

APPENDIX 3 – GOVERNANCE CRITERIA – STUDY-WIDE REVIEW PROCEDURE

Aims

The aims of the guidelines for the criteria are to:

- Set the standard for undertaking the NHS research governance review
- Ensure consistency of review across the NHS
- Allow for judgement to be used to manage specific situations
- Identify the information and communication required to support the review

Description

Each criterion has a category (indicated by a letter) and a specific number. Some criteria have a study-wide and a local element – details are given within the guidance for each criterion.

The study matrix in Appendix 2 shows which criteria are relevant to the different study types.

Each criterion has general introductory guidance, including wider contextual information. The guidance sets out the remit of other parties, including research ethics committees and sponsors, which should not be duplicated by the NHS research governance review.

The issues for consideration are described for the study-wide and local aspects, as relevant. Relevant resources providing background guidance are included, where appropriate. Reviewers are expected to be familiar with all the resources. The Research Governance Framework is not included in the resources as this is relevant to all aspects of the governance review.

The outcome of the review of each criterion should be described. The criteria for each study may be recorded as 'satisfied', 'not satisfied' or 'not applicable'. Additional information to support the assessment should be recorded.

UK-wide studies

Arrangements are in place to ensure a smooth permissions process for studies taking place across the UK. There is ongoing work to align the governance reviews across the UK.

It should be noted that studies using NIHR CSP do not require peer review, assessment of the protocol, or review of the arrangements for dissemination of results as part of CSP. The criteria for eligibility for adoption to the NIHR Portfolio are based on quality criteria that replace the requirement to assess the protocol, peer review, or dissemination of results. Elsewhere in the UK, these criteria may be assessed separately. The criteria for determining if a study is eligible for consideration for Clinical Research Network support are given at http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility/. NIHR-funded studies in Biomedical Research Centres (BRCs), Biomedical Research Units (BRUs) or Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) are able to use NIHR CSP, although they are not included on the NIHR CRN Portfolio as they do not require clinical infrastructure service support.

Process for conducting the study-wide review

- 1. Use the study matrix:**
Determine the relevant study-wide criteria for the study type.
- 2. Conduct a rapid initial assessment:**
Identify any issues that are likely to have a major impact on the ability of NHS organisations to issue permission for the study. Discuss the issues with the sponsor/ CI.
- 3. Review issues that only need to be looked at once for the study:**
Confirm details of study-wide arrangements such as regulatory approvals.
- 4. Identify issues that need to be resolved once for the study:**
Identify risks (to patients, staff, or study delivery) and potential problems, to resolve them once. Identify mitigation strategies that can be assessed locally. Where information is unclear or inadequate, request the information once for the study and make it available to local reviewers. Where there are hazards or problems with the study arrangements, obtain clarification once for the study or highlight the implications to the applicant and/or local reviewers.
- 5. Highlight information to support the local review:**
Provide additional clarity on the study, and guide the local review by providing information for reviewers to work from or clarifying whether any local criteria are not relevant. Describe for the local reviewers if there are arrangements that need to be managed locally.

A1. IRAS project filter completed correctly

Considering the study as a whole, have the project filter questions been completed correctly in IRAS?

Areas that may require *particular* attention are studies that involve:

- Ionising radiation, and specifically research exposures
- Human tissue samples
- Participants who are children
- Participants who are adults lacking capacity
- Students undertaking research as part of an educational qualification

B1. Participant information & consent documents and process

- Consider the proposed consent process to ensure that any legal implications presented by the study are highlighted.
- Highlight any specific requirements within the participant information sheet and consent process that may have local implications.
- Consider the accuracy of the information describing which organisation is responsible for providing care to the participant.
- Consider the accuracy of the information relating to insurance/ indemnity and compensation.
- Consider the accuracy of any information relating to study medication and a participant's treatment after their participation in the study.

D1. Risk to NHS Organisation assessed

- Review any potential risks to any of the NHS Organisations, and if there are any areas of concern these should be highlighted.

D2. Allocation of responsibilities and rights is agreed and documented

- Review the agreement template (or other relevant documents) to confirm the appropriate elements for agreement are present.

D3. Insurance/indemnity arrangements assessed

- Review the following aspects of the insurance / indemnity arrangements:
 - The level of insurance/indemnity and if it is appropriate to the study type and purpose
 - Any specific exclusions to the cover provided
 - If the study is being conducted by independent contractors (e.g. GP practices, NHS dental practices).

- For studies where equipment is to be loaned or gifted to a research site confirm that the supplier(s) of the equipment have registered with the Master Indemnity Agreement scheme(s) in the UK countries in which the study is to be conducted.

D4. Financial management arrangements assessed

- Consider whether the financial management arrangements have been appropriately described
- Assess the appropriateness of the cost identification and the attribution of costs for the study and the study procedures
- Assess whether the arrangements to cover the following are appropriate and in line with any guidance applicable to the attribution of cost:
 - Research costs
 - NHS service support costs
 - (Excess) treatment costs
 - HEI costs where members of the research team are employed by a HEI
- Consider the appropriateness of arrangements to reimburse other parties.

F1. Data Protection Act and data security issues assessed

- Ensure the arrangements for confidentiality and data security comply with the law, and with NHS-specific standards and codes. Obtain clarification from the sponsor/ Chief Investigator if there is uncertainty about the compliance of any aspects of the study.
- Identify whether the research only involves processing of data that have already been anonymised or pseudonymised.
- Identify who will have access to personal identifiable information in the course of identifying potential participants, undertaking research procedures or analysing research data.
- Where personal identifiable information will be anonymised or pseudonymised during the course of the research, assess whether the arrangements are clearly described.
- Identify any aspects of the arrangements for processing or storing data that local sites will need to consider.
- Assess the security of any arrangements for storing or transferring data on computers or through other electronic means.
- Assess whether the arrangements for transfer of data to other organisations are clearly described. Identify whether a Data Transfer Agreement is provided.
- Identify if data will be transferred outside the UK.
- Assess whether the information for participants accurately describes the handling of personal identifiable information and associated access permissions.

F2. Arrangements for compliance with the Clinical Trials Regulations assessed

- Assess whether the protocol and/or template contract/ agreement set out the arrangements clearly so that sites will understand what is expected of them. Obtain clarification if there is no clear description of the arrangements for the sites.
- Assess whether the expectations of the sponsor in delegating activities is appropriate and feasible for NHS sites. Highlight any aspects that NHS sites should consider whether they are capable of delivering.
- Assess whether the sponsor has provided clear information relating to consent. Where relevant, consider whether adequate and appropriate guidance is provided on the specific arrangements relating to adults lacking capacity, including ongoing consent and arrangements for withdrawal.
- Where there are different types of patient information sheets and consent forms, assess whether there is clear guidance from the sponsor for the circumstances in which the different documents are required.
- Consider whether there is clear information on expectations of the site in relation to the following:
 - monitoring
 - pharmacovigilance
 - consent
 - handling of IMP
 - security, storage and archiving of trial material, eg documents and samples.

F6. Compliance with any other applicable laws and regulations

- Assess whether the project may require review for compliance with requirements other than those set out specifically in this guidance. Examples include:
 - Storage, use or transfer of tissue in relation to a specific research project
 - Use of medical devices
 - Requirement for support under section 251 of the NHS Act 2006¹
 - Use of advanced therapy medicinal products
 - Use of gene therapy
 - Use of stem cells
 - Research involving offenders
- Ensure the arrangements for the study comply with any other relevant aspects of the law, and any other NHS-specific standards and codes. Obtain clarification from the sponsor if there is uncertainty about the legal compliance of any aspects of the study.
- Identify any specific legal requirements that local sites will need to consider.

For any study involving tissue/samples:

- Identify whether the study involves transferring tissue/ samples for use in the specific project or to a biobank
- Identify whether the study involves using tissue/samples held in a biobank

¹ See also 'Data Protection Act and data security issues assessed'

- Identify whether at the end of the study, tissue/samples will be:
 - transferred to an existing biobank, for which a licence is in place, if required
 - stored by the research team pending Research Ethics Committee favourable opinion for use in another project
 - stored by the research team in a tissue/biobank for which a new licence will be/ has been obtained, where required
- Where a tissue bank is involved, identify whether it is licensed. Assess the implications if voluntary ethical review of the biobank has not been obtained.

For investigations of medical devices:

- For investigations of medical devices regulated by MHRA, ensure that ethical review was by a REC within the National Research Ethics Service only.
- For all studies involving medical devices, identify whether the study is likely to require review by medical engineering or other experts at each site to ensure compliance with local policies.

For studies requiring support under section 251 of the NHS Act 2006

- Ensure that the requirements relating to security and processing of data are clearly described.

G1. Research Ethics Committee favourable opinion received

- Confirm that the study has a favourable opinion from a relevant Research Ethics Committee.
- Identify from correspondence any clarifications made by the applicant at the Research Ethics Committee meeting or subsequently.
- Confirm from correspondence that any conditions of the favourable opinion have been met.
- Confirm that any substantial amendments requiring ethical review have a favourable opinion.
- Confirm the version numbers of any documents received in the R&D application:
 - where ethical review is still underway, the versions are the same as those listed in the acknowledgement letter or subsequent correspondence from the Research Ethics Committee
 - where a favourable opinion has been issued, the versions are the same as those given a favourable opinion by the Research Ethics Committee in the initial favourable opinion or subsequent substantial amendments
 - where subsequent substantial or non-substantial amendments have not required notification to the Research Ethics Committee, the versions are consistent with the above.

G2. CTIMPs - Clinical Trial Authorisation (CTA) letter received

- Confirm that the study has a Clinical Trial Authorisation.
- Identify from correspondence any clarifications made by the applicant to the request for the Clinical Trial Authorisation. It may not be necessary or appropriate to view all correspondence between the sponsor and MHRA, as some may be commercially confidential, or not relevant to the NHS review.
- Confirm that any substantial amendments requiring review by the MHRA have been authorised.
- Confirm that there is evidence that any conditions of the Clinical Trial Authorisation have been met.

G3. Devices - MHRA notice no objection received

- Confirm that the study has a Notice of No Objection.
- Identify from correspondence any clarifications made in the request to MHRA. It may not be necessary or appropriate to view all correspondence between the sponsor and MHRA, as some may be commercially confidential, or not relevant to the NHS review.
- Confirm that any amendments requiring review by the MHRA have been authorised.
- Confirm that there is evidence that any conditions of the Notice of No Objection have been met.

G5. Other regulatory approvals and authorisations received

- Confirm that any regulatory approvals and authorisations are in place and any conditions imposed are met.