

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	Updated By	Approved By
1	01/10/2011	01/01/2012	15/12/2011	R&D Manager	Norfolk and Waveney Mental Health Trust Board
2	02/01/2012	05/02/2012	26/01/2012	R&D Manager	Norfolk and Suffolk Research Governance Committee (delegated authority)
2.1	06/02/2012	28/03/2013	29/03/2012	R&D Manager	Norfolk and Suffolk Research Governance Committee (delegated authority)
2.2	28/03/2012		28/03/2013	R&D Manager	Norfolk and Suffolk Research Governance Committee (delegated authority)
2.3	27/06/2014		26/06/2014	R&D manager	Norfolk and Suffolk Research Governance Committee (delegated authority)

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Organisation R&D management arrangements

Information on key contacts.

Organisation details	
Name of organisation	Norfolk and Suffolk NHS Foundation Trust
R&D lead / Director (with responsibility for reporting on R&D to the organisation Board)	Dr Jon Wilson
R&D office details:	
Name:	Dr Bonnie Teague
Address:	Research and Development, Hellesdon Hospital, Drayton High Road, Norwich, NR6 5BE, Norfolk
Contact number:	01603 421255
Contact email:	bonnie.teague@nsft.nhs.uk
Other relevant information:	The NWMHFT and SMHP merged on 1st January 2012
Key contact details e.g. Research governance lead, NHS Permissions signatory contact details	
Contact 1:	
Role:	Research Governance Lead, NHS Permissions Signatory
Name:	Dr Bonnie Teague
Contact number:	01603 421255
Contact email:	bonnie.teague@nsft.nhs.uk
Contact 2:	
Role:	NHS Permissions Signatory, Deputy Medical Director (Research)
Name:	Dr Jon Wilson
Contact number:	01603 421421
Contact email:	jon.wilson@nsft.nhs.uk
Contact 3:	
Role:	
Name:	
Contact number:	
Contact email:	

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
Research Facilitator	1	RM&G, Honorary Contracts/Letters of Access, Performance Management
Research Manager	1	Finance, Contracts
Research Development Officer	1	
Research Nurses	2.8	
Clinical Studies Officer	1	
Clinical Psychologists	2	
Assistant Psychologists	2	

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

Reporting structures
All research activity is reported and minuted by the monthly Trust Research Governance Committee, chaired by a lead Trust Clinician and CRN Eastern Partnership member. Updates are also provided to the Trust Board (KPIs and written/verbal reports) routinely.

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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
CRN Eastern	Partner Organisation

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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 East Anglia	Research Partner	Please contact R&D for any contact details of partner organisations		
University of Kent	Research Partner			
University of Hull	Research Partner			
University College London	Research Partner			
University of Birmingham	Research Partner			
University of Oxford	Research Partner			

University of Cambridge	Research Partner					
Eli Lilly	Research Partner					
Janssen Alzheimer Immunotherapy	Research Partner					
Medivation UK Ltd	Research Partner					
Drug Safety Research Unit	Research Partner					
Camden and Islington NHS Foundation Trust	Research Partner					
Lincolnshire Partnership NHS Trust	Research Partner					
Norfolk and Norwich University Hospitals NHS Foundation Trust	External provider of Pathology and Radiology services, Clinical Research and Trials Unit					

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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	No	No	Yes	No	Yes	Yes	
As participating organisation	Yes	Yes	Yes	Yes	Yes	Yes	
As participant identification centre	Yes	Yes	Yes	Yes	Yes	Yes	

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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			

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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
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 (e.g. number/type of scanners)	Contact name within service department	Contact email	Contact number	Details of any internal agreement templates and other comments
<i>Pharmacy</i>		Esther Johnston	esther.johnston@nsft.nhs.uk		Please contact R&D initially
<i>For all services, please contact Research and Development in the first instance.</i>					

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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
<i>Archiving</i>	Arrangement of archiving facilities	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>Contracts</i>	Arrangement of contractual agreements	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>Data management support</i>	Arrangement of data management support	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>Finance</i>	Arrangement of study finance management	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>Information Technology</i>	Arrangement of IT facilities	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>Legal</i>	Arrangement of Legal review	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>HR</i>	Arrangement of HR functions	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>Statistical support</i>	Arrangement of statistical support	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	
<i>Clinical Governance</i>	Arrangement of clinical governance	Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255	

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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
All areas of Mental health research, including:				
Dementia		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Mental Health Services		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Psychological Therapies		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Psychosis and Cognitive Behavioural Therapies		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Mental Health in Adults and Old Age Psychiatry		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Early Intervention in Psychosis		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Depression		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Improving Access to Psychological Therapies		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Wellbeing Services		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Patient Protected Engagement Time		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Forensic Mental Health Services		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255
Mental Health in Children and Adolescents (Youth)		Bonnie Teague	RDOfficemailbox@nsft.nhs.uk	01603 421255

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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 group)	Contact name	Contact email	Contact number

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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 from	Valid to
R&D001	Obtaining Research Approvals in the NSFT		26/09/2013	
R&D003	Research Integrity, Fraud and Misconduct		27/06/2014	
R&D004	Intellectual Property (IP)		22/09/2011	
R&D005	Conducting Clinical Trials of Investigational		27/06/2014	
R&D008	Research Trial Management: Trial Master Files		29/03/2012	
R&D009	Research Auditing and Monitoring Procedures		26/09/2013	
R&D012	Gaining Valid Informed Consent from		26/09/2013	
R&D013	Research Study Close-down and Archiving		26/09/2013	
R&D016	Research Adverse Event and Safety Reporting		29/08/2013	
R&D029	Research Industry Cost Distribution		28/07/2011	

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Information on the processes used for managing research passports.

Indicate what processes are used for managing research passports

The requirement for research passports is identified by the Research Office in accordance with Research Governance Framework and NIHR Research Passport regulations (Research in the NHS - Human Resources (HR) Good Practice Resource Pack). The Research Passport procedure is handled by the NSFT Research Office with support from HR.

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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

Escalation: Research Governance issues are reported to the Medical and R&D director (Deputy Medical Director), who reports to the Service Governance Sub-Committee or directly to the Board of Directors.

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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

Research and Development has prepared a list of all active studies in the Trust on the intranet. This list contains local contact details and brief study information, and is updated on a monthly basis. The R&D staff have access to a continually updated list of active studies, which is maintained by the office.

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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)

NNSFT has launched a Service User and Carer Involvement in Research initiative called INSPIRE, which will link the research needs and perspectives of service users and carers with clinical-academic research groups in order to develop and support clinical research into mental health conditions and services. The INSPIRE facilitator is the Research Development Officer.

INSPIRE is also supported with a biannual public forum, giving the opportunity for interested members of the public to hear about the research being conducted in the Trust.

RM&G: NHS organisations across CRN Eastern work proactively together to speed up the initiation of commercial clinical research across two or more organisations in the region by collectively sharing cost and contract negotiations and local governance review. The information from these reviews is shared with each organisation to allow a signed contract and NHS permission letter to be issued at each Trust within 30 days of receipt of a valid SSI submission.

The NHS organisations participating are

- Norfolk & Norwich University Hospitals NHS Foundation Trust
- James Paget University Hospitals NHS Foundation Trust
- The Ipswich Hospital NHS Trust
- Norfolk & Suffolk NHS Foundation Trust (Mental Health)

Where a study will require involvement from either primary care or the Ambulance service the same level of mutual assurance will be supported.

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