Definition of Responsibilities

The current version of all Hillingdon Hospital R&D Guidance Documents and Standard Operating Procedures are available from the R&D Intranet and Internet sites: www.thh.nhs.uk/Departments/Research/research.htm

Please ensure that you have the latest version.

Version Number: 3.0
Effective Date: 01.08.11
Review Date: 31.07.13

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<th>Edited by</th>
<th>Effective Date</th>
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1. BACKGROUND

To ensure the smooth and accurate conduct of research studies appropriately qualified personnel are required. This may include staff directly involved in the conduct of the research such as the Principal Investigator, co-investigator(s), research nurses and clinical trial coordinators.

In addition there may be staff associated with, but not directly involved in the research trial including clinicians, specialist nurses, pharmacists, radiologists and laboratory staff. For a trial to run safely it is essential that all staff involved are aware of the anticipated extent of their involvement and limits to their authority.

ICH Good Clinical Practice Guidelines define an investigator as “A person responsible for the conduct of the clinical trial at a trial site.” The investigator is responsible for protecting the integrity, health and welfare of the trial subjects during the trial. The investigator must be:

- Qualified by education, training and experience and legally allowed to practice medicine.
• Thoroughly familiar with the study protocol and the investigational product(s).
• Aware of, and compliant with Good Clinical Practice and any applicable regulatory requirements pertaining to clinical trial conduct.

If a team of investigators conducts a trial at a trial site the investigator responsible for leading the team is referred to as the Principal Investigator (PI). Other investigators are referred to as co-investigators or sub-investigators. The term investigator in this SOP refers to the PI and all co-investigators. The Principal Investigator maintains overall responsibility for the study locally and the conduct of their research team.

2. PURPOSE

To assist in the division and allocation of responsibilities and to clarify boundaries of responsibility within the local study team in order to ensure the smooth running of the trial. Where applicable, to provide the Sponsor with an overview of the division of responsibilities within the trial.

3. PROCEDURE

3.1 Who?

During the pre-study phase, the Principal Investigator has the responsibility of deciding which tasks will be delegated to appropriately qualified and experienced staff.

3.2 When?

Individual trial related duties and functions should be defined, established and allocated prior to the initiation of a trial. This delegation is an ongoing process and should be carried out as necessary during the course of the study.

3.3 How?

Delegating Responsibilities

1. Each trial will have a Principal Investigator, who has overall responsibility for:
   • The welfare of patients
   • The medical care of trial subjects
   • Informed consent
   • Conduct of the study in compliance with the protocol
   • Administration and management storage of investigational product as appropriate
   • Ensuring that local management needs are met
   • Obtaining approval of and continued communication with regulatory bodies e.g. Ethics Committee and Trust management / R&D
   • Safety reporting e.g. Adverse Events and Serious Adverse Events
The accurate and timely completion of trial data
Archiving
Training of research personnel

2. The PI can nominate an appropriately experienced person, for example Research Nurse or Clinical Trial Practitioner, to assist in the management of the trial at the investigational site. This person along with the PI, where required, should discuss and agree the allocation of tasks with staff members.

3. Some trial related responsibilities may be delegated to appropriately qualified personnel according to local practice. The allocation of tasks to appropriately qualified persons should be recorded on a Study Delegation Log with specimen signatures and initials of all involved. See Appendix A.

The Site Delegation Log (SDL)

4. All staff with delegated responsibilities should be included on the delegation log. The delegation log will detail which procedures have been delegated to them. Refer to the table in Appendix B for tasks commonly associated with clinical research team roles.

5. Each entry in the log should be countersigned and dated by the investigator.

6. The log must be kept up to date. If a member of the study team is no longer involved in the study, this must be recorded. Where new members join the study team, they must be added in a timely manner. Superseded versions of the delegation log must not be destroyed, in order to provide an audit trail for future inspections.

7. The study Sponsor should be made aware of the planned division of tasks. Contact names and roles of other individuals involved in the trial (e.g., Pharmacy, laboratory staff) should also be notified to the Sponsor. Updated copies of the log should be sent to the sponsor as required.

8. The delegation log should be filed appropriately in the investigator master site file. In the event that departments or clinical teams participate in multiple trials, it is suggested that one general delegation log is maintained. If the site file is archived by the sponsor ensure a copy remains on site.

9. The PI along with the research nurse or co-ordinator should review the need for additional staff to be added to the log, and discuss changes with the Sponsor as appropriate on an ongoing basis.

10. Role changes must be documented on the delegation log, e.g. adding personnel able to take consent.
4. OTHER RELATED PROCEDURES

Archiving and Destroying Documents.
Study Files and Filing
Taking Informed Consent

5. REFERENCES AND FURTHER READING


6. APPENDICES

Appendix A – Delegation Log Template
Appendix B – Approved Responsibilities of Site Staff
## CENTRE DELEGATION LOG

<table>
<thead>
<tr>
<th>Name</th>
<th>Role (eg. Research nurse, Co-investigator)</th>
<th>Responsibilities</th>
<th>Signature</th>
<th>Initials</th>
<th>Involvement with Trials</th>
<th>Principle Investigator Signature</th>
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<td>Date stopped</td>
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<td>5</td>
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### Responsibilities

- **A** – Determine eligibility
- **B** – Obtain Informed Consent
- **C** – Enter data and make corrections in Electronic CRF
- **D** – Lock electronic CRF data (sign-off)
- **E** – Perform key trial measurements
- **F** – Dispense trial medications
- **G** – Prescribe Study Drug
- **H** –
- **I** –
- **J** –
- **K** –
- **L** –
- **M** –
- **N** –
- **O** –
- **P** –
- **Q** –
- **R** –
- **S** –
- **T** –
- **U** –
### APPENDIX B - *APPROVED RESPONSIBILITIES OF SITE STAFF*

*This is not an exhaustive list and should be used in conjunction with the individuals Job description and KSF outline*

<table>
<thead>
<tr>
<th>Position</th>
<th>APPROVED RESPONSIBILITIES OF SITE STAFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>Overall responsibility for study at site  &lt;br&gt; Medical care and supervision of patients  &lt;br&gt; Delegation of study related duties  &lt;br&gt; Ensuring all staff delegated to work on trial are adequately informed as to protocol requirements and trained in study procedures  &lt;br&gt; Familiarity with Investigator Brochure (where available)  &lt;br&gt; Patient recruitment strategy  &lt;br&gt; Screening of patients  &lt;br&gt; Informed consent  &lt;br&gt; Signing of consent form (as appropriate to local policy &amp; practice)  &lt;br&gt; Randomisation (as appropriate to local policy &amp; practice)  &lt;br&gt; Administration of investigational product  &lt;br&gt; Collection of trial related blood samples  &lt;br&gt; Completion and return of CRFs and providing responses to data queries  &lt;br&gt; Prescriptions  &lt;br&gt; Documentation of adverse events  &lt;br&gt; Timely Serious Adverse Events reporting  &lt;br&gt; Initiation of new trial personnel  &lt;br&gt; Ethics committee approval/communications re: amendments  &lt;br&gt; Negotiation and completion of the financial agreement  &lt;br&gt; Indemnity, compensation and insurance  &lt;br&gt; Investigational Product accountability and monitoring of compliance  &lt;br&gt; Available for audit and inspections  &lt;br&gt; Archiving  &lt;br&gt; GCP Training of all study personnel  &lt;br&gt; Other as locally applicable to individual studies</td>
</tr>
<tr>
<td>Co-investigators</td>
<td>Medical care of patients  &lt;br&gt; Screening of patients for eligibility  &lt;br&gt; Informed consent</td>
</tr>
<tr>
<td><strong>SOP: Definition of Responsibilities</strong></td>
<td></td>
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<tr>
<td>----------------------------------------</td>
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</tbody>
</table>
| **Sign consent form**  
  Randomisation  
  Responsible for administration of study drug  
  Responsible for collection of trial specific blood samples  
  Completion and return of CRFs and providing responses to data queries  
  Prescriptions  
  Timely SAE reporting  
  Ethics committee obligations  
  Other as locally applicable to individual studies |
| **Other Physicians**  
  Medical care of patients  
  Screening of patients for eligibility  
  Informed consent  
  Randomisation  
  Administration of investigational product  
  Collection of trial specific blood samples  
  Completion and return of CRFs and providing responses to data queries  
  Prescriptions  
  Timely SAE reporting  
  Other as locally applicable to individual studies |
| **Research Nurse**  
  Screening of patients  
  Informed consent (according to local practice)  
  Randomisation  
  Completion and return of CRFs  
  Data queries  
  Documentation of adverse events in source data  
  Investigator/Study file set up and management  
  Support monitoring visits and audits and inspections  
  Preparation of paperwork for Ethics committee/R&D  
  Preparation of SAE reports for medical input and causality assessment  
  Taking and shipping of trial related samples  
  Other as locally applicable to individual studies |
| **Clinical Trials Coordinator / Data Manager**  
  Data entry  
  Completion and return of CRF’s  
  Data Queries  
  Support monitoring visits, audits and inspections |
<table>
<thead>
<tr>
<th>SOP: Definition of Responsibilities</th>
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<tbody>
<tr>
<td>Arranging and collecting research patient’s notes for own and other research personnel’s use</td>
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<tr>
<td>Liaising with other health professionals as required</td>
</tr>
<tr>
<td>Maintaining / allocating appropriate copies of research documentation in patient hospital and research records</td>
</tr>
<tr>
<td>Maintenance of study files to ICH GCP standards</td>
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<tr>
<td>Support lead study clinician and other research professionals in:-</td>
</tr>
<tr>
<td>Documentation of adverse events in data source</td>
</tr>
<tr>
<td>Investigator / study file set up and management</td>
</tr>
<tr>
<td>Preparation of paperwork for Ethics committee and R&amp;D approval</td>
</tr>
<tr>
<td>Preparation of SAE reports for medical input and causality assessment</td>
</tr>
<tr>
<td>Shipping of trial related samples if appropriate</td>
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</table>

<table>
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<th>(Research) Pharmacist / Clinical Trials Pharmacist</th>
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<tr>
<td>Review of protocol, labelling, storage etc and medicinal products product licences etc as required by law prior to Trust approval to enable the Clinical trials pharmacist to meet their legal responsibilities</td>
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<tr>
<td>Acknowledge receipt of trial supplies</td>
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<tr>
<td>Drug accountability and monitoring of compliance</td>
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<tr>
<td>Dispensing of Investigational Product to patients</td>
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<tr>
<td>Complete dispensing logs</td>
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<tr>
<td>Maintain Pharmacy file</td>
</tr>
<tr>
<td>Monitor storage of Investigational Product</td>
</tr>
<tr>
<td>Other as locally applicable to individual studies</td>
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</tbody>
</table>

* Supply and record logs may be delegated to suitably authorized staff where the Trial Design is sufficiently ‘electronically’ robust in agreement with the Research Pharmacist