NIHR Guideline B01
R&D Operational Capability Statement

DATE .....

Contents

1. R&D management arrangements

Information on key contacts.

Name of organisation	
R&D lead / Director (with responsibility for reporting on R&D to the organisation Board)	

Name:	
Address:	
Contact number:	
Contact email:	
Other relevant information:	

Role:	
Name:	
Contact number:	
Contact email:	

Role:	
Name:	
Contact number:	
Contact email:	

R&D office roles (e.g. Governance, contracts, etc)	Whole time equivalent	Comments
Research management		
Clinical study support		
Research assistant		

Reporting structures
Information on reporting structure in organisation, for example committees, boards

Research networks	
Information on how the organisation works with and receives support from the Comprehensive Local Research Network, Primary Care Network, topcs specific research networks	
Research network (name/location)	Role / relationship

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

2. Study capabilities

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

	CTIMPs (indicate phases)	Clinical trial of a medical device	Other clinical studies	Human tissue: Tissue samples studies	Study administering questionnaires	Qualitative study
As sponsoring organisation						
As participating organisation						
As participant identification centre						

Information on any licences held by the organisation which may be relevant to research.

Organisation licences		
Licence name Example: Human Tissue Authority licence	Licence details	Licence start date (if applicable)

3. 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.

Service department	Specialist facilities that may be provided (e.g. number/type of scanners)	Contact name within service department	Contact email	Contact number

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

Department	Specialist services that may be provided	Contact name within service department	Contact email	Contact number
Archiving				
Contracts				
Data management support				
Finance				
Information Technology				
Legal				
HR				
Pharmacy				

4. R&D interests

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

Area of interest	Details	Contact name	Contact email

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

National / local	Specialty group	Specialty area (if only specific areas within group)	Contact name

5. R&D planning and investments

Area of investment (e.g. Facilities, training, recruitment, equipment etc.)	Description of planned investment	Value of investment

6. R&D standard operating procedures register

Standard operating procedures		
SOP ref number	SOP title	SOP details

Research passports
Indicate what processes are used for managing research passports

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

7. 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

8. 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.

The three levels of readiness for research are:

Level 1 - PIC site leading to observational studies; investigator lead.
Level 2 - More complex non-commercial research;
Level 3 - Commercial and complex non-commercial research.