**Qualitative Protocol Template Swansea University**

**FULL TITLE OF THE STUDY**

1. Main details

|  |  |
| --- | --- |
| Chief Investigator name and contact email  |  |
| Student name and Number (if applicable)  |  |
| SU Internal ref. no.  | RIO xxx-xx |
| Study Design |  |
| Study Participants |  |
| Planned Size of Sample (if applicable) |  |
| Follow up duration (if applicable) |  |
| Planned Study Period |  |

|  |
| --- |
|  |
|  |  |

# LIST of CONTENTS

|  |  |
| --- | --- |
| **GENERAL INFORMATION** | **Page No.** |
| 1. TITLE PAGE
 | 1 |
| 1. LIST OF CONTENTS
 | 2 |
| 1. STUDY SUMMARY
 | 3 |
| 1. STUDY FLOW CHART
 | 4 |
| **SECTION**  |
| 1. BACKGROUND  |  |
| 2. RATIONALE  |  |
| 3. RESEARCH QUESTION/AIM(S)  |  |
| 4. STUDY DESIGN/METHODS |  |
| 5. STUDY SETTING |  |
| 6. SAMPLE AND RECRUITMENT |  |
| 7. ETHICAL AND REGULATORY COMPLIANCE |  |
| 8. DISSEMINATION POLICY |  |
| 9. REFERENCES |  |
| 10. APPENDICES |  |

1. **STUDY SUMMARY**

Please insert a brief synopsis of the study for quick reference.

# STUDY FLOW CHART

Please insert a flow diagram.

To give readers a schematic overview of the study and allow users of the document to follow the patient and study pathway accurately and with ease.

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

**STUDY PROTOCOL**

Insert title, consistent with the title on the front page

# 1 BACKGROUND

Aim: To place the study 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 study.
* 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.

# 2 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 study 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.

# 3 RESEARCH QUESTION/AIM(S)

Insert

 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.

**3.1** **Objectives**

Insert clearly define the study’s objectives (there may be more than one).

**3.2 Outcome**

Insert outline potential broad outcomes for the study which will reflect the research question aim(s).

# 4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Insert the study design, clearly describe the data collection methods and outline the roles involved in data collection. And describe the data analysis methods.

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

Data collection methods 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 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.

# 5 STUDY SETTING insert

* 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.
* 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 study.
* If there are any site specific requirements to run the study.
* 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.

**6 SAMPLE AND RECRUITMENT**

**6.1 Eligibility Criteria**

Insert the study population/sample

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

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

**6.1.1 Inclusion criteria**

The following are examples:

* Gender.
* Age range.
* Ethnicity.
* Socio economic grouping.
* Clinicalcondition.
* Location.

**6.1.2 Exclusion criteria**

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

* Outside of stated age range.
* Outside stated of location.
* Gender.

**6.2 Sampling**

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

**6.2.1 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 sample e.g. if you continue sampling until you reach saturation. This section should describe and justify how your sampling strategy answers your research question/aim(s).

**6.2.2 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 study.

**6.3 Recruitment**

Insert 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.

**6.3.1 Sample identification**

The following should be described in the protocol:

* Who will identify the participants and what method will be used?
* Who will identify participants/sample?
* 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?
* Details of the sources of identifiable personal information that will be used to identify potential participant. 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.
* 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.

# 7 ETHICAL AND REGULATORY CONSIDERATIONS

## Insert 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 sample. 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 study at the proposed sites.

**7.1 Research Ethics Committee (REC) and other Regulatory review & reports**

Insert that the study will receive ethical review and approval from the necessary regulatory bodies

The protocol should state that:

* Before the start of the study, a favourable opinion will be sought from a REC (researchers should check if they are required to gain a favourable opinion from the UK Health Departments Research Ethics Service NHS [REC](https://www.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements)) or other REC approval) for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

**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 at site.
* All correspondence with the REC will be retained.
* It is the Chief Investigator’s responsibility to produce the annual reports as required.
* The Chief Investigator will notify the REC of the end of the study.
* 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 study is declared ended.
* If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
* Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

**Regulatory Review & Compliance**

The protocol should state that:

* Before any site can enrol patients into the study, the Chief Investigator/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. Different arrangements for NHS and non NHS sites are described as [relevant](http://www.hra.nhs.uk/resources/hra-approval-guidance-for-sponsorschief-investigators-working-collaboratively-with-nhs-organisations-in-england/#3).
* For any amendment to the study, the Chief Investigator 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 Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as [amended](http://www.hra.nhs.uk/resources/after-you-apply/amendments/).

Amendments

Insert to describe the process for dealing with amendments

For studies that are outside of the NHS and do not require NHS REC review or NHS management approval amendments should be handled in line with the sponsors and site management organisations polices.

**For studies involving the NHS:**

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor’s responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

If applicable, other specialist review bodies (e.g. Confidentiality Advisory Group (CAG)) need to be notified about substantial amendments in case the amendment affects their opinion of the study.

Amendments also need to be notified to the [national coordinating function of the UK](http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/preparing-amendments/) country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

In all instances 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.*

Guidance on the categorisation of amendments for studies involving the NHS can be found on the HRA website. <http://www.hra.nhs.uk/resources/after-you-apply/amendments/>

**7.3 Peer review**

Insert the peer review process for the study which should be instigated and/or approved by the sponsor.

The protocol should provide details on who reviewed this study 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 National Institute Health Research (NIHR) Clinical Research Network (CRN) provide the following standard for peer review for studies:

**High quality peer review**

Peer review must be independent, expert, and proportionate:

1. **Independent**: At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators’ host institution and not involved in the study in any way. Reviewers do not need to be anonymous.
2. **Expert**: Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service based aspects of the protocol, and/or have the expertise to assess the methodological qualitative aspects of the study.
3. **Proportionate**: Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review.

**7.4 Patient & Public Involvement**

Insert 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

Guidance on involving the public in research can be found on the INVOLVE website. <http://www.invo.org.uk/>

**7.5 Protocol compliance**

Insert how protocol compliance will be managed

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

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 Chief Investigator and Sponsor immediately.
* Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

###

**7.6 Data protection and patient confidentiality**

Insert how patient confidentiality will be maintained and how the study is compliant with the requirements of the Data Protection Act 1998

The protocol should state that all investigators and study site staff must comply with the requirements of the Data Protection Act 1998 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, this involves:
* The creation of coded, depersonalised data where the participant’s identifying information is replaced by an unrelated sequence of characters.
* Secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media.
* Limiting access 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 is the data custodian?

7.7 Indemnity

Insert indemnity arrangements for the study

The following areas should be addressed in the protocol:

1. 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?
2. 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?
3. 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 study 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 study is covered under their own professional indemnity.
4. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?
5. If equipment is to be provided to site(s) for the purposes of the study, 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)

NB Usually 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 study; however, it may be a condition of REC favourable opinion to have these arrangements in place.

**7.8 Access to the final study dataset**

Insert who will have access to the final dataset

The protocol should:

* Identify the individuals involved in the study who will have access to the full dataset.
* Explicitly describe any restrictions in access for study investigators e.g. for some multicentre studies, only the steering group has access to the full study dataset in order to ensure that the overall results are not disclosed by an individual study site prior to the main publication.
* State if the study 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 patient documentation should reflect the future use of these data in research.

### 8 DISSEMINIATION POLICY

### 8.1 Dissemination policy

Insert the dissemination policy for the study

The protocol should state:

* + Who owns the data arising from the study.
	+ That on completion of the study, the data will be analysed and tabulated and a Final Study Report prepared.
	+ Where the full study report can be accessed.
	+ If any of the participating investigators will have rights to publish any of the study 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 and publication rights of the data from the study.
	+ Whether there are any plans to notify the participants of the outcome of the study, 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 PI and when would this information be provided e.g. after the Final Study Report had been compiled or after the results had been published.
	+ Whether the study protocol, full study 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.

**8.2 Authorship eligibility guidelines and any intended use of professional writers**

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

The protocol should detail:

* Guidelines on authorship on the final study 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).

### 9 REFERENCES

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

### 10. APPENDICIES

**10.1 Appendix 1- Required documentation**

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

**10.2** **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 |  |

**10.3** **Appendix 3 – 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.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.