

NIHR Guideline B01

R&D Operational Capability Statement

Version History

Version number RDOCS 002 V_11.2	Valid from 09/01/2020	Valid to 31/09/2020	Date approved 09/01/2020	Updated by Carole Paley
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Signed on behalf of the Trust Board by Karl Mainprize, Medical Director	
DATE	

Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	Airedale NHS Foundation Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Karl Mainprize, Medical Director
R&D Office details:	
Name:	Dr. Carole Paley, Head of Research
Address:	Airedale NHS Foundation Trust Research Office, Ward 12 location A-A27, Skipton Road, Steeton, Keighley, BD20 6TD
Contact Number:	01535 292278 (Direct line)
Contact Email:	carole.paley@nhs.net
Other relevant information:	

Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details	
Contact 1:	
Role:	Research Support and Governance Manager
Name:	Mechele Couch-Upite
Contact Number:	01535 294655
Contact Email:	mechele.couch-upite@anhst.nhs.uk
Contact 2:	
Role:	Research Support and Governance Officer
Name:	Lucy Sootheran
Contact Number:	01535 294655
Contact Email:	Lucy.soootheran@nhs.net
Contact 3:	
Role:	Research Support and Governance Facilitator
Name:	
Contact Number:	
Contact Email:	
Contact 4:	
Role:	Senior Research Sisters
Name:	Alison Shaw and Emma Dooks
Contact Number:	01535 293934/292279
Contact Emails:	alison.shaw4@nhs.net ; emma.dooks1@nhs.net
Contact 5:	
Role:	Clinical Lead for R&D
Name:	Dr Michael Crawford
Contact Number:	01535 293933
Contact Email:	michael.crawford@anhst.nhs.uk

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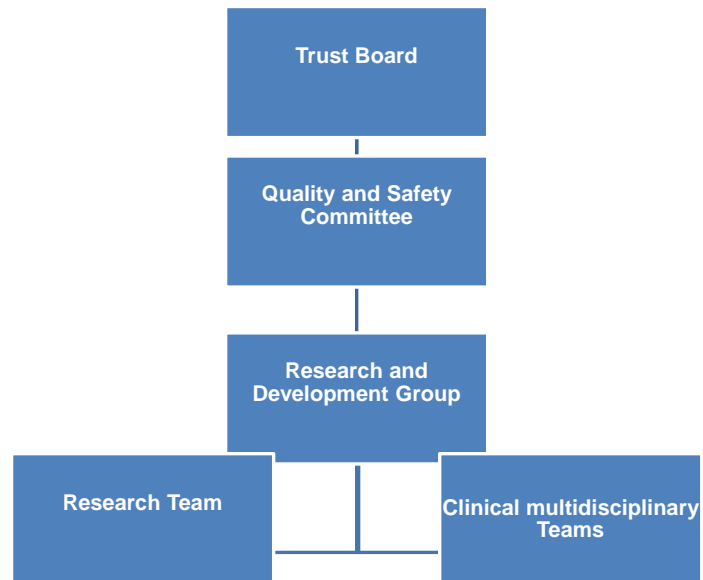
Information on staffing of the R&D Office

R&D Team		
R&D Office Roles (e.g. Governance, Contracts, etc)	Whole Time Equivalent	Comments indicate if shared/joint/week days in office etc
Head of Research and Innovation	0.85	
Research Support and Governance Manager	0.80	Working days: Monday-Thursday
Research Support and Governance Officer	0.40	Flexible working Monday-Friday
Research Support and Governance Facilitator	0.60	Flexible working Tuesday- Thursday
Senior Research Sisters	0.8 and 1.0	There is full-week cover

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Reporting Structures

The Research and Development Group (RDG) meets quarterly and reports into the Quality and Safety Committee which is a sub-committee of the Foundation Trust Board. An annual report is submitted to the Trust Board via the Quality and Safety Committee. In addition, quarterly KPIs are reported to the Board on an Integrated Governance dashboard which provides internal assurance. A flowchart showing the reporting structure is included below.



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Information on Research Networks supporting/working with the Organisation.

Information on how the Organisation works with the Local Clinical Research Network (LCRN) and the divisions/specialty groups.

Research Networks	
Research Network (name/location)	Role/relationship of the Research Network eg host Organisation
LCRN Yorks & the Humber	Partner Organisation
Divisions and Specialty groups	Working closely with the divisions and speciality leads in divisions and research delivery managers.

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Information on collaborations and partnerships for research activity (e.g. Biomedical Research Centre/Unit, Other NHS Organisations, Higher Education Institutes, Industry)

Current Collaborations / Partnerships				
Organisation Name	Details of Collaboration / Partnership (eg	Contact Name	Email address	Contact Number
Bradford Institute for Health Research (BIHR)	Partner organisation	Tracy Watson	tracy.watson@bthft.nhs.uk	01274 382342
Bradford District Care Trust	Memorandum of Understanding	John Hiley	john.hiley@bdct.nhs.uk	01274 363258
West Yorkshire R&D		Paul Carder	paul.carder@bradford.nhs.uk	01274 237406
NHS Airedale, Wharfedale and Craven CCG		Stella Johnson	Rebecca.Harper@bradford.nhs.uk	

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Organisation Study Capabilities

Information on the types of studies that can be supported by the Organisation to the relevant regulatory standards

Types of Studies Organisation has capabilities in (please tick applicable)					
	CTIMPs (indicate Phases)	Clinical Trial of a Medical Device	Other Clinical Studies	Study Administering Questionnaires	OTHER
As Sponsoring Organisation	N/A	N/A	✓	✓	
As Participating Organisation	✓ (phases II-IV)	✓	✓	✓	
As Continuing Care Site	✓	✓	✓	✓	
As Participant Identification Centre	✓ (phases II-IV)	✓	✓	✓	

Add lines in the table as required by selecting and then copying a whole Excel row which is a part of the table (note: select and copy the row **not** cells in the row).

Then select a **row** in the table and 'insert copied cells'. (Please do not select and copy individual cells or groups of cells as this does not preserve formatting.)

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Which licences does the organisation hold which may be relevant to research?

Organisation Licences			
Licence Name	Licence Details	Licence Start Date (if applicable)	Licence End Date (if applicable)
Example: Human Tissue Authority Licence			
Material Transfer Agreement	The agreement between the Ethical Tissue Bank (University of Bradford) and Airedale NHS Foundation Trust	19/05/2015	N/A

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Organisation Services

Information on key clinical services contacts and facilities/equipment which may be used in studies for supporting R&D governance decisions across the organisation.

Clinical Service Departments				
Service Department	Specialist facilities that may be provided (eg	Contact Name within Service Department	Contact email	Details of any internal agreement templates and other comments
<i>Pathology</i>	Clinical Chemistry	Dr Afruj Ruf	afruj.ruf@anhst.nhs.uk	
	Haematology/Blood Transfusion	Dr Afruj Ruf	afruj.ruf@anhst.nhs.uk	
	Histopathology	Dr Afruj Ruf	afruj.ruf@anhst.nhs.uk	
	Microbiology	Dr Afruj Ruf	afruj.ruf@anhst.nhs.uk	
<i>Radiology</i>	CT: 2 scanners. 128 slice and 64 slice	Deborah Walker	deborah.walker@ansht.nhs.uk	
	MRI: 1 scanner.1.5 Tesla	Deborah Walker	deborah.walker@ansht.nhs.uk	
	Plain film: 3 available units all linked to PACS	Deborah Walker	deborah.walker@ansht.nhs.uk	
	Ultrasound: 3 available units	Deborah Walker	deborah.walker@ansht.nhs.uk	
	DEXA: 1 scanner	Deborah Walker	deborah.walker@ansht.nhs.uk	
	Fluoroscopy: 2 units	Deborah Walker	deborah.walker@ansht.nhs.uk	
	Nuclear medicine	Deborah Walker	deborah.walker@ansht.nhs.uk	This service is based at Bradford but contact may be made via Radiology.
	Specialist radiological protection advice (based in Bradford)	Shaun Beggs	shaun.beggs@bthft.nhs.uk	A service-level agreement exists between Airedale NHS FT and the RPA advisor at St Lukes, Bradford.
<i>Pharmacy</i>	Aseptics	Andrew Gash	andrew.gash@anhst.nhs.uk	
		Gill Darnbrook	gillian.darnbrook@anhst.nhs.uk	

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Information on key management contacts for supporting R&D governance decisions across the organisation.

Management Support e.g. Finance, Legal Services, Archiving				
Department	Specialist services that may be provided	Contact Name within Service Department	Contact email	Details of any internal agreement templates and other comments
<i>Archiving</i>	Storage of archived materials, e.g. patient notes.	Carole Paley, Head of Research & Innovation	carole.paley@anhst.nhs.co.uk	R&D Archiving SOP
<i>Contracts</i>	Review of clinical trial agreements and main signatory	Carole Paley, Head of Research & Innovation	carole.paley@anhst.nhs.co.uk	
<i>Data management support</i>	data management and administrative	Helen Henson	helen.henson@nhs.net	
<i>Finance</i>	Controls R&D finance (income/exp) and provides budget and forecast information.	Richard Barrett	richard.barrett@anhst.nhs.uk	
<i>Information Technology</i>	Advice on implementation of IT systems and software to support research and maintenance of current systems, email accounts and internal Sharepoint.	Andrew Leng	andrew.leng@anhst.nhs.uk	
<i>Information Governance</i>	Advice on IG issues, data protection and confidentiality.	Jenny Pope, Head of IG or Kevin Denham, IG Manager	jenny.pope@anhst.nhs.uk kevin.denham@anhst.nhs.uk	
<i>Research Support and Governance</i>	Advice and support on Resarch Governance, ethics and R&D approvals from first interest to study closure and archiving. Performance records and data storage.	Mechele Couch-Upite, Research Support and Governance Manager	mechele.couch-upite@anhst.nhs.uk	
<i>HR</i>	Head of HR. Will provide contact details of correct HR advisor on Hon contracts, research passports, letters of access, staffing.	Joanne Harrison	joanne.harrison@anhst.nhs.uk	Formal organisational commitment to supporting the Research Passport scheme.
<i>Statistical support</i>	Occasional support/advice on statistics may be arranged.	Carole Paley, Head of Research & Innovation	carole.paley@nhs.net	Researchers are expected to organise their own statistical support. However, occasionally this is not possible and we have SPSS support and advice available for this eventuality.
<i>Caldicott Guardian</i>	Caldicott Guardian Review	Dr Justin Tuggey	justin.tuggey@anhst.nhs.uk	
<i>Healthcare Governance</i>	Healthcare governance, CQC, quality and safety	Helen Kelly	helen.kelly@anhst.nhs.uk	
<i>Clinical Quality Analyst</i>	Quality and Safety	Caroline Booton	caroline.booton@anhst.nhs.uk	CQC registration, Quality Account

Add lines in the table as required by selecting and then copying a whole Excel row which is a part of the table (note: select and copy the row **not** cells in the row). Then select a **row** in the table and 'insert copied cells'. (Please do not select and copy individual cells or groups of cells as this does not preserve formatting.)

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Organisation R&D Interests

Information on the areas of research interest to the Organisation

Organisation R&D Areas of Interest					
Area of Interest	Details	Contact Name	Contact Email	Contact Number	
Oncology (Medical)	Consultant Medical Oncologist	Dr Shazza Rehman	shazza.rehman@anhst.nhs.uk	01535 292947	
Oncology (Medical)	Consultant Medical Oncologist	Dr Andrew Conn	andrew.conn@bthft.nhs.uk	01535 292947	
Oncology (Medical)	Consultant Medical Oncologist	Dr Simon Brown	simon.brown@bthft.nhs.uk	01535 292947	
Haematology	Consultant Haematologist	Dr Emma Nga	emma.nga@anhst.nhs.uk	01535 293480	
Urology	Consultant Urologist	Mr Philip Koenig	philip.koenig@anhst.nhs.uk	01535 292136	
Surgery	Consultant Surgeon	Ms Claire Murphy	claire.murphy@anhst.nhs.uk	01535 292156	
Surgery	Consultant Surgeon	Mr Omer Baldo	omer.baldo@anhst.nhs.uk	01535 292136	
Surgery	Consultant Surgeon	Mr Chris Newman	chris.newman@anhst.nhs.uk	01535 292146	
Surgery	Consultant Surgeon	Mr Basit Khan	basit.khan@anhst.nhs.uk	01535 292159	
Surgery	Consultant Surgeon	Mr Tarig Ahmed	tarig.ahmed@anhst.nhs.uk	01535 292146	
Gastroenterology	Consultant Gastroenterologist	Dr Chris Healey	chris.healey@anhst.nhs.uk	01535 292037	
Gastroenterology	Consultant Gastroenterologist	Dr Richard Shenderey	richard.shenderey@anhst.nhs.uk	01535 292368	
Gastroenterology	Clinical Specialist IBD Nurse	Joanna McConnell	joanna.mcconnell@anhst.nhs.uk	01535 292369	
Diabetes	Consultant Diabetologist	Dr Andrew Pettit	andrew.pettit@anhst.nhs.uk	01535 292027	
Diabetes	Consultant Diabetologist	Dr Thet Koko	thet.koko@anhst.nhs.uk	01535 294385	
Paediatrics	Consultant Paediatrician	Dr Pronab Bala	pronab.bala@anhst.nhs.uk	01535 292426	
Paediatrics	Consultant Paediatrician	Dr Matthew Babirecki	matthew.babirecki@anhst.nhs.uk	01535 292434	
Paediatrics	Consultant Paediatrician	Dr Geeta Suryanarayan	Geeta.Suryanarayan@anhst.nhs.uk	01535 292414	

Obstetrics and Gynaecology	Consultant Obstetrician	Dr Kathleen Graham	kathleen.graham@anhst.nhs.uk	01535 293225	
Obstetrics and Gynaecology	Consultant Obstetrician	Dr Sumita Bhuyia	sumita.bhuyia@anhst.nhs.uk	01535 292226	
Obstetrics and Gynaecology	Consultant Obstetrician	Mr Stephen Porter	stephen.porter@anhst.nhs.uk	01535 292205	
Obstetrics and Gynaecology	Consultant Obstetrician	Miss Juhi Siddiqui	juhi.siddiqui@anhst.nhs.uk	01535 293227	
Histopathology	Consultant Histopathologist	Dr John O'Dowd	john.odowd@anhst.nhs.uk	01535 293468	
Histopathology	Consultant Histopathologist	Dr Philip Da Costa	philip.DaCosta@anhst.nhs.uk	01535 293467	
Microbiology	Consultant Microbiologist	Dr Emma Williamson	emma.williamson@anhst.nhs.uk	01535 293465	
Palliative Care	Consultant in Palliative Medicine	Dr Linda Wilson	linda.wilson@anhst.nhs.uk	01535 292184	
Palliative Care	Consultant in Palliative Medicine	Dr Mike Hughes	mike.hughes@anhst.nhs.uk	01535 292184	
Respiratory Care	Consultant in Respiratory Medicine	Dr Alan Hart-Thomas	Alan.Hart-Thomas@anhst.nhs.uk	01535 292064	
Respiratory Care	Consultant in Respiratory Medicine	Dr Su Ann Leong	sueann.leong@anhst.nhs.uk		
Stroke	Consultant Stroke Physician	Dr.Eman AbdusSami	Eman.AbdusSami@anhst.nhs.uk	01535 292055	
Cardiology	Consultant Cardiologist	Dr Basel Hanbali	basel.hanbali@anhst.nhs.uk	01535 292017	
Cardiology	Consultant Cardiologist	Dr John Smyllie	john.smyllie@anhst.nhs.uk	01535 293016	
Cardiology	Consultant Cardiologist	Dr Hossam Elmahy	hossam.elmahy@anhst.nhs.uk	01535 292017	
Cardiology	Consultant Cardiologist	Dr Richard Best	richard.best@anhst.nhs.uk	01535 292017	
Anaesthetics	Consultant Anaesthetist	Dr Wendy Lum Hee	wendy.lumhee@anhst.nhs.uk	01535 292185	
Anaesthetics	Consultant Anaesthetist	Dr Julian Hood	julian.hood@anhst.nhs.uk	01535 292185	
Anaesthetics	Consultant Anaesthetist	Dr Gary Reah	gary.reah@anhst.nhs.uk	01535 292185	
Anaesthetics	Consultant Anaesthetist	Dr Rachel Ingham	rachel.ingham@anhst.nhs.uk	01535 292185	
Orthopaedics	Consultant Orthopaedic Surgeon	Mr David Bowe	david.bowe@anhst.nhs.uk	01535 292116	
Orthopaedics	Consultant Orthopaedic Surgeon	Mr Peter Leggeter	peter.leggeter@anhst.nhs.uk	01535 292095	
Orthopaedics	Orthopaedic Registrar	Mr Avijeet Ghosh	avijeet.ghosh@anhst.nhs.uk	01535 292116	
Orthopaedics	Research nurse and main contact for clinical trials for this area of interest.	Emma Dooks	emma.dooks@anhst.nhs.uk	01535 292279	

Rheumatology	Consultant Rheumatologist	Dr Shabina Sultan	shabina.sultan@anhst.nhs.uk	01535 292067	
Rheumatology	Research nurse and main contact for clinical trials for this area of interest.	Emma Dooks	emma.dooks@anhst.nhs.uk	01535 292279	
Matrons	Head of Nursing (integrated care)	Annie McCluskey	Annie.McCluskey@anhst.nhs.uk	01535 292123	
Matrons	Head of Nursing (surgery)	Denise Todd	denise.todd@anhst.nhs.uk	01535 292121	
Maternity	Research Midwife and main contact for clinical trials for this area of interest.	Emma Dooks	emma.dooks@anhst.nhs.uk	01535 292279	
Maternity and Generic	Research Nurse/Midwife and main contact for clinical trials for this area of interest.	Sophie Packham	sophie.packham@nhs.net	01535 292839	
Rehabilitation Medicine	Consultant Rehabilitation	Elizabeth Stoppard	elizabeth.stoppard@anhst.nhs.uk	01535 292747	
Elderly Medicine	Consultant Elderly Medicine	Dr Paul Milnes	paul.milnes@anhst.nhs.uk	01535 292744	
Occupational Therapy	Occupational Therapy Professional Lead	Sue Atkinson	sue.atkinson@anhst.nhs.uk	01535 293422	
Cancer - haematology and oncology	Lead research nurse and main contact for clinical trials for this area of interest.	Alison Shaw	alison.shaw@anhst.nhs.uk	01535 293934	
Cancer - haematology and oncology	Clinical Nurse Specialist Haematology and Oncology.	Pat Dyminski	patricia.dyminski@anhst.nhs.uk	01535 292838	
Cardiology/Stroke	Lead research nurse and main contact for clinical trials for this area of interest.	Brigid Hairsine	brigid.hairsine@anhst.nhs.uk	01535 292839	
Cardiology/Cancer	Clinical Trials Coordinator and main contact for clinical trials for this area of	Claire Kurasz	claire.kurasz@anhst.nhs.uk	01535 292837	
Cancer - haematology and oncology	Lead research nurse and main contact for clinical trials for this area of interest.	Fiona Farquhar	fiona.farquhar@anhst.nhs.uk	01535 292837	
Cancer - haematology and oncology	Lead research nurse and main contact for clinical trials for this area of interest.	Hayley Bates	hayley.bates@anhst.nhs.uk	01535 292839	

Gastroenterology	Research Nurse and main contact for clinical trials for this area of interest.	Emma Dooks	emma.dooks@anhst.nhs.uk	01535 292279	
Gastroenterology/Neuro/Diabetes	Clinical Trials Coordinator and main contact for clinical trials for this area of	Sally Mitchell	sally/mitchell@anhst.nhs.uk	01535 292838	
Critical Care and Digital Care	Nurse consultant	Rachel Binks	rachel.binks@anhst.nhs.uk	01535 292268	
Neurology	Consultant Neurologist	Dr Marek Kunc	marek.kunc@anhst.nhs.uk	01535 292743	
Neurology	Consultant Neurologist	Dr Zbigniew Slowinski	zbigniew.Slowinski@anhst.nhs.uk	01535 292743	
Neurology	Research Nurse and main contact for clinical trials for this area of interest.	Emma Dooks	emma.dooks@anhst.nhs.uk	01535 292279	
Paediatrics	Research nurse and main contact for clinical trials for this area of interest.	Amy Kitching	amy.kitching@anhst.nhs.uk	01535 292385	
Therapy services	Therapy services manager	Freya Sledding	freya.sledding@anhst.nhs.uk	01535 294851	

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Information on Local / National Specialty group membership within the Organisation which has been shared with the LCRN

Specialty Group Membership (Local and National)

National / Local	Specialty Group	Specialty Area (if only specific areas within group)	Contact Name	Contact Number
Yorkshire & the Humber Local Clinical Research Network (LCRN)	Divisions 1-6	N/A	admin.crn.yorkshumber@nhr.ac.uk	0113 206 7583

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Organisation R&D Planning and Investments

Planned Investment

Area of Investment (e.g. Facilities, Training, Recruitment, Equipment etc.)	Description of Planned Investment	Value of Investment	Indicative dates

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Organisation R&D Standard Operating Procedures Register

Standard Operating Procedures			
SOP Ref Number	SOP Title	SOP Details	Valid to
RD/SOP/01	Preparation, Review and Approval of Standard Operating Procedures for Research	Describes the procedures used when preparing SOPs.	31/03/2020
RD/SOP/02	Setup and Control External Agreements	Describes the procedures used when setting up research agreements and contracts with external organisations.	31/03/2020
RD/SOP/03	Setup and Control Internal Agreements	Describes the procedures used when setting up research agreements with internal departments within the Trust.	31/03/2020
RD/SOP/04	Setup and Control Study Processes	Describes the checks and processes required in study set-up which enable the Trust to manage risks to itself, its staff and patients, and to the integrity of the Study	31/03/2020
RD/SOP/05	Granting NHS Permission for Research Projects that are NOT Clinical Trials of Investigational Medicinal Products (CTIMPs)	Describes the processes involved when setting up trials which are not trials of investigational medical products.	VOID
RD/SOP/06	Confirming Local Capacity and Capability for Clinical Trials	Describes the processes involved when confirming capacity and capability for clinical trials of all types	31/03/2020
RD/SOP/07	Audit and Monitoring of clinical trials	Describes the procedures the R&D office uses when providing a proportionate level of oversight of a study on behalf of the Trust.	31/03/2020
RD/SOP/08	R&D SAE/SUSAR Handling Procedure	Describes the processes used when an expected or unexpected serious adverse event occurs.	31/03/2018
RD/SOP/09	Site Study Closedown	Describes the process of closing a study.	31/03/2020
RD/SOP/10	Setting up and Controlling Finance	Describes the financial processes involved prior to the start of a study.	VOID
RD/SOP/11	Overseeing Organisational Study Finance	Describes the overseeing of financial processes during the study and finalising the study finances on closedown	31/03/2021

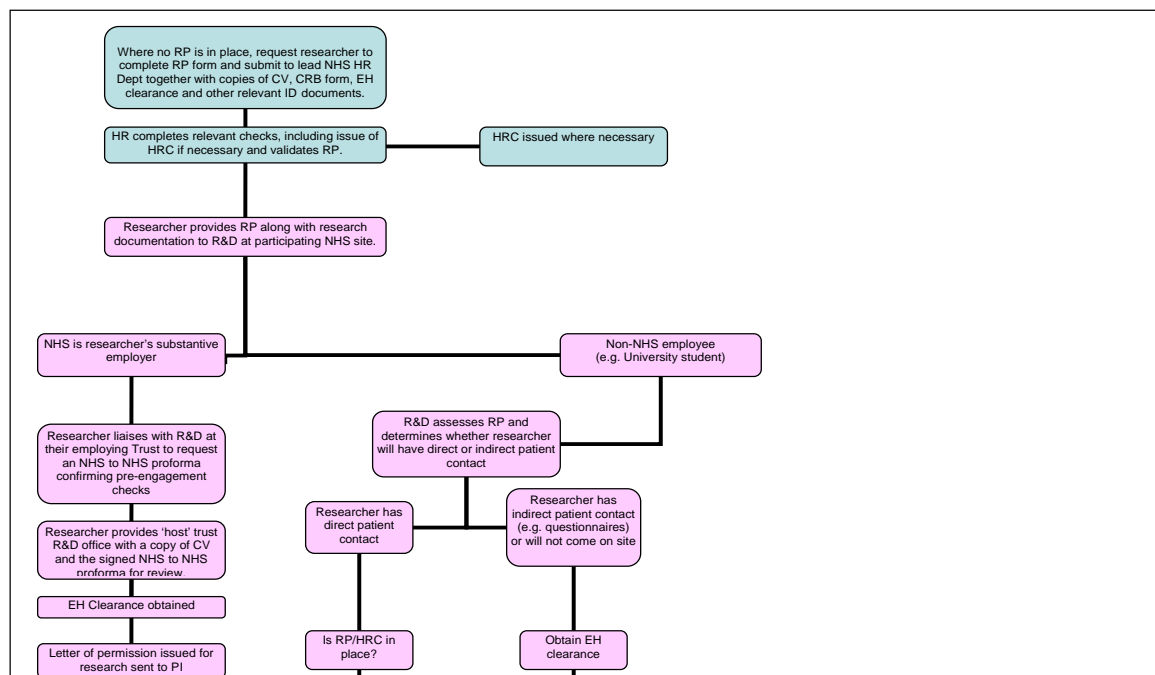
RD/SOP/12	Processing and managing Amendments	Describes the processes involved in checking and agreeing study amendments	31/03/2021
RD/SOP/13	Archiving of Study Documents	Describes the process for archiving all study documents locally	30/09/2021
RD/SOP/14	Application Process of An Honorary Contract, Research Passport or Letter of Access	Describes the processes involved in agreeing access to researchers from outside the trust.	31/03/2020
RD/SOP/15	Site File Set-Up and Maintenance	Describes how trial site files should be set up, what they should contain and the procedures for maintaining them.	31/03/2020
RD/SOP/16	Obtaining Informed Consent in Clinical Trials	Describes the process involved in obtaining informed consent for participants taking part in clinical trials	31/03/2020
RD/SOP/17	Costing and trial authorisation procedure for Key Service Support Departments	Gives a description of how departmental authorisation is obtained prior to trial set-up and how trials should be costed.	31/03/2020
RD/SOP/18	Set-up and management of clinical trials (hosted studies only)	Describes how clinical trials are set up and managed (hosted studies) from the receipt of a site specific information form and throughout the course of the trial.	31/03/2020
RD/SOP/19	Handling of medical records	Describes the process of booking out, retrieving and returning medical records.	31/03/2020
RD/SOP/20	Histopathology Procedures	Describes the processes involved when samples such as tumour blocks need to be retrieved from Histopathology.	31/03/2020
RD/SOP/21	Manage Participating Organisation Study Planning Tool	Describes the activities to complete an early and quick study planning assessment using the Participating Organisation Study Planning Tool	31/03/2020
RD/SOP/22	Manage the R&D Operational Capability Statement	Describes the activities to manage the content of the R&D Operational Capability Statement	31/03/2020
RD/SOP/23	Lone/Community Working in Research	Describes the procedures and safeguards to be taken when lone working	31/03/2020
RD/SOP/24	HRA Approval Process	Describes the process of study approval by the Health Research Authority which includes ethics review.	VOID

RD/SOP/25	Data Protection in Clinical Research	Describes the processes and procedures necessary for the protection of participant data.	01/12/2019
RD/SOP/26	Serious Breaches of GCP or Trial Protocol	Explains the procedures to be undertaken when a serious breach of trial protocol occurs.	01/12/2019
RD/SOP/27	MHRA Inspection Procedure	Explains the procedures to be undertaken when the MHRA inform the organisation that a GCP inspection will take place.	24/06/2022
RD/SOP/28	Electronic Records in Research	Explains the processes and procedures involved in ensuring that the use of electronic records meets research governance regulations.	24/06/2022
RD/SOP/29	Using the EDGE Database	This provides details of how the EDGE database should be used and the processes involved, including links to step-by-step guides.	24/06/2022

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Indicate what processes are used for managing Research Passports

Research Passports (RPs) are managed by the R&D Office and HR in accordance with the current guidance: HR Good Practice Resource Pack (http://www.nihr.ac.uk/systems/pages/systems_research_passports.aspx). The flowchart for processing research passports and letters of access (LOAs) is shown below.



Escalation Process

Information on the agreed Escalation Process to be used when R&D governance issues cannot be resolved through normal processes: The Research and Innovation Strategy Group (RISG), chaired by the R&D Clinical Lead (co-chaired by the Medical Director), will discuss any issues arising which cannot be resolved through day to day governance processes. Depending on the issue, the matter may also be referred to the relevant specialist, e.g. the Trust legal representative, the Caldicott Guardian, Risk Manager, Medical Director or Assistant Director of Healthcare Governance. The matter may also be discussed by the Quality Assurance & Improvement Committee, the Clinical Learning Forum or the Executive Assurance Group. If the issue is a Suspected Unexpected Serious Adverse Reaction (SUSAR) this will be reported via the Risk Department and escalated through the Serious Incidents Requiring Investigation procedure within the Trust (see SIRI policy). All adverse events and reactions are automatically reported to the trials office for the Trial concerned.

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Planned and Actual Studies Register

The Organisation should maintain or have access to a current list of planned and actual studies which its staff lead or collaborate in.

Comments

In addition to using the national EDGE database, the Trust holds an internal database and tracker which lists all the current and planned studies. All studies undergoing the approval process are tracked at each stage and studies currently running are monitored for level of patient recruitment and performance against target recruitment. All National Portfolio studies currently running are listed on AireShare, together with their protocols and other study documentation.

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Other Information

For example, where can information be found about the publications and other outcomes of research which key staff led or collaborated in?

Other Information (relevant to the capability of the Organisation)

Information regarding publications, conference presentations/posters and the outcomes of research are held in the R&D Office and published in the Annual Report, on the external Trust website and the Quality Account.

A register of IP is also held in the R&D office. All documentation, lists of SOPs and lists of publications and presentations are published on AireShare.