

# NIHR Guideline B01

## R&D Operational Capability Statement

May 2011

Note: This spreadsheet is protected to help avoid inadvertent changes. However there is no password set so that users can unlock the sheet and edit their own content if required.

### Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
Statement 001	23/12/2014	03/03/2016	14/12/2014	23/12/2014	28/11/2014
Statement 002			Medical Director	Quality Governance Committee and The Trust Board on 03/03/2015	Dr. Tanweer Ahmed and Discussed & agreed with R & D Director
Statement 003	20/11/2018	31/12/2021	Trust R & I Committee 15/05/2018 Clinical Management Board 21st June 2018 Quality Governance Committee 20th November 2018		Updated on 22/11/2018 Discussed with Medical Director on 24/05/2018

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### Organisation R&D management arrangements

Information on key contacts.

Organisation details	
Name of organisation	United Lincolnshire Hospitals NHS Trust
R&D lead / Director (with responsibility for reporting on R&D to the organisation Board)	Dr. Neill Hepburn-Medical Director with responsibility for reporting on R & I to the Trust Board/Professor Tanweer Ahmed (Joint R & I Director & Director of LCRF & IP Lead).Professor Paul Lee Co-Director R & I)
R&D office details:	
Name:	Simone Seychell, PA to Prof T. Ahmed
Address:	Lincolnshire Clinical Research Facility (LCRF), Lincoln County Hospital, Lincoln, LN2 5QY
Contact number:	01522 512512 extn 582059
Contact email:	simone.seychell@ulh.nhs.uk
Other relevant information:	
Key contact details e.g. Research governance lead, NHS Permissions signatory contact details	
Contact 1:	
Role:	Joint R & I Director & Director of LCRF & IP Lead
Name:	Prof Tanweer Ahmed
Contact number:	01522 573941
Contact email:	tanweer.ahmed@ulh.nhs.uk
Contact 2:	
Role:	Co-Director of R & I
Name:	Prof. Paul Lee
Contact number:	01205 446311
Contact email:	paul.lee@ulh.nhs.uk
Contact 3:	
Role:	Medical Director
Name:	Dr Neill Hepburn
Contact number:	01522 573978
Contact email:	neill.hepburn@ulh.nhs.uk

Add further contacts by selecting and then **copying** the five Excel **rows** (i.e. whole rows) above for Contact, role, name, number and email. Then select the **blank row** under 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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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
R & I Co-Director	1.25 PAs	Consultant Physician 90%, R & D 10%
Director of Lincolnshire Clinical Research Facility/Joint Director of R & I & IP Lead	1 wte	70% role is to manage Clinical Research Facility and 30% is R & I Management and Governance
Research Manager	0.8 wte	3 days/week Research Governance and 1 day/week Quality assurance
Study Support Service Facilitator	0.8 wte	To support Research governance & study Feasibility across the Trust
Study Support Service coordinator	1 wte	To support R & I team
PA to Director of LCRF and Joint Director of R & I & IP Lead	1 wte	To Support Joint R & I Director and Director of LCRF and R & I meetings
Project manager	0.4 wte	To support R & I Department

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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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Information on reporting structure in organisation (include information on any relevant committees, for example, a clinical research board / research committee / steering committee).

Reporting structures
The Trust R & I Committee meets 3 times/year. The Committee is Chaired by the Joint R & I Director/Director of LCRF and co-chair by Co-Director of R & I and reports to the Trust Quality Governance Committee. The committee discuss all issues related to R & I including Research Governance & LCRF including patient recruitment targets

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Information on research networks supporting/working with the organisation.

Information on how the organisation works with the Comprehensive Local Research Network (CLRN), Primary Care Research Network (PCRN), Topic Specific Clinical Research Networks (TCRN).

Research networks	
Research network (name/location)	Role/relationship of the research network e.g. host organisation
NIHR East Midlands Clinical Research Network	The ULH Trust is supporting portfolio and non-portfolio studies. The NIHR CRN funds to employ Research Manager, RM & G Facilitator, Information Co-ordinator and Study support service coordinator. In addition, the CRN funds a large clinical trials infrastructure to support clinical trials. The clinical trials infrastructure staff is employed by the Lincolnshire Clinical Research Facility (LCRF) based in Lincoln, Pilgrim and Grantham hospitals. There are a large number of nurses/officers at band 6. In addition, LCRF also employ pharmacy staff funded by the CRN which support clinical trials (A4C banding from band 3 to 8a). The CRN also fund a consultant radiographer band 8c, Medical Physicist, band 8d. The CRN also fund a number of consultant sessions.

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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 (e.g. university/organisation joint office, external provider of pathology services to organisation, etc, effective dates)	Contact name	Email address	Contact number

University of Lincoln	The Trust has 8 on-going collaborative research projects.	Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	01522 512512 extn 582059
University of Nottingham	The Trust has on-going collaborative research projects.	Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	01522 512512 extn 582059
Collaboration of Leadership and Applied Health Research and Care (CLAHRC)-East Midlands	The Trust has been working collaboratively with CLAHRC and host studies	Dr T. Ahmed	tanweer.ahmed@ulh.nhs.uk	01522 512512 extn 582059
Academic Health Science Network (AHSN) East Midlands	The Trust has been working collaboratively with AHSN	Dr Neill Hepburn/Dr T. Ahmed	tanweer.ahmed@ulh.nhs.uk	01522 512512 extn 582059

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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	Human tissue: Tissue samples studies	Study administering questionnaires	Qualitative study	OTHER
As sponsoring organisation	Phase II, III & IV (subject to available resources)	√	√	√	√	√	
As participating organisation	Phase II, III & IV	√	√	√	√	√	
As participant identification centre	√	√	√	√	√	√	

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Information on any licences held by the organisation 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			
NA			

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For organisations with responsibilities for GPs: Information on the practices which are able to conduct research.

Number/notes on General Practitioner (GP) practices
NA

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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 (e.g. number/type of scanners)	Contact name within service department	Contact email	Contact number	Details of any internal agreement templates and other comments
Cellular pathology		Fraser Sim	fraser.sim@ulh.nhs.uk		
Radiology		Cheryl Hooper	cheryl.hopper@ulh.nhs.uk		
Pharmacy		Jayne Borley	Jayne.Borley@ulh.nhs.uk		
Radiotherapy Physics		Dr. Martin Cawley	martin.cawley@ulh.nhs.uk		
Blood sciences		Andy Cawthra	Andrew.Cawthra@ulh.nhs.uk		
Radiotherapy		Lee Beresford	Lee.Beresford@ulh.nhs.uk		
Occupational Therapy		Anita Cooper	anita.cooper@ulh.nhs.uk		
Physiotherapy		Sean East	Sean.East@ulh.nhs.uk		
IRMER Procedure		Michael Wynn-Jones	michael.wynn-jones@ulh.nhs.uk		
Chemotherapy		Marie Beck	Marie.Beck@ulh.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	Contact number	Details of any internal agreement templates and other comments
Archiving		Sarah Fahy	Sarah.Fahy@ulh.nhs.uk	01522 512512 extn 582552	
Contracts		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	01522 512512 extn 582059	
Finance		Scott Brown & Dr T. Ahmed	scott.brown@ulh.nhs.uk & tanweer.ahmed@ulh.nhs.uk		
HR		Stuart Selkirk	laura.devita@ulh.nhs.uk		
Information Technology		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk		
Legal		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk		
Data management support		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk		
Statistical support		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk		
Training		Sarah Fahy	Sarah.Fahy@ulh.nhs.uk		
Grant Applications		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk		
Portfolio and non portfolio Recruitment management		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk		
Intellectual Property		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk		

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## Organisation R&D interests

Information on the research areas of interest to the organisation (provide detailed or summary information as appropriate).

Organisation R&D areas of interest				
Area of interest	Details	Contact name	Contact email	Contact number
Cancer		Dr. T Ahmed/Dr. Ciro Rinaldi	tanweer.ahmed@ulh.nhs.uk	01522 512512 extn 582059
Stroke		Dr. T Ahmed/Paul Lee	tanweer.ahmed@ulh.nhs.uk	
Paediatric		Dr. T Ahmed/Paul Lee	tanweer.ahmed@ulh.nhs.uk	
Diabetes		Dr. T Ahmed/Paul Lee	tanweer.ahmed@ulh.nhs.uk	
Dementia and Neurodegenerative diseases		Dr. T Ahmed/Paul Lee	tanweer.ahmed@ulh.nhs.uk	
Musculoskeletal		Dr. T Ahmed/Paul Lee	tanweer.ahmed@ulh.nhs.uk	
Gastrointestinal		Dr. T Ahmed/Paul Lee	tanweer.ahmed@ulh.nhs.uk	
Cardiovascular		Dr. T Ahmed/Dr Kelvin Lee	tanweer.ahmed@ulh.nhs.uk	

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Information on local / national specialty group membership within the organisation which has been shared with the CLRN.

Specialty group membership (local and national)					
National / local	Specialty group	Specialty area (if only specific areas within)	Contact name	Contact email	Contact number
Local	Reproductive Health & Child Birth		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	01522 512512 extn
Local	Paediatric		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	
Local	Musculoskeletal		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	
Local	Gastrointestinal		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	
Local	Cardiovascular		Dr. T. Ahmed	tanweer.ahmed@ulh.nhs.uk	

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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
relocation and refurbishment of LCRF accommodation in Pilgrim	In process of relocation		Completed
LCRF office plan for new accommodation, ongoing discussions to have purpose built or refurbished LCRF accommodation	In process of writing Business case, £650,000 ring-fenced for LCRF contribution	in region of £2 million	1 -2 years

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## Organisation R&D standard operating procedures register

Standard operating procedures				
SOP ref number	SOP title	SOP details	Valid from	Valid to
SOP 1	How to write an SOP		Version 1 published on 10/03/10, version 2 published on 24/05/2012, version 3 currently in validation	Valid
SOP 2	Template SOP		Version 1 published on 10/03/10, version 2 published on 24/05/2012, version 3 currently in validation	Valid
SOP 3	Adverse Events/Serious Adverse Evenets and Suspected and Unexpected Serious Adverse events		Version 1 published on 10/03/10, version 2 published on 21/07/2011, version 3 currently being edited	Valid
SOP 4	Code Breaking-Single/Double Blinded trials		Version 1 published on 10/03/10, version 2 published on 12/03/2014	Valid
SOP 6	Storage and Archiving of Research Documents		Version 1 published on 10/03/10, version 2 published 01/10/14, version 3 published on 01/06/2017	Valid
SOP 7	Trial Master File		version 1 published on 17/08/2010	Valid
SOP8	Preparation and submission of all progress reports		Version 1 published on 17/08/2010, version 2 published on 04/08/18	Valid
SOP 9	Training Record		Version 1 published on 17/8/10, Version 2	Valid
SOP 10	Document Version Control		Version 1 published on 17/8/10, Version 2 published on 12/7/17	Valid
SOP 11	Standard Operating Procedure for Serious Breaches		Version 1 published on 17/08/2010	Valid
ULH R & D -IP 1	Intellectual Property Policy		Version 2 published 02/09/2013	Valid
ULH R & D -	Research Fraud and Misconduct		Version 2 published 17/06/2014	Valid
ULH R & D	Research Policy		Version 1.2 published 09/06/2014	Valid
SOP12	Auditing SOP		21/07/2011	Valid
SOP13	Authorised Signatory		Version 1 published 11/05/2012	valid
SOP14	Research Study planning and feasibility		Version 2 published 22/03/2013	valid
SOP15	Sponsorship		Version 1 published on 20/08/2013	Valid
SOP16	Non-pharmacy research staff-IMP related responsibilities		Version 1 published on 16/12/2013, version 2 published on 10/08/18	Valid
SOP17	Safe operation of -80 Freezer		Version 1 published on 27/03/2014	Valid
SOP18	Safe Handling of Dry Ice		Version 2 published on 17/04/2018	Valid
SOP20	EDGE Clinical Research		Version 1 published on 15/03/2016	Valid
SOP21	Identification of potential research participants		Version 1 published on 05/07/2016	Valid
SOP22	Localising Patient Information		Version 1 published on 22/06/2017	Valid

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Information on the processes used for managing research passports.

**Indicate what processes are used for managing research passports**

The processing of R & D passport is over seen by the Director of LCRF & Joint Director of R & I & IP Lead as per national guideline and facilitated by Study Support service Facilitator/Research Manager for non-portfolio and portfolio studies

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Information on the agreed escalation process to be used when R&D governance issues cannot be resolved through normal processes.

**Escalation process**

The escalation process for individual process is

Research Manager or LCRF Manager > Director of LCRF/Joint R & I Director, IP Lead > Joint R & I Director or Medical Director if R & I Director is Principal Investigator > Medical Director > Cheif Executive

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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 in which they are involved.

### Comments

NIHR CRN purchased new EDGE software which the R & I Department uses for maintaining comprehensive information about all research projects which are completed, on going and are in follow up stage with detail of staff involved.

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## Other information

For example, where information can be found about the publications and other outcomes of research which key staff have led or have otherwise contributed.

### Other information (relevant to the capability of the organisation)

Please contact Simone Seychell, PA to Dr. T. Ahmed at [simone.seychell@ulh.nhs.uk](mailto:simone.seychell@ulh.nhs.uk) or visit website

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