**Non-CTIMP Protocol Template**

This protocol template is intended for use in clinical trials and other clinical research studies which **are not** Clinical Trials of Investigational Medicinal Products (CTIMPs) or High Risk trials which are Sponsored or Co-Sponsored by the University of Aberdeen and/or NHS-Grampian.

It is recommended that Section Headings in the protocol template are retained but they may be adapted to suit particular studies or marked as Not Applicable. Other sections may be added as required by the specific study. It is also recommended that, where appropriate, a Consort flow diagram is completed at the same time as the protocol.

Black text is suggested text and should be amended accordingly.

All coloured guidance text is hidden text and will not print. Follow these instructions to view:

* Word 2003: Open the Tools > Options menu, then go to the View tab. Select the Hidden Text check box, then click OK.
* Word 2007: Click the Office button. Click the Word Options button, and then select Display on the left. Select the Hidden Text check box, then click OK
* Word 2010: Click File then Options. Click Display. Select to show hidden text.

**Study Protocol**

|  |  |
| --- | --- |
| Full Title: | *insert the full study title* |
| Study Acronym: | *insert study acronym* |
| Sponsor: | **insert Sponsor/Co-Sponsor and insert details as appropriate** |
| Sponsor Reference Number: | **insert Sponsor number before finalisation** |
| Funder: | **insert name of Funder** |
| Chief Investigator: | **insert name of CI, including Title** |
| REC Reference Number: | **insert REC number before finalisation** |
| R&D Reference Number: | **insert R&D number before finalisation** |
| ISRCTN / Clinicaltrials.gov No: | **insert ISRCTN number or equivalent, and amend text** |
| Version Number and Date: | **insert version number and date of each version** |

**If the trial is multi-site, or has a coordinating Trial Centre, add specific details e.g. contact names, addresses etc. on this front page or in an Appendix.**

#### **Table of Contents**

*Insert a table of contents*

# 

#### **Protocol Approval**

*Insert full title of project This should be the same title as written in the IRAS form*

***Important information for CI’s:***

* ***Any conflict of interest should be declared to Sponsor and documented in the protocol***
* ***The CI must be an employee of the University of Aberdeen or NHS Grampian and must be employed for the full duration of the project. If the CI is to change for any reason, Sponsor must be notified immediately via*** [***researchgovernance@abdn.ac.uk***](mailto:researchgovernance@abdn.ac.uk)***.***

**Signatures**

**By signing this document I am confirming that I have read, understood and approve the protocol for the above study.**

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| Chief Investigator |  | Signature |  | Date |
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**The final version of the protocol must be signed off before distribution**

#### **List of Abbreviations**

**Compile a list of abbreviations as appropriate.**

|  |  |
| --- | --- |
| CI | Chief Investigator |
| CNORIS | Clinical Negligence and Other Risks Scheme |
| CRF | Case Report Form |
| DMC | Data Monitoring Committee |
| GCP | Good Clinical Practice |
| ISF | Investigator Site File |
| PI | Principal Investigator |
| PMG | Project Management Group |
| R&D | Research and Development |
| REC | Research Ethics Committee |
| SOP | Standard Operating Procedure |
| TMF/SMF | Trial/Study Master File |
| TSC | Trial/Study Steering Committee |
| *Other* |  |

#### **Summary**

*Enter a short summary of your research project.*

|  |  |
| --- | --- |
|  | **Introduction** |
|  | **Background** |
|  | *This section should include background information, any reviews of previous studies, disease particulars etc.* |
|  | **Rationale for Study** |
|  | *Explain why the research questions being asked are important and justify the reason for the study taking place.* |
|  | **Study Objectives** |
|  | **Objectives** |
|  | **Primary Objective** |
|  | *State the main research question you aim to answer with this research project* |
|  | **Secondary Objectives** |
|  | *Detail any secondary objectives if applicable.* |
|  | **Outcomes** |
|  | **Primary Outcome** |
|  | *Identify a single response variable (primary endpoint/outcome) to answer the primary research question.* |
|  | **Secondary Outcomes** |
|  | *Detail any secondary outcomes.* |
|  | **Study Design** |
|  | **Study Description** |
|  | *Give details on what exactly you plan to do. Include details on project visits, what interventions/tasks/questionnaires/interviews the participant will undertake etc. and state the endpoints of the project.*  *State if the participants GP will be informed of their participation in the study. Ensure that consent to do this is obtained on the informed consent form.*  *If the participant cannot take part in other research during the study, state how you will check that they are not involved in other research and how this will be documented.*  *If any treatment/medication is to be withdrawn throughout the duration of the study please state this and explain why. Also, if any treatment is to continue after the study has finished please give further information.*  *If there will be any reimbursement to the participant please state this.* |
|  | **Study Flowchart** |
|  | *A flow chart detailing the study processes can be included here or attached as an appendix.* |
|  | **Study Matrix** |
|  | *A matrix is a table that details the study processes for participants and when they will happen. For example it can list the study visits and what will happen at each one, e.g. blood tests, scans, interviews etc. A study matrix can be included here or attached as an appendix.* |
|  | **Study Population** |
|  | **Number of Participants** |
|  | *State the required sample size and the patient/volunteer population to be recruited e.g. participants with heart disease, healthy volunteers etc.* |
|  | **Inclusion Criteria** |
|  | *State the criterion that deems the participant suitable to take part in the study.* |
|  | **Exclusion Criteria** |
|  | *State the criterion that excludes the participant from taking part in the study***.** |
|  | **Participant Selection and Enrolment** |
|  | **Identifying Participants** |
|  | *State who will identify the participants for the study and how this will be done. Please note that when recruiting NHS patients, only members of the direct clinical care team can contact a potential participant and pass on information on about a research project. State where participants will be identified from e.g. registers, clinics, GP practices etc.* |
|  | **Consenting Participants** |
|  | *State who will take consent from participants. This should be done by an appropriately trained member of the research team. If study specific training is to be provided, please state who will do this. If this is a multi-centre project state who will verify that appropriately trained personnel will be obtaining consent at all sites and where consent forms from other sites will be stored.* *If informed consent will not be sought, please state why.*  *State how long each participant will have to consider taking part in the project. Usually they should be given at least 24 hours to consider the information. If this cannot be achieved, please explain why.* *State how consent will be recorded e.g. in writing using a consent form, verbally etc.* *If you are consenting vulnerable participants (e.g. adults who do not have the capacity to consent for themselves, children, participants with learning difficulties etc.) then additional information will be required on the consent process. Give information on who will determine whether the participant is able to consent, and who will consent on their behalf if they are unable to do so. Further guidance can be found on the HRA website:* [*http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/*](http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/)  *It is also important to state what will happen if a participant loses capacity during the research project. Will they be withdrawn from the study? Will data be destroyed or kept for use within the study with permission? Will a relative/guardian be able to provide consent for them to continue?*  *If you are asking for consent to contact the participant for participation in any future research studies, or to use any data or samples obtained for future research, it is important that this is clear in the protocol, as well as in the PIS and consent forms.*  *If any procedures require separate consent forms this should also be stated.* |
|  | **Screening for Eligibility** |
|  | *List any screening requirements such as laboratory or diagnostic testing necessary to meet any noted inclusion or exclusion criteria. It is particularly important to state if any of these will be performed before the participant can be consented.* |
|  | **Ineligible and Non-Recruited Participants** |
|  | *Detail the procedure for ineligible and non-recruited participants and state how their data will be handled.* |
|  | **Randomisation and Blinding** |
|  | **Randomisation Details** |
|  | *State the type of randomisation that will be used. Detail the process of how different arms will be allocated between participants in enough detail to theoretically enable a full reproduction of the process. State who will provide randomisation (whether done in house or by a 3rd party) and the point of contact for randomisation. State what validation process are in place and how often they are tested.* |
|  | **Blinding** |
|  | *Describe in detail any blinding processes to be used in the study. Describe the procedures for un-blinding and how this will be documented. State who is responsible for un-blinding.* |
|  | **Withdrawal Procedures** |
|  | *Give a full description of the withdrawal criteria and the process for withdrawing participants from the study. Include information on documentation to be completed, if participants will be replaced and if data will be retained (with permission).* |
|  | **Study and Safety Assessments** |
|  | **Detail any specific safety assessments required for the study. Describe the measures that will be used to determine subject safety during the study. These may include physical examination, blood tests and adverse event reporting. Stipulate the times at which safety evaluations will be conducted**  **If applicable, detail the procedure for reporting any incidental findings that could be detected during the study. Ideally the participants GP should be notified. If the participant is to be called back to discuss any findings, this should be done through the NHS and not the University of Aberdeen.** |
|  | **Data Collection and Management** |
|  | **Data Collection** |
|  | *Detail how data will be collected throughout the course of the study (e.g. CRFs, questionnaires, interviews etc.), whether this will be done electronically, manually, or a mixture of both. State where the data will be collected from (source data) e.g. medical records, questionnaires etc.* *State how both electronic and manual files will be securely stored (e.g. secured shared drive, locked filing cabinets etc.) and kept confidential (e.g. by the use of unique ID numbers). If identifiable data will be stored please state this and ensure that the patient is aware of this on the PIS and consent is given to hold this data. It is also imperative that it is clear where the subject log will be kept.* *If you are using an external company for transcribing any audio recorded interviews, please state this and ensure that Research and Innovation are contacted so a contract can be put in place.* |
|  | **Data Management System** |
|  | *If a data management plan has been created please state who wrote this and where it is held.*  *If a database is being used for the project, state what type of database will be used, whether it is bespoke or off the shelf, where it will be held, who owns the license for it, what back up/recovery procedures are in place and state how access will be restricted. Give details of any validation processes and quality control measures and how often these will be done. State who will manage data queries, especially for multicentre studies.*  *If anonymous data will be shared with another institution or 3rd party, state how this will be done and that consent will be obtained from participants to do so.*  *State where data will be stored at the end of the research project.* |
|  | **Labs and Samples Analysis** |
|  | *Detail the laboratory involved (whether in house or a 3rd party) and where it is based. Detail if the appropriate accreditations and agreements are in place. Detail what samples will be taken, the procedure for this, how they will be analysed and by who. Detail what will happen to the samples after the study is completed.* |
|  | **Statistics and Data Analysis** |
|  | **Sample Size Calculation** |
|  | *Provide justification for the sample size/power calculation or precision taking account of dropout rates and other relevant assumptions, etc. Provide an estimate of the recruitment period in which the required sample size will be achieved and justification for this estimate.* |
|  | **Proposed Analysis** |
|  | *Fully describe the statistical analysis plan including the summary measures to be reported, the methods of analysis and a description of any non-statistical methods that might be used.*  *State if a statistician was involved in the development of the protocol and if a statistical analysis plan is in place. If so, please state where this is held.*  *If statistical support is being provided by a 3rd party, state who will do this and whether a contract is in place.*  *State what type of analysis programme will be used and who owns the license for this.* |
|  | **Missing Data** |
|  | *Describe how missing data will be accounted for and handled. Also describe the strategies in place to minimise the loss of data.* |
|  | **Transfer of Data** |
|  | *If data is to be transferred between sites/collaborators please state how this will be done securely. Please note that all data* ***MUST*** *be anonymised before it is transferred* |
|  | **Trial/Study Management and Oversight Arrangements** |
|  | **Trial/Study Management Group** |
|  | **Each study, no matter the number of participants or number of collaborating sites, should establish a trial management group (TMG) to set and review the day to day management of the study. The TMG should include the CI, PI, study manager or equivalent, , research nurse if appropriate. Other grant holders can be included but not all of the co-applicants need to be included. A CHaRT member of staff can be included if the CI feels it appropriate.**  The trial/study will be co-ordinated by a Study/Study Management Group, consisting of eg the grant holder (CI), external PIs, Study Manager, Research Nurse*insert as appropriate*. |
|  | **Trial/Study Management** |
|  | A Clinical Research Fellow/Study Manager/Coordinator/Research Nurse *insert as appropriate* will oversee the study and will be accountable to the CI. The Clinical Research Fellow/Study Manager/Coordinator/Research Nurse *insert as appropriate* will be responsible for checking the CRFs for completeness, plausibility and consistency. However, this remains the overall responsibility of the CI. Any queries will be resolved by the CI or delegated member of the study team.  A study-specific Delegation Log will be prepared for each site, detailing the responsibilities of each member of staff working on the study. |
|  | **Trial/Study Steering Committee** |
|  | **The TSC is responsible for providing expert oversight, monitoring and supervising the progress of the research. The TSC acts as a body to take responsibility for the scientific integrity of the Research Project e.g. validity of the protocol, assessment of quality and conduct of the research and the scientific quality of the final report/ publication.**  **The text below is suggested text only - amend as appropriate. If no TSC will be established, the reason for not having a TSC should be included in this section instead e.g. remit will be carried out as part of the PMG.**  A Trial Steering Committee (TSC) will be established to oversee the conduct and progress of the study. The terms of reference of the TSC, the draft template for reporting are detailed in Appendix 1. |
|  | **Data Monitoring Committee** |
|  | **The DMC is responsible for the review of safety and efficacy data as required and will provide updates and recommendations to the PMG, TSC, sponsor(s) and/or CI as appropriate.**  **The text below is suggested text only - amend as appropriate. If no DMC will be established, the reason for not having a DMC should be included in this section instead e.g. remit will be carried out as part of the TMG.**  An independent Data Monitoring Committee (DMC) will be established to oversee study progress. The terms of reference of the DMC are detailed in Appendix2. |
|  | **Inspection of Records** |
| **12.1** | The CI, PIs and all institutions involved in the study shall permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation. |
|  | **Good Clinical Practice** |
|  | **Ethical Conduct of the Study** |
|  | The study will be conducted in accordance with the principles of good clinical practice (GCP).  In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study. |
|  | **Confidentiality** |
|  | All laboratory specimens, evaluation forms, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor or its designee. The CI and study staff involved with this study will 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 will be obtained for the disclosure of any said confidential information to other parties. |
|  | **Data Protection** |
|  | The CI and study staff involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the PIS.  The CI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate study staff.  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. |
|  | **Insurance and Indemnity** |
|  | *Delete as appropriate:* The University of Aberdeen] [and] [Grampian Health Board] [is] [are] [Sponsoring] [Co-Sponsoring] the study.  **Insurance** – *select the applicable text form the list below:*   * *Select if University sponsoring/co-sponsoring:* The University of Aberdeen will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study. * *Select if NHS Grampian sponsoring/co-sponsoring:* Grampian Health Board will maintain its membership of the Clinical Negligence and Other Risks Insurance Scheme (“CNORIS”) which covers the legal liability of Grampian in relation to the study]. * S*elect if University staff involved and NHS patients involved:* Where the study involves University of Aberdeen staff undertaking clinical research on NHS patients, such staff will hold honorary contracts with Grampian Health Board which means they will have cover under Grampian’s membership of the CNORIS scheme.   **Indemnity:** *delete as appropriate:* The [Sponsor] [Co-Sponsors] [does not] [do not] provide study participants with indemnity in relation to participation in the Study but [has] [have] insurance for legal liability as described above. |
|  | **Study Conduct Responsibilities** |
|  | **Protocol Amendments, Deviations and Breaches** |
|  | The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor (in the first instance), REC and NHS R&D Office(s). Amendments to the protocol or other study documents will not be implemented without these approvals.  In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.  In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form “Breach Report Form”. |
|  | **Study Record Retention** |
|  | Archiving of study documents will be*insert details*.  *For University of Aberdeen employees, archiving facilities are available in the Health Sciences Building archive. For NHS Grampian employees, Oasis is a secure offsite facility that provides archiving services that has been approved for use by NHS Grampian. Please see SOP-QA-32 “Archiving Data from Interventional Research Projects” which can be found at* [*http://www.abdn.ac.uk/clinicalresearchgovernance/sops*](http://www.abdn.ac.uk/clinicalresearchgovernance/sops) |
|  | **End of Study** |
|  | The end of study is defined as last patient last visit (LPLV)/database lock/other*insert as appropriate*. The Sponsor, CI and/or the TSC 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 Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants.  A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study. |
|  | **Reporting, Publication and Notification of Results** |
|  | **Authorship Policy** |
|  | Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analyzed and tabulated, and a clinical study report will be prepared. |
|  | **Publication** |
|  | The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.  Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion). |
|  | **Peer Review** |
|  | *Document procedures for peer review – these may be funder specific or involve an internal department. Peer review is where an independent “expert” (relevant clinician, allied health professional or a member of any other relevant professional group) examines the proposed project to consider aspects such as design quality, feasibility, acceptability and importance of the topic etc.* |

# **APPENDIX 1: References**

***Please detail in a numbered list***

# **APPENDIX 2: Study Steering Committee *delete as appropriate***

# **APPENDIX 3: Data Monitoring Committee *delete as appropriate***