STANDARD OPERATING PROCEDURE FOR OVERSIGHT

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Supersedes: P08/PF2  Revision Date: 31st March 2014

Author: Gay Bineham
Position: R&D Manager Hillingdon Hospital
Approved by: R&D Steering Group

Revision History

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<tr>
<td>Version no: 1</td>
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<td>NIHR RSS Framework</td>
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<td>recommendations</td>
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<td>Version no: 2</td>
<td>31.07.13</td>
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- The development of this SOP has been spearheaded by the Trust R&D Manager. The SOP will be ratified by the Trust Research and Development Steering Group. This SOP will be reviewed every 2 years or sooner if changes in legislation or regulations warrant revision.
- This SOP will be made available to all necessary R&D staff and investigators/research staff within the Trust. A Master Copy will be stored in the R&D Office SOP file. A copy of this SOP will be held on the Trust intranet site in the R&D Pages.
- The SOP will be implemented throughout The Hillingdon Hospital NHS Foundation Trust and training, if requested, will be available through the R&D Office and the Trust research web page.
- It is not currently anticipated that these documents will be archived.
- All applicable R&D Staff will be required to sign the declaration (PART A) to confirm that they have read and understood the information given in this SOP and will undergo any associated training that is required by the R&D Office.
- Any subsequent amendments to this SOP will be circulated to all relevant R&D staff and where necessary may be required to resign the declaration to confirm compliance.

1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes the activities to provide a proportionate (i.e. related to the operational risk) level of oversight of a study on behalf of the organisation. It should be used by the R&D office in a participating organisation.

1.2. Outcome: The R&D office (or other body with delegated responsibility) will have exercised proportionate oversight of the study during study delivery. This is not related to the study.
oversight / monitoring provided by the sponsor / Chief Investigator (CI).

1.3. Oversight provides a form of governance process ‘quality control and management’ which is intended to provide governance assurance for the participating organisation.

1.4. Oversight can consist of:
   a. specific oversight activities that are the responsibility of the NHS Organisation (researchers ongoing employment status, financial management),
   b. Study specific oversight activities to ensure issues are resolved
   c. Auditing and other Research Governance responsibilities.

1.5. The approach taken for each study should be proportionate to the operational risks identified for the study.

1.6. It is expected that the approach, intensity and frequency of oversight activities (including whether to include / exclude the study from routine audits) are agreed and planned within an agreed timeframe and documented in a study oversight plan.

1.7. The R&D office will undertake additional specific oversight activities in the case of any exceptional activity or events identified during the study.

R&D office study oversight activities

1.8. Confirming with the identified HR Manager that contracts of employment for research personnel are current and renewed if they are about to expire. This includes letters of access when issued

1.9. Ensure that there are financial control mechanisms in place to oversee the agreed finances for the study. Where appropriate, monitoring that the amount received is adequate for the activity undertaken. This is particularly important when acting as a repatriation site for studies where patients are consented in another organisation. This may also require the facilitation of invoices.

Issue resolution management

1.10. This consists of the R&D office providing oversight support for the Principal Investigator (PI) when required, for example, to enable improvements in:
   - Delivering study processes,
   - Meeting external agreement obligations
   - Meeting internal agreement obligations,
   - Managing exceptions not relating to study processes, internal or external agreements.
   - Monitor and managing recruitment time to target requirements

1.11. The R&D office is expected to provide a proportionate approach to support, based on identified risks and to follow up on any actions given to the PI to resolve the issues.

Audits

1.12. An audit is undertaken to establish that staff are working to an agreed standard. The standard may be detailed in the following:
   - Organisation’s / study specific research SOP’s
   - Study agreement (internal and external)
   - Study protocol
   - Organisation’s policies and procedures

1.13. The audit should be proportionate to the risks associated with the study:
- Study processes are being followed in line with the study protocol, the organisation’s policies, and standard operating procedures (SOPs) provided by the sponsor or the participating organisation.
- The PI is checking that external agreement obligations are being met
- The PI is checking that internal agreement obligations are being met including honorary research contractual obligations.

1.14. Auditing activities are the responsibility of the R&D office within the participating organisation. Studies can be selected for audit either at the start of the study or when a study is in progress. Any study can be considered for review as part of an audit. The R&D Steering group will decide which studies are to be part of the planned audit programme on an annual basis or more frequently as needed.

1.15. This will be based on:-
- A study is considered high risk to the organisation
- A study is not considered high risk to the organisation but is selected as part of a group of studies identified for audit.
- Issues have been identified as part of routine oversight that suggest that the study needs to be subjected to a more in-depth audit

1.16. 10 – 15% of studies should be identified for routine audit annually. This should include a mixture of high risk and low risk studies.

PROCEDURE

Managing R&D office study oversight activities

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<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1 R&amp;D office and nominated HR manager</td>
<td>Maintain details of all honorary research contract and letters of access issued.</td>
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</tr>
<tr>
<td>2 R&amp;D office and nominated HR manager</td>
<td>Work with the Human resources department to review records to identify if any project specific or 3 yearly Honorary contracts / letters of access require renewing and working with researcher renew if appropriate.</td>
<td></td>
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<tr>
<td>3 R&amp;D office and nominated HR manager</td>
<td>Follow-up with researchers to ensure Honorary contracts / letters of access used as part of the study are renewed at the appropriate time.</td>
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<tr>
<td>4 R&amp;D office and nominated HR manager</td>
<td>Follow-up with researchers to ensure Honorary contracts / letters of access that may be required in future are renewed at the appropriate time.</td>
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<tr>
<td>5 R&amp;D Office and Finance</td>
<td>Identify any shortfalls in study finance and work with the PI and Study centre / CLRN to review finances</td>
<td></td>
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<tr>
<td>6 R&amp;D Office and PI and finance</td>
<td>Monitor repatriated studies and local recruitment to ensure that the costs associated with the local research activity meets the costs of undertaking the study follow-up</td>
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Manage issue resolution

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<th>Responsibility</th>
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<tr>
<td>1 PI and R&amp;D office</td>
<td>PI R&amp;D office</td>
<td>Confirm that the PI and relevant research staff understand study requirements related to: - managing external agreements, - managing internal agreements, - managing study processes,</td>
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<td>2 PI</td>
<td>PI</td>
<td>If an issue arises during the study, escalate and seek support from the R&amp;D office.</td>
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<tr>
<td>3 R&amp;D office</td>
<td>R&amp;D office</td>
<td>Manage the resolution of the issue with the PI / researcher in a proportionate way based on risk. Escalate appropriately the issue if the R&amp;D office is unable to provide the necessary support.</td>
</tr>
<tr>
<td>4 R&amp;D office</td>
<td>R&amp;D office</td>
<td>Follow up with the PI on the actions taken to ensure the issue has been resolved.</td>
</tr>
<tr>
<td>5 R&amp;D Office and PI</td>
<td>R&amp;D Office and PI</td>
<td>Time to target - Monitor recruitment of 1st patient in relation to study approval to ensure that agreed timelines are met</td>
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Manage audits

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<tr>
<td>1 R&amp;D steering group</td>
<td>R&amp;D office</td>
<td>Identify which studies should be subjected to routine audit in a specific year based on - Identified risk of the study - number of patients recruited - complexity of the study and documentation, - investigator's and site's past performance, - rate of occurrence of adverse events - Study phase and status of investigational medicinal product - Level of oversight by sponsor - Number of study amendments</td>
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<td>2 R&amp;D office</td>
<td>R&amp;D office</td>
<td>Using the Trust's standard audit template create a study specific audit plan detailing the audit activities to be undertaken. Notify the sponsor of any auditing to be carried out if appropriate. Produce an audit plan that details the purpose, extent and which documents are to be audited. It should also state how any major concerns detected during the audit would be handled</td>
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<tr>
<td>3 R&amp;D office</td>
<td>R&amp;D office</td>
<td>Prepare for audit. - Identify documents required for review and request documents from the PI or other study personnel - Arrange with PI convenient time to undertake the audit - Review safety reports for the study. - Review recent correspondence. - If this is a re-audit review previous audit report and only re-audit areas identified in previous audit that needed review.</td>
</tr>
<tr>
<td>4 R&amp;D office</td>
<td>R&amp;D office</td>
<td>Conduct the audit with study team as detailed in the audit plan. This should include - the trial master file for all essential documents - site personnel ICH training log and site delegation log, - Study monitoring by the sponsor. - Amendments to protocol - SAEs for the site. - For the selected x% Informed consent documentation</td>
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<tr>
<td>5 R&amp;D office</td>
<td>R&amp;D office</td>
<td>Complete the follow up activities. This includes the following:</td>
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<td>Responsibility</td>
<td>Undertaken by</td>
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|                | R&D office    | - Provide verbal feedback to the study team.  
|                |               | - Complete an audit report using a standard audit report form within 1 month of the audit taking place.  
|                |               | - Notify the PI of any non-compliance and request appropriate actions including corrections to be completed by an agreed date.  
|                |               | - Identify a re-audit time frame with the PI.  
|                |               | - File the audit report. A copy is expected to be retained and filed with the study site master file.  
| 6              | R&D office    | Communicate the findings of the audit to the sponsor. This includes sending a copy of the audit report to the sponsor and discussing any urgent concerns immediately by phone / email.  |

2. **SUPPORTING MATERIAL**

Note: Insert references to any relevant supporting material for this SOP:

- Audit templates

GB/ Reviewed April 2013
Please refer to http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx for guidance on specific activities which are eligible for a CRB disclosure.

PART A

Declaration of Compliance

I hereby confirm by signing of this declaration that I have read and understood the information in the NWLH NHS Standard Operating Procedure for Confirming Study Definition SOP No. RDSOP007 Version 1 Dated 15/04/2011 and where applicable will attend any necessary training required.

This SOP maybe subject to change from time to time due to modifications in National Legislation and Trust Policies, and therefore I agree to adhere to any subsequent amendments.

Signature: Date:

Name (Please Print):

Position: