**DIRECTORATE OF RESEARCH AND INNOVATION**

**Joint Research and Development Office / Clinical Research Facility** *[delete as appropriate, if Written Procedure applies to Trust wide research, leave blank]*

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| Document Number:  GOSH/ICH/POL/S/YYY  GOSH/ICH/SOP/S/YYY  GOSH/ICH/WI/S/YYY  *[To be issued by Document Owner]* | | Version Number: |
| Title: | | |
| Effective Date: | *Same as implement by date / DD-MMM-YY (if different from the implementation date)* | |

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| --- | --- | --- |
|  | Name | Position |
| Authored by: |  |  |
| Approved by: |  |  |

1. **Scope**

*A brief statement providing the context of the Written Procedure and outlining the limits of the process or procedure, including the staff and areas to which the document pertains.*

*If there is a specific legal basis to the Written Procedure, this could be included here if required.*

*Suggested text:*

This SOP is applicable to

* All Great Ormond Street Hospital for Children (GOSH) or UCL Great Ormond Street Institute of Child Health (ICH) staff working on clinical research.

Further to the requirements listed in this SOP, personnel must also comply with:

* Any additional study-specific requirements mandated by the PI, Sponsor or R&I.

1. **Purpose**

*Brief statement outlining the purpose of the Written Procedure*

1. **Definitions/Abbreviations**

*A list of pertinent definitions and/or abbreviations that may require clarification for the Written Procedure to be understood.*

*If not applicable; write NA.*

*Some common deviations/abbreviations to consider:*

**Clinical Research** – As per UK Framework for Health and Social Care Research and HRA/MRC ‘Is my study research?’ tool.

**CRF** – Clinical Research Facility

**EPR** – Electronic Patient Record *[use this instead of naming Epic]*

**GCP** – Good Clinical Practice

**PI** – Principal Investigator

**NIHR** – National Institute for Health Research

1. **Responsibilities**

Duties may be delegated but the responsibility always remains with those listed.

*The personnel responsible for the major tasks associated with the Written Procedure and their responsibilities; e.g.*

* 1. *[Personnel 1] is responsible for:*
  2. *[Personnel 2] is responsible for:*

*TIP: Instead of using ‘he/she’ use ‘they’ to be more gender inclusive.*

*Suggested text:*

* 1. All study staff are responsible for
     + Ensuring their practice meets the requirements of this SOP, the protocol, GCP and any applicable legislation, policies, procedures or guidelines.

1. **Procedure**

*Details of how the process or procedure is carried out. If there are associated documents or references, these can be detailed in the relevant sections below. Separate headings should be used as appropriate; e.g.*

* 1. *Heading 1*
  2. *Heading 2*

*TIP: Instead of using ‘he/she’ use ‘they’ to be more gender inclusive.*

*Include ‘Support and Escalation’ and ‘Compliance’ sections. Suggested text:*

* 1. **Support and Escalation**

If a staff member has questions or queries they can ask for support from a more experienced colleague or their line manager. If the query is related to a specific study, then the study research nurse, PI and/or CRA may also be able to help.

If a staff member becomes aware of an issue or has any concerns then this must be escalated to the appropriate person(s) in a timely manner (see SOP/R/005 Reporting and Escalation for Research).

* 1. **Compliance**

*Describe the compliance checks e.g. [XX] will be reviewed during routine monitoring/audit.*

Compliance with this SOP will be reviewed during routine monitoring/audit.

Systematic or persistent failure to comply with the study procedures and/or this SOP will be seen as non-compliance to GCP and must be bought to the attention of the Head of Governance, Clinical Trials and Contracts who will decide the appropriate action.

1. **Related Documents**

*List of internal documents related to the Written Procedure (e.g. Trust policies, templates, etc.).*

*If not applicable; write NA.*

1. **References**

*A list of external documents and/or sources referenced by the author during the writing of the Written Procedure (e.g. ICH, MHRA or HRA guidance).*

*If not applicable; write NA.*

1. **Appendices (If applicable)**

*Do not include templates, forms, checklist etc. as appendices; these should be separate documents and listed under ‘Related Documents’.*

*Section can be deleted if not applicable.*