study documentation can be destroyed with permission from the sponsor after the minimum retention period has elapsed.

## END OF STUDY

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

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

For studies involving NHS REC and R&D Office(s), the end of the study must be reported to NHS REC and R&D Office(s) and any co-sponsors within 90 days, or 15 days if the study is terminated prematurely. A summary report of the study must be provided to the NHS REC within 1 year of the end of the study.

## CONTINUATION OF TREATMENT/CARE FOLLOWING THE END OF STUDY

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

## INSURANCE AND INDEMNITY

The Sponsor/s are 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 Sponsors' 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/s require 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 outwith 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

Include any references to support protocol text

*Insert additional appendix and details or delete.*