Quality Control Document:

Protocol Development Tool for non-CTIMPs & Studies

# Purpose

The clinical research protocol is an essential part of the research project and should describe as much detail about the project as possible. This protocol development tool for non-Clinical Trials of an Investigational Product (non-CTIMPs) and studies is created in line with [HRA guidance](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/) and is designed to be used when developing the project protocol. It provides an outline of the key elements the protocol should describe, including the background, rationale, objectives, design, methodology, statistical considerations and organisation of non-CTIMPs and studies. This document is designed to be used in conjunction with the Protocol Template for non-CTIMPs & Studies (UoB-ESD-QCD-004). For CTIMPs, see Protocol Template for CTIMPs (UoB-CLN-PRO-QCD-002).

Note: for clinical research approved by a University of Birmingham (UoB) research ethics committee (REC), the role of CI may be referred to as the principal investigator (PI), or the supervisor for postgraduate research students.

# Related documents

* UoB-CLN-PRO-QCD-002 Protocol Template for CTIMPs
* UoB-ESD-QCD-004 Protocol Template for non-CTIMPs & Studies
* UoB-ESD-QCD-005 Essential Document Checklist
* UoB-ESD-QCD-006 Version Control Log
* UoB-ESD-SOP-001 Essential Documents Development and Maintenance
* UoB-GCP-POL-001 UoB Principles of GCP for Clinical Research
* UoB-PRV-SOP-001 Peer Review

Note the UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

# References

* HRA approval: <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/#3>
* HRA ethics guidance on payments and incentives in research: <https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-guidance-payments-incentives-research.pdf>
* HRA guidance on amending an approval: <https://www.hra.nhs.uk/approvals-amendments/amending-approval/>
* HRA guidance on informing participants and seeking consent: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/>
* HRA guidance on protocol: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>
* NIHR INVOLVE - Information for researchers: <https://www.invo.org.uk/find-out-more/how-to-involve-people/information-for-researchers/>
* UoB clinical trials cover: <https://intranet.birmingham.ac.uk/finance/insurance/liability/clinical-trials.aspx>
* UoB position paper on clinical research registration: <https://www.birmingham.ac.uk/documents/college-mds/crct/uob-position-papers/uob-position-paper-clinical-research-registration-v1.0-vd-14-jan-2021.pdf>

PROTOCOL

# Title page

Aim: to provide title information, version control details and reference number. The title page may also include any relevant logos associated with the project.

## Full/long title of the project

Aim: to identify the project to enable retrieval from literature or internet searches. It should be immediately evident what the project is investigating and on whom to allow rapid judgment of relevance.

## Short title/acronym

Aim: to provide a summary of the long title. It is usually the title used on information sheets and consent forms for research participants or others giving consent or assent on their behalf.

The short title should be:

* sufficiently detailed to make clear to participants what the research is about in simple English
* if acronyms are used the full title should explain them. The proposed acronym should not drive the long title.

## Protocol version number and date

Aim: to track changes to the document for project conduct, review, and oversight so it is clear which is the most recent document.

Version control (entered into the Footer):

* all draft versions should be numbered 0.1, 0.2 etc
* the final version for submission should be numbered 1.0
* the changes made relative to the previous protocol version should be listed after submission.

## Research reference numbers

Aim: to provide a summary of the research unique identifiers for quick reference.

The table below should be completed, and if required, additional reference number/rows in the table can be added.

|  |  |
| --- | --- |
| IRAS number: | The unique identifier generated by Integrated Research Application System (IRAS) for the project. This will be the primary reference number used by the REC, Health Research Authority (HRA) and sites to identify the project and should be quoted in all project-related correspondence as well as on all participant literature. This number will not be applicable for UoB REC-approved projects. |
| Sponsor reference number (RG number): | Generated by the Research Governance Team (as the Sponsor Office). Enter if applicable. |
| REC reference number: | For UoB REC approved projects this will be the Ethics Reference Number (ERN). |
| Public registry number (e.g. ISRCTN): | For information on selecting the most appropriate public registry for your research, please see the [UoB position paper on clinical research registration (PDF - 218 KB)](https://www.birmingham.ac.uk/documents/college-mds/crct/uob-position-papers/uob-position-paper-clinical-research-registration-v1.0-vd-14-jan-2021.pdf).  |
| Funder number: | Generated by the funder. Enter if applicable. |

It is recommended that when using the protocol template, the statement below is included within this section.

* “This protocol has regard for the HRA guidance”.

If any of the sections in the protocol template are removed, the statement below should be used instead.

* “This protocol does not have regard to the HRA guidance and order of content”.

# Signature page

Aim: to provide confirmation that the CI and Sponsor have an agreed and approved the protocol.

Please see the protocol template for the written statements. The chief investigator should sign the protocol once it has been finalised.

# Table of contents

Aim: to provide an overview of the protocol’s contents and organisation.

This table of contents has been automatically generated in Microsoft Words, and is currently based on the first two heading levels. The entire table or the page numbers only can be updated by sectioning the table and clicking ‘Update Table’. The table of content can be updated, edited or manually re-created as required.

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# Key contacts

Aim: to provide a list of key contacts for quick reference.

Insert full details (including address, phone number and email, as applicable) of the key study contacts. This may include but not be limited to the following:

* Chief Investigator
* Study/trial co-ordinator
* Sponsor
* Joint-sponsor(s)/co-sponsor(s)
* Funder(s)
* Key protocol contributors
* Committees
* Medical oversight

# Project summary

Aim: to provide a brief synopsis of the project for quick reference.

The protocol should include information for the headings listed below. It may be helpful to create a table; where required, additional headings/rows can be added.

* Project title
* Internal ref. no (or short title)
* Project design
* Participants
* Planned recruitment target (if applicable)
* Follow up duration (if applicable)
* Planned study period
* Research question/aim

# Funding and support in kind

Aim: to declare all funding and/or support in kind for this project.

Insert the names and contact details of all organisations providing funding and/or support in kind.

# Role of sponsor and funder

Aim: to clarify the potential influence of sponsor and funders over the project.

The sponsor can be defined as the company, institution, or organisation assuming overall responsibility for the initiation and management of the project and is not necessarily the main funder. Identification of the sponsor provides transparency and accountability.

The protocol should explicitly outline the roles and responsibilities of the sponsor(s) and any funder(s) in project design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. It is also important to state whether the sponsor(s) or funder(s) controls the final decision regarding any of these aspects of the project.

# Roles & responsibilities of management committees/groups & individuals

Aim: to outline any committees or groups involved in project coordination and conduct.

For each committee/group the protocol should state their roles and responsibilities and degree of independence from Sponsor and Investigators. If not included in the document the protocol should state where the information on the committee/group can be found.

## Patient & public involvement group

Public involvement plays an important role in project design and planning and can help reduce delays in approvals. Public involvement in project design and documentation can help with the acceptability of a project to the public which in turn can assist with set-up and recruitment. Ongoing involvement of the public can help understand blockages to recruitment and the acceptability and relevance of findings.

For guidance on Patient & Public Involvement see [NIHR INVOLVE information for researchers](http://www.invo.org.uk/find-out-more/information-for-researchers/).

# Protocol contributors

Aim: to describe all the contributors to the protocol.

The protocol should:

* explicitly outline the roles and responsibilities of the sponsor and any funders in project design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results
* it is also important to state whether the sponsor or funder controls the final decision regarding any of these aspects of the project
* describe in what aspects of the protocol design have patients, service users, and/or their carers or members of the public been involved.

# Key words

Aim: to help in the future when searching for the protocol or for relevant publications.

Insert relevant key words to describe the project; no more than 6 phrases.

# Project flow chart

Aim: to give readers a schematic overview of the project.

A flow diagram should be included.

Careful consideration must be given by the protocol authors to ensure that the protocol is sensibly structured and ordered to allow users of the document to follow the patient and project pathway accurately and with ease. Flow diagrams are helpful tools to guide users of the protocol through the participant and project pathway. A schedule of events can be included as an appendix to the protocol.

For project designs using fewer complex methods a Gantt chart or timeline of activity outlining the timing of project management is helpful.

See also Appendix 2 – Schedule of Procedures

# Protocol

Insert title, consistent with the title on the front page.

1. Background

Aim: to place the project in the context of available evidence.

The background should be supported by appropriate references to published literature on the area of interest:

* a thorough literature review of relevant studies and analysis, new research should build on formal review of prior evidence
* a brief description of the proposed project
* a description of the population to be studied.

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 terms and concepts is likely to be beneficial.

1. Rationale

Aim: to explain why the research questions/aim(s) being addressed are important and why closely related questions are not being covered.

This should include:

* a clear explanation of the research question/aim(s) and the justification of the project i.e. why the question is worth asking and, through consultation with public and patient groups, why this is worthwhile to participants or wider service delivery
* a contextual framing of the research question/aim(s) in relation to relevant policy and historical and/or literature bases.
1. Theoretical framework

Aim: to describe the theoretical framework for the project.

A clear explanation of the proposed approach and why it is suitable to address the gaps outlined in the Background section.

Briefly outline a system of concepts, from published literature, that frames your project.

Can be presented either visually or textually.

1. Research question/aims

Aim: to define the primary research question/aim(s).

The objectives may be phrased using neutral wording (e.g. “to explore renal patients’ perceptions of their first dialysis session”) rather than in terms of a particular direction of effect.

* 1. Objectives

Aim: to clearly define the project’s objectives (there may be more than one).

An objective describes what the project is expected to achieve, and the steps required to achieve the desired outcome.

* 1. Outcome

Aim: to outline potential broad outcomes for the project which will reflect the research question aim(s).

The outcome is based on the results identified by the research.

1. Design and methods of data collection and data analysis

Aim: to describe the project design. To clearly describe the data collection methods and outline the roles involved in data collection. To clearly describe the data analysis methods.

A suitable design should be chosen to reflect the aim(s) of the project and the chosen theoretical framework. A suitable design might include ethnography, interviews, focus groups, documents, and so on.

Procedures and timelines should be defined, including randomisation and blinding where applicable.

The number of expected participants and justification for participant population should be detailed.

* Data collection methods (including identifying source documents such as case report forms (CRFs)) should be described in detail.
* Observation- What will be observed? What resources or equipment will be used if recording observation? Who will be observing?
* In-Depth Interviews- How will the prompt guide or interview schedule be developed? Who is conducting the interviews? By telephone or in person? How are the interviews being recorded?
* Focus Groups-Who is leading the focus group? How are the focus groups being recorded?

Data analysis methods may include content analysis, the constant comparative method, framework analysis, interpretative phenomenological analysis, and so on. The methodology for analysis linked to outcome measures should be described.

The protocol should clearly describe how and by whom data will be (for example):

* transcribed
* coded
* de-identified
* stored/transferred
* accessed
* archived.

Any software to be used in assisting the analysis should be specified.

The process for human tissue collection, storage, processing and analysis (to include destruction/storage after use) should be detailed, where applicable. If the project is restricted only to sample analysis, this should be stated.

1. Project setting

Aim: to state where the data will be collected, explain what activities will take place in that site, and justify the choice of site and any special requirements.

The protocol should address:

* where and how you are accessing your participants?
* how the research setting is appropriate to address the research question/aim(s)?
* if it is a multicentre or single centre project
* if there are any site-specific requirements to run the project
* outline if there are different ‘types’ of activity being undertaken at each site (e.g. identifying or recruiting) and what the specific requirements are for each.
1. Participant recruitment
	1. Eligibility criteria

Aim: to define the population of interest.

This section should set out precise definitions of which participants are eligible for the project, defining both verifiable inclusion and exclusion criteria. Inclusion criteria should define the population the project is aiming to include.

The choice of criteria can affect recruitment and attrition to the project.

* + 1. Inclusion criteria

The following are examples:

* sex and/or gender
* age range
* ethnicity
* socio economic grouping
* clinical condition
* location
* ability to provide informed consent.
	+ 1. Exclusion criteria

These are usually dependant on the inclusion criteria. The following are examples:

* outside of stated age range
* outside of stated location
* sex and/or gender.
	1. Sampling

Aim: to clearly explain and justify the detail of sampling in terms of volume and technique.

* + 1. Size of sample

Aim: to explain the rationale behind the size of the sample.

It may not always be possible to estimate the size of a target recruitment e.g. if you continue recruiting until you reach saturation. This section should describe and justify how your recruitment strategy answers your research question/aim(s).

* + 1. Sampling technique

Aim: to describe the selection of participants.

This section should detail the methods of selection used for example:

* at random, snowball, convenience sampling, purposive sampling?
* where has the sample been derived from?
* what is the rationale for this sampling strategy? The rationale should reflect the methodological and theoretical framework for the project.
	1. Recruitment

Aim: to describe how participants are identified and recruited.

This section should give details of the participant eligibility screening process for the project including methods of identifying eligible participants/sample.

For tissue only projects: if no participants will be recruited, this should be stated so and that only the samples that are already collected from the participants who consented to their use in biomedical research will be used in the project.

* + 1. Sample identification

The following should be described in the protocol (as applicable).

* Who will identify the participants/sample and what method will be used?
* What resources will be used?
* Will any participants be recruited through Patient Identification Centres (PICs)?
* Will any participants be recruited by publicity; posters, leaflets, adverts or websites?
* Will Clinical Research Networks (CRN) be involved, and will it be registered on the National Institute Health Research (NIHR) portfolio?
* Details of the sources of identifiable personal information that will be used to identify potential participants. In the case of healthcare research on patients usually only a member of the patient’s existing clinical care team should have access to patient records without explicit consent in order to identify potential participants, check whether they meet the inclusion criteria or make the initial approach to patients. If the research proposes to use someone outside the clinical team to identify suitable participants or as first contact with the participant, the reason for this should be explained with prior consent from the participant. Appropriate access should be in place (for example; honorary NHS contact/Letter of Access/ Research Passport).
* The arrangements for referral if the participants are to be identified by a separate research team.
* If patient or disease registers are used to identify potential participants a brief description of the consent and confidentiality arrangements of the register should be included.

The protocol should also detail all intended payments to participants e.g. reasonable travel expenses for any visits additional to normal care.

Please refer to HRA guidance on [payments to participants (PDF - 305 KB)](https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-guidance-payments-incentives-research.pdf).

* + 1. Consent

Informed consent must be obtained prior to the participant undergoing any activities that are specifically for the purposes of the project, including screening.

The protocol should fully describe the process of gaining informed consent which could involve:

* discussion between the potential participant or his/her legally acceptable representative and an individual knowledgeable about the research, about the nature and objectives of the project and possible risks associated with their participation
* the presentation of written material (e.g., information leaflet and consent documents) which must be approved by the REC, local regulatory requirements and legal requirements
* the opportunity for potential participants to ask questions.
* assessment of capacity. For consent to be ethical and valid in law, participants must be capable of giving consent for themselves, unless defined by law. A capable person will:
* understand the purpose and nature of the research
* understand what the research involves, its benefits (or lack of benefits), risks and burdens
* understand the alternatives to taking part
* be able to retain the information long enough to make an effective decision
* be able to make a free choice
* be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity).

Where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected.

For a very limited range of activities – such as some ethnographic observations – individuals in a research setting may not be deemed to be research “participants” and it may not be possible to gain consent from each individual observed. In such instances, a full explanation should be given of how the rights and privacy will be protected for those observed or otherwise involved in some way in a research activity for which it is not proposed to gain individual consent.

For further details on the ethical considerations of informed consent for research see the HRA’s guidance on [informing participants and seek consent](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/).

The process for withdrawal, including the subsequent impact on data and sample storage should be detailed.

1. Storage and analysis of human tissue

Aim: to describe the procedure for dealing with human tissue.

The protocol should describe the procedure for dealing with human tissue with reference to the following:

* the criteria for the collection, analysis, storage and destruction of human tissue
* the arrangements for sample collection
* the arrangements for sample analysis
* the storage arrangements for samples
* the destruction arrangements for samples.
1. Safety reporting

For definitions refer to [Glossary of Terms](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/Glossary-of-Terms.aspx).

Aim: to explain how Adverse Events will be recorded, reported and followed up.

The protocol should define and clarify what safety reporting will be undertaken and how this will be recorded.

Note: for some types of research, safety reporting may not be necessary in which case this should be stated and justified in this section.

1. Ethical and regulatory considerations

Aim: to explain how the research question/aim(s) and design/methods fit into the ethical and regulatory framework. A clear explanation of the risk and benefits to the participants should be included as well as addressing any specific needs/considerations of the participants. State how the data collection methods used uphold the dignity of the participants.

The protocol should also include a justification of how the protocol is in line with relevant legislation or requirements to gain approval to conduct the project at the proposed sites.

* 1. Assessment and management of risk

Aim: to describe a risk analysis plus risk management if the researcher were to come into information which had safeguarding implications.

A clear explanation of any risk/potential risks of the project.

A risk management plan for dealing with any potential risk/harm to the participant. For example, whilst undertaking an interview the researchers obtain information that the participant is suicidal. What mechanisms for safeguarding the participant would be put in place? Who should the information be shared with to mitigate harm to the participant?

A management plan for dealing with safeguarding issues for potential harm to others. For example, if the participant discloses information about intention to harm others. What mechanisms for safeguarding others outside of the research would be put in place? Who should the information be shared with to mitigate harm to others?

* 1. Research ethics committee (REC) and other regulatory review & reports

Aim: to demonstrate that the project will receive ethical review and approval from the necessary regulatory bodies.

The protocol should state that:

* before the start of the project, a favourable opinion will be sought from a REC for the protocol, informed consent forms and other relevant documents e.g. advertisements.

Note: researchers should check if they are required to gain a favourable opinion from a NHS REC or another REC e.g. a UoB REC.

For NHS REC reviewed research:

* substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement this at site
* all correspondence with the REC will be retained
* it is the CI’s responsibility to produce the annual reports as required
* the CI will notify the REC of the end of the project
* an annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the project is declared ended
* if the project is ended prematurely, the CI will notify the REC, including the reasons for the premature termination
* within one year after the end of the project, the CI will submit a final report with the results, including any publications/abstracts, to the REC.
	+ 1. Regulatory review & compliance

The protocol should state the following.

* Before any site can enrol participants into the project, the CI/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance. See [HRA approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/#3) for guidance on different arrangements for NHS and non-NHS sites.
* For any amendment to the project, the CI or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The CI or designee will work with sites (R&D departments at NHS sites as well as the project delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the project as amended. See also HRA guidance on [amending an approval](https://www.hra.nhs.uk/approvals-amendments/amending-approval/).
* The University of Birmingham’s Clinical Research Compliance Team may carry out compliance visits to monitor adherence with applicable standards and regulations.
	+ 1. Amendments

Aim: to describe the process for dealing with amendments.

The protocol should describe:

* the process for making amendments
* who will be responsible for the decision to amend the protocol and for deciding whether an amendment is substantial or non-substantial?
* how substantive changes will be communicated to relevant stakeholders (e.g., REC, R&D, regulatory agencies)
* how the amendment history will be tracked to identify the most recent protocol version.

See also HRA guidance on [amending an approval](https://www.hra.nhs.uk/approvals-amendments/amending-approval/).

* 1. Peer review

Aim: to describe the peer review process for the project which should be instigated and/or approved by the sponsor.

The protocol should provide details on who reviewed this protocol e.g. the funder or an internal Trust department/committee, but not include individual names unless the person in question gives their express permission.

The Department of Health (DoH) [Eligibility Criteria for NIHR Clinical Research Network (CRN) Support](https://www.nihr.ac.uk/documents/researchers/collaborations-services-and-support-for-your-research/run-your-study/Eligibility%20Criteria%20for%20NIHR%20Clinical%20Research%20Network%20Support.pdf) provides a standard for high-quality peer review of studies, whereby it must be independent, expert and proportionate. See also the Peer Review SOP (UoB-PRV-SOP-001) for the process of obtaining a peer review.

* 1. Patient & public involvement

Aim: to describe the involvement of the Public in the research.

This section of the protocol should detail which aspects of the research process have actively involved, or will involve, patients, service users, and/or their carers, or members of the public in particular:

* the acceptability of the research
* design of the research
* management of the research
* undertaking the research
* analysis of results
* dissemination of findings.

Note: where there is no patient and public involvement, justification should be provided, see also the UoB Principles of GCP for Clinical Research (UoB-GCP-POL-001).

Guidance on involving the public in research can be found on the [INVOLVE website](https://www.invo.org.uk/).

* 1. Protocol compliance

Aim: to demonstrate how protocol compliance will be managed.

Protocol deviations, non-compliances, or breaches are departures from the approved protocol. A serious breach is defined as a breach that is likely to affect to a significant degree the safety or physical or mental integrity of the participants, or the scientific value of the project.

The protocol should state that:

* accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the CI and Sponsor immediately
* significant deviations from the protocol which are found to frequently recur are not acceptable; these will require immediate action and could potentially be classified as a serious breach.

The protocol should detail how the quality of the project will be assured, and what monitoring will take place (as applicable).

The process for reporting suspected serious breaches must be detailed.

* 1. Data protection and confidentiality

Aim: To describe how participant confidentiality will be maintained and how the project is compliant with the requirements of the Data Protection Act 2018.

The protocol should state that all investigators and site staff must comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles.

The protocol should describe the means whereby personal information is collected, kept secure, and maintained. In general, the items listed below should be considered/detailed.

* How will participant’s identifying information be replaced by an unrelated sequence of characters (i.e., coded, depersonalised data)?
* Where samples are being collected, these should only be identified by participant number. Those conducting sample analysis should not have access to participant identifiable information.
* Secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media.
* Access is limited to the minimum number of individuals necessary for quality control, audit, and analysis
* How the confidentiality of data will be preserved when the data are transmitted to sponsors and co-investigators?
* How long the data will be stored for?
* Who will be the data custodian?
	1. Indemnity

Aim: to fully describe indemnity arrangements for the project.

The following areas should be addressed in the protocol.

* What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?
* What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?
* What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research? Note that if the project involves sites that are not covered by the NHS indemnity scheme (e.g. GP surgeries in primary care) these investigators/collaborators will need to ensure that their activity on the project is covered under their own professional indemnity.
* Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?
* If equipment is to be provided to site(s) for the purposes of the project, the protocol should describe what arrangements will be made for insurance and/or indemnity to meet the potential legal liability arising in relation to the equipment (e.g. loss, damage, maintenance responsibilities for the equipment itself, harm to participants or site staff arising from the use of the equipment).

Note: usually in the indemnity arrangement the responsibility for sections 1 & 2 lie with the sponsor, section 3 with the participating site and section 4 with the sponsor. Section 4 is not mandatory and should be assessed in relation to the inherent risks of the project; however, it may be a condition of REC favourable opinion to have these arrangements in place.

For further information, please see the UoB intranet page on [insurance](https://intranet.birmingham.ac.uk/finance/insurance/liability/clinical-trials.aspx) (UoB login required).

* 1. End of study and archiving

Aim: to clarify the definition of the end of the study/trial and archiving arrangements, including timelines for archiving.

* 1. Access to the final dataset

Aim: to describe who will have access to the final dataset.

The protocol should:

* identify the individuals involved in the project who will have access to the full dataset
* explicitly describe any restrictions in access for investigators e.g. for some multicentre studies, only the steering group has access to the full dataset in order to ensure that the overall results are not disclosed by an individual site prior to the main publication
* state if the project will allow site investigators to access the full dataset if a formal request describing their plans is approved by the steering group
* if it is envisaged that that dataset will be used for secondary analysis this can only be undertaken with the consent of the participants. All participant documentation should reflect the future use of these data in research.
1. Dissemination policy
	1. Dissemination policy

Aim: to describe the dissemination policy for the project.

The protocol should state:

* who owns the data arising from the project
* that on completion of the project, the data will be analysed and tabulated and a final report prepared
* where the full report can be accessed
* if any of the participating investigators will have rights to publish any of the data
* if there are any time limits or review requirements on the publications
* whether any funding or supporting body needs to be acknowledged within the publications and whether they have reviewed the data and/or have any publication rights of the data from the project
* whether there are any plans to notify the participants of the outcome of the project, either by provision of the publication, or via a specifically designed newsletter, presentation etc
* if it is possible for the participant to specifically request results from their Principal Investigator (PI) and when would this information be provided e.g. after the final report had been compiled or after the results had been published
* whether the protocol, full report, anonymised participant level dataset, and statistical code for generating the results will be made publicly available; and if so, describe where, the timeframe and any other conditions for access.
	1. Authorship eligibility guidelines and any intended use of professional writers

Aim: to describe who will be granted authorship on the final report.

The protocol should detail:

* guidelines on authorship on the final report
* criteria for individually named authors or group authorship (The International Committee of Medical Journal Editors has defined authorship criteria for manuscripts submitted for publication, known as the Vancouver Protocol).
1. References

List the literature and data that are relevant to the project, and that provide background for the project. Please ensure the text contains appropriate cross references to this list.

1. Appendices
	1. Appendix 1 – required documentation

List here all the local documentation you will require prior to initiating a participating site (e.g. CVs of the research team, participant information sheet (PIS) on headed paper etc.). Documents do not need to be attached to the protocol – this is only an example list of the documents you will require to see evidence of from each site prior to opening a site.

* 1. Appendix 2 – schedule of procedures (example)

|  |  |
| --- | --- |
| **Procedures** | **Visits (insert visit numbers as appropriate)** |
| **Screening** | **Baseline** | **Week 4** | **Week 8** | **6 Months** |
| Informed consent | x |  |  |  |  |
| Demographics |  | x |  |  |  |
| Medical history |  | x |  |  |  |
| Observation of treatment |  | x | x | x | x |
| Focus group |  |  |  |  | x |
| Interview  |  |  |  | x |  |

* 1. Appendix 3 – amendment history

List details of all protocol amendments here whenever a new version of the protocol is produced. See example table below. Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

|  |
| --- |
| The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version |
| **Amendment number** | **Date of amendment** | **Protocol version number** | **Type of amendment** | **Summary of amendment** |
| AM01 | 28-Oct-2019 | 2.0 | Substantial amendment | Changes in eligibility criteria |
| NS01 | 15-Sep-2020 | 3.0 | Non-substantial amendment | Changes in study contact details |
| AM02 | 16-Jun-2022 | 4.0 | Substantial amendment | Change in definition of the end of the study |