

NIHR Guideline B01

R&D Operational Capability Statement - Weston Area Health NHS Trust

Version History

| Version number | Valid from | Valid to | Date approved | Approved by | Updated by |
|----------------|------------|------------|---------------|-------------|------------|
| v1.0 | 01/09/2011 | 01/09/2012 | | | |

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Organisation R&D Management Arrangements

Information on key contacts

| Organisation Details | |
|--|---|
| Name of Organisation | Weston Area Health NHS Trust |
| R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board) | Dr. Serena Hillman, Associate Medical Director for Research and Development |
| Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details | |
| Contact 1: | |
| Role: | Interim Chief Executive - Permissions signatory |
| Name: | Peter Colclough |
| Contact Number: | 01934 636363 x3001 |
| Contact Email: | petercolclough@nhs.net |
| Contact 2: | |
| Role: | Medical Director - Permissions signatory |
| Name: | Nick Gallegos |
| Contact Number: | 01934 636363 x3001 |
| Contact Email: | nick.gallegos@nhs.net |

Add further lines as required

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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 part time/full time/shared/joint etc |
| R&D Manager/Senior Research Nurse | 1 | Full time |
| Research Officer | 0.8 | Part time |
| R&D Administrator | 0.67 | Part time (commencing 26/09/2011) |
| | | |
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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 R&D Department sits within the Trusts Elective Division. The department is overseen by the Research Committee which meets quarterly.

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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 |
|---|---|
| Western Comprehensive Local Research Network (WCLRN) | The Trust is a member organisation of WCLRN. As a CLRN member the organisation employs, with CLRN funding, a number of research nurses and support staff working in various specialities. |
| Avon, Somerset & Wiltshire Cancer Research Network (ASWCRN) | ASWCRN fund a research nurse and clinical trials officer to work on the cancer portfolio. |
| South West Diabetes Research Network (SW DRN) | Work closely with SW DRN - targeted funding from WCLRN provides research nurse for diabetes |
| South West Stroke Research Network (SW SRN) | Work closely with SW SRN to recruit participants to stroke studies |
| South West Dementias & Neurodegenerative Disease Research Network (DenDRON) | Work closely with DenDRON to recruit participants to DenDRON studies |

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Information on collaborations and partnerships for research activity (e.g. BRC, BRU, 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 Hospitals Bristol NHS Foundation Trust | Service level agreement to provide some research governance functions - Diana Benton | | Diana.Benton@UH Bristol.nhs.uk | 0117 342 0233 |
| University Hospitals Bristol NHS Foundation Trust | WCLRN funded solicitor based at UHB for legal advice relating to research - Nicola Latchem | | Nicola.Latchem@UH Bristol.nhs.uk | 0117 342 0229 |

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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 | Yes | Yes | Yes | |
| As Participating Organisation | Yes (2 & 3) | Yes | Yes | Yes | Yes | Yes | |
| As Participant Identification Centre | Yes (1, 2 & 3) | Yes | Yes | Yes | Yes | Yes | |

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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 | | | |
| Human Tissue Authority | Pathology | Renewed Annually | |
| | | | |
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PCT ONLY: Information on the practices which are able to conduct research

| Number/notes on General Practitioner (GP) Practices |
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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 |
| Pathology | CPA Accreditation | Kemlo Rogerson | kemlorogerson@nhs.net | x3321 | |
| Radiology | MRI & spiral CT scanners | Dr John O'Brien | john.obrien@nhs.net | x3340 | |
| Pharmacy | Clinical trials pharmacist and technician | Kathy Beard | kathy.beard@nhs.net | x5362 | |
| Cardiology | Echocardiogram, ECG | David Hartell | david.hartell@nhs.net | x3430 | |
| Oncology Day Unit | Cytotoxic chemotherapy | Corrine Thomas | corrinethomas@nhs.net | x5653 | |
| Outpatients | | Amanda Bessant | amanda.bessant@nhs.net | x3426 | |
| Radiotherapy (at Bristol Haematology & Oncology Centre) | | Katherine King | katherine.king@UHBristol.nhs.uk | 0117 342 3103 | Arranged through BHOC Radiotherapy Department |

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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 |
| Archiving | Kewstoke Storage - arrange via R&D Department | Vivienne Pixton | vivienne.pixton@nhs.net | 01934 881135 | |
| Finance | | Karen Wingrove | karen.wingrove@nhs.net | x5082 | |
| Information Technology | | IT Helpdesk | wnt-tr.ITServiceDesk@nhs.net | x3850 | |
| Legal | Contracts, Material Transfer Agreements | Nicola Latchem | Nicola.Latchem@UHBristol.nhs.uk | 0117 342 0229 | |
| Human Resources | Research Passports, Honorary contracts | Susie Sims | susie.sims@nhs.net | x3190 | |
| South west Research Design Service | Statistical support, protocol development | Rosie Greenwood - Research Design Service | rosemary.greenwood@uhbristol.nhs.uk | 0117 342 0234 | |
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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 | Urology, Breast, Radiotherapy Colorectal | Dr Serena Hilman Dr Marjorie Tomlinson | serena.hilman@nhs.net marjorie.tomlinson@nhs.net | x5847 |
| Diabetes | Type 1 & 2 | Dr Parag Singal | paragsingal@nhs.net | x3803 |
| Rheumatology | Rheumatoid Arthritis, Psoriatic Arthritis | Dr Sandra Green | sandragreen2@nhs.net | x3708 |
| Occupational Therapy | Parkinson's Disease, Rheumatology | Sarah Whitford | sarah.whitford@nhs.net | x3739 |
| Gastroenterology | Inflammatory Bowel Disease Probiotics | Dr Andrew Bell | andrewbell1@nhs.net | x3814 |
| Cardiology | Acute Coronary Syndrome | Dr John Edmond | jedmond@nhs.net | x5730 |

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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 |
| None | | | | | |
| | | | | | |
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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 |
| N/A | | | |
| | | | |
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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 | Preparation, approval, review and issue of SOPs | v1.0 28.1.10 | | | 01.07.2010 | | 01.07.2012 |
| SOP 2 | Departmental office procedures | v1.0 25.5.10 | | | 01.07.2010 | | 01.07.2012 |
| SOP 3 | R&D personnel, training, sickness, annual leave & | v1.0 25.5.10 | | | 01.07.2010 | | 01.07.2012 |
| SOP 4 | R&D procedures for gaining approval, monitoring, reporting and post approval | v1.0 25.5.10 | | | 01.07.2010 | | 01.07.2012 |
| SOP 5 | Research Passport procedure | v1.0 21.08.09 | | | 21.08.2009 | | 21.08.2011 - currently going through re ratification process |
| SOP 6 | First research investigational medicinal product prescription | v1.0 23.11.09 | | | 10.12.2009 | | 10.12.2011 |
| SOP 7 | Clinical Trial - introduction, setting up, running & closure of a study | v1.0 25.5.10 | | | 01.07.2010 | | 01.07.2012 |
| SOP 8 | Intellectual property | v1.0 21.08.09 | | | 21.08.2009 | | 21.08.2011 - currently going through re ratification process |
| SOP 10 | Staffing the R&D Department | v1.0 09.12.10 | | | 27.01.2011 | | 27.01.2013 |

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Information on the processes used for managing Research Passports

Indicate what processes are used for managing Research Passports

R&D SOP No. 5 - Contact Research & Development Department for guidance

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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

Unresolved issues in relation to Research Governance are escalated to the Associate Medical Director for R&D. Issues that cannot be resolved at this level are escalated to the Chief Executive (including appeals). The Chief Executive's decision is final.

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Planned and Actual Studies Register

A list of current and planned studies is available from the R&D Department on request.

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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 on research within WAHT can be found on the Trust's website - http://www.waht.nhs.uk/Departments/Clinical_Governance/Research/default.htm

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