Protocol

Your protocol is a full description of your research study and will act as a ‘manual’ for members of the research team to ensure adherence to the methods outlined.

IRAS Form

The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care research in the UK and the IRAS application form captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NHS / HSC Research Ethics Committees
- National Offender Management Service (NOMS)
- Social Care Research Ethics Committee

Participant Information Sheet (PIS)

The Participant Information Sheet should describe clearly what a potential participant should expect if they agreed to take part in your study. You may need more than one PIS depending on your cohort of participants, for example, versions that are suitable for children and young people. Examples and templates are available via the HRA at http://www.hra-decisiontools.org.uk/consent/

Informed Consent Form (ICF)

A consent form should normally be used to record the consent process and a participant's agreement to take part in your study. When producing your consent form you should consider what is appropriate for your type of study and the participants who will be involved.

If you are producing consent forms to be used by legal representatives, ensure that the language used addresses them appropriately. Make it clear you are asking them for consent on behalf of, or advice with respect to a child/young person or adult lacking capacity. Examples and templates are available via the HRA at http://www.hra-decisiontools.org.uk/consent/
Research Data Management (RDM) Plan

Management of data is an essential part of good research practice. Most research funders and many academic publishers now have mandates requiring research data to be properly managed and, where possible, shared. Just as importantly though, properly managed research data is easier for you to work with.

Research Data Management refers to the storage, curation, preservation and provision of continuing access to digital research data. To help you plan, organise, access, and preserve & share your electronic research data, contact the RDM Support Team at rdm@lancaster.ac.uk. For more information about RDM, visit http://www.lancaster.ac.uk/library/rdm/.

Confirmation of funding letter

This confirms for the sponsor that the research is adequately funded for the duration of the study and may be required if the study is applying for adoption to the NIHR Clinical Research Network Portfolio.

HRA Statement of Activities (SoA) and Schedule of Events (SoE)

The Statement of Activities and Schedule of Events should be used to provide information on participating NHS organisations in England and Wales. A template Statement of Activities for each site type should be completed and accompanied by a completed Schedule of Events as part of your submission. The two documents allow the sponsor to make clear what activities will be undertaken locally and the cost type for each activity i.e. research cost, service support cost or treatment cost. Templates are available at https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/.

Model agreement

If an agreement other than the Statement of Activities or template model Non-Commercial Agreement (mNCA) will be used for your study, any changes to the model agreement must be made clear in your application to the HRA or an explanation of why an alternative agreement template will be used. For agreement templates, visit https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx

Evidence of peer review

The sponsor of the research is responsible for the assessment of the scientific quality of the proposed research. The research proposal must be subjected to review by experts in the relevant fields able to offer independent advice on its quality and arrangements for review should be commensurate with the scale of the research and the potential risks or burdens involved for participants.

Ordinarily, studies funded by a major grant-giving body will have been appropriately reviewed at the grant application stage.
Chief Investigator’s Curriculum Vitae (short)

A CVs is expected to be submitted by the Chief Investigators, local Principal Investigators (if known at the time of application) and academic supervisors (for submission with student applications). A CV template is available at https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/

Evidence of relevant training e.g. GCP certificate

The Chief Investigator should provide evidence of any relevant training such as Good Clinical Practice (GCP).

Draft delegation log

The principle of delegation of duties is that the duty can be delegated but not the responsibility. This delegation may be from Sponsor to Chief Investigator, Chief Investigator to Principal Investigator or Principal Investigator to members of the site study team.

The delegation log should include the Principal Investigator, sub-investigator(s), trial/study coordinator(s) and all other clinical staff who routinely see trial subjects or who have specific data collection/interpretation duties. This log should also include any contracted specialists performing protocol-required examinations. Add new or replacement staff as appropriate.

A template delegation log can be found at https://www.nihr.ac.uk/our-faculty/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/gcp-resources/gcp.htm