**Information on Qualitative Research Study Protocol Template – please read before starting**

This protocol template has been designed for qualitative clinical research studies that do not fall within the scope of the Medicines for Human use (Clinical Trials) Regulations 2004 and involve no clinical interventions or clinical procedures, and no use of human tissue samples or other human biological materials.

If you are unsure as to how to categorise your study, CTRG or R&D staff will be happy to advise you.

The template is available for use by all investigators who are carrying out qualitative clinical research studies sponsored by the University of Oxford or Oxford University Hospitals (OUH) NHS Foundation Trust if they so wish. However, there is no requirement to do so, provided that another acceptable protocol template is used. Other templates and guidance are available, for example via the HRA qualitative protocol development tool at <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>

All advisory text are highlighted in yellow. These should all be deleted before finalising the document. All sample text is in ‘basic text’ style. This text of course will be altered or deleted as required while you produce the draft. Where advisory text regarding <relevant possible options> is inserted into sample text, delete as needed.

Where a section is not relevant, this should be stated clearly and the section header retained. There may be instances where rearrangement of the subsections within section 9 is appropriate, in order to match with the order of study processes. Instructional text for deletion/rearrangement is highlighted in blue.

Repetition of information throughout the protocol is not necessary; it may be useful to cross-reference other sections of the protocol to avoid repetition.

Should you require any assistance, contact CTRG (University) or R&D (NHS) as early as possible in the planning stage:

<https://researchsupport.admin.ox.ac.uk/ctrg>

<https://www.ouh.nhs.uk/researchers/default.aspx>

**Study Title:**  insert full title including brief reference to the design, disease or condition being studied, and primary objective

**Internal Reference Number / Short title:** This should be assigned by the investigator/department (may be deleted if not required)

**Ethics Ref:** Insert

**IRAS Project ID:** Insert

**Date and Version No:** Insert

|  |  |
| --- | --- |
| **Chief Investigator:** | Insert name and contact details, including institutional affiliation |
| **Investigators:** | Insert names of key collaborators, including institutional affiliations |
| **Sponsor:** | University of Oxford/Oxford University Hospitals NHS Foundation Trust (Delete as appropriate)  (Address of Sponsor) |
| **Funder:** | Insert details of organisation providing funding |
| **Chief Investigator Signature:** | The approved protocol should be signed by author(s) and/or person(s) authorised to sign the protocol |

Please declare any/no potential conflicts of interest.

**Confidentiality Statement**

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

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# KEY STUDY CONTACTS

Insert full details of the key study contacts including the following; add/remove headings as necessary.

|  |  |
| --- | --- |
| **Chief Investigator** | Full contact details including phone, email and fax numbers |
| **Sponsor** | Oxford University Hospitals NHS Foundation Trust/University of Oxford Delete as appropriate  Full contact details including phone and email. |
| **Funder(s)** | Names and contact details of all the organisations providing funding and /or support in kind for this study. |
| **Academic Advisor(s) or Supervisor(s)** | Full contact details including phone, email and fax numbers (If applicable) of all advisers or supervisors. |

# LAY SUMMARY

It may be useful to include a copy of the lay summary from the IRAS form here. Suggested length, as per IRAS form A6-1 is 300 words.

# SYNOPSIS

It may be useful to include a brief synopsis of the study for quick reference and /or to use as a standalone document. Complete information and, if required, add additional rows.

|  |  |
| --- | --- |
| Study Title | Please ensure this is in accordance with the title page and the IRAS form |
| Internal ref. no. / short title | Please ensure this is in accordance with the title page and the IRAS form |
| Sponsor | Oxford University Hospitals NHS Foundation Trust/University of Oxford Delete as appropriate  (Address of Sponsor) |
| Funder | Names and contact details of all the organisations providing funding and/or support in kind for this study. |
| Study Design, including methodology |  |
| Study Participants, including sampling strategy |  |
| Sample Size | Specify a number or estimate a likely range e.g. 15-20 |
| Planned Study Period | Include both the total length of the project and the duration of an individual participant’s involvement (actively involved phase and all follow up – including any long term follow up via medical records and registries etc.). |
| Planned Recruitment period | Indicate start and end dates for recruitment |
| Aim/Research Questions/Objectives | |
| Primary |  |
| Secondary (if applicable) |  |

# ABBREVIATIONS

Define all unusual or ‘technical’ terms related to the project. Add or delete as appropriate to your study. Maintain alphabetical order for ease of reference.

|  |  |
| --- | --- |
| CI | Chief Investigator |
| CRF | Case Report Form |
| CTRG | Clinical Trials & Research Governance, University of Oxford |
| CUREC | Central University Research Ethics Committee |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| NHS | National Health Service |
| RES | Research Ethics Service |
| PI | Principal Investigator |
| PIL | Participant/ Patient Information Leaflet |
| R&D | NHS Trust R&D Department |
| REC | Research Ethics Committee |
| SOP | Standard Operating Procedure |

# BACKGROUND AND RATIONALE

Include the following:

Brief background to the study, including justification for the research. Provide a review of the relevant literature which would situate and justify the current study. Include references to literature and data that are relevant to the study and that provide background for the study.

Outline of the main research questions.

Brief description of the data collection methods (e.g. face-to-face interviews, observation, focus groups, document review etc.).

Summary of the known and potential risks and benefits, if any, to human participants. For example, could interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Description of the population to be studied.

# AIM / RESEARCH QUESTIONS / OBJECTIVES

Whereas clinical and other quantitative research is framed in terms of primary and secondary objectives with correlating outcome measures, qualitative work is usually organised according to its aims (overall purpose and research question) and objectives (questions or tasks to reach that aim).

The wording of the aim / research questions and objectives should be clear, unambiguous and as specific as possible – the study will be judged on how, and how well, the objectives were satisfied. Complete table below with all relevant information.

|  |
| --- |
| **Aim / Research Questions / Objectives** |
| Example: From - Low et al., BMC Geriatrics (2017) 17:81 [DOI 10.1186/s12877-017-0473-9]  Aim:  To explore ageing family carers’ caregiving experiences and the plans they have to provide care for themselves and their ageing children with mild or moderate intellectual disability (ID). |
| Objectives:  1. To explore family carers’ perspectives of current caring needs and types of care needed by the person with ID;  2. To examine the extent to which the current level of support has met family carers’ expectations and  needs, and the caring needs of the person with ID;  3. To examine the plans family carers have for continuing the care of the person with ID as carers  themselves are getting older;  4. To explore how family carers plan to achieve/implement their plans for continuing care of the person with ID person from now until later life.  5. To develop a theoretical framework that captures the family carers’ experiences and processes of planning to meet the current and continuing care needs of community-dwelling persons with ID. |

# STUDY DESIGN

## Methodology

Briefly describe the methodology for your qualitative work, e.g., action research, case study, conversation analysis, ethnography, grounded theory, interpretative phenomenological analysis, narrative, or discourse analysis etc.

Explain why the proposed methodology is appropriate to the aim/research questions.

## Sampling Strategy

Briefly describe the sampling strategy for your study e.g. critical case sampling, criterion sampling, maximum variation sampling, purposive sampling, snowball (chain) sampling, theoretical sampling, volunteer (convenience) sampling

Explain why the proposed sampling strategy is appropriate to the aim/research questions

## Methods of Data Collection

Describe the method(s) of data collection to be used (e.g. open-ended questionnaire, interview schedule, focus group, participant or non-participant observation), whether data collection is face-to-face or remote (e.g. via telephone, skype or other internet software), and how data will be recorded (e.g. note taking (field notes), audio recording, video recording). Provide a rationale for why these are appropriate methods to address the research question(s)/aim(s).

State the range of possible settings where data collection is likely to take place (including e.g. participants’ home or work place, GP surgeries, nursing homes, hospice, hired meeting rooms/halls, researcher’s office, cafes/coffee shops) and why they are seen as appropriate to address the research question(s)/aim(s).

## Methods of Data Analysis

Describe the method of data analysis to be used (**e.**g. Analytic Induction, Conversation Analysis, Discourse Analysis, Event Analysis, Framework Analysis, Grounded Theory, Hermeneutic Analysis, Heuristic Analysis, Interpretive Phenomenological Analysis, Thematic Analysis etc.). Provide a rationale for why this is an appropriate method to address the research question(s)/aim.

## Study Sequence and Duration

Give the expected duration of individual participation, number of visits/interviews or questionnaires, a description of the sequence and duration of all study periods e.g. screening, interview, review of transcripts, if applicable.

Include a flowchart for the project (here, or as an appendix) if appropriate.

# PARTICIPANT IDENTIFICATION

## Study Participants

Give an overall description of the study participants and state the approximate number of participants required to complete (commence). This may be influenced by the quality of data, scope of the study (whether broad or in-depth) the nature of the topic, study design and qualitative method(s). See Morse, J.M. (2000) “Determining Samples Size” Qualitative Health Research 10 (1), 3-5 If you propose to continue sampling until you reach thematic data saturation please give an estimate of the likely sample range (e.g. n=12-30 etc.). Describe how you will select your cases and your criteria for recognising thematic data saturation / ending data collection. Provide a rationale for your decisions as appropriate for allowing you to address your research question(s)/aim.

Example:

20 - 30 participants aged 16-21 years old who received dexamethasone within the last 5 years during treatment for acute lymphoblastic leukaemia or lymphoblastic lymphoma.

Example:

General practitioners, nurse practitioners and healthy volunteer smokers

## Inclusion Criteria

Example criteria only (amend as appropriate):

* Participant is willing and able to give informed consent for participation in the study.
* Male or Female, aged 18 years or above.
* Diagnosed with required disease/severity/symptoms, or part of specific group to be studied
* Additional study specific criteria as required.

## Exclusion Criteria

Example criteria only (amend as appropriate):

The participant may not enter the study if ANY of the following apply:

* Specify any diseases/disorders/ conditions that would preclude entry into the study.
* Additional study specific criteria as required.

Note: ensure each criterion is stated as either an inclusion or an exclusion criterion, but not as both. For example, it is not necessary to include ‘Male or female aged under 18’ among the example exclusion criteria above as this is already covered by the inclusion criterion ‘Male or female, aged 18 or above’.

# STUDY ACTIVITIES

Add schedule of activities here or as an appendix, if appropriate.

Describe all study activities in detail in the subsections below. The participant and study pathways should be clear. It should also be clear where the study data is being collected (at the GP surgery, face to face at the participant’s home, or by phone etc.), and who it is that is collecting the study data at those locations (surgery staff, midwives, or the central research team etc.).

## Recruitment

State if the study is multicentre or single centre i.e. where and how do you plan to recruit participants?

Describe how you will identify potential participants, including some or all of the following: response posters in GP practices, nurses in relevant hospital clinics, notices in educational institutions/supermarkets/other public places, advertisements on charity websites and/or in charity newsletters. If not detailed above (section 7: *Study Design)* then state how the research setting(s) (e.g., GP surgeries, nursing homes, hospices, participants’ homes, hired meeting rooms/halls, researcher’s office, cafes/coffee shops, etc.) is/are appropriate to address the research question(s)/aim(s)

Describe how potential participants will be identified, approached, screened and recruited. Specify who will identify potential participants and who will approach them and whether, in the case of patients, the person(s) identifying potential participants have routine access to the relevant data to be able to identify them.

## Informed Consent

Specify who will take informed consent, how and when it will be taken. Informed Consent must be obtained prior to any study related activities being undertaken. In the case of most postal and/or internet surveys, completion or return of the survey implies consent and a separate consent form will not be required

For further details on the ethical considerations of including persons who cannot consent for themselves see the guidance on the HRA website: <http://www.hra-decisiontools.org.uk/consent/>

Example:

The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information [this may vary depending on the circumstances of the study], and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site.

## Screening and Eligibility Assessment

Describe the screening procedures in detail (if relevant) such as demographics, medical history, questionnaires, mental capacity assessment.

Note: Consent is required before performing any study specific screening activity, tests, assessments, questionnaires, scales, etc. For example, if screening requires completion of a screening questionnaire about the potential participant’s current levels of anxiety and depression then written informed consent would be needed to collect that study specific information and establish eligibility / ineligibility.  In such cases study staff cannot screen the potential participants before they have given their written informed consent. There are cases where screening may be achieved by a review of *existing clinical data obtained during routine assessments collecte*d *as part of routine care and not specifically collected for the study.* For example a study interested in interviewing only those cancer survivors who had an early diagnosis of their disease (i.e., Stage 1 & 2 only) might seek verbal permission from the potential participants to perform a review of their medical history to establish that fact. The potential participants may consent verbally to this review of existing data. The ethics application should be clear about the relationship between the records reviewer and the potential participants, that is, is the reviewer part of the team responsible for the potential participant’s care or are they someone from outside that team? If found eligible, the potential participant would be invited to participate and to sign an informed consent form for the study.

State that there will be no exceptions made regarding eligibility, i.e., that each participant must satisfy all the approved inclusion and exclusion criteria of the protocol. \* Note that changes to the approved inclusion and exclusion may be made by substantial amendment only.

Specify the maximum duration allowed between screening and recruitment (if applicable).

## Subsequent Visits

Specify the time points at which participants will be followed up and what further data collection (e.g., questionnaires, interviews, focus groups, and observations) will be undertaken at those times. The data collection activities must reflect the stated aims and objectives of the study. Specify if the data collection takes place at clinic visits, by telephone or skype, at the participant’s home or other location. Add window periods for the study visits/assessments if applicable, for example, ‘at 3months +/- 7 days’. **Clearly number the study visits**.

If there is only one study visit /assessment or no study visits and this section is not applicable then please make a clear statement to that effect and retain the sub-section header.

## Discontinuation/Withdrawal of Participants from Study

Example:

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

* The occurrence of significant distress during study interviews
* Inability to comply with study procedures
* Participant decision

Participants may choose to stop their active involvement in study assessments but choose to remain on passive study follow-up. Participants may also withdraw their consent, meaning that they wish towithdraw from the study completely. In the case of withdrawal from active involvement consider the following options for a tiered withdrawal from the study. Not all the options may be relevant to your study. The options elected for use in the study must be covered in the participant information sheet.

According to the design of the study, participants may have the following three options for withdrawal;

1. Participants may withdraw from study assessments and further study communication but allow the study team to continue to access their medical records and any relevant hospital data that is recorded as part of routine standard of care; i.e., disease progression data, routine patient reported outcome data and quality of life questionnaire data etc.
2. Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.
3. Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal. The data already collected would not be used in the final study analysis\*.

\*Note any limits to this type of withdrawal should be explained in the participant information sheet. In particular, consideration to audio recordings must be made. If an audio recording has already been transcribed and anonymised, would you be able to exclude their data? Where participants were part of a focus group, consider whether an individual’s data impinges on/is directly related to that of other participants. Where the team wish to use all the data collected up to point of withdrawal, careful consideration should be given to the inclusion of this option in the PIS.

In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including, but not limited to:

delete/add as appropriate

* Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
* Significant protocol deviation
* Significant non-compliance with study requirements

State whether withdrawal from the study will result in exclusion of the data for that participant from analysis.

State whether or not withdrawn participants will be replaced.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

## Definition of End of Study

The definition of end of study must be provided. In most cases the end of study will be the date of the last visit of the last participant.

Example:

The end of study is the date of the last <visit / telephone follow up / home visit> of the last participant.

Example:

The end of study is the point at which all the study data has been entered and queries resolved.

# ANALYSIS

## Description of Analytical Methods

Describe method of analysis for objectives (e.g., thematic analysis, constant comparative method (i.e., grounded theory), framework analysis, interpretive phenomenological analysis) and why this is an appropriate method for addressing your research question(s) or aim(s). Include a description of how you will address *either 1)* the reliability and validity *or 2)* the rigour and trustworthiness of the analysis[[1]](#footnote-2).

Examples (1):

*External reliability* through taking the same social role as the original researcher when replicating a previous study.

*Internal reliability* by high levels of agreement between two or more members of the research team with regard to what they have seen or heard and in the thematic structure obtained from analysis of transcripts.

*Internal validity* by a good match between the researchers’ observations and their developing theory

*External validity* by the extent to which the findings of the study can be generalised across other settings

Examples (2):

*Credibility* refers to how confident the qualitative researcher is that the study’s findings are ‘accurate’ *Triangulation*, where different types or sources of data are used, and *participant validation (or ‘member checking’)*, where participants are given an account of the findings and asked whether they reflect their perspectives and/or experiences.

*Transferability* refers to the extent to which the research study’s findings are applicable to other contexts including similar situations, similar populations, and similar phenomena.

*Confirmability* refers to the extent to which the study findings are based on participants’ responses and not on the personal biases or motivations of the researcher. This involves making sure that researcher bias does not skew the interpretation of what the research participants said to fit a certain narrative. Confirmability can be established by an audit trail which sets out each step in the analysis of data and provides a rationale for the decisions made, thus providing evidence that the study’s findings accurately portray participants’ responses.

Include details as to what participant data will be used and any qualitative data analysis software proposed to aid the coding and analysis.

# DATA MANAGEMENT

## Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

## Data Recording and Record Keeping

Describe method(s) of data entry, transcription and management, including details of data management tools, for example, qualitative data management and analysis software (eg NVivo, ATLAS.ti, MAXQDA) etc.

Example:

All study data will be entered on <a paper CRF and/or a <<*quote software used* >>.

The participants will be identified by a unique study specific number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

Describe where, and for how long, participant voice and/or video recordings, interview transcripts and anonymised data will be retained. If an external transcriber or transcription service is being used, outline how participant confidentiality will be protected. For example, typically there would be a contract with the transcriber, and they delete all data on its return to the researcher. This needs to be set out in the PIS as well, since the transcriber is a third party data processor.

If no identifiable, personal data will be retained centrally (i.e. by the sponsoring organisation), but rather this will be held at individual sites **only**, please state this explicitly.

If participants are given the option to be approached for future research, please be aware that under GDPR, it is necessary to retain the consent form as the basis for retention of details and future approach. Those contact details should be held securely, separately from the research data, and kept updated.

Ensure compliance with the relevant Sponsor organisation’s data policy. For University of Oxford sponsored studies please refer in particular to the University of Oxford’s:

Data Protection Checklist <https://researchsupport.admin.ox.ac.uk/policy/data/checklist>

Practical Considerations <https://researchsupport.admin.ox.ac.uk/policy/data/practical>

# QUALITY ASSURANCE PROCEDURES

Provide details of how data monitoring and other quality control measures will be performed, and who will undertake these activities.

Example:

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

# ETHICAL AND REGULATORY CONSIDERATIONS

Describe ethical considerations relating to the study. Include general and study specific ethical considerations.

Examples below:

## Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki. NB. The 2008 Declaration of Helsinki provides detail on what must be included in a protocol: funding, sponsorship, affiliations and potential conflicts of interest, incentives to participate and compensation for harm.

## Approvals

Consider the following text:

Following Sponsor approval the protocol, informed consent form, participant information sheet <and any proposed advertising material> will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

## Other Ethical Considerations

Include any other ethical considerations specific to the study e.g. involvement of vulnerable participants, or participants who are unable to consent for themselves; possibility of criminal disclosure or issues of safeguarding.

## Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

## Participant Confidentiality

Example:

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s), <with the exception of the CRF, where participant initials may be added>.  All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants’ personal data.

For University of Oxford sponsored studies please refer in particular to the University of Oxford’s:   
Data Protection Checklist <https://researchsupport.admin.ox.ac.uk/policy/data/checklist>

Practical Considerations <https://researchsupport.admin.ox.ac.uk/policy/data/practical>

OUH researchers see <https://www.ouh.nhs.uk/privacy/default.aspx>

## Expenses and Benefits

Detail all intended payments to participants and any other benefits (Declaration of Helsinki requirement).

Example:

Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

# FINANCE AND INSURANCE

## Funding

Describe financing arrangements, including all the organisations providing finance and /or support in kind for this study).

## Insurance

Describe insurance arrangements

**Either** *for OUH sponsored studies*:

NHS bodies are legally liable for the negligent acts and omissions of their employees. If a participant is harmed whilst taking part in a clinical research study as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances.

In exceptional circumstances an ex-gratia payment may be offered.

**Or** *for University of Oxford sponsored studies:*

The University of Oxford maintains Public Liability and Professional Liability insurance which will operate in this respect.

## Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

# PUBLICATION POLICY

The publication policy should cover authorship, acknowledgements, and review procedures for scientific publications. If there is a department or institution policy, or agreement, the protocol can refer to it. Ensure that the publication policy stated here is consistent with any contract applicable to the study. Consider describing how study results may be disseminated to study participants.

Example:

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by <insert details>. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

# DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

**Either** *for University of Oxford sponsored studies:*

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

***Or*** *for OUH sponsored studies:*

Ownership of IP generated by employees of the OUH vests in OUH.  The protection and exploitation of any new IP is managed by the IP and Research Contracts Team at OUH unless it is generated in collaboration with Oxford University in which case this is led by the University’s technology transfer office, Oxford University Innovations.

If the section is not applicable state ‘not applicable’ and retain the section header.

# ARCHIVING

Describe the arrangements for archiving the study including location and duration of storage. These details should correspond with those provided in the participant information sheet.

# REFERENCES

Insert references used in text (preferably in alphabetical order of first author).

# APPENDIX A: STUDY FLOW CHART

Optional

# APPENDIX B: AMENDMENT HISTORY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol Version No.** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
|  |  |  |  |  |

List details of all protocol amendments here whenever a new version of the protocol is produced. This is not necessary prior to initial REC submission.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, and HRA (where required).

1. See Bryman A. (2001) Social Research Methods. Oxford University Press, pp270-274. [↑](#footnote-ref-2)