**Instructions:** *All blue italics is for guidance only and once section complete the blue italics must be deleted.*

*All Orange Italics is mandatory text and should be retained in the protocol, the font should be changed before submission.*

**FULL/LONG TITLE OF THE STUDY**

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

**SHORT STUDY 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*
* *Ideally unique as to enable easy search from internet searches*

**PROTOCOL VERSION NUMBER AND DATE**

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

*Version control:*

* *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**

|  |  |
| --- | --- |
| **IRAS Number: if applicable** | The unique identifier generated by Integrated Research Application System (IRAS) for the project. This will be the primary reference number used by Research Ethics Committee, Health Research Authority and sites to identify the project and should be quoted in all project related correspondence as well as on all participant literature. |
| **SPONSORS Number:** | *RIGO will provide this* |
| **FUNDERS Number:** | *Generated by the Funder. Enter if applicable* |

Confidentiality Statement

The Information contained in this document is the property of the University of Surrey and is provided to you in confidence as an investigator, potential investigator, or consultant for review by you, your staff and applicable regulators. It is understood that this information will not be disclosed to others without written authorisation from the University of Surrey Research Integrity and Governance Office except to the extent necessary to obtain written consent from those persons to whom will take part in the study.

# LIST of CONTENTS (optional)

# KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

|  |  |
| --- | --- |
| Chief Investigator | Full contact details including phone, email and fax numbers |
| Study Co-ordinator | Full contact details including phone, email and fax numbers |
| Sponsor | Full contact details including phone, email and fax numbersThe sponsor can be defined as the individual, company, institution, or organisation assuming overall responsibility for the initiation and management of the study, and is not necessarily the main funder. Sponsorship responsibilities may be shared by joint- or co-sponsors |
| Joint-sponsor(s)/co-sponsor(s)  | Full contact details including phone, email and fax numbers of ALL organisations assuming sponsorship responsibilities as a joint- or co-sponsor/s (If applicable) |
| Funder(s) | Names and contact details of ALL organisations providing funding and/or support in kind for this study |
| Key Protocol Contributors | Full contact details including phone, email and fax numbers (If applicable) |
| Committees | Full contact details including phone, email and fax numbers  |

**STUDY SUMMARY**

*Aim: Useful to include a brief synopsis of the study for quick reference. Complete information and, if required, add additional rows.*

|  |  |
| --- | --- |
| Study Title |  |
| Internal ref. no. (or short title) |  |
| Study Design |  |
| Study Participants |  |
| Planned Size of Sample (if applicable) |  |
| Follow up duration (if applicable) |  |
| Planned Study Period |  |
| Research Question/Aim(s) |  |

**INVESTIGATORS**

|  |  |  |
| --- | --- | --- |
| **NAME** | **Position** | **Signature (optional, Mandatory CTIMPs)** |
|  |  |  |
|  |  |  |

# STUDY FLOW CHART (Optional)

*Aim: To give readers a schematic overview of the study*

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 study pathway accurately and with ease. Flow diagrams are helpful tools to guide users of the protocol through the patient and study pathway. A schedule of events can be included as an appendix to the protocol.

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

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

**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)

*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.*

**3.1** **Objectives**

*Aim: To clearly define the study’s objectives (there may be more than one).*

**3.2 Outcome**

*Aim: To 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

*Aim: To describe the study 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 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.*

**Definition of End of Study**

*The definition of the end of the study should be documented in the protocol.*

*For most clinical trials this will be the date of the last visit of the last participant. It may also be the completion of any follow-up monitoring and data collection, as described in the protocol. For international studies, this is the end of study in all participating countries, not just in the UK.*

*For studies involving human tissue, the analysis of the samples should be undertaken as part of the data collection****before****the end of study is declared.*

*Any retained tissue for possible future evaluation after the end of study has been declared should be with the appropriate licence, and should be undertaken as described in the protocol and within the terms of consent from the donors. Otherwise a new proposal for REC review would need to be submitted .*

*Any change to the end of study definition after approval has been given for the research should be notified as an amendment to the appropriate review bodies.*

# 5 STUDY 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 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**

 *Aim: To define 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**

Examples:

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

**6.1.2 Exclusion criteria**

These are usually dependant on the inclusion criteria. Examples:

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

**6.2 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*.

**6.2.1 Participant 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.*

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

**6.2.2 Consent**

 *Informed consent must be obtained prior to the participant undergoing any activities that are specifically for the purposes of the study.*

*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 study 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. 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 guidance notes available on the HRA website.

<http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>

**6.2.2 Withdrawal of Consent**

*Aim: To outline the process for a participants withdrawal of consent, or lose capacity to demonstrate continuing consent. What will happen to data already obtained. Will any further data be collected?*

# 7 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 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 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 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?*

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

*7.2.1 Approvals. Before the study commences a favourable opinion on the protocol and associated documents will be sought from the UK Health Departments Research Ethics Service, the HRA, and confirmation of capability and capacity from NHS sites where necessary. All correspondence with the REC will be retained.*

*7.2.2 Amendments. Should any amendments to the protocol be required the researcher will contact the University RIGO office (Sponsor) to determine if its substantial or non-substantial, upon clarification of the amendment categorisation, the researcher will submit the amendment as per current HRA practice, the amendment will not be implemented until all approvals have been completed.*

*7.2.3 Annual Progress reports. 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 following HRA current practice*

*7.2.4 The researcher will notify the REC of the end of the study with 90 days of the last data collection point using HRA current practice.*

*7.2.5 End of study report. Within one year after the end of the study, the researcher will submit a final report with the results, including any publications/abstracts, to the REC.*

**7.3 Supervisor/ Peer review**

*Aim: to describe the 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 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 (optional but recommended)**

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

*This section of the protocol should detail which aspects of the research process (design, management, dissemination) have actively involved, or will involve, patients, service users, and/or their carers, or members of the public in particular;*

* *Who and how many people were involved; what relevant lived experience do they have?*
* *How did they help with the design of the research (meetings, activities, how often)?*
* *Will the involvement continue through the study?*
* *How has the involvement made the research relevant, important and acceptable to both those who take part and those who will benefit?*

*See* [Helping to ensure public involvement informs ethical review: checklist for applicants - Health Research Authority (hra.nhs.uk)](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/resources/helping-ensure-public-involvement-informs-ethical-review-checklist-applicants/) *for more details on this section*

* 1. **Protocol compliance, adverse events reporting and breaches**

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

*7.5.1 Minor protocol deviations will be documented on the relevant forms and reported to the Chief Investigator or supervisor and Sponsor.*

*7.5.2 Adverse events will be discussed with the researcher’s supervisor and the sponsor, adverse events will be documented in the trial files. Serious adverse events will be reported to the Sponsor as per the sponsor SOP.*

*7.5.3 Serious Breaches of the protocol, where a participant has been put at risk by a deviation from the approved protocol will be reported to the sponsor as per SOP*

**7.6 Data protection and patient confidentiality**

*Aim: To describe how patient confidentiality will be maintained and how the study is compliant with the requirements of the Data Protection Act 2018 (GDPR)*

*The protocol should state that all investigators and study site staff must comply with the requirements of the Data Protection Act 2018 (GDPR) 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?*

* 1. Indemnity and Insurance

*If conducted on NHS Premises:*

*The sponsor has in place relevant insurance for the design and the management of the study. The NHS indemnity scheme is in place to provide insurance for the conduct of the research on NHS premises. The sponsor has arrangements in place for payment of compensation in the event of harm to the research participants where no legal liability arises.*

*If no research activity (other than participant identification) on NHS Premises:*

*The sponsor has in place relevant insurance for the design, conduct and the management of the study. The sponsor has arrangements in place for payment of compensation in the event of harm to the research participants where no legal liability arises*

**7.8 Access to the final study dataset**

*Aim: to describe 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

Aim: to describe 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 Protocol History

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