

## APPENDIX 3 – GOVERNANCE CRITERIA – LOCAL 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/](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 undertaking the local review**

- 1. Use the study matrix:**  
Determine the relevant local criteria for the study type.
- 2. Look at the study-wide review:**  
Review any issues and resolution or mitigation described in the study-wide review. Where the study-wide and local reviews are being undertaken in parallel, the study-wide criteria should be reviewed regularly during the local review.
- 3. Complete the NIHR Research Support Services (RSS) planning assessment:**  
Identify any 'showstopper' criteria that will prevent permission being issued by the site. Identify any rate-limiting criteria that will affect the organisation's ability to issue permission swiftly. Review the rate-limiting criteria first and put in place arrangements to minimise any delaying factors.
- 4. Rely on local quality assurance:**  
Following RSS principles, take account of local systems and processes within the organisation or the research team that can be relied on as assurances that the criteria have been addressed. Local quality assurance (QA) systems such as SOPs/ policies, monitoring systems and audits within the host organisation allow the organisation to minimise the need for up-front detailed review by relying on effective systems for identifying and addressing issues as they arise.
- 5. Take a proportionate and pragmatic approach:**  
Different studies and situations require different approaches. Consider any hazards, consequences, mitigation and opportunity cost.

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**B1. Participant information & consent documents and process**

- Participants should normally receive information that is local to the site where they are participating in the study. Ensure local information given to potential participants provides:
  - Information about the site e.g. name of site, address and telephone number (usually included in the letterhead of the site)
  - Contact details of the local investigator(s), and if applicable, other members of the research team, e.g. research nurses
  - Emergency contact information, if appropriate
  - Contact information for complaints and, where appropriate, independent advisors.
- Assess whether the arrangements for seeking consent at the site (including the staff involved) can be conducted in accordance with the REC approved arrangements.
- Where it is planned to include participants who may not adequately understand verbal explanations or information written in English, assess the practical arrangements to be made at a site for the provision of information to participants in a format that meets their needs.

**Primary Care:** For primary care studies with independent contractors such as GP practices and NHS dental practices, it is the responsibility of the independent contractor to ensure that the local information is provided and is in place before the research is started.

**B2. Emergency/Backup/Support arrangements assessed**

- Assess whether the potential risks have been clearly described and where there are areas of concern, whether suitable risk management plans and safeguards can be implemented to minimise potential risks (e.g. the effects of additional treatments or changes in treatment; the effects of additional invasive procedures or exposures).
- Assess whether any emergency procedures that may be necessary have been clearly described and can be conducted at the site in accordance with the REC approved arrangements (e.g. to protect the participant in the event of a life-threatening incident or adverse event).
- Assess whether any other backup/support arrangements that may be necessary have been clearly described and can be conducted at the site in accordance with the REC approved arrangements (e.g. to support a participant or research staff when discussing upsetting/embarrassing topics or news; sensitivity to a participant's confidentiality/data security; notification of other health or social care staff with an interest in the participant's care).
- Consider whether appropriate mechanisms for identifying and reporting safety concerns / incidents can be implemented locally (including out of hours, if relevant).
- Consider any arrangements that might need to be put in place to ensure that other healthcare professionals are aware of the participant's involvement in the study, and are able to report any safety concerns/ incidents.

**Primary Care:** For primary care studies conducted by an independent contractor it is the responsibility of the independent contractor to ensure that appropriate emergency/

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backup/support arrangements are implemented and are in place before the study is initiated. However, the independent contractor should be following any policies implemented by the NHS Organisation to which they provide services under NHS contract.

For primary care studies with NHS staff it is the responsibility of the NHS Organisation to ensure that appropriate emergency/backup/support arrangements are implemented and are in place before the study is initiated.

### **C1. Principal Investigator (PI)/research team suitability assessed**

- Are there any concerns about whether the Principal Investigator is appropriately qualified and trained to undertake their task(s) in the study and assume responsibility for the conduct of the study at the site?
- Are there any concerns about whether the other members of the research team are appropriately qualified and trained to undertake their task(s) in the study at the site?
- Are there any concerns about whether the management of the study within the NHS Organisation can be appropriately conducted by the PI and the research team?
- Consider whether any possible conflict of interest from personal involvement with the sponsor or funder has been declared by the PI or research team member, and ensure their employer is aware of this.
- Ensure any necessary local clinical or management supervision is arranged.

### **D1. Risk to NHS Organisation assessed**

- Review any potential hazards to the NHS Organisation, consider the consequences, and where there are areas of concern ensure suitable risk management plans and safeguards are introduced to minimise and control the probability and/or impact of potential risks.

**Primary Care:** For primary care studies, the considerations of risk and implementation of suitable risk management plans and safeguards is the responsibility of the independent contractor. However the independent contractor should be following any policies implemented by the NHS Organisation to which they provide services under NHS contract.

### **D2. Allocation of responsibilities and rights is agreed and documented**

- Assess whether the allocation of responsibilities between the parties is appropriate to the study without creating unnecessary burden.
- Assess whether the delivery of the allocated responsibilities can be sustained for the duration of the study.
- Ensure that appropriate agreements are in place before the study is initiated.

**Primary Care:** For primary care studies with independent contractors such as GP practices and NHS dental practices, the agreement will normally be between the sponsor and the independent contractor. It will therefore be the independent contractor's responsibility to ensure that fully signed and appropriate agreements are in place before the study is initiated.

For primary care studies with employees of the NHS Organisation, it is the responsibility of the NHS Organisation to ensure that fully signed and appropriate agreements are in place before the study is initiated because of their responsibilities as an employer.

In some instances, the allocation of responsibilities and rights may be described in another document such as a GP agreement or GP information sheet.

#### **D4. Financial management arrangements assessed**

- Assess whether all the study costs have been appropriately identified and attributed.
- Consider whether the NHS Organisation would be willing to support the study within the financial arrangements described.

**Primary Care:** For primary care studies with independent contractors, the negotiations regarding financial management and costs will normally be between the sponsor and the independent contractor, particularly for commercial studies. It would be the independent contractor's responsibility to ensure that financial management arrangements and costs are appropriate, and have been documented before signing an agreement with the sponsor. For non-commercial studies, review of financial arrangements may be undertaken on behalf of GPs by the NHS research governance review.

For primary care studies with NHS staff and/or which use NHS facilities e.g. laboratories or x-ray, the NHS Organisation should ensure that financial management arrangements and costs are appropriate, and have been documented before signing an agreement with the sponsor.

#### **D5. Implications for internal departments assessed**

- Assess the additional workload required to support the study for the duration of the required support.
- Assess the impact of the additional workload on the division's/department's ability to deliver their services to non-research activities required by the organisation.
- Consider the implementation of any additional processes or procedures to support the research activity.
- Consider any additional resources, equipment or facilities required to support the activity.
- Consider any long term retention/archiving requirements e.g. imaging, study records, pharmacy worksheets, etc.

**Primary Care:** For primary care studies with independent contractors it is the responsibility of the independent contractor to ensure the relevant internal management authorisations are in place before the study is initiated (e.g. senior practice partner; Caldicott guardian of the practice).

#### **D6. Adequacy of facilities assessed**

- Assess the adequacy of facilities for any novel procedures or for procedures not part of existing clinical activity.
  - Assess the ability of the local facility to meet any quality requirements of the sponsor.
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- Assess the availability of resources required and any additional resources needed.
- Assess the availability of equipment needed and any additional equipment and storage requirements.
- Assess the availability and use of facilities and any additional facilities required.
- Consider the impact of undertaking a study on current resources, equipment and facilities.

#### **E1. Risks to researcher assessed**

- Where the NHS Organisation is the employer of the researcher:
  - Take account of the following risks to the researcher's career and reputation: service pressures on time available for research, inadequate patient recruitment, non-completion of research, and damage to reputation arising from misconduct.
  - Obtain the relevant clinical or management internal authorisation to confirm that the research activities will be managed within that department/unit/practice, and that the employer is aware of the risks to the employee.
- Where the NHS Organisation is the employer of the researcher:
  - Use the pre-engagement checks assessment and the Research Passport or NHS-to-NHS arrangements to ensure that the employer is aware of the employee's activities.<sup>1</sup>
- Where students or junior staff are involved in conducting research:
  - Ensure that adequate clinical /management supervision arrangements are in place.
- Ensure that occupational health and health and safety requirements are addressed through the above arrangements.
- Assess any risks to the researcher arising from the location of the research procedures and identify any specific arrangements required (e.g. where lone worker arrangements need to be put in place).
- Assess any risks to the researcher arising from the participant population and identify any specific arrangements required, and whether the researchers have the relevant experience to be able to assess and to deal with possible risks (e.g. prison research).

#### **F1. Data Protection Act and data security issues assessed**

- Where relevant, assess whether the individuals who will have access to personal identifiable information, for which the NHS Organisation is responsible, are in accordance with the organisation's policies.
- Ensure arrangements are in place for secure access to, and processing of, personal identifiable information in accordance with the organisation's policies.

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<sup>1</sup> See Principal Investigator (PI)/research team Human Resources arrangements in place

- Ensure that the arrangements for anonymisation or pseudonymisation of personal identifiable information set out in the protocol can be undertaken locally, if relevant.
- Assess whether the arrangements for transfer of data to other organisations are in accordance with the organisation's policies.
- Ensure that the arrangements are agreed between the relevant parties, eg in a Data Transfer Agreement.
- Assess the compliance of any archiving arrangements with NHS policies.
- Ensure that the arrangements for storage of data at the site during and after the study can be undertaken locally.

**Primary Care:** Where research is being undertaken through independent contractors, it is the independent contractor's responsibility to ensure that arrangements meet local policies and standards. Independent contractors may seek advice to meet their responsibilities.

## **F2. Arrangements for compliance with the Clinical Trials Regulations assessed**

- Determine whether the site has SOPs/ policies and systems in place to undertake the activities expected by the sponsor. If not, ensure that study-specific arrangements are put in place.
- Assess whether there are local arrangements in place for identifying personal or professional legal representatives where the study involves adults unable to consent for themselves.
- Assess whether the research team and other relevant staff suitably resourced and trained to comply with:
  - the research procedures set out in the protocol and other supporting information such as study manuals or procedures
  - the requirements for reporting to the sponsor on progress and pharmacovigilance
  - the monitoring arrangements expected by the sponsor
  - the arrangements approved by the REC for seeking consent – in particular where the study involves adults unable to consent for themselves, participants under the age of 16 or emergency research
  - the arrangements for handling of IMP
  - the arrangements for security, storage and archiving of trial material, eg documents and samples
- Where the sponsor is providing the IMP, ensure that it will provide evidence of Qualified Person (QP) certification for each batch of IMP once available (which will be after permission is issued). Such assurance may be a copy of the QP certification document or a letter or email confirmation from the sponsor (the communication may apply to more than one batch).<sup>2</sup>

**Primary Care:** Where research is being undertaken through independent contractors, the arrangements may be agreed directly between the independent contractor and the sponsor.

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<sup>2</sup><http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM11>

Independent contractors may seek advice to meet their responsibilities.

### **F3. Arrangements for compliance with the Mental Capacity Act assessed**

- Determine whether the site has SOPs/ policies and systems in place to undertake the activities approved by the REC. If not, ensure that study-specific arrangements are put in place.
- Assess whether there are local arrangements in place for identifying personal or nominated legal consultees separate from the research team.
- Assess whether the research team is suitably resourced and trained to comply with the requirements for:
  - Initial assessment of capacity
  - Ongoing assessment of capacity
  - Arrangements for adults who may become incapacitated during the course of the research
  - Research involving emergency treatment

**Primary Care:** Where research is being undertaken through independent contractors, it is the independent contractor's responsibility to ensure that arrangements meet local policies and standards. Independent contractors may seek advice to meet their responsibilities.

### **F4. Principal Investigator (PI)/research team Human Resources arrangements in place**

- Consider whether the site has HR systems in place to ensure appropriate management and supervision of researchers. If not, ensure that study-specific arrangements are put in place.
- Ensure the arrangements are documented in appropriate contracts or agreements.

*For employees of the NHS Organisation (including those with honorary clinical contracts) or employees of independent contractors providing services to the NHS:*

- Ensure that internal authorisation from the relevant department/directorate/ practice is obtained in accordance with the organisation's standard procedures.

*For other individuals not employed by the organisation (including students):*

- Review the pre-engagement checks required for each individual, taking account of the activities to be undertaken.
- Where required, review the pre-engagement checks assured by the employer or place of study, using the Research Passport.
- Put in place arrangements for issuing Honorary Research Contracts, Letters of Access or other agreements/contracts or verify that an appropriate organisational level agreement is in place (e.g. students on an educational placement)
- Put in place arrangements for day-to-day management and supervision, as appropriate.

*For GPs, dentists, opticians and pharmacists who are independent contractors:*

- It is the responsibility of the individual and the practice to ensure that the research activities are appropriately managed and supervised.

**F5. Radiation - Arrangements for compliance with IRMER assessed**

- Ensure that appropriate internal authorisation is obtained to confirm that the employer's responsibility relating to research exposures is met.

**Primary Care:** Where research is being undertaken through independent contractors, it is the independent contractor's responsibility to ensure that arrangements meet local policies and standards. Independent contractors may seek advice to meet their responsibilities. Use of ionising radiation in primary care is rare, but may be relevant to research conducted by dentists.

**F6. Compliance with any other applicable laws and regulations**

- Assess whether the NHS Organisation is able to comply with the requirements of any other relevant legislation.
- For studies involving tissue ensure that arrangements for any transfer and for disposal or long-term use of the tissue are agreed and documented. Ensure that any local Human Tissue Authority (HTA) licences are in place, together with arrangements for compliance with the Human Tissue Act 2004.
- For studies involving devices regulated by MHRA, investigators are required to comply with the standards in BS EN ISO 14155. There is no requirement for GCP under the Medical Devices Directive or Regulations. In order to meet the requirements of the Directive, ISO 14155 should be followed instead of GCP for medical device studies. Ensure that appropriate investigators are appropriately trained.

**Primary Care:** Where research is being undertaken through independent contractors, it is the independent contractor's responsibility to ensure that arrangements meet local policies and standards. Independent contractors may seek advice to meet their responsibilities.

**G4. Radiation - Administration of Radioactive Substances Advisory Committee (ARSAC) approval received**

- Confirm that there is an ARSAC Research Certificate for the study. The relevant local practitioner can provide confirmation, which may be provided by email rather than by providing a copy of the certificate.