**Template Protocol for Qualitative Research**

<Study Acronym>

<Full study title>

<Short study title>

To provide a summary of the long title. It should be used on information sheets and consent forms for research participants. The short title should make it clear to participants what the research is about in simple English. If acronyms are used the full title should explain them.

<Version number and date>

To track changes to the document for study conduct, review, and oversight so it is clear which is the most recent document.

MAIN SPONSOR: Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable)

SPONSORS Number: [Generated by the Sponsor. Enter if applicable]

FUNDERS: xxx

STUDY COORDINATION CENTRE: xxx

IRAS Project ID: The unique identifier generated by IRAS for the project. This will be the primary reference number used to identify the project and should be quoted in all projects related documents.

REC reference: xxx

**Protocol authorised by:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name & Role** | **Position** | **Date** | **Signature** |
|  |  |  |  |

**Study Management Group**

Chief Investigator:

Co-investigators:

Statistician:

Study Management:

**Study Coordination Centre** *(may not be applicable)*

For general queries, supply of study documentation, and collection of data, please contact:

Study Coordinator:

Address:       **Registration:**

Tel:       E-mail:

Fax:       Web address:

**Clinical Queries**

Clinical queries should be directed to xxx who will direct the query to the appropriate person

**Sponsor**

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Research Governance and Integrity Team

Imperial College London and Imperial College Healthcare NHS Trust

Room 215, Level 2, Medical School Building

Norfolk Place

London, W2 1PG

**Tel**: **0207 594 9480**

[Imperial College - Research Governance and Integrity Team (RGIT) Website](https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/)

**Roles & Responsibilities of Study Management Committees/Groups**

Study Steering Groups

To outline any committees or groups involved in study coordination and conduct.

Patient & Public Involvement Group

Public involvement plays an important role in study design and planning and can help reduce

delays in approvals. For guidance on Patient & Public Involvement follow this link:

http://www.invo.org.uk/find-out-more/information-for-researchers

**Funder**

[Who is funding the study]

This protocol describes the xxx study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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**Glossary of Abbreviations**

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**Keywords**

[Insert a list of keywords]

**Study Summary**

|  |  |
| --- | --- |
| **TITLE** |  |
| **DESIGN** |  |
| **AIMS** |  |
| **OUTCOME MEASURES** |  |
| **POPULATION** |  |
| **SAMPLE SIZE** |  |
| **ELIGIBILITY**  **FOLLOW-UP** |  |
| **duration** |  |

**Reference diagram**

[if appropriate]

# INTRODUCTION

* 1. BACKGROUND

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 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.

* 1. RATIONALE FOR CURRENT STUDY

This should include: A clear explanation of the research question/aim(s)hypothesis and the justification of the study i.e. why the question is worth asking.

* 1. RESEARCH QUESTION/AIM(S)

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.

# STUDY OBJECTIVES

[List the primary, secondary and other study objectives]

# STUDY DESIGN and METHODS of DATA COLLECTION

To clearly describe the data collection methods, sample size and outline the roles involved in data collection.

To clearly describe the data analysis methods.

To clearly describe the duration and time points of the study.

A suitable design might include ethnography, interviews, focus groups, documents, and so on.

Data collection and storage methods

1. Observation- Who will be observing and what will be observed? What resources or equipment will be used if recording observation?
2. In-Depth Interviews- How will the guide or interview schedule be developed? Who is conducting the interviews? By telephone or in person? How are the interviews being recorded?
3. Focus Groups-Who is leading the focus group? How are the focus groups being recorded?

Data analysis methods

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

* Transcribed/ Coded or De-identified.
* Stored/Transferred/ Accessed and Archived.
  1. STUDY SETTING

To state where the data will be collected, Where and how you are accessing your participants? Explain what activities will take place in that site, and justify the choice of site and any special requirements.

If it is a multicentre or single centre study.

1. If there are any site specific requirements to run the study.
2. 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. RECRUITMENT

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

[Are there endpoints to the study?] List the primary and secondary outcomes measures.

# PARTICIPANT ENTRY

* 1. PRE-REGISTRATION EVALUATIONS

[What tests need to be included before a participant can enter the study? Eg, FBC, LFT, biopsy, CT scan. All screening procedures should be included]

* 1. INCLUSION CRITERIA

[Include justifications, if necessary]

The following are examples:

* Gender.
* Age range.
* Ethnicity.
* Socio economic grouping.
* Clinical condition.
* Location.
  1. EXCLUSION CRITERIA

[Include justifications, if necessary]

* 1. WITHDRAWAL CRITERIA

[Describe procedures for stopping early Decribe what will happen to the data following withdrawal. For example will it be retained or destroyed? ]

* 1. **SAMPLING**

[To explain the rationale behind the size of the sample]

This section should detail the methods of selection used.

* 1. Assessment and management of risk

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 study.

· 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?

# ASSESSMENT AND FOLLOW-UP

[Will there be a follow up? When and what will their assessments consist of? Efficacy assesments, if applicable, should be included] Describe how incidental findings will be identified, reviewed and reported, and to which individuals they will be reported to (i.e. GP, clinical care team).

[Definition of end of study]

# STATISTICS AND DATA ANALYSIS

[Statistical plan, eg sample size calculation and data analysis.]

Data and all appropriate documentation will be stored for a minimum of 10 years *(5 years if ICHT sponsored study)* after the completion of the study, including the follow-up period.

# REGULATORY ISSUES

* 1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the xxx Research Ethics Committee (REC) and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

* 1. CONSENT

(If study does not involve consent, this section is not relevant)

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant’s best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

For further details on the ethical considerations of informed consent for research see the guidance notes available on the HRA website. http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/

* 1. CONFIDENTIALITY

Pseudonymised data is data that can be linked back to a person (e.g. coded data). It is considered both personal and identifiable data. Anonymised data is data that has no code and cannot be linked back to a person (e.g. aggregated data for publication, data without a code that cannot be linked back to a person)

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Data will be anonymised/pseudonymised (delete as applicable)

Data will be transferred to (insert third party name as appropriate or delete)

* 1. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study/ Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study (delete as applicable)

* 1. SPONSOR

Imperial College London/Imperial College Healthcare NHS Trust (delete as applicable) will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

* 1. FUNDING

xxx are funding this study. [Any per participant payments, investigator payments should be detailed here]

* 1. AUDITS

The study may be subject to audit by Imperial College London/ Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

# STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through xxx.

*(delete once inserted) CI to include study specific reporting requirements/notification responsibilities for the study*

# PUBLICATION POLICY

[The study's publication policy should be described in full including where the full study report can be accessed]

# REFERENCES

[List of useful and relevant references for the study]

**EXAMPLE APPENDICES**

Appendices should be additional information to the protocol and can consist of:

* Common Terminology Criteria for Adverse Events (NCI CTC)
* RECIST criteria
* WHO / ECOG Performance status
* PIS, Consent form, GP letter (although may be more practical to have them separate)
* Expected side effects
* Schedule of events table

**Appendix 1. Summary of investigations, treatment and assessments**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Procedures** | | **Week of Treatment** | | | | | | | | |
|  | Pre-treatment | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Informed consent | X |  |  | X |  |  | X |  |  |  |
| Demographic | X |  |  |  |  |  |  |  |  |  |
| Medical History | X |  |  |  |  |  |  |  |  |  |
| ECG | X |  |  |  |  | X |  |  |  |  |
| Observation of Treatment | X |  |  |  |  |  |  |  |  |  |
| Focus Group | X | X | X | X | X | X | X | X | X | X |
| Interview | X |  |  |  |  |  |  |  |  |  |