**Information on use of Protocol Template – please read before starting**

**When this template is to be used:**

This protocol template has been designed for non-interventional clinical research studies. These studies are those that do not change the care pathway of the participant (with the exception of obtaining consent) and include the following types of projects defined in the IRAS system

* Basic Science study involving procedures with human participants
* Study administering questionnaires/interviews for qualitative or mixed quantitative/qualitative analysis
* Study involving qualitative methods only
* Study limited to working with human tissue samples and/or analysis of data
* Study limited to working with data.

Further details on the categorisation of project types is available in the IRAS system, on the project filter screen, by clicking the   icon beside each project type. This can also be discussed with your research facilitator. Please ensure that you are using the correct template prior to beginning drafting your protocol, if the incorrect template is used this may result in delays to study set up whilst data is transferred to the correct template.

**Notes for completion:**

All advisory text are highlighted in blue. These should all be deleted before finalising the document.

Text in Black should be maintained if the section is required.

Do not delete sections that may not be relevant. Please indicate section as “N/A” which will be reviewed as part of the sponsorship process.

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 the JRES Research Governance Team as early as possible in the planning stage.

**DELETE THIS PAGE WHEN FINALISING THE PROTOCOL**



|  |  |
| --- | --- |
| **FULL/LONG TITLE OF THE STUDY** |  |
| **SHORT STUDY TITLE / ACRONYM**The short title should be:* Sufficiently detailed to make clear to participants what the research is about in simple English
* If acronyms are used the full title should explain them. The proposed acronym should not drive the long title
 |  |
| **PROTOCOL VERSION NUMBER AND DATE**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
 |  |
| **IRAS Number:** |  |
| **JRES Reference Number** |  |
| **Funder Reference Number:** |  |
| **This protocol has regard for the HRA guidance and order of content** |

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

|  |
| --- |
| **For and on behalf of the Study Sponsor:** |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name (please print):...................................................................................................... |  |  |
| Position: ...................................................................................................... |  |  |
| **Chief Investigator:** |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name: (please print):...................................................................................................... |  |  |

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| --- |
| KEY STUDY CONTACTS |
| Chief Investigator | Full contact details including full postal address, phone, email and fax numbers |
| Study Co-ordinator | Full contact details including full postal address, phone, email and fax numbers |
| Sponsor | St Georges University of LondonORSt Georges, University Hospitals NS Foundation Trust Name:Position:Email: researchgovernance@sgul.ac.ukSt Georges Joint Research & Enterprise Service (JRES), Cranmer Terrace SW17 ORE |
| 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** |
| 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) |  |

|  |
| --- |
| **FUNDING AND SUPPORT**  |
| **FUNDER(S)** | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
|  |  |

**ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS**

**Study Steering Groups**

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

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

Patient & Public Involvement Group

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

delays in approvals. Public involvement in study design and study documentation can help with the acceptability of a study to the public which in turn can assist with study set-up and recruitment. Ongoing involvement of the public can help understand blockages to recruitment and the acceptability and relevance of study findings.

For guidance on Patient & Public Involvement follow this link:

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

*Example table:*

|  |
| --- |
| **Trial Steering Group** |
| **Chair** | **Name, Title** |
| **Member** | **Name, Title, Role** |
| **Member** | **Name, Title, Role** |
| **Member** | **Name, Title, Role** |

**PROTOCOL CONTRIBUTORS**

:

 Explicitly outline the roles and responsibilities of the sponsor and any funders in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

 It is also important to state whether the sponsor or funder controls the final decision regarding any of these aspects of the study.

 Describe in what aspects of the protocol design have patients, service users, and/or their carers, or members of the public been involved.

# STUDY Schematic

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

|  |
| --- |
| **ABBREVIATIONS** |
| AE  | Adverse Event  |
| AR  | Adverse Reaction  |
| CI  | Chief Investigator  |
| CRF  | Case Report Form  |
| GCP  | Good Clinical Practice  |
| GP  | General Practitioner  |
| HRA | Health Research Authority  |
| ICF  | Informed Consent Form  |
| ISF  | Investigator Site File  |
| NHS  | National Health Service  |
| NIHR  | National Institute for Health Research  |
| PI  | Principal Investigator  |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SGUL | St Georges, University of London |
| SGHFT | St Georges, University Hospitals NHS Foundation Trust |
| JRES | (St Georges) Joint Research and Enterprise Services |
|  |  |
|  |  |
|  |  |
|  |  |

**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 THEORETICAL FRAMEWORK**

Aim: To describe the theoretical framework for the study.

* A clear explanation of the proposed approach and why it is suitable to address the gaps outlined in the BACKGROUND section.
* Briefly outline a system of concepts, from published literature, that frames your study.
* Can be presented either visually or textually.

# 4 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.

**4.1** **Objectives**

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

**4.2 Outcome**

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

# 5 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.

# 6 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.

**7 SAMPLE AND RECRUITMENT**

**7.1 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.

**7.1.1 Inclusion criteria**

The following are examples:

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

**7.1.2 Exclusion criteria**

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

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

**7.2 Sampling**

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

**7.2.1 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).

**7.2.2 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.

**7.3 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.

**7.3.1 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.

**7.3.2 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.

JRES templates should be utilized when drafting the Patient information and consent forms

**Consent provisions for collection and use of participant data and biological specimens**

The protocol should state:

• if data and/or biological specimens will be acquired, transferred and stored during the trial

• if the data and/or biological specimens will be used for a specified subset of studies or for submission to ethically approved research tissue banks for future specified or unspecified research

• what options participants will be given in respect to their participation in ancillary research including:

* whether participation in the ancillary research is required for participation in trial or if participants may opt out but still participate in the main trial
* consent for the use of their data and specimens in specified protocols
* consent for use in future research unrelated to the clinical condition under trial
* consent for submission to an unrelated bio-bank
* consent to be contacted by trial investigators for further informational and consent-related purposes

• whether their withdrawal from the research is possible and what will happen to material provided up to that point:

* for example if the data and/or specimens will be coded and identifiable
* what withdrawal means in this context
* what information derived from the specimen related research will be provided to them, if any

7.3.3 **Data collection tool**

The protocol should state the method of data collection for the purpose of the project.

Case Report Forms will be designed by the CI.

* On paper CRFs all data should be entered legibly in black ink. If the Investigator makes an error, it will be crossed through with a single line in such a way to ensure that the original entry can still be read. The correct entry will then be clearly inserted. The amendment will be initialled and dated by the person making the correction immediately. Overwriting or use of correction fluid will not be permitted.
* On eCRF’s the CI will provide logins to relevant and trained site level members of the research team.

It is the Investigator’s responsibility to ensure the accuracy of all data entered and recorded in the CRFs. The Staff Delegation of Responsibilities Log should identify all trial personnel responsible for data collection, entry, handling and managing the database.

## You should also consider the following information in this section:

## Describe procedures for data collection and recording. Please specify if data is to be recorded directly onto the CRF and/or firstly into source documents (i.e. medical notes). If data will be recorded in the CRF and medical notes, you must specify what data will be recorded in either of the documents and why. Please identify source documentation, and define if this is to be transcribed into the CRF.

7.3.4 **Biological** **Sample Handling**

The protocol should state:

* Samples that will be taken from each participant (e.g. blood, urine, tissue),
* The volume of sample, and the frequency of sampling.
* Details as to how the sample will be processed and stored once taken,
* Who will have access (i.e. Study team only for this project, or will it be stored long-term for use in future ethically approved studies/biobank),
* Duration and location of storage
* Overview of the laboratory analyses and processes that will be performed.

# 8 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.

## **8.1 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?

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

Before the start of the study, a favourable opinion will be sought from an appropriate REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

**For HRA- 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.
* It is the Chief Investigator’s responsibility to produce the annual reports and submit the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
* The Chief Investigator will notify the REC of the end of the study within one year after the end of the study.
* If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

**Regulatory Review & Compliance**

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.

Amendments

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/).

**8.3 Peer review**

Aim: to describe 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.

**8.4 Patient & Public Involvement**

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

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

* The acceptability of the research
* Design of the research
* Management of the research
* Undertaking the research
* Analysis of results
* Dissemination of findings

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

**8.5 Protocol compliance**

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

All protocol deviations 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.

###

**8.6 Data protection and patient confidentiality**

All data should be handled in accordance with the Data Protection Act 2018 (UK implementation of the EU General Data Protection Regulation (GDPR)).

Any Case Report Forms (CRFs) will not bear the participant’s name or other directly identifiable data. The participant’s trial Identification Number (ID) only, will be used for identification. The Subject ID log can be used to cross reference participant’s identifiable information.

## You should also complete the following information in this section:

1. **Describe the nature of the processing:** how will you collect, use, store (and delete if relevant) data during the study? How will you ensure this is kept securely and limited to those who require access? What is the source of the data? Will you be sharing data with anyone? You might find it useful to refer to a flow diagram or another way of describing data flows. What types of processing identified as likely high risk are involved?
2. **Describe the scope of the processing:** what is the nature of the data, and does it include special category (health, race, ethnic origin, genetics, sexual orientation and or sex life) data? Are you including children and/or other vulnerable groups? How much data will you be collecting and using (data collection should be kept to minimal required for the purpose of processing/ aim of the project)? How long will you keep it data for (5 years post study termination/ end),
3. **Describe any movement of data:** Is data being sent only to the controller (sponsor) or any 3rd party and or collaborator for processing? How is data being transferred between processor (site) and controller (sponsor) or 3rd party? Is data leaving the UK? Is data leaving the EU? If so what security measures are being taking to mitigate any breach n data protection and confidentiality? Are data subjects (patients/participants/volunteers) aware of these arrangements via the information sheet?

8.7 Indemnity

**St George’s University of London sponsored research:**

St George’s University of London holds insurance to cover participants for injury caused by their participation in the clinical trial. Participants may be able to claim compensation if they can prove that St George’s has been negligent. This includes negligence in the writing of the protocol, or selection of trial resources.

Where the Trial is conducted in a hospital, the hospital has a duty of care to participants. St George’s University of London will not accept liability for any breach in the hospital’s duty of care, or any negligence on the part of hospital employees. .

If a participant indicates that they wish to make a claim for compensation, this needs to be brought to the attention of St George’s University of London immediately.

Failure to alert St George’s University of London without delay and to comply with requests for information by the sponsor or any designated Agents may lead to a lack of insurance cover for the incident.

**St George’s University Hospitals NHS Foundation Trust sponsored research:**

St Georges University Hospitals NHS Foundation Trust is party to NHS Litigation Authority (NHSLA) / NHS Resolution. As an NHS body it is liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate.

**8.8 Access to the final study dataset**

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

:

* 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.

### 9 DISSEMINIATION POLICY

### 9.1 Dissemination policy

Publication: “Any activity that discloses, outside of the circle of trial investigators, any final or interim data or results of the Trial, or any details of the Trial methodology that have not been made public by the Sponsor including, for example, presentations at symposia, national or regional professional meetings, publications in journals, theses or dissertations.”

All scientific contributors to the Trial have a responsibility to ensure that results of scientific interest arising from Trial are appropriately published and disseminated. The Sponsor has a firm commitment to publish the results of the Trial in a transparent and unbiased manner without consideration for commercial objectives.

To maximise the impact and scientific validity of the Trial, data shall be consolidated over the duration of the trial, reviewed internally among all investigators and not be submitted for publication prematurely. Lead in any publications arising from the Trial shall lie with the Sponsor in the first instance.

**Before the official completion of the Trial,**

All publications during this period are subject to permission by the Sponsor. If an investigator wishes to publish a sub-set of data without permission by the Sponsor during this period, the **Steering Committee/the Funder** shall have the final say.

Exempt from this requirement are student theses that can be submitted for confidential evaluation but are subject to embargo for a period not shorter than the anticipated remaining duration of the trial.

**Up to 180 days after the official completion of the Trial**

During this period the Chief Investigator shall liaise with all investigators and strive to consolidate data and results and submit a manuscript for peer-review with a view to publication in a reputable academic journal or similar outlet as the Main Publication.

* The Chief Investigator shall be senior and corresponding author of the Main Publication.
* Insofar as compatible with the policies of the publication outlet and good academic practice, the other Investigators shall be listed in alphabetic order.
* Providers of analytical or technical services shall be acknowledged, but will only be listed as co-authors if their services were provided in a non-routine manner as part of a scientific collaboration.
* Members of the Steering Group shall only be acknowledged as co-authors if they contributed in other capacities as well.
* If there are disagreements about the substance, content, style, conclusions, or author list of the Main Publication, the Chief Investigator shall ask the Steering Group to arbitrate.

**Beyond 180 days after the official completion of the Trial**

After the Main Publication or after 180 days from Trial end date any Investigator or group of investigators may prepare further publications. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor’s reasonable comments shall be reflected. All publications related to the Trial shall credit the Chief and Co-Investigators as co-authors where this would be in accordance with normal academic practice and shall acknowledge the Sponsor and the Funders.

**9.2 Archiving Arrangements**

Each site will be responsible for their onsite level study archiving. The trial essential TMF along with any central trial database will be archived in accordance with the sponsor SOP.

### 10 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.

### 11. APPENDICIES

**11.1** **Appendix 2**

|  |
| --- |
| **Schedule of Procedures** |
| **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 |  |

**13.3** **Appendix 3**

|  |
| --- |
| **Amendment Log** |
| **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/ HRA/site.