NHS
Great Ormond Street Hospital for Children
Research and Innovation

DIRECTORATE OF RESEARCH AND INNOVATION

Written Procedure Matrix

Staff members will be distributed written procedures based on the below Written Procedure Matrix. It is mandatory for staff members that are distributed written procedure to document that they have read and understood that procedure (in accordance with SOP GOSH/ICH/SOP/R/002 'Training Requirements for Staff Participating in Clinical Research'.

Written Procedures may be relevant to additional staff depending on their role and/or delegated tasks. Staff should document that they have read and understood procedures relevant to them. All written procedures are accessible to all staff (either through Q-Pulse or by request).

The Principal Investigator (PI) is responsible for ensuring written procedures are disseminated to the appropriate members of their study team.

The definition of 'research' is as per the UK Framework for Health and Social Care Research and HRA/MRC 'Is my study research?' tool.

Procedures in highlighted rows are/may be relevant to CIs/PIs.

Research Written Procedures

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R/001	Writing, Approval, Distribution, Control and Review of Written Procedures	All R&I staff	
SOP/R/002	Training Requirements for Staff Participating in Clinical Research	All R&I staff Research Lab Staff **GOSH/ICH PIs for all research studies** **External PIs working in research co-/sponsored by GOSH**	All GOSH/ICH staff working on clinical research studies All external staff working in clinical research co-/sponsored by GOSH

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R/003	Computer Systems Validation (CSV) for Systems used in Research	Quality Assurance R&D Clinical Trials Team R&D Governance Team Research Information R&I Head of Clinical Research Operations, Clinical Research Delivery Manager, Service Manager, Head of Nursing & Patient Experience, Research Matrons, Specialist Clinical Trials and Quality Assurance Pharmacist **GOSH/ICH CIs/PIs who are setting up a computer system for a research study**	Staff involved in setting up the use of a computer system for clinical research
SOP/R/004	Archiving	Clinical Trials Pharmacy Clinical Delivery Team Molecular and Cellular Immunology ICH Non-Clinical Delivery Team Quality Assurance R&D Clinical Trials Team R&D Governance Team Research Lab Staff **GOSH/ICH CIs/PIs for all research studies**	All GOSH/ICH staff working on clinical research studies

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R/005	Reporting and Escalation for Clinical Research Studies	Clinical Trials Pharmacy Clinical Delivery Team Molecular and Cellular Immunology ICH Non-Clinical Delivery Team Quality Assurance R&D Clinical Trials Team R&D Governance Team Research Lab Staff **GOSH/ICH CIs/PIs for all research studies**	All GOSH/ICH staff working on clinical research studies
SOP/R/006	Study Documentation and Monitoring, Audit and Inspection	Clinical Trials Pharmacy Clinical Delivery Team Molecular and Cellular Immunology ICH Non-Clinical Delivery Team Quality Assurance R&D Clinical Trials Team R&D Governance Team Research Lab Staff **GOSH/ICH CIs/PIs for all research studies**	All GOSH/ICH staff working on clinical research studies
SOP/R/009	R&I Directorate Operations	All R&I staff	

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R/010	Investigator Site Research Team Responsibilities	Clinical Trials Pharmacy Clinical Delivery Team Molecular and Cellular Immunology ICH Non-Clinical Delivery Team Quality Assurance R&D Clinical Trials Team R&D Governance Team Research Lab Staff **GOSH/ICH CIs/PIs for all research studies**	All GOSH/ICH staff working on clinical research studies
SOP/R/034	Informed Consent for Research	Clinical Delivery Team Molecular and Cellular Immunology ICH Non-Clinical Delivery Team Quality Assurance R&D Clinical Trials Team R&D Governance Team **GOSH/ICH CIs/PIs for all research studies**	All GOSH/ICH staff working on clinical research studies
SOP/R/035	Dose Escalation	Clinical Trials Pharmacy Quality Assurance R&D Clinical Trials Team R&D Governance Team **GOSH/ICH CIs/PIs for research studies involving dose escalation**	Staff involved in set-up/conduct of studies that involve dose escalation

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R/037	Unblinding	Clinical Trials Pharmacy Quality Assurance R&D Clinical Trials Team R&D Governance Team **GOSH/ICH CIs/PIs for research studies involving blinding**	Staff involved in set-up/conduct of studies that involve blinding
CT05	Designing a Case Report Form (CRF)	R&D Clinical Trials Team	CIs for GOSH co-/sponsored CTIMP Any staff delegated to design the CRF
CT11	Subject Screening, Enrolment and Identification Logs	R&D Clinical Trials Team	All GOSH/ICH staff working on CTIMP co-/sponsored by GOSH All external staff working on CTIMP co-/ sponsored by GOSH

R&D Written Procedures

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R&D/001	CTIMP Sponsorship	R&D Clinical Trials Team Research Finance Team	CIs applying for GOSH co-/sponsorship for a CTIMP
SOP/R&D/002	Clinical Research Adoptions Committee (CRAC) SOP	CRAC Committee Members	
SOP/R&D/003	Essential Documents for Trials Master File	R&D Clinical Trials Team	

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R&D/004	Identification and approval of sponsorship for non-CTIMPs	R&D Clinical Trials Team R&D Governance Team Research Finance Team	CIs applying for GOSH co-/sponsorship for a non-CTIMP
SOP/R&D/005	Amendments	R&D Clinical Trials Team R&D Governance Team	CIs for GOSH co-/sponsored studies if delegated this task in the Sponsor agreement
SOP/R&D/006	Monitoring CTIMPs	R&D Clinical Trials Team	
SOP/R&D/007	Pharmacovigilance and Safety Reporting	R&D Clinical Trials Team	CIs for GOSH co-/sponsored studies if delegated this task in the Sponsor agreement
SOP/R&D/014	Obtaining and Maintaining Approvals for GOSH Sponsored CTIMPs	R&D Clinical Trials Team	CIs for GOSH co-/sponsored studies if delegated this task in the Sponsor agreement
SOP/R&D/015	Vendor Management for GOSH Sponsored Clinical Trials	R&D Clinical Trials Team R&D Contracts Team	CIs for GOSH co-/sponsored studies if delegated this task in the Sponsor agreement
SOP/R&D/017	Research grants support and management	R&D Grants Team Research Finance Team	
SOP/R&D/021	Commercial Research Invoicing & Reallocation of Funds	R&D Clinical Trials Team R&D Governance Team Research Finance Team	
SOP/R&D/023	Indemnity	R&D Clinical Trials Team R&D Governance Team	
SOP/R&D/024	Data Protection	R&D Clinical Trials Team R&D Governance Team	
SOP/R&D/025	Human Tissue Act Compliance	R&D Clinical Trials Team R&D Governance Team	

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/R&D/027	R&D Permissions	R&D Clinical Trials Team R&D Governance Team	
SOP/R&D/028	Research Passports, Letters of Access & Honorary Research Contracts	R&D Clinical Trials Team R&D Governance Team	
CT02	Regulatory Green Light Process for Clinical Trials of Investigational Medicinal Products	R&D Clinical Trials Team	
RG30	Auditing of Research Studies	Quality Assurance R&D Clinical Trials Team R&D Governance Team	
GA33	Internal Grant Scheme Procedure	R&D Grants Team NIHR GOSH BRC Team Research Finance Team	

CRF Written Procedures

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/CRF/001	Ordering, Storage and Administration Of Medicines In The CRF	Clinical Delivery Team Clinical Trials Pharmacy	PIs and Investigators for CRF studies
SOP/CRF/002	Booking Appointments, Admission, Discharge and Transfer of Study Participants in the CRF	Clinical Delivery Team Non-Clinical Delivery Team	

Document Number GOSH/ICH/	Document Title	Distribution List/Copy Holders	Additional Relevant Staff Members
SOP/CRF/003	Clinical Research Facility (CRF) Operations	Clinical Delivery Team Non-Clinical Delivery Team Clinical Trials Pharmacy Director of CRF	PIs and Investigators for CRF studies
SOP/CRF/006	Emergency Scenario Training Programme	Clinical Delivery Team	

R&I Staff Groups Key

Clinical Delivery Team	Head of Nursing, Matrons, Practice Educator, Senior Research Nurses, Research Nurses, Practice Facilitator, Assistant Research Practitioner (ARP), Health Care Assistant (HCA)
Clinical Trials Pharmacy	Principal Pharmacist for Clinical Trials and Audits, Specialist Clinical Trials and Quality Assurance Pharmacist, Specialist Clinical Trials Pharmacist, Senior Clinical Trials Pharmacy Technician
Molecular and Cellular Immunology ICH	Clinical Project Manager, ICH (Finance & Contracts) Coordinator
NIHR GOSH BRC Team	Deputy Director of Operations, BRC Research Coordinator, Rare Disease Cohorts Theme Coordinator, BRC Training Facilitator
Non-Clinical Delivery Team	Head of Operations, Clinical Research Delivery Manager, Research Portfolio Manager, CRF Service Manager, Senior Research Coordinators, Research Coordinators, Data Managers, Office Manager, Research Administrators and Receptionists
PPI/E	PPI/E Lead in Research
Quality Assurance	R&I Quality Assurance Manager, Quality Assurance / Research Governance Officer
R&D Clinical Trials Team	Head of Governance, Clinical Trials and Contracts, Clinical Trials Manager, Clinical Trials Coordinator
R&D Contracts Team	Head of Governance, Clinical Trials and Contracts, Contracts Manager, Contracts Officer
R&D Governance Team	Head of Research Governance, Clinical Trials and Contracts, Research Governance Manager, Research Management,

	Research Governance Officer, QA & Research Governance Officer, Research Governance Administrators
R&D Grants Team	Senior Research Project Manager, Clinical Research Facilitator, Clinical Research Administrator - Registration
R&I Directors	Director of R&I, Deputy Director of R&I, Director of the CRF, PA / Office Manager
Research Communications	Research Communications Manager, Senior Communications and Engagement
Research Finance Team	Finance Manager, Management Accountant, Finance and Performance Manager, Research Costing and Grants Administrator, Research Finance Lead: Commercial, Research Administrator
Research Hospital	Project Manager: Research Hospital, Programme Coordinator
Research Information	Systems and Data Manager
Research Lab Staff	Pathology Lead Quality and Risk Manager Laboratory Medicine, Research Lab Manager, Biomedical Scientist, Medical Laboratory Assistant