The Trust is committed to promoting an environment that values diversity. All staff are responsible for ensuring that all patients and their carers are treated equally and fairly and not discriminated against on the grounds of race, sex, disability, religion, age, sexual orientation or any other unjustifiable reason in the application of this policy, and recognising the need to work in partnership with and seek guidance from other agencies and services to ensure that special needs are met.
Change History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Reason</th>
<th>Ratification Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 1</td>
<td>Sept 2011</td>
<td>Fiona Smith</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
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S02: Confirm Study Definition

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to confirm the categorisation of a study. It is should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office has confirmed the categorisation of the study and determined the appropriate regulatory framework, governance and other processes which need to be followed by the sponsoring organisation and participating organisations.

1.3. The categorisation of the study can include (this list is not exhaustive):

a. Clinical Trials of Investigational Medicinal Products (CTIMPs).
c. Gene Therapy Medicinal Products.
d. Clinical investigations or other studies of medical devices.
e. Other clinical trials or clinical investigations.
f. Research involving data collection through questionnaire / interview or other intervention with participants.
g. Quantitative / qualitative analysis.
h. Study limited to working with human tissue samples and / or data.
i. Study involving qualitative methods only.
j. Research involving data collection through questionnaires or other intervention with participants.
k. Research tissue bank.
l. Research database.
m. Other research.

1.4. The important categorisations are those that identify the need to comply with the processing requirements of a regulatory framework or other such guidance.

1.5. The R&D office reviews submitted study information with the investigator to confirm that the study is research as distinct from service evaluation and audit. Classification of the study to research or service evaluation determines whether research governance and management is required.

1.6. The R&D office reviews the submitted study information with the investigator to correctly identify the study category and to ensure it is conducted according to the appropriate legal regulations and governance frameworks. Misclassification may lead to inadequate or excessive study processes and governance. Where the decision may be unclear the R&D office will ask for an opinion from the appropriate regulatory authority.
2. PROCEDURE

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R&amp;D office</td>
<td>Confirm study is ‘research’.</td>
</tr>
<tr>
<td>2</td>
<td>R&amp;D office</td>
<td>Identify study categorisation. Use MHRA Clinical Trials algorithm if appropriate.</td>
</tr>
<tr>
<td>3</td>
<td>R&amp;D office</td>
<td>Confirm study categorisation with regulatory authority if clarification required.</td>
</tr>
<tr>
<td>6</td>
<td>R&amp;D office</td>
<td>Advise investigator.</td>
</tr>
</tbody>
</table>

3. SUPPORTING MATERIAL

Copy of the MHRA Clinical Trials algorithm for supporting study categorisation is attached.

Supporting material for the MHRA Clinical Trials Algorithm:


ii Substance is any matter irrespective of origin e.g. human, animal, vegetable or chemical that is being administered to a human being.

iii This does not include derivatives of human whole blood, human blood cells and human plasma that involve a manufacturing process.

iv Somatic cell therapy medicinal products use somatic living cells of human (or animal) origin, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventative effect (in humans) through metabolic, pharmacological and immunological means.

v Any ingested product which is not a medicine is regarded as a food. A food is unlikely to be classified as a medicine unless it contains one or more ingredients generally regarded as medicinal and indicative of a medicinal purpose.

vi The Cosmetic Directive 76/768/EC, as amended harmonises the requirements for cosmetics in the European Community. A "cosmetic product "means any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity with the view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours.
vii Efficacy is the concept of demonstrating scientifically whether and to what extent a medicine is capable of diagnosing, preventing or treating a disease and derives from EU pharmaceutical legislation.

viii Assignment of patients to a treatment group by randomisation planned by a clinical trial protocol cannot be considered as current practice.
**MHRA Clinical Trials Algorithm**

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is it a medicinal product (MP)?</strong></td>
<td><strong>Is it not a medicinal product?</strong></td>
<td><strong>What effects of the medicine are you looking for?</strong></td>
<td><strong>Why are you looking for those effects?</strong></td>
<td><strong>How are you looking for those effects?</strong></td>
</tr>
<tr>
<td>If you answer no to all the questions in column A, the activity is not a clinical trial on a MP.</td>
<td>If you answer yes to the question below in column B the activity is not a clinical trial on a MP.</td>
<td>If you answer no to all the questions in column C the activity is not a clinical trial under the scope of Directive 2001/20/EC.</td>
<td>If you answer no to all the questions in column D the activity is not a clinical trial under the scope of Directive 2001/20/EC.</td>
<td>If you answer yes to all these questions the activity is a non-interventional trial which is outside the scope of Directive 2001/20/EC.</td>
</tr>
<tr>
<td>If you answer yes to any of the questions below go to column B.</td>
<td>If you answer yes to any of the questions below go to column C.</td>
<td>If you answer yes to any of the questions below go to column D.</td>
<td>If you answer yes to any of the questions below go to column E.</td>
<td>If your answers in columns A,B,C &amp; D brought you to column E and you answer no to any of these questions the activity is a clinical trial within the scope of the Directive.</td>
</tr>
<tr>
<td><strong>A.1 Is it a substance or combination of substances presented as having properties for treating or preventing disease in human beings?</strong></td>
<td><strong>B.1 Are you only administering any of the following substances?</strong></td>
<td><strong>C.1 To discover or verify/compare its clinical effects?</strong></td>
<td><strong>D.1 To ascertain or verify/compare the efficacy of the medicine?</strong></td>
<td><strong>E.1 Is this a study of one or more medicinal products, which have a marketing authorisation in the Member State concerned?</strong></td>
</tr>
<tr>
<td>i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis or is otherwise administered for a medicinal purpose?</td>
<td>• Human whole blood;</td>
<td>• To discover or verify/compare its safety of the medicine?</td>
<td>• To ascertain or verify/compare the safety of the medicine?</td>
<td><strong>E.2 Are the products prescribed in the usual manner in accordance with the terms of that authorisation?</strong></td>
</tr>
<tr>
<td>A.2 Does the substance function as a medicine?</td>
<td>• Human blood cells;</td>
<td>• To discover or verify/compare its pharmacological effects, e.g. pharmacodynamics?</td>
<td>• To discover or verify/compare its adverse reactions?</td>
<td><strong>E.3 Does the assignment of any patient involved in the study to a particular therapeutic strategy fall within current practice and is not decided in advance by a clinical trial protocol?</strong></td>
</tr>
<tr>
<td>i.e. can it be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis or is otherwise administered for a medicinal purpose?</td>
<td>• Human plasma;</td>
<td>• To identify or verify/compare its adverse reactions?</td>
<td>• To study or verify/compare its absorption, distribution, metabolism or excretion?</td>
<td><strong>E.4 Is the decision to prescribe a particular medicinal product clearly separated from the decision to include the patient in the study?</strong></td>
</tr>
<tr>
<td>A.3 Is it an active substance in a pharmaceutical form?</td>
<td>• Tissues except a somatic cell therapy medicinal product;</td>
<td>• A food product (including dietary supplements) not presented as a medicine;</td>
<td>• A cosmetic product</td>
<td><strong>E.5 Will no diagnostic or monitoring procedures be applied to the patients included in the study, other than those which are applied in the course of current practice?</strong></td>
</tr>
<tr>
<td></td>
<td>• A pharmaceutical product</td>
<td></td>
<td>• A medical device</td>
<td><strong>E.6 Will epidemiological methods be used for the analysis of the data arising from the study?</strong></td>
</tr>
</tbody>
</table>
S03: Ensure Study Protocol is Managed

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to ensure the study protocol is managed by the senior investigator. It should be used by the R&D office in a sponsoring organisation.

1.2. The activities include:
   a. ensuring there is an investigator process for managing the development of the study protocol and amendments throughout the study duration
   b. ensuring an appropriate peer review has been conducted

1.3. Outcome: The R&D office has ensured that there is a robust study protocol management process with peer review in place.

Ensure there is a process to manage the study protocol

1.4. A study protocol should contain:
   a. a clear research question which when answered provides value that justifies any risks associated with the study. It describes how this activity is important to the NHS and to service users
   b. an appropriate research methodology
   c. recruitment criteria, targets and recruitment approach
   d. initial costings

1.5. The R&D office is not expected to review the protocol for quality of the science, but is expected to ensure the senior investigator has prepared clear and complete documentation to support governance requirements of the sponsoring and participating organisations.

1.6. It is expected that the investigator’s protocol management approach includes a process proportionate to the risks associated with the study for:
   a. developing the study protocol
   b. obtaining relevant R&D approvals
   c. managing amendments to the protocol - in particular assessing amendments for whether they require new R&D approvals to be obtained (see guideline ‘S04 Ensure study funding and approvals are managed’)
   d. recording the changes with version control and distributing changes to relevant stakeholders including participating organisations

Ensure peer review is undertaken

1.7. All research proposals require appropriate peer review (also referred to as ‘scientific quality review’, ‘independent scientific review’ or ‘independent review’).

1.8. Peer review is the assessment of a research proposal by ‘reviewers’ who are experts in the relevant field of study or discipline. Reviewers are able to offer
independent advice on the scientific validity of the study. The peer review process ensures the methodology employed in a study will produce robust and credible results. It is expected that the reviewer is independent from the research study and that they should not have had any input into the design, supervision, collaboration, recruitment, conduct and subsequent analysis of the study.

1.9. It is the responsibility of the sponsoring organisation (usually the R&D office) to ensure that an appropriate peer review has been undertaken. In certain instances it may be necessary for the organisation to arrange peer review when it has not already happened as part of a competitive funding process. All NIHR Clinical Research Network Portfolio studies are expected to have been peer reviewed and it is not expected that this will be repeated by a sponsoring organisation.

1.10. The organisation should have an agreed list of acceptable peer review organisations, for example:

   a. Medical Research Council (MRC)
   b. charities e.g. Wellcome Trust, Cancer Research UK
   c. industry partners

1.11. In some circumstances peer review is conducted when research proposals are submitted for funding e.g. MRC funding. It is utilised as a means of using research colleagues’ comments to assess the quality and relevance of the proposal as a basis for deciding to fund.

2. PROCEDURE

Ensure there is a study protocol management process

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R&amp;D office</td>
<td>Check that the senior investigator has a process for managing development, approvals and amendments proportionate to risks associated with the study.</td>
</tr>
<tr>
<td>2</td>
<td>R&amp;D office</td>
<td>If required, support the senior investigator in setting up an appropriate process.</td>
</tr>
<tr>
<td>3</td>
<td>R&amp;D office</td>
<td>Check that the process is implemented.</td>
</tr>
</tbody>
</table>

Ensure peer review has been conducted

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R&amp;D office</td>
<td>Review the evidence of the peer review having been completed and cross reference with the organisations list of ‘accepted peer reviewers’.</td>
</tr>
</tbody>
</table>

1 RDInfo website: [http://www.rdinfo.org.uk/flowchart/Section4b.htm](http://www.rdinfo.org.uk/flowchart/Section4b.htm)

Medical Research Council Reviewers Handbook 2010-2011
### Optional (additional) process for supporting investigators: Example procedure for supporting the investigator on study design

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Senior investigator</td>
<td>R&amp;D office</td>
<td>Contact R&amp;D office with study proposal or protocol.</td>
</tr>
<tr>
<td>2 R&amp;D office</td>
<td></td>
<td>Advise the senior investigator on the available support for developing a study protocol e.g. study protocol template or provision of support e.g. Research Design Service (RDS) or local support.</td>
</tr>
<tr>
<td>3 Senior investigator</td>
<td>R&amp;D office</td>
<td>Develops the study protocol in accordance with advice received.</td>
</tr>
<tr>
<td>4 R&amp;D office</td>
<td></td>
<td>Follow up on and review outcome of the advice provided to the senior investigator.</td>
</tr>
</tbody>
</table>
S04: Ensure Study Funding and Approvals are Managed

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to ensure study funding and approvals are confirmed. It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office has confirmed all necessary approvals are obtained and can be managed throughout the duration of the study.

1.3. These activities monitor whether the following approvals have been completed by the investigator:
   a. Funding award letter
   b. Sponsor's authorisation letter / authorisation in the Integrated Research Application System (IRAS)
   c. Research Ethics Committee (REC) favourable opinion letter
   d. MHRA Clinical Trial Authorisation (CTA) with request for approval (if required).
   e. Other permissions and approvals (if required) including:
      i) National Information Governance Board (NIGB) for Health and Social Care or equivalent body
      ii) Gene Therapy Advisory Committee (GTAC)
      iii) MHRA no objection letter
   f. Cover for appropriate insurance and indemnity

1.4. It is expected that the Chief Investigator (CI) will confirm there is evidence of these approvals. The sponsoring organisation is expected to use its discretion as to whether a wet or electronic signature is acceptable.

1.5. It is expected that the organisation will comply with this SOP so as to satisfy sponsor requirements under the responsibilities stated within the Department of Health Research Governance Framework for Health and Social Care.

1.6. It is expected that the organisation will be aware of and manages all changes in the validity of the approvals when circumstances change or when there are material changes to the study. For example, a substantial amendment is defined as one that is likely to significantly affect any of the following:
   a. Safety or physical or mental integrity of the subjects of the study
   b. Scientific value of the study
   c. Conduct or management of the study
   d. Quality or safety of any investigational medicinal product used in the study

1.7. For management of the study protocol see guideline ‘S03 Ensure Study Protocol is Managed’.

1.8. The R&D office may support the CI in obtaining the relevant approvals e.g. assistance with submission to Research Ethics Committee. However, the R&D office needs to be aware of and take necessary precautions to avoid any potential conflicts of interest that may arise when providing such support with assuring approvals on behalf of the sponsoring organisation.
2. PROCEDURE

Ensure study funding and approvals are obtained and remain valid

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1</td>
<td>R&amp;D office</td>
<td>Confirm funding has been awarded and evidenced through a funding award letter.</td>
</tr>
<tr>
<td>2</td>
<td>R&amp;D office</td>
<td>Confirm peer review is evidenced (See guideline S03).</td>
</tr>
<tr>
<td>3</td>
<td>R&amp;D office</td>
<td>Confirm the MHRA Clinical Trials Authorisation letter / letter of no objections is evidenced (if required).</td>
</tr>
<tr>
<td>4</td>
<td>R&amp;D office</td>
<td>Confirm there is a sponsor authorisation for ethics submission.</td>
</tr>
<tr>
<td>5</td>
<td>R&amp;D office</td>
<td>Confirm there is a favourable opinion letter from the REC.</td>
</tr>
<tr>
<td>6</td>
<td>R&amp;D office</td>
<td>Verify that favourable opinion is valid for the sites in question.</td>
</tr>
<tr>
<td>7</td>
<td>R&amp;D office</td>
<td>Confirm any / all other approvals have been obtained e.g. NIGB, GTAC.</td>
</tr>
<tr>
<td>8</td>
<td>R&amp;D office</td>
<td>Confirm investigator will inform R&amp;D office of changes to study that may affect approvals.</td>
</tr>
<tr>
<td>9</td>
<td>R&amp;D office</td>
<td>Assess any changes with the CI to ensure approvals are still valid and actions are being undertaken by the CI.</td>
</tr>
<tr>
<td>10</td>
<td>R&amp;D office</td>
<td>Ensure other approvals are confirmed as appropriate.</td>
</tr>
</tbody>
</table>
S05: Manage Sponsoring Organisation Study Planning Tool

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to complete an early and quick study assessment using the Sponsoring Organisation Study Planning Tool ('the planning tool'). It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office understands how to manage key operational risks and record proportionate management actions needed to complete the sponsoring decision process for the study. A key output is a list of proportionate management actions to manage the identified risks and issues.

1.3. This planning tool is used to assess the organisation's readiness to manage study operational risks (either itself or with support from the Clinical Research Networks or an alliance organisation) during study R&D approvals or delivery of the study.

1.4. The NIHR expects an experienced Research Manager to use this tool in conjunction with the local investigator and other service managers in the organisation as appropriate and depending on the complexity of the study.

1.5. Use of the planning tool depends on an understanding of risks associated with the study and the capabilities of the organisation e.g. a high risk study in an experienced site may be addressed by routine management processes, whereas a low risk study in an inexperienced site may require additional management actions to mitigate risk, etc.

1.6. Use of the planning tool also depends on circumstances in the organisation at that particular time. For example, the study may depend on the availability or not of key resources or staff when the study is expected to be delivered.

1.7. The planning tool is intended to assess the likelihood of the organisation successfully completing the sponsoring decision process within a reasonable timescale and of completing the study effectively and safely. It is a tool to ensure operational risks are identified early and addressed proportionately.

1.8. It is not intended to be overly intrusive to existing processes but is used to identify early and quickly any additional management inputs which can be addressed sooner rather than later. The key output is a list of management actions to manage any identified risks.

1.9. The findings from the planning tool can be used to feedback issues or concerns to the senior investigator. This helps to ensure that risks or issues are managed by the correct person. It may mean that the senior investigator can be informed early that an organisation is unable to sponsor the study at this time.

1.10. This process requires access to:
   a. timely and relevant information about the study from the senior investigator,
   b. decision support information in the organisation’s R&D Operational Capability Statement or similar documentation,
c. relevant experience and professional judgement of the Research Manager in early consultation with the senior investigator.

1.11. The planning tool considers 12 areas of operational risk for a sponsoring organisation to consider during the sponsoring decision-making process or when delivering the study. These are:

a. Legal and regulatory.
b. Local alignment.
c. Investigator team support.
d. Research team support.
e. Science design.
f. Patient safety design.
g. Patient group design.
h. Feasibility planning and completion.
i. Management and monitoring.
j. Sponsor accountability.
k. Finance.
l. External agreements.

1.12. Each area has a simple test question as part of using the planning tool which determines how the organisation will manage the risk during the sponsoring decision or study delivery, namely:

- Can any risk be addressed using existing operating procedures during R&D approvals or study delivery?
  or
- Can any risk be addressed with small changes to existing operating procedures (i.e. untested, but unlikely to be problematic)?
  Example: the usual contact is unavailable but an experienced substitute is available.
  or
- Can any risk be addressed but with more significant changes to existing procedures (i.e. untested and may require more management involvement)?
  Example: the usual contact is unavailable and no substitute is available.
  or
- Would any risk require significant changes to existing procedures (i.e. to the extent that there may be a high risk of not being successful)?
  Example: the required research support resources will be unavailable throughout the study period.

1.13. The Research Manager should note the management actions (proportionate to the study risks) which can be used to plan, delegate and manage relevant activities for R&D approval processes or study delivery.

1.14. The output of the planning tool is a summary of areas requiring attention. Over time, when taken together, the outputs from the tool for several studies may identify issues requiring attention in the R&D Operational Capability Statement.

1.15. The planning tool can be repeated when material changes are made to study protocol / processes / staffing / agreements etc to reassess any new risks and to plan how to manage them.
2. PROCEDURE

Complete Sponsoring Organisation Study Planning Tool and review summary

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R&amp;D office</td>
<td>On becoming aware of new a study through contact with investigator, create a copy of the Sponsoring Organisation Study Planning Tool for this study.</td>
</tr>
<tr>
<td>2</td>
<td>R&amp;D office &amp; senior investigator</td>
<td>Assess response to areas in planning tool. Select appropriate response.</td>
</tr>
<tr>
<td>3</td>
<td>R&amp;D office &amp; senior investigator</td>
<td>Develop proportionate risk management actions.</td>
</tr>
<tr>
<td>4</td>
<td>R&amp;D office</td>
<td>Discuss findings with investigator as appropriate.</td>
</tr>
<tr>
<td>5</td>
<td>R&amp;D office</td>
<td>Use findings to plan R&amp;D approvals or study delivery activities or actions. Monitor undertaking of the actions. Review as necessary.</td>
</tr>
</tbody>
</table>

3. SUPPORTING MATERIAL

NIHR Research Support Services Participating Organisation Study Planning Tool

S06: Give Decision on Sponsoring

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to give a sponsoring decision to the investigator on behalf of the organisation. It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office has notified the investigator of the sponsoring decision on behalf of the sponsoring organisation.

1.3. Sponsor responsibilities may be shared with other organisations (co-sponsors) and it is expected that in making the sponsoring decision for the organisation all sponsor responsibilities will be clearly documented and attributed.

1.4. The decision is supported using the Sponsoring Organisation Study Planning Tool (see ‘S05 Manage Sponsoring Organisation Study Planning Tool’) which highlights if key operational risks have been, or are expected to have been, addressed.

1.5. Prior to giving a decision on sponsoring it is expected that the R&D office has:

   a. confirmed the categorisation of a study
   b. confirmed there is a robust study protocol management process
   c. confirmed all necessary approvals are being managed
   d. assessed operational risks using the Sponsoring Organisation Study Planning Tool and documented how any identified risks are being mitigated

1.6. Following the decision to sponsor a study, the sponsoring organisation is responsible for continued oversight of its involvement in the conduct of the study including provision for all monitoring arrangements whether they are conducted by the sponsoring or participating organisation.

1.7. Sponsoring organisations are expected to put in place adequate arrangements for ongoing management and oversight of the research which is proportionate to the risks associated with the study.

1.8. The R&D office should confirm that the Chief Investigator is completing those activities for which they are responsible including:

   a. Undertaking participating site feasibility.
   b. Making available the relevant study approvals to participating sites or other organisations leading on governance checks.
   c. Setting up and controlling study processes.
   d. Making these study processes available to participating organisations.
### 2. PROCEDURE

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R&amp;D office</td>
<td>Assess the risks associated with the organisation sponsoring this study (using the planning tool). This will depend on the study and the capabilities of the organisation at the time the decision is being taken.</td>
</tr>
<tr>
<td>2</td>
<td>R&amp;D office</td>
<td>Consider if risks are being managed or are expected to be managed using a proportionate risk management plan.</td>
</tr>
<tr>
<td>3</td>
<td>R&amp;D office</td>
<td>Confirm that pre-requisite activities have been completed or are expected to be completed satisfactorily for: a. study categorisation (see guideline S02 Confirm Study Definition), b. study protocol management (see guideline S03 Ensure Study Protocol is Managed), c. study approvals and funding (see guideline S04 Ensure Study Funding and Approvals are Managed).</td>
</tr>
<tr>
<td>4</td>
<td>R&amp;D office</td>
<td>Confirm and record sponsoring decision.</td>
</tr>
<tr>
<td>5</td>
<td>R&amp;D office</td>
<td>Communicate the decision to the senior investigator.</td>
</tr>
<tr>
<td>6</td>
<td>R&amp;D office</td>
<td>Confirm that the senior investigator is completing those activities for which they are responsible including: a. undertaking participating site feasibility, b. making available the relevant study approvals to participating sites or other organisations leading on governance checks, c. setting up and controlling study processes, d. making these study processes available to participating organisations.</td>
</tr>
</tbody>
</table>
S07: Provide and Manage Agreements

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to provide and manage agreements with external parties such as study participating organisations. It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office is able to manage external agreements throughout the study, including preparation for signature, confirmation of signatures and subsequent amendments.

1.3. External agreements include those between:
   a. the sponsoring and participating organisation(s)
   b. the Sponsor and another co-Sponsor
   c. the Sponsor and Funder
   d. the Sponsor, participating organisation and Contract Research Organisation (CRO)
   e. the Sponsor and other organisations (for example, participant identification centre)

1.4. External agreements can include ‘contracts’ or ‘clinical trial agreements’ or similar documents relating to a single study. They also include framework agreements which make provision for a group or class of studies. There are often circumstances when it is sufficient to agree key aspects of the relationship (such as roles and responsibilities) in a simpler written form (such as an email). The form of the external agreement should be proportionate to the measures needed to manage risks associated with the study and the type / nature of the participating organisation or other organisation involved.

1.5. When applicable, it is expected that wherever possible the Sponsor will use standard agreed templates for the agreements without modification. This enables other parties to process agreements without excessive legal review and minimises delays.

1.6. External agreements are used to document and agree aspects of the relationship including (but not exclusively):
   a. roles and responsibilities
   b. financial and legal considerations including indemnity
   c. standards of service
   d. regulatory obligations including data protection
   e. intellectual property considerations
   f. confidentiality considerations
   g. termination considerations

1.7. A study may involve the use of tripartite external agreements, for example between the sponsor, the participating organisation and a university. The organisation should obtain additional advice for such agreements.
1.8. This SOP does not cover employment / access type agreements with individuals including:
   a. honorary research contracts
   b. letters of access

2. PROCEDURE

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 R&amp;D office</td>
<td></td>
<td>Confirm the external agreement parties and the agreement requirements with the investigator.</td>
</tr>
<tr>
<td>2 R&amp;D office</td>
<td></td>
<td>Issue appropriate draft agreements to each party using the appropriate form. Where possible use standard templates without modification to minimise additional legal review.</td>
</tr>
<tr>
<td>3 R&amp;D office</td>
<td></td>
<td>Conduct discussions with the parties and update agreements if necessary.</td>
</tr>
<tr>
<td>4 R&amp;D office</td>
<td></td>
<td>Ensure any necessary legal review is undertaken.</td>
</tr>
<tr>
<td>5 R&amp;D office</td>
<td></td>
<td>Ensure that agreements are signed by an authorised representative.</td>
</tr>
<tr>
<td>6 R&amp;D office</td>
<td></td>
<td>Ensure agreements are filed / retained in accordance with NHS / Department of Health policy for record retention.</td>
</tr>
</tbody>
</table>

3. SUPPORTING MATERIAL

Example agreement templates include:

- The model Clinical Investigation Agreement (mCIA) for medical technology industry sponsored research carried out in NHS hospitals: 
  The NHS-ABHI mCIA (England) 2008 (DOC)
  [http://www.nihr.ac.uk/files/docs/NHS-ABHI%20mCIA.doc](http://www.nihr.ac.uk/files/docs/NHS-ABHI%20mCIA.doc)

- The tripartite mCIA for use by organisations and the medical technology industry for use in a tripartite format by NHS bodies, sponsors and CROs: 
  CRO mCIA England (DOC)
  [http://www.nihr.ac.uk/files/docs/CRO%20mCIA%20England%202009.doc](http://www.nihr.ac.uk/files/docs/CRO%20mCIA%20England%202009.doc)

- The pharmaceutical industry-funded trials in NHS hospitals agreement: 
  The NHS-ABPI-BIA model Clinical Trial Agreement 2006 (DOC)
• The tripartite model clinical trial agreement (mCTA) for use by organisations and pharmaceutical companies:
  CRO mCTA England (DOC)
  http://www.nihr.ac.uk/files/docs/CRO%20mCTA%20England.doc

• Non-commercial agreement (not endorsed by NIHR):
  http://www.ukcrc.org/regulationgovernance/modelagreements/mnca/
S08: Ensure NHS Permission is Received by the Chief Investigator

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to ensure that copies of the NHS Permission letter for each participating organisation are received by the Chief Investigator (CI). It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office has confirmed that the CI has received a copy of all NHS Permission letters from participating organisations.

1.3. It is essential that the Sponsor has been notified when NHS Permission is given by a participating organisation and that there is a permanent record of the appropriate NHS Permission letter for each site involved in the study. This confirms that:

   a. the participating organisation is able to conduct the study to appropriate standards
   b. the participating organisation has carried out appropriate checks to satisfy its responsibilities as a care organisation under the Research Governance Framework for Health and Social Care
   c. any clinical negligence at that participating organisation which occurs as part of the study will be covered by NHS indemnity schemes or by independent contractors’ professional indemnity insurance

1.4. It is expected that the NHS Permission letter will be received from a participating organisation by the CI before the study can commence at the site.

2. PROCEDURE

Note: R&D office in the below table refers to the sponsoring organisation R&D office

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
</table>
| 1 R&D office   |                | Ensure that the CI understands that:
|                |               | a. The Principal Investigator (PI) for each site is expected to apply for and obtain NHS Permission for that site. Where there is no PI (“no local investigator”) then the CI is expected to apply for NHS Permission at that site.
<p>|                |               | b. Only when the CI has a copy of the appropriate NHS Permission letter can the study begin at the participating organisation. |
| 2 CI           |                | Request a copy of the NHS Permission letter from the PI. On receipt file a copy in the trial master file (TMF). Inform the sponsor (R&amp;D office) of receipt. |</p>
<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>R&amp;D office</td>
<td>Confirm receipt of the NHS Permission letter which enables the study to commence at that participating organisation.</td>
</tr>
<tr>
<td>4</td>
<td>R&amp;D office</td>
<td>Track any changes to the NHS Permission letter noting any relevant actions required.</td>
</tr>
<tr>
<td>5</td>
<td>R&amp;D office</td>
<td>If the NHS Permission letter is not received, ensure the CI is aware that the study cannot commence at the site.</td>
</tr>
</tbody>
</table>
SOP: Research and Development Department Guidelines for Management of Trust Sponsored Studies (Version 1)
Research and Development Department
Date of Ratification: Sept 2011
Date of Review: Sept 2014
Ref: 2011-161

S09: Ensure Study Oversight

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to oversee a study throughout the study period. It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office (or an organisation with delegated responsibility) is able to provide proportionate oversight during the study on behalf of the sponsoring organisation.

1.3. ‘Ensure study oversight’ provides quality control checks or processes which enables all studies, whether they are subject to planned monitoring or not, to have the management and quality controls in place to protect the organisation in its role as Sponsor.

1.4. Study oversight can consist of:
   a. Monitoring
   b. External agreement oversight
   c. Study tracking

1.5. All studies have an element of oversight by the sponsor which will vary based on the type of study (e.g. CTIMPs, non-CTIMPs) and the risk management plan (as an output of the study planning tool; see guideline ‘S05 Manage Sponsoring Organisation Study Planning Tool’).

1.6. It is expected that the type, frequency and intensity of these oversight activities will be documented within an oversight plan (see section 2 below).

1.7. When an organisation is both sponsoring and participating in a study, both this guideline and the guideline ‘P08 Oversee Study’ can be used to enable all aspects of oversight to be completed. In these cases it is expected that a combined oversight plan can be used for governance purposes.

Monitoring

1.8. The Sponsor is responsible for monitoring during a study. This will typically be delegated to the R&D office with some activities being undertaken by the Chief Investigator (CI).

1.9. Monitoring consists of a review of the study through a combination of remote monitoring of sites, on-site visits and follow up activities related in part to the study planning assessment and operational risk management plan (see guideline ‘S05 Manage Sponsoring Organisation Study Planning Tool’).

1.10. Where relevant, monitoring should always be completed in line with good clinical practice and other regulatory requirements. The purpose of study monitoring is to verify that:
   a. the rights and well-being of human subjects are protected,
b. the reported study data is accurate, complete, and verifiable from source documents,
c. the conduct of the study is in compliance with the approved study protocol/amendments, with Good Clinical Practice (GCP), and with the applicable regulatory requirements.

1.11. Monitoring activities can be delegated to external parties but the sponsoring organisation is still accountable.

External agreement oversight

1.12. The R&D office provides oversight support when required for the CI in order to ensure external agreement obligations are met by other parties. When issues arise the R&D office is expected to provide support that is proportionate to the risks associated with the study and to follow up on any actions given to the CI to resolve the issues.

1.13. The potential issues that the CI may raise with the R&D office can be noted prior to study start and documented in the study oversight plan (see section 2).

Study tracking

1.14. It is expected that the R&D office will be aware of all studies being sponsored by the organisation (in set-up, active and long-term follow-up phases).

The R&D office is expected to ensure up to date information is stored regarding active and closed sponsored studies and that an annual report on the progress of studies is received from the CIs.

2. PROCEDURE

Develop study oversight plan

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>For co-sponsorship studies, agree monitoring responsibilities prior to study start.</td>
</tr>
<tr>
<td>2 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Prior to study start, determine the frequency and intensity of oversight activities. It is expected that these will be influenced by the risk management plan.</td>
</tr>
<tr>
<td>3 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>For all new studies develop a study specific oversight plan. This details the frequency and intensity of oversight activities. The oversight plan is expected to be agreed with the study CI. The oversight plan documents oversight</td>
</tr>
</tbody>
</table>
Responsibility | Undertaken by | Activity
---|---|---

activities within the following areas proportionate to risk assessment decisions. (A non-CTIMPs study may have an oversight plan which involves a minimal amount of oversight and can be limited to reviewing external agreement obligations and study tracking):

a. Monitoring:
The agreed monitoring plan is expected to be included in the oversight plan. It is expected that the plan will provide information on the following:
   i) The appointed monitor.
   ii) Frequency of monitoring visits.
   iii) Areas to be covered at the initial visit and subsequent visits.
   iv) Frequency of interim visits.
   v) Proportion of subjects to be reviewed.
   vi) Definition of source data and extent of source data verification.
   vii) The data which will be checked as part of the monitoring visit.
   viii) Handling of the study protocol deviations e.g. creation and assessment of file notes.
   ix) Verification of drug accountability records (if applicable).
   x) How monitoring visits will be documented e.g. reports and who will review these.
   xi) Process for dealing with non-compliance and an associated escalation process.

b. External agreement obligations.
c. Study tracking:
It is expected that the oversight plan details the method which will be used to establish if a study is still in progress, nearing completion or closed as planned. An example of this would be in the form of an email to the CI and PIs to request information on the study in addition to receiving their annual reports. The R&D office is expected to document these responsibilities.
## Monitoring

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Review and complete monitoring activities with the CI on a frequency appropriate with the risks associated with the study. For low risk studies, the R&amp;D office may not need to conduct a review of investigator monitoring activities.</td>
</tr>
<tr>
<td>2 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Provide the CI with guidance and specific actions which are expected to be completed to resolve any issues or risks which have been highlighted through monitoring.</td>
</tr>
<tr>
<td>3 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Follow up with the CI on the actions which are expected to have been completed to ensure the issue or risk highlighted through monitoring has been rectified.</td>
</tr>
<tr>
<td>4 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Complete any analysis on monitoring activities for future improvements.</td>
</tr>
</tbody>
</table>

## External agreement oversight

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Ensure external agreements are signed as appropriate prior to commencement of study at sites or start of contracted services.</td>
</tr>
<tr>
<td>2 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Confirm that the CI and relevant research staff fully understand the study requirements related to managing external agreements.</td>
</tr>
<tr>
<td>3 CI</td>
<td></td>
<td>If an issue or risk arises during the study, escalate the matter and seek support from the R&amp;D office.</td>
</tr>
<tr>
<td>4 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Manage the resolution of the issue or risk with the CI / researcher in a proportionate way based on risk. If the R&amp;D office is unable to provide necessary support then escalate the issue to relevant parties.</td>
</tr>
</tbody>
</table>
Responsibility | Undertaken by | Activity
--- | --- | ---
5 | Sponsor (typically delegated to the sponsoring R&D office) | Follow up with the CI on the actions to ensure the issue or risk has been resolved.

Study tracking

Responsibility | Undertaken by | Activity
--- | --- | ---
1 | Sponsor (typically delegated to the sponsoring R&D office) | Conduct the agreed study tracking activities (from the oversight plan) with the CI in order to track the progress of the study. As a minimum this is expected to include receipt of an annual report from the CI and PIs. The annual report is expected to contain information on changes to end dates or extensions to funding.

2 | Sponsor (typically delegated to the sponsoring R&D office) | Oversight of study progress should also include an appropriate level of review of any changes made to the trial after initial approval e.g. protocol amendments and ensuring confirmation of appropriate approvals.

3. SUPPORTING MATERIAL

Additional summary information of roles and responsibilities

<table>
<thead>
<tr>
<th>Oversight Process</th>
<th>Chief Investigator responsibilities</th>
<th>R&amp;D office responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Monitoring</td>
<td>a. Ensure any monitoring activities which have been delegated to the CI in line with the study monitoring plan are completed, documented and assessed for trends periodically.</td>
<td>a. Ensure a monitoring plan has been developed in line with the risk management plan. b. Ensure any issues which are highlighted during monitoring are resolved through appropriate actions, and periodically check for inter and intra-study trends to inform process improvements.</td>
</tr>
<tr>
<td>Oversight Process</td>
<td>Chief Investigator responsibilities</td>
<td>R&amp;D office responsibilities</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 2. External Agreement Oversight   | a. Ensure all PIs understand their external agreement obligations.  
b. Where appropriate, escalate issues to R&D office when PIs do not meet their obligations.                                                                                                                  | a. Provide advice to CIs when issues arise with PIs not meeting their external agreement obligations.                                                                                                                                       |
|                                   |                                                                                                                                                                                                                                     | b. Follow up with the CI to ensure all actions are completed and issues are resolved.                                                                                                                                               |
| 3. Study Tracking                 | a. Provide the R&D office with an annual report on study progress for all sites.  
b. Provide any other applicable reports determined through the risk management plan.                                                                                                                                    | a. Review reports. Record and store the annual reports provided by the CI.                                                                                                                                                        |
|                                   |                                                                                                                                                                                                                                     | b. Conduct periodic review of the reports to highlight any trends.                                                                                                                                                                |
S10: Ensure Study Closedown is Managed

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to confirm that a study has been closed appropriately. It should be used by the R&D office in a sponsoring organisation.

1.2. These procedures address the Sponsor responsibilities covering:
   a. notification of study closure to relevant parties
   b. final report completion and maintenance,
   c. archiving of essential documents which individually and collectively permit evaluation of the conduct of studies and the quality of the data

1.3. Outcome: The R&D office has confirmed the study is completed and closed appropriately at all sites.

Study closure

1.4. Study closure is expected to occur according to the definition outlined in the study protocol.

1.5. Studies can be terminated prior to the planned closure date or event because of:
   a. unsafe events attributed to the study IMP (Investigational Medicinal Products)
   b. poor toleration of the IMP
   c. slow recruitment
   d. sponsor decision
   e. investigator decision
   f. regulatory decision (e.g. MHRA)

1.6. In regulated trials, the sponsor has a legal responsibility to notify the licensing authority and Research Ethics Committee that the study has terminated early at that site within 15 days of the termination. Regulatory bodies, such as MHRA, will also need to be notified for certain types of study.

1.7. In order to support accurate reporting of research activity in the organisation the R&D office should keep up to date records of study closure tracking dates and study end dates.

Final report

1.8. The sponsor is responsible for managing the publication of final reports (including scientific reports) at the conclusion of the study.

Archiving

1.9. ‘Essential documents’ are expected to be archived. They should be stored in a way that allows accurate reporting, interpretation and verification in (Schedule 1, Part 2 (9) of Medicines for Human Use (Clinical Trials) Regulations SI 2004 No.1031). This is in line with Good Clinical Practice.
1.10. For other clinical trials, and for other study designs, the responsible individual from the sponsoring organisation is to archive documents in line with the NHS / Department of Health policy for record retention (and in line with the applicable regulations).

2. PROCEDURE

Manage study closure

Note: The specific activities in this procedure may vary according to processes specified in the study protocol.

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Chief</td>
<td>Investigator (CI)</td>
<td>Determine whether the study: a. is due to conclude as described in the study protocol, or b. requires an extension to the end date, or c. is to terminate early and why.</td>
</tr>
<tr>
<td>2 CI</td>
<td></td>
<td>Notify the sponsor (typically the R&amp;D office) regarding study conclusion or extension requirements.</td>
</tr>
<tr>
<td>3 R&amp;D office</td>
<td></td>
<td>Maintain the relevant databases with the end date and study status related to closure or extension based on information from the CI.</td>
</tr>
<tr>
<td>4 R&amp;D office</td>
<td></td>
<td>Notify study finance staff that a study has concluded.</td>
</tr>
<tr>
<td>5 R&amp;D office</td>
<td></td>
<td>Inform the Research Ethics Committee (REC) that the study has concluded using the relevant end of study form (see section 3 for an example). Submit the end of study form to the main REC within 90 days of the end of the study or within 15 days if the study terminated early (Schedule 1, Part 2 (27) of Medicines for Human Use (Clinical Trials) Regulations SI 2004 No.1031). Where a study is terminated early or halted temporarily, reasons should be given. <strong>For CTIMPs:</strong> Notify the MHRA within 90 days of the trial ending.</td>
</tr>
<tr>
<td>6 R&amp;D office</td>
<td></td>
<td>Finalise the study files ensuring all necessary documents are included from all sites.</td>
</tr>
</tbody>
</table>

Manage study report

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 R&amp;D office</td>
<td></td>
<td>Identify and confirm a study is due to close. Issue a conclusion date confirmation e-mails to the investigators (see section 3 for an example).</td>
</tr>
</tbody>
</table>
### Manage archiving

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CI</td>
<td></td>
<td>Collate, organise and maintain essential documents in a legible and accessible form.</td>
</tr>
<tr>
<td>2 CI</td>
<td></td>
<td>Contact relevant service departments e.g. pharmacy and request their study files so that all records can be transferred to the sponsoring organisation’s archive.</td>
</tr>
<tr>
<td>4 R&amp;D office</td>
<td></td>
<td>Advise the participating organisation’s PI on the requirements for transferring the documents to the sponsoring organisation’s archive.</td>
</tr>
<tr>
<td>5 R&amp;D office</td>
<td></td>
<td>Advise the CI on requirements for transferring documents to the sponsoring organisation’s archive.</td>
</tr>
<tr>
<td>6 CI</td>
<td></td>
<td>Arrange for a full set of accurate and auditable records to be collated and listed for transfer to the sponsoring organisation’s archive.</td>
</tr>
<tr>
<td>7 CI</td>
<td></td>
<td>Check that all records for that study have been sent to the sponsoring organisation’s archive.</td>
</tr>
<tr>
<td>8 R&amp;D office</td>
<td></td>
<td>As appropriate review the archived records to determine if records are suitable for destruction. Consideration is expected to be given to regulations affecting legal documents and the Data Protection Act since personal data should not be kept for longer than necessary. Once authorisation for destruction of records is given by all parties concerned, destroy the records as confidential waste and log the destruction on a disposal register database.</td>
</tr>
</tbody>
</table>
### 3. SUPPORTING MATERIAL

**Example forms**

**Declaration of end of study form**

For all studies except clinical trials of investigational medicinal products.

To be completed in typescript by the Chief Investigator and submitted to the Research Ethics Committee that gave a favourable opinion of the research (“the main REC”) within 90 days of the conclusion of the study or within 15 days of early termination. For questions with Yes/No options please indicate answer in bold type.

#### 1. Details of Chief Investigator

<table>
<thead>
<tr>
<th>Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Telephone:</td>
<td></td>
</tr>
<tr>
<td>E-mail:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>

#### 2. Details of Study

<table>
<thead>
<tr>
<th>Full title of study:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Research sponsor:</td>
<td></td>
</tr>
<tr>
<td>Name of main REC:</td>
<td></td>
</tr>
<tr>
<td>Main REC reference number:</td>
<td></td>
</tr>
</tbody>
</table>

#### 3. Study duration

<table>
<thead>
<tr>
<th>Date study commenced:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date study ended:</td>
<td></td>
</tr>
<tr>
<td>Did this study terminate prematurely?</td>
<td>Yes / No</td>
</tr>
<tr>
<td></td>
<td><em>If yes please complete sections 4, 5 &amp; 6, if no please go direct to section 7.</em></td>
</tr>
</tbody>
</table>

#### 4. Circumstances of early termination

What is the justification for this early termination?

#### 5. Temporary halt

<table>
<thead>
<tr>
<th>Is this a temporary halt to the study?</th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, what is the justification for temporarily halting the study? When do you expect the study to re-start?</td>
<td>e.g. Safety, difficulties recruiting participants, trial has not commenced, other reasons.</td>
</tr>
</tbody>
</table>
### 6. Potential implications for research participants

Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them.

### 7. Final report on the research

Is a summary of the final report on the research enclosed with this form? **Yes / No**

*If no, please forward within 12 months of the end of the study.*

### 8. Declaration

<table>
<thead>
<tr>
<th>Signature of Chief Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print name:</td>
</tr>
<tr>
<td>Date of submission:</td>
</tr>
</tbody>
</table>
Sample email communication from sponsor (R&D office) to Chief Investigator

<<Insert Organisation>>
<< Insert Address>>

<<Insert Contact details>>

Dear <<Insert CI name>>,

Your research study “<<Insert study name>>”, R&D Unit <<Insert R&D number>>, has reached the end date we have on our database.

Please reply either to confirm that the study has closed or to give us a new extended end date and confirmation from the Funder. Your research administrator will contact you six months after the end date to finalise any outstanding accounts in line with study Closedown procedures.

Please also let me have the number of participants recruited to your study.

If <<insert organisation>> is the main site, end of study notification should be sent to the R&D Unit and the Main REC (and the MHRA if a clinical trial of a medicinal product) within 90 days of conclusion date.

On closure of the study, the study records should be sent to the organisation’s archive in accordance with records management procedures. Contact <<insert contact name>> for further guidance. Please quote the R&D ID number in all correspondence regarding archiving.

Finally I would be pleased to receive references for any peer-reviewed papers you may produce and to help with our organisations’ reporting requirements.

Thank you for your assistance.

Kind regards,

<<Insert name>>

<<Insert role and contact number>
SF1: Ensure Setup of Study Finance

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities used when setting up study finances. It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office has confirmed study funding arrangements with the funder(s) and that appropriate study finance management processes are in place.

1.3. These guidelines are subject to Department of Health and / or NIHR guidance.

Develop study costs

1.4. It is expected that sponsoring organisations will ensure that study costs are identified in accordance with current Department of Health and / or NIHR guidance (see references in section 3).

Confirm funding

1.5. It is expected that sponsoring organisations will ensure that funding arrangements are confirmed with Funder(s) based on identified costs.

Set up study finance processes

1.6. It is expected that sponsoring organisations will set up processes and, where appropriate, systems to capture and manage study costs.

2. PROCEDURE

Develop study costs

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office or CI)</td>
<td></td>
<td>Identify study costs based on Department of Health and NIHR guidance.</td>
</tr>
</tbody>
</table>

Confirm funding

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office or CI)</td>
<td></td>
<td>Confirm funding arrangements with Funder(s).</td>
</tr>
</tbody>
</table>
Setup finance processes

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Set up appropriate study finance management processes and systems.</td>
</tr>
</tbody>
</table>

3. SUPPORTING MATERIAL

Website link for HSG(97)32 Responsibilities for meeting patient care costs associated with research and development in the NHS:

Website link for ARCO (Attributing revenue costs of externally funded non-commercial research in the NHS) guidance:

Website link to guidance on funding treatment costs:
SF2: Ensure Study Finance Oversight

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to oversee study finances. It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office will have exercised proportionate oversight of finances during the study.

1.3. These guidelines are subject to Department of Health and / or NIHR guidance.

Oversee study finances

1.4. It is expected that the sponsoring organisation will ensure that the appropriate study finance processes set up by the organisation are followed throughout the study in accordance with current Department of Health and / or NIHR guidance.

2. PROCEDURE

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td></td>
<td>Oversee and follow finance processes set up for the study.</td>
</tr>
</tbody>
</table>
SF3: Ensure Study Finances are Completed

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to close down the study finances. It should be used by the R&D office in a sponsoring organisation.

1.2. Outcome: The R&D office will have properly closed down the finances for a study in accordance with current Department of Health and / or NIHR guidance.

1.3. These guidelines are subject to Department of Health and / or NIHR guidance.

Closedown study finances

1.4. It is expected that the sponsoring organisation will finalise study finances, complete cost recovery processes and provide relevant information to funding organisation(s) in accordance with current Department of Health and / or NIHR guidance.

2. PROCEDURE

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor (typically delegated to the sponsoring R&amp;D office)</td>
<td>Complete finance processes for the study including those for final cost recovery.</td>
<td></td>
</tr>
</tbody>
</table>