JRO/RM&G/SOP-05

Standard Operating Procedure (SOP) for Obtaining NHS Permission

<table>
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<tr>
<th>SOP ID Number</th>
<th>Version Number</th>
<th>Approved by</th>
<th>Effective Date</th>
<th>Review Date</th>
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<td>2</td>
<td>S.Kerrison</td>
<td>18th May 2012</td>
<td>18th May 2014</td>
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**Author:**
Name and Job Title
Anna Jones – Research Network Coordinator
Rajinder Sidhu – RM&G Network Manager
Hameedah Bogle-Dawoud – Senior Research Administrator

**Approved by Date:**
Version 2 approved by 18th May 2012
Version 1 approved by 13th September 2011

**Target Trusts**
Royal Free London NHS Foundation Trust
University College London Hospitals NHS Foundation Trust

**Target Audience**
JRO staff involved in the approval of studies

**Related SOPs**
JRO SOP for categorisation of studies and sponsorship of “simple studies”
JRO SOP for setting up and controlling external agreements for hosted studies

**Revision Chronology**

<table>
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<td>11th Sept 2011</td>
<td>Version 1 amended to incorporate findings from Royal Free NHS Permissions SOP Audit and review of initial SOP</td>
<td>Rajinder Sidhu and Hameedah Bogle-Dawoud</td>
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### 1. SUMMARY

This Standard Operating Procedure (SOP) outlines the processes undertaken by the Joint Research Office for the approval of host studies to take place on NHS Trust premises. This approval is referred to as NHS Permission.

The SOP is for use by JRO staff involved in the issuing of NHS Permission for studies

### 2. DEFINITIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Chief Investigator</td>
<td>The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the Study involves researchers at more than one site, the person who takes primary responsibility for the design conduct and reporting of the Study whether or not that person is an Investigator at any particular site. Research Governance Framework for Health and Social Care, 2nd Edition 2005</td>
</tr>
<tr>
<td>Clinical Trial of Investigational Medicinal Product (CTIMP)</td>
<td>Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or Study absorption, distribution, metabolism and excretion of one or more investigational product(s) with the object of ascertaining its (their) safety and/or efficacy. NIHR RSS Framework (including Appendix 1 – Glossary of Terms and Acronyms) <a href="http://www.nihr.ac.uk/systems/Pages/RSS_Documents.aspx">http://www.nihr.ac.uk/systems/Pages/RSS_Documents.aspx</a></td>
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<tr>
<td>Governance Report</td>
<td>The Governance Report summarises the outcome of all governance checks and indicates the documents that are provided as evidence. It is generated by the Responsible Individual and is provided to the NHS Permission Signatory as evidence to support the granting of NHS Permission. NIHR RSS Framework – P07 Give NHS Permission <a href="http://www.nihr.ac.uk/systems/Pages/RSS_Documents.aspx">http://www.nihr.ac.uk/systems/Pages/RSS_Documents.aspx</a></td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>The leader responsible for a team of individuals conducting a Study site. Research Governance Framework for Health and Social Care, 2nd Edition 2005</td>
</tr>
<tr>
<td>NIHR Guideline</td>
<td>A Document which describes the standard procedures expected of any Organisation that manages research activity within the framework of NIHR Research Support Services.</td>
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3. PURPOSE and SCOPE

This SOP forms part of the suite of SOPs which will implement the NIHR Research Support Framework. This SOP describes the procedure for granting NHS Permission for studies at the Royal Free London NHS Foundation Trust and University College London Hospitals NHS Foundation Trust. These two Trusts remain separate legal entities, and therefore permission of studies wishing to take place at both sites must be obtained for each site. The process, documentation and supporting guidance for both JRO sites, are, similar (with minor differences to accommodate local Trust specific variations).

Obtaining NHS permission is an essential precondition to conduct any research or clinical trial as required by the Research Governance Framework for Health & Social Care 2005 (2nd Edition) and the Clinical Trial Regulations. This requires the completion of all study preparation activities.

NHS permission for research ensures that:

a) Study processes are agreed, documented and in place to support the delivery of the study.

b) The organisation is aware of the potential impact of the research in terms of risks, resources, financial and legal implication and has made the necessary arrangements to support the activity.
c) Confirms that appropriate checks have been made and that clinical negligence will be covered by NHS indemnity schemes or by independent contractors’ professional indemnity insurance during the course of the research.

The conclusion of this process is for the NHS Permission signatory to issue the NHS Permission letter to the Investigator. This allows research to commence at the Trust.

This SOP is for use by RM&G, Contracts and Finance personnel (JRO Office) involved in the issuing of NHS Permission for all studies taking place at the Royal Free London NHS Foundation Trust or University College London Hospitals NHS Foundation Trust.

4. BACKGROUND

This SOP complies with

- RG framework Research Governance Framework for Health and Social Care 2005 (2nd Edition), whereby it is the responsibility of the NHS Trust to be aware and approve all research undertaken in their organisation, or involving participants, organs, tissue or data before the research may commence. Trusts must be satisfied that the research fulfils all of the requirements of the Research Governance Framework. This includes:
  - Ensuring all research is of a high scientific and ethical standard,
  - Ensuring researchers have the appropriate honorary or substantive contracts with the Trust
  - Ensuring financial probity.
  - NIHR RSS framework
  - NIHR CSP framework
  - Good Clinical Practice (GCP)
  - European Directives for CTIMPs as 2001/20/EC and 2005/20/EC (these Directives were transposed into UK law as statutory instruments SI2004/1031, SI2006/1928) and subsequent amendments incorporating elements of ICH GCP tripartite guidelines (E6).
  - Human Tissue (Quality and Safety for Human Application) 2007
  - Medical Devices Regulations 2002
  - Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER)
  - Human Tissue Act 2004
  - Data Protection Act 1998
  - Mental Capacity Act 2005

5. RESPONSIBLE PERSONNEL AND THEIR DUTIES

<table>
<thead>
<tr>
<th>Responsible Person e.g. RNC</th>
<th>Summary of duties</th>
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</table>
| The Principal Investigator (PI) | • Responsible for submitting local study supporting documentation for participating site NHS permission.  
• Ensure the study can only commence, once local NHS permission has been granted.  
• Filing the NHS Permission letter in the ISF.  
• Responsible for reporting events to the JRO office that issued local NHS Permission. |
<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
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</table>
| Research Administrators (SRA)    | • Confirming that a new proposal is research with reference to the NRES Defining Research Leaflet Table (see Appendix 1).  
• Operating the research approval process as outlined in the JRO approval pathways  
• Maintaining a record of all research undertaken through or within the NHS Trust.  
• Maintaining the online research database (ReDA) including accuracy of data held on the system.  
• Processing new research study submissions, assessing documentation for completeness.  
• To ensure governance checks are completed for all studies  
• Forward interventional research proposals to RNCs for processing.  
• Issue NHS Permission letter to CI/PI and forward a copy to Pharmacy and/or Medical Physics according to the type of study.  
• Filing of the NHS Permission letter within the JRO Study File and uploading to ReDA document repository. |
| Research Network Coordinators    | • Confirming that a new proposal is research with reference to the NRES Defining Research Leaflet Table (see Appendix 1).  
• Operating the research approval process as outlined in the JRO approval pathways  
• Facilitate and co-ordinate new interventional research study submissions, assessing project documentation for completeness, and where necessary liaising with investigators to keep them informed of where projects are in the Sponsor/approvals process.  
• Liaise with Cost Accountants and Contract Managers to ensure research proposals are costed and contractual arrangements are in place prior to signing of the study and or site agreement  
• Processing of research applications through CSP that are considered for NIHR adoption using CSP ReDA.  
• Completion of research governance checks (including those used for CSP for issuing the Governance Report). |
| RM&G Network Manager             | • Official sign-off for research proposals prior to issuing NHS Permission  
• Overseeing, maintaining and updating when necessary the operational aspects of the JRO approval process on behalf of the Divisional Manager or Director of JRO. |
| Contract Manager                 | • Responsible for putting together any research-related agreement required as part of the JRO approval process.  
• Liaise and negotiate with internal and external parties (particularly, for commercial studies, the Sponsor and/or CRO). |
6. PROCEDURE

There are 3 core process steps in the granting of NHS permission:
1: Registration and costing
2: Review and governance and
3: Granting of NHS Permission.

6.1 Registration and Costing

6.1.1 Entry Points

There are two points of entry into the JRO approval process:

A: Through notification through the Centralised System for Granting NHS Permission (CSP)

An outline of the purpose and scope of the CSP system can be found at [http://www.crncc.nihr.ac.uk/about_us/processes/csp](http://www.crncc.nihr.ac.uk/about_us/processes/csp)

New study alerts should be received by the Senior Research Administrator (SRA) directly from the Central and East London Comprehensive Local Research Network (CEL CLRN). This is via email directly to the SRA

B: Through direct communication from the study team (standard process)

Studies that will not be processed through the CSP system indicate such through question 5a of the IRAS filter question. Submission of these studies can take the form of an email, or in some cases, physical file delivered to the JRO. The SRA should receive these files and emails in the first instance.

6.1.2 Allocation

For all studies the SRA will determine if the study falls into a simple or complex risk category (see appendix 1). This in turn determines which person in the JRO will deal with the approval of the study (SRAs, basic and Research Network Coordinators (RNC), complex).

The SRA will determine such through review of the IRAS filter Questions (as outlined in appendix 1)

The SRA should then:

- Register the study on ReDA 2, the JRO database, through allocating a ReDA number to the study. This is the unique identifier for the study for each site. ReDA is then populated with the necessary data requirements (see appendix 2)
- Where the study is to be allocated to an RNC, the SRA will alert the RNC through a ReDA alert, accessed through the ‘project reminders’ tab. The message is set to the attention of the relevant RNC, with an appropriate reminder title (such as, ‘new project’), and a due date of the day of registration. Once sent, this reminder appears in the work area of ReDA for the RNC to collect
- Where the study is allocated to the SRA, no further alerts at the allocation stage are required.
• Indicate the name of the assigned RNC/SRA in the information tab of ReDA under 'JRO lead'
• Produce a JRO study approval/assessment checklist (see appendix 3)

The pathway for the approval of the study will then divides into two paths:

• Externally Sponsored Clinical Trial and all Commercially Sponsored Trials
• All other forms of study

6.1.3 Externally Sponsored Clinical Trial and all Commercially Sponsored Trials

The required first documents are the NHS REC approved (or close to being approved) protocol, the R&D form, the completed NIHR study costing template (completed with departments expected costs and procedures) and budget (see http://www.nihr.ac.uk/industry/Pages/default.aspx for template) and the contract template. The SRA should:

• Upload the documents onto ReDA, document repository
• Alert the RNC through a ReDA alert message to the receipt of required first documents
• Print the first documents, compile a study file, and hand to the RNC
• Start the ReDA clock, through the events tab, choosing the field ‘record against selected location’, and enter the event: “date of receipt”, with the current date
• Send an alert message through ReDA to the Cost Accountant to notify them of the costing template
• Send an alert message through ReDA to notify the Contracts Manager of the contract template
• Add an event to the ReDA events field, to demonstrate handover to the Cost Accountant and to the RNC

The Cost Accountant should:

• Follow the applicable JRO SOP/guidance for the costing of Research Studies
• Liaise with the required support departments to clarify local costs (from the submitted template), and check and cost/verify the amount of time spent on the study by Trust clinical staff and service providers.
• Ensure that the Pharmacy department have notified the Cost Accountant of the agreed pharmacy costs.
• Confirm the study costs with the PI, the Sponsor and/or the Sponsor’s Representative (CRO).
• On completion, should sign the study Site Specific Information (SSI) form to indicate the Trust’s acceptance of the agreed costing. The Pharmacy Department should likewise, sign the SSI form to confirm their agreement of Pharmacy costs and resources or provide an email confirmation.
• Ensure ReDA events field is updated with progress and milestones relating to the costing process
• Inform the RNC, through ReDA alerts, of the agreement of costing for the study
• Sign JRO study checklist/assessment form

The Contract Manager should:

• Liaise with the RNC to clarify any samples transfer, sub-contracting, indemnity and any local issues (from the submitted template),
• Liaise with the PI, the Sponsor and/or the Sponsor’s Representative (CRO) to finalise.
• Ensure ReDA events field is updated with progress and milestones relating to the contracts process
• Inform the RNC, through ReDA alerts, of the agreement of contract
• Sign JRO study checklist/assessment form

The RNC should:

• Send an alert message through ReDA to the Contracts Manager with a description of the study, insurance details, data or material transfer
• Request the study documentation and send the assessment checklist for approval (see appendix 3)
• Liaise with site regarding the site initiation visit (SIV) and confirm date; the SIV can occur before R&D approval but only if the contracts and the costing elements are close to being finalised.
• Ensure ReDA events field is updated with the receipt of these documents
• Upload documents to the ReDA document repository

For CSP studies, there is a requirement for the documents which were submitted to the REC, to be made available within 30 days of the validation of the SSI form. Therefore, in addition, the RNC should:

• Follow the appropriate NIHR CSP procedures to ensure the correct processes for administering and verifying documents is followed (as per the most recent NIHR CSP operating manual)
• Aim to request the full required documentation set as soon as possible

6.1.4 All other forms of study

6.1.4.1 Non-CSP processed studies

The required full documents are essential for the processing of all other forms of study.

On receipt of these documents SRA should:

• Upload the documents onto ReDA, document repository and tick these off on the checklist (appendix 3)
• Alert the RNC (if applicable) through a ReDA alert message to the receipt of required first documents
• Print the documents, compile a study file, and hand to the RNC (if applicable) or retain and tick these off on the checklist (appendix 3)
• Start the ReDA clock, through the events tab, choosing the field ‘record against selected location’, and enter the event: “date of receipt”, with the current date
• If applicable, add an event to the ReDA events field, to demonstrate handover to the RNC

It is expected that such studies, have already been viewed by the JRO Cost Accountant to determine if costs are appropriate. In the rare cases where this has not been agreed, the Cost Accountant should be referred the SSI form to determine such. An alert through ReDA and the applicable ReDA event field should be completed by the SRA or RNC (where applicable)

6.1.4.2 CSP Processed studies

Once the SSI validation request is received, the SRA will register the study on ReDA, and:

• Upload the documents onto ReDA, document repository
• Alert the RNC through a ReDA alert message to the receipt of required first documents
• Print the required documents, compile a study file, and tick these off on the checklist (appendix 3) and hand to the RNC
• Add an event to the ReDA events field, to demonstrate handover to the RNC
The RNC should:

- Follow the current CSP operational guidance on the validation of the SSI form.
- Start the ReDA clock, through the events field, record against selected location, and enter the event: “date of receipt”.
- Follow the appropriate NIHR CSP procedures to ensure that the process for acquiring the full document set is followed
- Aim to request the full required documentation set as soon as possible, within or after this CSP timeframe
- Pass the SSI form to the Cost Accountant

6.1.4.3 for all studies

The Cost Accountant should:

- Determine if a costing is required
- Cost the NHS Support costs
- Where the study is processed through the CSP system, assist the PI in the completion of the costing element of the Service Support Cost application if applicable
- Under direction from the RNC, cost Research or Equipment costs to be reimbursed from the Sponsor (if applicable)
- On completion, sign the study SSI form and the JRO study checklist/assessment form or update ReDA events

In cases where the RNC considers that a contract maybe required, the agreement on costings should then be indicated to the Contracts Manager (JRO) for the initiation of the study Contract. The Cost Accountant should inform the RNC, for them to then brief the Contracts Manager on the requirements for the contract.

6.2 Review and Governance

On receipt of full documents (for all study types), the RNC (or in the case of low risk studies, the SRA), should:

- Check the JRO form for the mention of a study related drug or device
- Where a drug or device is noted, assess the requirement for MHRA (or other approvals)
- Where a drug or device requires MHRA approval, check evidence of such compliance or evidence of not requiring such approvals
- Following the guidance/processes of the JRO Contracts Team, review the study for the requirements for agreements or contracts. In applicable cases, notify the relevant contracts manager, through a ReDA alert, to the requirements, and provide full required information.
- Check that the procedures and resources required have been agreed through the presence of all authorised signatories on the SSI form
- Check if there is a requirement for radiology authorisation
- Where there is a radiology requirement, follow JRO process for obtaining radiology authorisation
- Check that all other adequate governance and regulatory approvals are in place.
- Check all documents received against the REC and MHRA approvals to ensure document control and correct versioning on locally headed paper
- Check for the presence of any conditions of REC or MHRA approval, and their completion
- Check that all CVs and GCP certificates (within 2 years for CTIMP studies) of all named staff on the SSI form have been submitted
- Check that all staff who are not employed at Trust site has adequate honorary or other contracts in place. If not, to follow JRO processes for obtaining Research Honorary Contracts or Letters of Access, or refer to the appropriate HR Department
- Upload all documents onto the document repository of ReDA
- Print all documents, and complete the paper JRO file for the study
- Ensure ReDA 2 is completed with all study and Trust related information
- Compile all final documents, and prepare file for final approval
- Where the study is NIHR UKCRN adopted, complete all the required checks on the CSP system as instructed by the current CSP operating manual and local CEL CLRN processes

In cases where a Contract is required, the Contracts Manager:

- Follows the applicable JRO SOP/guidance for the requirement and issuing of Contracts
- Progress with the Contract, through liaison between the Sponsor (or their rep) and the PI
- initiate the signing of the final contract once an agreement is reached
- On receipt of the sponsor’s signature, re-review the contract and initial each page to indicate such.
- Pass the partially signed Contract to the SRA to send to the authorised signatory for the Trust for his/her signature on behalf of the Trust
- Inform the RNC of all updates as to the progress of the study, through regular meetings and alert messages and events on ReDA
- Sign the JRO checklist/assessment form to confirm the completion of the contract or update ReDA events

The SRA should:

- ensure returned contracts are handed to the assigned RNC

The RNC (or in the case of low risk studies, the SRA), should:

- collate all completed documents and contracts and pass to the final Quality Assurance Checks

6.3 NHS Permission

The full study pack should be passed for JRO Quality Assurance to a senior member of the team (RM&G Network Manager, QA Manager or in some cases, another Research Network Coordinator). The RNC (or SRA in the case of low risk studies) should:

- Notify the RM&G Manager (or equivalent) through a ReDA alert message that the study is ready for QA
- Ensure all study documents are uploaded onto the ReDA document repository
- Ensure the completed paper file is left for the attention of the QA’er in the office allocation trays.

The RM&G Network Manager (or other authorised QA), should:

- Access the file, either electronically or in the hard copy within 2 days
- Use the Quality Assurance Checklist (Appendix 5)
- Check the study documents against the REC letter to ensure all relevant documents are as per version and date listed on the REC approval (and all subsequent amendments) letter
- Check the REC and MHRA approvals for any conditions of approval and evidence these have been met
- Following JRO guidance on the requirements for contracts and agreements, ensure that appropriate contracts or agreements are in place to cover this
- Check the SSI form to ensure all authorisation signatures are in place
- Check for the authorisation of any IRMER requirements (radiation)
- Check all investigators have submitted CVs and to date, GCP certificates
Where the study is NIHR adopted, that a service support cost application is either in progress or has been submitted and a governance report is present

Notify the RNC or SRA of any queries or further requirements and note these in the checklist and on ReDA events under event “other”, markings as “QA”

Where all documents are in place, sign the JRO checklist/assessment form to indicate approval or update ReDA events

The RNC should hand the completed file to the SRA for the issue of the JRO approval letter (NHS Permission). The SRA should:

- ensure all ReDA fields are complete
- ensure all documents are in place and filed in the correct JRO folder
- email the PI, study coordinator and sponsor (and RNC if applicable) with the JRO approval letter and to collect a hard copy from the JRO
- Upload a copy of the JRO approval letter to the document repository of ReDA
- For CSP studies, ensure the RNC uploads a copy of the approval letter to the CSP document repository
- Ensure the paper file is stored in the appropriate place and manner in the JRO office
- Set-up any related alerts or notifications on ReDA (e.g., the end date of an honorary contract)
- Ensure the approval letter and copy of the Contract is collected and signed out by the PI or his/her representative
- Where the Contract is to be posted back to the Sponsor, to ensure this is arranged

The process above is also outlined in Appendix 4 In the form of a flow diagram

7. IMPLEMENTATION & TRAINING

This SOP has been produced as a development of a number of guidance documents on this process. The training for the guidance documents is documented separately from this SOP.

This SOP will be disseminated to all Joint Research Office staff, and a training session held. Individual training in ReDA use will also be provided. For this SOP, a training log will be developed and signed by each person who will use this SOP.

8. PUBLICATION & COMMUNICATION

This SOP is published on the JRO website: http://www.ucl.ac.uk/joint-rd-unit and can also be found on the UCL S: drive, UCLH G drive and Royal Free Z drive.

The fully approved and signed master copy is also stored in a designated binder within the JRO. Any further changes to the SOP after this point will have to be undertaken through the Document Control System.

9. REVIEW

SOPs will be reviewed every 2 years unless an earlier review is required.
10. REFERENCES

JRO office Website: http://www.ucl.ac.uk/joint-rd-unit


NIHR RSS Framework (including Appendix 1 – Glossary of Terms and Acronyms)
http://www.nihr.ac.uk/systems/Pages/RSS_Documents.aspx

NIHR Coordinated System for Gaining NHS Permission
http://www.crncc.nihr.ac.uk/about_us/processes/csp

http://www.nihr.ac.uk/systems/Pages/RSS_Documents.aspx

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http://www.crncc.nihr.ac.uk/about_us/processes/csp

11. SIGNATURES

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12. APPENDICES

Appendix 1: Definition of Complex and Simple Studies (JRO)
The following extracts are taken from the JRO SOP for the categorisation of studies into simplex and complex for the purposes of allocation to JRO staff and the path for NHS Permission

Box 1:
“Simple” or “Complex”
Any study where the following boxes are selected for screening question 2 on the NHS R and D and NHS REC form should be deemed a “simple” study. Any other studies should be treated as “complex”.
- Study administering questionnaires/ interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissues samples (or other biological samples) and data
- Study limited to working with data

Box 2
Rules for UCLH, RFH or UCL Sponsorship of “Simple” studies

1. UCLH and Royal Free will sponsor non CTIMPs where
   • The study is registered and managed within the JRO
   • The study is single site and recruiting only NHS patients at the site sponsoring the study.

2. UCL will sponsor other “simple” studies if Chief Investigator (CI) has a substantive employment contract or an honorary contract/passport with UCL.

3. UCL will sponsor student studies, if students are undertaking a recognised course with UCL

4. The JRO has flexibility in how it allocates sponsorship particularly for single site and student studies. In some circumstances, it might be advisable to take a pragmatic approach to allocation of sponsorship. The Senior Research Network Manager will advise.
Appendix 2: Flowchart for “Simple” and “Complex” studies

1. Study sent to SRA, or RNC
   - SRA, DIO or RNC to register and assign R and D
   - SRA, and RNC decides “simple” or “complex” according to definition below based on question A5 of ethics form - see Box 1. Flag set on REDA accordingly

   - Simple
   - Complex

2. SRA or DIO to decide if sponsorship required – see Box 2 for sponsorship rules.
   - Y
   - UCL sponsorship - DIO
   - Other sponsor i.e. hosted study
   - No

3. Does the study need a contract?
   - Y
   - Refer to contracts and finance team. Contracts to inform SRA or DIO if contract required and flag set
   - Is UCLH or RFH host approval required?
     - Y
     - UCLH or RFH Host approval process
     - N
     - Agree study after documentation entered onto database

4. RNC. then follow SOP on complex
## Appendix 3: R&D Checklist

Please ensure to enclose all applicable documents in one submission to ensure swift review and approval. Please alert the sponsor about any contract/agreement or material transfer agreement and forward an initial draft of this document together with the above documents if possible.

<table>
<thead>
<tr>
<th>Short title:</th>
<th>PI:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Document</strong></td>
<td><strong>Version &amp; Date</strong></td>
</tr>
<tr>
<td>R&amp;D Form (Parts A-D) – fully signed and dated PDF or fully signed and dated hard copy</td>
<td>N / A</td>
</tr>
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</table>

*If for any reason it is not possible to get hold of a fully signed R&D form, a fully signed REC form can be accepted. This may be the case if the Ethics submission was submitted using the 'old' NRES system etc.*

<table>
<thead>
<tr>
<th><strong>Document</strong></th>
<th><strong>Version &amp; Date</strong></th>
<th><strong>Submitted</strong></th>
<th><strong>R&amp;D only</strong></th>
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<tbody>
<tr>
<td>Site-Specific Information Form – signed and dated PDF or hard copy (Signed and dated by Principal Investigator, Clinical Director, Finance and Pharmacy if applicable.)</td>
<td>N / A</td>
<td></td>
<td></td>
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<tr>
<td>Research protocol (REC approved version)</td>
<td>N / A</td>
<td></td>
<td></td>
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<tr>
<td>Summary CV for Principal Investigator (PI) – signed and dated</td>
<td>N / A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary CV for local researchers, research nurses, coordinators etc. (as listed on SSI form) – signed and dated</td>
<td>N / A</td>
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<tr>
<td>Letter(s) of Access or Honorary Research Contract(s)</td>
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<td>REC favourable opinion letter including all correspondence (including most recent amendment)</td>
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<td>Research participant information sheet(s) – REC approved version(s) on locally headed paper with local information</td>
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<tr>
<td>Research participant consent form(s) – REC approved version(s) on locally headed paper with local information</td>
<td></td>
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<tr>
<td>GP/consultant information sheets or letters – REC approved version on locally headed paper with local information</td>
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<tr>
<td>Letter from funder</td>
<td>N / A</td>
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<tr>
<td>Evidence of insurance or indemnity (non-NHS sponsors only) Minimum £ 5.000.000 cover</td>
<td>N / A</td>
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<td>ARSAC certificate</td>
<td>N / A</td>
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<tr>
<td>IRMER form</td>
<td>N / A</td>
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<tr>
<td>Confirmation of authorisation from MHRA (including most recent amendment)</td>
<td>N / A</td>
<td></td>
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<tr>
<td>Confirmation of any other regulatory approvals (e.g. NIGB) and all correspondence</td>
<td>N / A</td>
<td></td>
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<tr>
<td>GCP certificates for all participating staff as listed on SSI form if CTIMP (no more than 2 years old)</td>
<td>N / A</td>
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Document not required if study is submitted through CSP ReDA
<table>
<thead>
<tr>
<th>R&amp;D ONLY</th>
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<tbody>
<tr>
<td>ReDA Ref:</td>
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<tr>
<td>Commercial</td>
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<tr>
<td>CTIMP</td>
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<tr>
<td>NON CE-MARKED DEVICE</td>
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<table>
<thead>
<tr>
<th>Contract prepared by:</th>
<th>Date</th>
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<tbody>
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<td>N / A</td>
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Finance sign-off (by)

Contract signed by authorised signatory

<table>
<thead>
<tr>
<th>QA review by:</th>
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Issues to consider before QA sign-off: | Date issue resolved |
<table>
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<td>3</td>
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<td>4</td>
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</tbody>
</table>

Final QA sign-off:
Appendix 4: Flowchart for processing studies for NHS Permission

1: REGISTRATION and COSTING

- Investigator makes contact with the Research Office through the Senior Research Administrator (SRA) Research Network Coordinator (RNC). Required documentation checklist/information is sent.
- SRA receives study and registers onto the database (ReDA).
- SRA determines if the study is complex or simple studies retained by SRA, complex and CSP studies to RNC.
- Study passed to RNC for validation of the SSI form through ReDA CSP. RNC sends request for CSP defined core documentation to the local study team and study coordinator – required to move to next steps.

Commercially Sponsored Studies and Externally Sponsored Ctimps

- Study protocol, draft costing (using the National NIHR template), the study budget and draft SSI form passed to JRO Cost Accountant by the SRA.
- Cost Accountant from the Research Office who will discuss and finalise the study costs between the Sponsor, PI and Service Support Departments at the Royal Free. On completion, costs are sent to the RNC responsible for the study and allocated Contracts Manager.

2: REVIEW and GOVERNANCE

- Where a Contract is required, a Contract Manager from the JRO office will be allocated and will be in touch to initiate this between the PI and the Sponsor.
- Contract Manager instructs Sponsor to sign agreed contract and return to JRO. On receipt, Contracts Manager signs each page acknowledging its content.
- Contract sent to the authorised signatory for final signature and returned to the RNC.

- RNC Complies all documents and passes study for QA to RM&G Manager.

Other Studies

- Study draft SSI form passed to JRO Cost Accountant by the SRA. Study is priced for local costs.

- RNC will review all documentation for completeness, version control and to identify any outstanding documentation. RNC will also review the local governance requirements, including the requirements for honorary contracts or additional departmental signatories.

- Where the study is being processed through the UKCRN CSP system, RNC will complete relevant checks and request final governance report.

3: APPROVAL

- RM&G Manager QA of study. Where items or points require clarity, RNC/SRA informed and follows through RM&G Manager signs the Project Assessment Form to confirm the study can be approved for NHS permission.
- SRA issue NHS Permission letter.
Appendix 5: Quality Assurance Checklist

To complete the quality checks for new applications you, the identified QA person for this study, will need to complete Table 1 by initialling under the appropriate column “yes” or “no” to indicate whether the section has been completed to satisfaction, add any comments or N/A for sections that are not relevant, add your details, sign and date. Relay your comments via ReDA Events back to the SRA/RNC dealing with the study for action.

<table>
<thead>
<tr>
<th>R&amp;D ID</th>
<th>Title/ACRONYM</th>
<th>UKCRN ID</th>
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<table>
<thead>
<tr>
<th>Table 1 - Quality Check for Study Application</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>R&amp;D checklist (version and date)</td>
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<tr>
<td>Global Checks</td>
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<tr>
<td>Local Checks</td>
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<tr>
<td>Contract</td>
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<tr>
<td>Costings</td>
<td></td>
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<tr>
<td>Pharmacy authorisation</td>
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<tr>
<td>CRF Adoption</td>
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</table>

### ReDA

- Clocks started and stopped
- Core field completed and accurate
- Events completed
- Reminders set
- Documents uploaded

Name & Title of QA person: ___________________________ Date: ______________ Signatures: ___________________________

QA Governance checklist version 1.7 dated 17 May 2012
Use Table 2 & 3 to complete the governance checks for non-portfolio studies or as a guide as part of QA. Table 3 provides study specific governance checks.

<table>
<thead>
<tr>
<th>Table 2 - Governance Checks</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. R&amp;D Checklist</td>
<td></td>
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<tr>
<td>NHS R&amp;D form fully signed and dated</td>
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<tr>
<td>Site Specific Information (SSI) form signed and dated</td>
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<tr>
<td>Research protocol (REC approved version)</td>
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<tr>
<td>Summary CV for Principal Investigator signed and dated</td>
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<tr>
<td>Summary CV for local researchers as listed on the SSI form</td>
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<tr>
<td>Letter(s) of Access or Honorary Research Contract(s)</td>
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<tr>
<td>REC favourable opinion letter including all correspondence (including most recent amendment)</td>
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<tr>
<td>GTAC notice of favourable opinion (gene therapy)</td>
<td></td>
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<tr>
<td>Research participant information sheet(s) - REC approved version(s) on locally headed paper with local information</td>
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<tr>
<td>ARSAC certificate</td>
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<tr>
<td>IRMER form/ Email confirmation of IRMER compliance</td>
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<tr>
<td>MHRA authorisation</td>
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<tr>
<td>- MHRA notice of acceptance for clinical drug trials</td>
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<tr>
<td>- MHRA notice of no objection for clinical investigation for medical devices</td>
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<tr>
<td>- MHRA email confirmation that the study does not fall under the clinical trials regulations (mechanistic)</td>
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<td>Confirmation of any other regulatory approvals (e.g. NIGB) and all correspondence</td>
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<td>GCP certificates for all participating staff as listed on SSI form if CTIMP (no more than 2 years old)</td>
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<tr>
<td>2. Contract</td>
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<tr>
<td>All signatures in place (Sponsor/CRO, where applicable pharmacy, chief investigator, NHS site)</td>
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<tr>
<td>Each page initialled</td>
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<tr>
<td>A contract is not required if the study is a non-commercial simple study taking place within UK</td>
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<tr>
<td>- only sending anonymised data (or pseudo-anonymised but only we hold the key) and no tissue samples (with no funds exchanged)</td>
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<tr>
<td>- sending personal data and/or tissue samples, but this is clearly defined in protocol (with no funds exchanged)</td>
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<tr>
<td>Material Transfer Agreement (MTA) for tissue collected outside of the ethically approved project.</td>
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<tr>
<td>MTA is not required if the protocol includes the following:</td>
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<tr>
<td>- It clearly states that material is being shared with other organisations</td>
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<tr>
<td>- It clearly identifies and describes the organisations involved</td>
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<tr>
<td>- Information about IP and working within the human tissue regulations is included</td>
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</table>

QA Governance checklist version 1.7 dated 17 May 2012
### 3. Costings
- Service support costs considered and applied
- Costing authorisation

### 4. RDMIS
- Global checks
- Local checks
- NIHR adoption confirmation

### 5. ReDA
- COMPLEX STUDY tick box in the “Management” tab
- Mechanistic, MHRA Devices or RG Devices selected in “Study Type” in the “Management” tab
- Events completed for contract
- Events completed for costing
- Reminders set for renewal of principal investigator GCP training 4 months before expiry.
- Reminders set for renewal of ARSAC research licence two months before expiry date.
- Reminders set for renewal of honorary research contracts, letters of access if these expire before the end of the study.
- Reminders set to contact CI to confirm storage of unknown tissue after the end of the ethically approved study.

### Table 3 - Study Specific Governance Checks

<table>
<thead>
<tr>
<th>Completed</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
</table>

#### 1. Intervention

**Clinical Trial (Investigational Medicinal Product / Advanced Therapy)**
- Check EudraCT number is consistent on MHRA notice and REC notice of ethical approval and EMA confirmation letter
- Summary of product Characteristics
- Investigator Brochure
- EMA confirmation of trial categorisation (combination therapy)

**Mechanistic Study**
- Confirmation of drug source and drug supply
- IMP Compliance Manager, Sponsor Pharmacist Risk Assessment

**Medical Device**
- Protocol and agreement are consistent with safety reporting requirements
- Product information
- Manufacturer confirmation the study falls within the product indications
- Manufacturer details for safety incident reporting
- CE-mark certificate
- Declaration of Conformity
- NHS R&D form Medical Physics authorisation

**Radiation**
- NHS R&D form Part B section 3 C2 lead Medical Physics Expert declaration signature confirming research protocol complies with IRMER
- NHS R&D form Part B section 3 D3 lead Clinical Radiation Expert declaration signature confirming
### Radioactive Substances
- NHS R&D form Part B section 3 D1 where radioactive substances are to be used, an ARSAC research licence is required by the participating site with an expiry date in 5 years time.

### 2. Patient Information Sheet
- Ensure local information has been included especially local study contact details and PALS (Patient Advice & Liaison Service)
- Information about who to contact if the patient wants to make a complaint
- Appropriate insurance and indemnity arrangements for different type of patients: (NHS, pregnant women, children, patients lacking capacity, healthy volunteers)

### Patient lacking capacity
- Ensure NHS R&D form (Part B section 6) includes arrangements for assessing capacity
- Legal representatives nominated for mentally incapacitated adults (SSI 13-1)
- Advocate information sheet and consent form
- Where a patient is to be found to lack capacity during the progress of the study, to ensure there are appropriate arrangements in place

### Data Transferred outside of the EEA
- Ensure patients are informed if their data is to be transferred outside of the EEA and to obtain their consent for this arrangement.

### Tissue Storage
- Ensure patients are informed that their tissue will be stored for future unknown research and to obtain their consent for this arrangement

### 3. Use of Data
- Ensure NHS R&D form (A36-A45), protocol, PIS and ICF are clear and consistent with regards to the collection and storage of data.
- Provide details of what sort of data will be collected anonymised or pseudo-anonymised and who is the custodian of the data.
- Ensure that where data is transferred that is done through secure means only.
- Where data is being collected by external collaborators use a Data Transfer Agreement.
- Where data is to be transferred outside of the EEC to ensure the NHS form, protocol, patient information sheet and consent form include details for these arrangements.
- If the study does not seek consent to ensure that an application is made to the NIGB and a notice of no objection is obtained prior to starting the study.

### 4. Collection of Human Tissue Samples
- Where samples are to be collected for future unknown research to ensure that the NHS R&D form (Part B section 4-5), protocol, PIS and ICF reflect this.
- Appropriate Human Tissue Authority (HTA) licence