**JRMO Research Protocol for**

**Interventional Studies**

*<This template CANNOT be used for MHRA-regulated studies or research studies>*

**Full Title** *<full title of study>*

**Short Title** *<short title of study>*

**Sponsor** *<delete as applicable>*

* Barts Health NHS Trust

*OR*

* Queen Mary University of London

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**IRAS Number** *<IRAS number>*

**Edge Number** *<Edge number>*

**REC Reference** *<REC Reference number>*

**Chief Investigator (CI)** *<CI title and name >*

*<CI job title>*

*<CI postal address>*

*<CI telephone number>*

*<CI email address>*

**List of sites** *<name of site>*

*<Principal Investigator (PI) name at site>*

*<postal address of site>*

*<telephone number of site>*

*<email address of main contact at site>*

*<REPEAT FOR EACH SITE>*

**List of laboratories** *<name of laboratory>*

*<name of head of laboratory>*

*<postal address of laboratory>*

*<telephone number of laboratory>*

*<email address of main contact at laboratory>*

*<REPEAT FOR EACH LABORATORY>*

**List of technical departments** *<name of technical department>*

*<name of head of technical department>*

*<postal address of technical department>*

*<telephone number of technical department>*

*<email address of main contact at technical department>*

*<REPEAT FOR EACH TECHNICAL DEPARTMENT>*

**List of central facilities** *<name of central facility>*

*<name of head of central facility>*

*<postal address of central facility>*

*<telephone number of central facility>*

*<email address of main contact at central facility>*

*<REPEAT FOR EACH CENTRAL FACILITY>*

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# Glossary

*<Please insert any abbreviations and key terms>*

# Signature page

*<DELETE AS APPLICABLE>*

*<Signature Agreement Option 1 (CI takes responsibility for statistics)>*

**Chief Investigator Agreement**

The study as detailed within this research protocol will be conducted in accordance with the principles of Good Clinical Practice, the UK Policy Framework for Health and Social Care Research, and the Declaration of Helsinki and any other applicable regulations. I agree to take responsibility for the statistical analysis and oversight of this study.

**Chief Investigator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*<OR>*

*<Signature Agreement Option 2 (separate statistician). This option should be used if the study involves randomisation (including batch allocation) or a cohort study of n=1000+ participants>*

**Chief Investigator Agreement**

The study as detailed within this research protocol will be conducted in accordance with the principles of Good Clinical Practice, the UK Policy Framework for Health and Social Care Research, and the Declaration of Helsinki and any other applicable regulations. I delegate responsibility for the statistical analysis and oversight to a qualified statistician (see declaration below).

**Chief Investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Statistician’s Agreement**

The study as detailed within this research protocol will be conducted in accordance with the current UK Policy Framework for Health and Social Care Research, the World Medical Association Declaration of Helsinki (1996), principles of ICH E6-GCP, ICH E9 - Statistical principles for Clinical Trials and ICH E10 - Choice of Control Groups.

I take responsibility for ensuring the statistical work in this protocol is accurate, and I take responsibility for statistical analysis and oversight in this study.

**Statistician’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# Summary and synopsis

|  |  |
| --- | --- |
| **Short title** | *<short title of study>* |
| **Methodology** | *<type of study*> |
| **Research sites** | *<list each site where research will take place e.g. NHS Trusts, educational institutions, etc.>* |
| **Objectives / aims** | *<brief statement of key objectives>* |
| **Number of participants** | *<number of participants expected to be recruited in the whole study>* |
| **Inclusion and exclusion criteria** | *<summarise inclusion and exclusion criteria>* |
| **Statistical methodology and analysis (if applicable)** | *<delete if not applicable>*  *<briefly describe the statistical methodology to be used in the study>* |
| **Study duration** | *<estimated duration for the main study protocol (i.e. time from receipt of all approvals to the time the last participant has completed all study procedures)>* |

# Introduction

*<The introduction should describe how the proposed study relates to available evidence.>*

## Background

*<Discussion of research topic including historical background, literature review and study population. Include a thorough literature review of relevant studies and analysis. The proposed research should build on formal review of prior evidence. Include a brief description of the proposed study and a description of the population to be studied.>*

## Preclinical data

*<Include any relevant preclinical data with reference to up to date literature.>*

## Clinical data

*<Include all previous clinical data relating to the indication of investigation as documented within the literature.>*

## Rationale

*<Explain why the research questions/aims being addressed are important. Give a clear explanation of questions/aims and justification of the study. Show how, if applicable, consultation with public/patient groups has been undertaken (further information to be given about PPI in section 12). How the proposed study might be beneficial to participants or wider service delivery.>*

## Risks / benefits

*<A summary of known and potential risks and benefits to human participants along with justification of the treatment period, which is supported by the literature related to the disease or condition and treatment for this indication. This should be a summary of the detailed explanation and mitigation plans outlined in section 10.>*

# Study objectives

## Primary objective

*<State the main question(s) that the study aims to definitively answer, or the hypothesis it aims to test.>*

## Secondary objective

*<State the secondary question(s) that the study also aims to answer.>*

## Primary endpoint

*<State what will be measured to answer the primary objective(s).>*

## Secondary endpoint

*<State what will be measured to answer the secondary objective(s).>*

# Study population

*<Include a description which outlines the type of participants to be studied. Describe how the participants will be selected for the study, e.g. from outpatient clinics, referring physicians or use of advertisements. State how the participants will be contacted and whether any vulnerable groups will be included. Include durations of participation.>*

*<This section should set out precise definitions of which participants are eligible for the study, defining both inclusion and exclusion criteria.>*

## Inclusion criteria

*<A set of criteria which determines the participant is eligible to participate in the study. The following are examples:*

* + *Able and willing to give informed consent (additional measures have to be in place if children, vulnerable adults or adults unable to give consent are included)*
  + *Gender*
  + *Age range*
  + *Description of study population or cohort (clinical diagnosis)*
  + *Ethnicity*
  + *Socio economic grouping>*

## Exclusion criteria

*<A set of criteria which determines that the participant is ineligible to participate in the study. These are usually dependent on the inclusion criteria. The following are examples:*

* + *Unwilling or unable to give consent*
  + *Gender*
  + *Inability to understand written and / or verbal English*
  + *Medical history*
  + *Participation in other studies*
  + *Vulnerable individuals (this should correspond with statements relating to vulnerable individuals in section 7.3).*

*<If multiple cohorts or population groups are being used a Study Scheme Diagram may be helpful.>*

## Vulnerable participant considerations

*< State clearly if the study will involve the participation of vulnerable participants or not (use HRA definitions) If yes, insert the following statement:>*

The PI is responsible for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

*< If vulnerable participants will be excluded, please ensure this is reflected in the exclusion criteria (section 7.2).>*

# Study design

*<Describe the study design. Clearly describe the data collection methods and outline the roles involved in data collection. Clearly describe the data analysis methods.>*

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

*<Data collection methods should be described in detail. The following are examples:*

* + *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?>*

# Study procedures

*< This section should include a full description of the study procedures, which may include the following topics. The following list of topics is a guide only and should be deleted if not applicable:*

* + *Informed consent*
  + *Screening and recruitment*
  + *Randomization procedures (blinding, unblinding etc.) including code breaks*
* *Study interventions*
  + *Schedule of study interventions (per participant, per visit): example table template below.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Study intervention*** | ***Visit 1*** | ***Visit 2*** | ***Visit 3*** |  |
| *Medical history* |  |  |  |  |
| *Questionnaire* |  |  |  |  |
| *Interview* |  |  |  |  |
|  |  |  |  |  |

* *Study drugs / intervention / device / technique (if applicable)*
* *Concomitant medications*
* *Criteria for discontinuation*
  + *Procedure for collecting data, including Case Report Forms (CRFs) and storage*
  + *Follow-up procedures*
  + *Laboratory assessments (see more in the laboratories section [14])*
  + *Radiology assessments*
  + *Participant withdrawal (including data collection, retention or replacement for withdrawn participants)*
  + *End of study definition (be specific about how this is measured; e.g. the end of collecting new data).*

# Assessment and management of risk

*<Define any possible harm that the study may cause to participants and researchers, and state how the risk of these harms will be mitigated. Potential issues to consider include:*

* *Side effects or complications of investigational procedures*
* *Risks associated with the collection and processing of biological samples*
* *Risks associated with the use of radiation*
* *Mental and emotional harm (e.g. caused by questionnaires or interviews about sensitive issues)*
* *Financial loss for participants>*
* *Increased risk of needle stick injuries*
* *Visiting homes of participants in deprived areas>*

*<Describe risk mitigation strategies for each potential harm. Possible strategies could include:*

* *Establishing trial committees*
* *Counselling participants on possible side-effects and how to treat them*
* *Establishing an urgent medical advice line*
* *Introducing procedures to manage known side-effects*
* *Using protective clothing and equipment*
* *Using clinical trial monitors>*

# Statistical considerations

*<The Research Design Service (RDS) advises that an independent statistician’s involvement is not a requirement for qualitative studies. However it is strongly recommended that you seek the advice of a statistician (and get the statistician’s agreement on the Signature Agreement section 3) if your study:*

* *Involves randomisation (including batch allocation)*
* *Cohort study of n=1000+ participants.>*

*<If you would like statistical advice and you are at the pre-funding application stage with intention to apply to a peer-reviewed funder, please contact the Research Design Service (RDS) London. If you need further assistance regarding statistical help, please contact the JRMO.>*

*<If you are not employing an independent statistician, the CI declares responsibility for the statistics and statistical oversight of the study (see CI’s Signature Agreement section 3).>*

## Sample size

*<Insert details including rationale and justification.>*

## Method of analysis

*<Describe the statistical methods which will be used in the analysis of data, including any interim analyses and the level of significance that is to be used.>*

*<Include any descriptive analyses as well as any statistical tests to be used.>*

*<For lab studies, detail the analysis methodology for the samples.>*

*<Include information for any statistical forms or graphical forms to be used.>*

*<Include a description of primary and secondary endpoint analysis (if applicable).>*

# Ethics

*<This section should state how, or from which, REC approval will be sought (if applicable).>*

*<Summarise the main ethical, legal, or management issues arising from the study and say how they will be addressed. The following are examples:*

* *Informed consent*
* *Recruitment*
* *Inclusion / exclusion criteria*
* *Study design*
* *Risks, burdens, and benefits*
* *Confidentiality*
* *Conflicts of interest.>*

# Public Involvement

*<Public involvement is fundamental to ensure high quality clinical research that brings real benefits, e.g. for patients and the NHS. Describe the public involvement that has already taken place and how they have informed the development of the study. Describe plans for future public involvement activity, during and after the study.*

*<The Research Engagement and Diffusion team can provide information and guidance on how to involve patients and the public in studies via* [*Patientsinresearch.bartshealth@nhs.net*](mailto:Patientsinresearch.bartshealth@nhs.net) *or at* [*www.jrmo.org.uk/performing-research/involving-patients-in-research/*](http://www.jrmo.org.uk/performing-research/involving-patients-in-research/)*>*

# Data handling and record keeping

## Data management

*<This section should describe the arrangements for storing paper and electronic study records. This should include:*

* *A description of the methods of data capture to be used*
* *The design of data capture forms*
* *Transfer and storage of the data in a central study database.>*

*All data generated by the study must be stored securely with a full audit trail.>*

## Source data

*<Source data are the original forms of data used in the study. Some source data will be generated directly by the study (e.g. questionnaire responses) while others may need to be collected from other ‘source documents’ (e.g. a participant’s medical history in their case notes). This section should define the source data for your study and how source documents will be used and maintained.>*

## Confidentiality

*<Information related to participants should be kept confidential and managed in accordance with the Data Protection Act, the General Data Protection Regulation (GDPR), NHS Caldecott Principles, the UK Policy Framework for Health and Social Care Research, and the conditions of Research Ethics Committee favourable opinion. This section should explain the arrangements to ensure the confidentiality of study participants. Areas to consider include:*

* *The identification of potential participants*
* *The anonymisation of research data*
* *Access to participant healthcare records and source documents.>*

## Record Retention and Archiving

*<The UK Policy Framework for Health and Social Care Research requires that research records are kept for 25 years after the study has completed. For studies involving Barts Health NHS Trust patients, undertaken by Barts Health NHS Trust staff, or sponsored by Barts Health NHS Trust or Queen Mary, University of London, the approved repository for long-term storage of local records is the Trust Corporate Records Centre. This section should explain the arrangements for archiving study documentation after the study has ended, and the final destruction of the records.>*

# Laboratories *<delete this section if not applicable>*

*<This section will not be applicable to some studies. If it is not applicable to your study then please delete this section from your protocol.>*

*<For the sub-headings below, it is acceptable to provide a high level summary in this section if a separate laboratory manual will be submitted with the protocol.>*

## Central and local laboratories

*<This section should state the names of any central laboratories that will be used in the study and the research activities that will take place at each laboratory. Where each site’s local laboratory will conduct some research activities for that site, the site will be named and it is not necessary to additionally name each local laboratory individually.>*

## Sample collection and preparation

*<Describe how samples will be collected and prepared. Include:*

* *Requirements for collection and labelling samples*
* *Pseudo-anonymisation of samples*
* *Documenting chain of custody arrangements and receipt of samples*
* *Sample storage conditions.*

## Laboratory procedures

*<This section should detail each type of laboratory procedure that will take place during the study and the time points when they will take place.>*

## Sample storage and transfer

*<This section should describe the arrangements for transferring processed samples from sites to the coordinating centre, and the arrangements for storing samples centrally and at sites.>*

# Interventions and tools *<delete any sections that are not applicable>*

## Devices

*<Describe each device to be used in the study. Include:*

* *Name*
* *Manufacturer*
* *Indication*
* *CE mark status*
* *Source of device*
* *Full instructions on how the device will be used.>*

*<If intending to use a device which does not have a CE mark, or to use a CE-marked device outside of its standard indication, MHRA approval may be required. Please contact the JRMO for further information.>*

## Techniques and interventions

*<Describe all techniques and interventions being used, giving detailed explanations for how to conduct each technique. Please state whether each technique is patented. Techniques could include, e.g. surgical interventions, physiotherapy, or counselling.>*

## Tools

*<Describe all tools which are not medical devices that will be used, e.g. validated questionnaires, interview schedules, or pain scales.>*

## Medicinal product

*<Describe all medicinal products to be used, including:*

* *Name*
* *Indication*
* *Licensing status*
* *Dosing schedule*
* *Route of administration*
* *Source of Medicinal Product*
* *Storage and dispensing*
* *Contraindications*
* *Side-effects>*

*<If the study involves medicinal products it may be classed as a Clinical Trial of an Investigational Medicinal Product (CTIMP) or an Advanced Therapy Medicinal Product (ATMP) and require approval from the MHRA. Please contact the JRMO for more information.>*

## Other biological or chemical products

*<Describe all biological or chemical products which are not considered medicinal products (e.g. food supplements, cosmetic products, and human whole blood). Include:*

* *Name*
* *Dosing schedule*
* *Route of administration*
* *Source*
* *Storage*
* *Contraindications*
* *Side-effects>*

*<If the study involves a biological or chemical product it may require approval from the MHRA. Please contact the JRMO for more information.>*

# Safety reporting

*<Safety information must be collected for all interventional studies, but do not collect more information than needed.>*

*<Generally speaking:*

* *Adverse Events (AEs) and Adverse Reactions (ARs) should be recorded*
* *Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) should be reported to the CI as medical assessor for the sponsor and coordinating team.*
* *All unexpected SARs (SUSARs) must be reported to the JRMO and REC.>*

*<For device studies some of the terminology surrounding safety reporting differs, e.g. device defects, recalls and alerts. Please seek additional guidance from the JRMO.>*

*<For a multi-site study, consider how sites will report SAEs and SARs to the CI.>*

*<For further guidance on this, refer to the Health Research Authority website and JRMO SOPs.>*

## Adverse Events (AEs)

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

An AE is any untoward medical occurrence in a participant to whom an intervention has been administered, including occurrences which are not necessarily caused by or related to that intervention. An AE can therefore be any unfavourable or unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with study activities.

## Adverse Reaction (ARs)

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

An AR is any untoward and unintended response in a participant to an intervention. All adverse events judged by either the reporting investigator or the sponsor as having a reasonable causal relationship to the intervention qualify as adverse reactions. The expression ‘reasonable causal relationship’ means in general that there is evidence or an argument to suggest a causal relationship.

## Notification and reporting of Adverse Events and Reactions

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

If the AE is not defined as serious, the AE will be recorded in the study documents and the participant followed up by the research team. The AE will be documented in the participants’ source documents, the Case Report Form (CRF), and, where appropriate, medical records.

## Serious Adverse Events (SAEs) or reactions

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

A serious adverse event (SAE) is defined as an untoward occurrence that:

* Results in death,
* Is life-threatening,
* Requires hospitalisation or prolongation of existing hospitalisation,
* Results in persistent or significant disability or incapacity,
* Consists of a congenital anomaly or birth defect, or
* Is otherwise considered medically significant by the investigator.

SARs will be reported to the REC where in the opinion of the CI the event was serious and:

* Related (it may have resulted from administration of any of the research interventions), and
* Unexpected (the type of event is not listed in the protocol or other Reference Safety Information as an expected occurrence).

## Notification and reporting of Serious Adverse Events

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

Serious Adverse Events (SAEs) that are considered to be ‘related’ and ‘unexpected’ will be reported to the sponsor within 24 hours of learning of the event, and to the REC within 15 days in line with the required timeframe.

*<For multi-centre studies, describe the process for host sites to report SAEs to the CI and sponsor.>*

*<For blinded studies only; (delete black text* ***only*** *if study is not blinded) :>*

The treatment code for the participant will be broken when reporting an ‘unexpected and related’ SAE. The unblinding of individual participants by the PI / CI in the course of a clinical study will only be performed if necessary for the safety of the study participant.

*<Detail how unblinding of individual participants will be achieved whilst maintaining the study team blind.>*

*<If certain serious adverse event(s) are commonly experienced by the study population unrelated to the study activities, they can be listed here with a statement that they will be recorded but not reported. However if participants experience these serious adverse event(s) in a more severe manner than expected, these should be reported in the usual manner.>*

## Urgent Safety Measures

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

The CI will take urgent safety measures if necessary to ensure the safety and protection of the clinical study participant from immediate hazards to their health and safety. The measures will be taken immediately. The approval of the REC prior to implementing urgent safety measures is not required. However the CI will inform the sponsor and REC of this event immediately.

The CI will inform the REC in writing within 3 days, in the form of a substantial amendment. The sponsor (Joint Research Management Office (JRMO)) will be sent a copy of the correspondence with regards to this matter.

## Overview of the Safety Reporting responsibilities

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

The CI is the medical assessor on behalf on the sponsor and will review all events reported. The CI will ensure that safety monitoring and reporting is conducted in accordance with the sponsor’s requirements.

*<Outline the processes and organisation within the study team to ensure that all SAE reporting is conducted in accordance with the sponsor’s timelines.>*

# Monitoring and auditing

*<The text in black below is standard wording which should appear in every protocol. Do not delete the text in black.>*

The sponsor or delegate retains the right to audit any study, study site, or central facility. Any part of the study may be audited by the funders, where applicable.

*<Describe what monitoring will be performed on this study. The JRMO may not able to offer monitoring or review monitoring reports but is happy to discuss the need for monitoring and the type of monitoring appropriate for the study.>*

*<The aim of monitoring is to ensure data integrity as well as compliance to the protocol and GCP. When deciding on the level of monitoring consideration should be given to how the CI can be assured that the data that is being collected is accurate, of good quality, and would stand up to robust scrutiny. Resource should not be the determining factor in the level of monitoring conducted.>*

*<Example of wording:*

“On site monitoring will be performed as per the study monitoring plan. Monitoring will include source data verification.”>

# Trial committees

*<Outline how the CI will ensure appropriate oversight of the study data and participant safety, and any committees or groups involved in study coordination and conduct. As a minimum all studies should have a study management group consisting of the CI, PIs, collaborators, grant holders, statisticians, and study coordination team.>*

*<State if there will be any data monitoring / steering / safety committees set up for this study and explain their role. Describe the extent of the role of this committee and their involvement within the study. JRMO SOP47 should be read to ensure the CI fully understands the types of committees and when they are needed.>*

*<For most studies using this template, the deciding factor may be the scale of the study (number of participants, number of sites, etc.). A trial management/steering committee is advised for all multi-centre studies. This usually consists of the CI, PIs, statistician and other key collaborators. Please seek advice from JRMO for further details.>*

# Finance and funding

*<This section is important for transparency. Provide the names and contact details of ALL organisations providing funding and / or ‘support in kind’ for this study (including internal funding and donations) and free equipment should also be listed here.>*

# Indemnity

*<Delete only one of the statements in black below as appropriate, depending on sponsor institution.>*

*<Queen Mary sponsored>*

The insurance that Queen Mary University of London has in place provides cover for the design and management of the study as well as "No Fault Compensation" for participants, which provides an indemnity to participants for negligent and non-negligent harm.

*OR*

*<Barts Health sponsored>*

NHS indemnity scheme will apply. It provides cover for the design, management, and conduct of the study.

*<The following areas should be addressed:*

* *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?*
* *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?*
* *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.*
* *Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?*
* *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).>*

*<Usually the responsibility for the first and second points lie with the sponsor, responsibility for the third point lies with the participating site, and the fourth point with the sponsor. The fourth point 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.>*

*<If additional insurance or indemnity has been obtained to cover the study then this should also be stated here. This applies specifically to Queen Mary University of London sponsored studies with international or non-NHS sites. Please seek advice from the JRMO in these cases.>*

# Dissemination of research findings

*<This section should outline the plans to disseminate the results of the research. Even when there is no intention to publish the results, this section should explain how the results of the study will be used. Areas to discuss could include:*

* *Publication in a peer reviewed journal*
* *Acknowledging the sponsor in the findings*
* *Publication of the results on a publically accessible database*
* *Presentation at academic conferences*
* *Use in student work such as dissertations or theses*
* *Communicating results to former study participants and the public*
* *Involving research participants in the dissemination process*
* *Internal dissemination at Barts Health NHS Trust and Queen Mary University of London*
* *Use of the results to change practice or to develop new research or innovation.>*

# References

*<Please use a recognised referencing system. 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.>*

*<NOTE: Before finalising the protocol, please update the table of contents (right-click any heading and select “Update field”, then change to the option of “Update entire table”).>*

**This protocol is based on JRMO Protocol template for Interventional Studies;**

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