

NIHR Guideline B01

R&D Operational Capability Statement

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Version History

Version number	Valid from	Valid to	Date approved	Approved by	Updated by
Statement 001	30-Sep-11	30-Sep-13	01/08/2011	R&D Committee	
Statement 002	28/03/2013	27/03/2014	28/03/2013	Board of Directors	

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Organisation R&D management arrangements

Information on key contacts.

Organisation details	
Name of organisation	University Hospitals Birmingham NHS Foundation Trust
R&D lead / Director (with responsibility for reporting on R&D to the organisation Board)	Tim Jones, Executive Director of Delivery
R&D office details:	
Name:	Hilary Fanning, Deputy Director of Delivery
Address:	1st Floor, Education Centre, Queen Elizabeth Hospital, Mindelsohn Way, Edgbaston, Birmingham B15 2WB
Contact number:	T: 0121 371 4185 F:0121 371 4204
Contact email:	hilary.fanning@uhb.nhs.uk
Other relevant information:	
Key contact details e.g. Research governance lead, NHS Permissions signatory contact details	
Contact 1:	
Role:	Head of R&D Governance
Name:	Dr Chris Counsell
Contact number:	T: 01213714185
Contact email:	chris.counsell@uhb.nhs.uk
Contact 2:	
Role:	Head of R&D Operations
Name:	Joanne Plumb
Contact number:	T: 01213713702

Contact email:	joanne.plumb@uhb.nhs.uk
Contact 8:	
Role:	R&D Administrator
Name:	Helen Langston,
Contact number:	T: 01213714185
Contact email:	helen.langston@uhb.nhs.uk
Contact 4:	
Role:	Research & Development - Clinical Trials Manager
Name:	Kabir Mohammed
Contact number:	T: 01213714188
Contact email:	Kabir.Mohammed@uhb.nhs.uk
Contact 3:	
Role:	Research Contracts and Governance Manager
Name:	Louisa Bailey
Contact number:	T: 01213714239
Contact email:	Louisa.Bailey@uhb.nhs.uk
Contact 3:	
Role:	Research Business Manager
Name:	Lesley Devaney
Contact number:	0121 371 4225
Contact email:	lesley.devaney@uhb.nhs.uk
Contact 3:	
Role:	Research Business Manager
Name:	Helen Hunt
Contact number:	0121 371 4182
Contact email:	Helen.hunt@uhb.nhs.uk

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
<p>The Trust R&D website provides details of all the Core R&D staff can be found on our website (www.uhbresearch.co.uk). Across the different specialities in the Trust there are research nurses, trial co-ordinators and statisticians who support our clinicians to deliver research. These posts are a mix of full-time and part-time.</p>		

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

Reporting structures
<p>There is a fortnightly Senior Team Operations Group which discusses in detail operational issues within Research and Development (R&D). This group feeds into the R&D Committee which is chaired by the Executive Director of Delivery and meets 6 times a year. The Board of Directors receives an annual and bi-annual Research and Development (R&D) report every year which outlines the current and planned work within R&D.</p>

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
Birmingham & Black-Country CLRN	Host Organisation - We work closely with the CLRN and other member organisations in the BBC to ensure that the network achieves national targets to secure future funding and reputation.

Pan Birmingham Cancer Research Network (PBCRN)	Host Organisation - We work closely with the PBCRN and other cancer member organisations as we host the region's radiotherapy service and many cancer tertiary services. We want to ensure that the network achieves national targets to secure future funding and reputation.
Diabetes Clinical Research Network	Affiliate - UHB employ Diabetes Research Staff to work across several hospitals delivering diabetic research across the network.
Stroke Research Network	Affiliate - UHB has a very close working relationship with the Lead Stroke Research Network Nurse and has increased studies and recruitment. Together we have been able to demonstrate a real dedication to advancing stroke care by integrating stroke research alongside clinical care. Our anticipated recruitment was 60 patients this year but we have delivered 102 patients. Our vision is to continue growth in Stroke research and be seen as a hyperacute stroke research service.
Dementias and Neurodegenerative Diseases Research Network	Affiliate - We're a regional centre the team and therefore the team works differently to others in that they provide an outreach research service to visit patients at home for their trial visit.

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)	Email address
Birmingham Health Partners	<p>Birmingham Health Partners (BHP) is a joint working agreement between the University of Birmingham and University Hospitals Birmingham NHS Foundation Trust.</p> <p>Established in November 2011, it enhances the longstanding working relationship between the two institutions and enables patients to benefit from new therapies delivered by expert clinicians working alongside top research scientists and world-leading clinical trials teams.</p> <p>Based at the new Queen Elizabeth Hospital Birmingham and under the transitional directorship of Professor Charlie Craddock, BHP will fuel collaborative projects in key research areas including cancer, immunology and infection, experimental medicine and chronic disease, and is intended to strengthen and develop the global reputations of both the University and the Trust.</p>	<p>Please visit our contacts page on our website for details www.uhbresearch.co.uk</p>

<p>Birmingham and the Black Country Chronic Disease Research Centre (CDRC)</p>	<p>The Birmingham CDRC, hosted by UHB, houses clinics in which cohorts of patients with arthritis, kidney, lung and endocrine disease can be studied using shared facilities, while at the same time providing resources for disease specific assessments. There is a cross-disciplinary approach to inflammation with careful characterisation of cohorts of patients to explore how pathology is manifested and differs across different organs and to explore cardiovascular, bone and periodontal co-morbidity.</p> <p>The Comprehensive Local Research Network has pump-primed the development of this Centre with dedicated research fellows and nurses for each speciality and bespoke database development. The CDRC will be physically co-located with the Centre for Translational Inflammation on the first floor of the new Queen Elizabeth Hospital.</p>	<p>Please visit our contacts page on our website for details www.uhbresearch.co.uk</p>
<p>Birmingham Centre for Clinical Haematology</p>	<p>The Birmingham Centre for Clinical Haematology oversees one of the most active academic and clinical haematology practices in the world. The centre hosts an internationally competitive early phase clinical trials portfolio. Its mission is to develop and deliver novel drug and transplant therapies in patients with haematological malignancies.</p>	<p>Please visit our contacts page on our website for details www.uhbresearch.co.uk</p>

<p>Collaboration for Leadership in Applied Health Research and Care (CLAHRC) programme</p>	<p>The CLAHRC-BBC undertakes high-quality applied health research focused on the needs of patients, the results of which can be put into practice in the NHS. Activity is based upon six core aims:</p> <ul style="list-style-type: none"> •To assess if changes to NHS services work, where, for whom and at what cost. •To develop cross-cutting research topics to enrich evaluations. •To encourage and support sustainable research activity in partnership with NHS organisations in our region and beyond. •To build upon existing relationships between academics, NHS staff, patients and the public. •To build a cohesive knowledge management function. •To create and build international collaborations. 	<p>Please visit our contacts page on our website for details www.uhbresearch.co.uk</p>
<p>Cancer Research UK Centre</p>	<p>CRUK launched its first super cancer centre in Birmingham in 2010 to draw together world class research and provides more than £8 million funding each year. CRUK is setting the pace for national and international progress for genetics, gene therapy and the link between viruses and some cancers, as well as focusing on cancers of the prostate and bladder and leukaemia. It is a leading centre for clinical trials.</p>	<p>Please visit our contacts page on our website for details www.uhbresearch.co.uk</p>

<p>Experimental Cancer Medical Centre</p>	<p>Birmingham ECMC aims to improve the feasibility and quality of research in the areas of immunotherapy and gene therapy, translational genetics and biomarkers. This is being conducted in many different types of cancer. The centre has established bio-repositories, developed antibody-based assays and conducted various immunotherapy/gene therapy trials. Launched in October 2006, the ECMC network is jointly supported by Cancer Research UK and the Departments of Health for England, Scotland, Wales and Northern Ireland, providing a total of £35 million over five years to fund a network of 19 ECMCs across the UK</p>	<p>Please visit our contacts page on our website for details www.uhbresearch.co.uk</p>
<p>Healing Foundation for Burns</p>	<p>UHB, along with research partners University of Birmingham, Birmingham Children's Hospital, the Royal Centre for Defence Medicine and University College London, are currently working with the Healing Foundation to establish a major centre for research in burns. This follows a comprehensive, international and expert-led Peer Review and Selection Process which was completed in June 2011. The centre will provide a vital, international base for clinically-driven, patient relevant research into all aspects of burns care, from prevention and acute care to longer-term rehabilitation.</p>	<p>Karen Piper E: karen.piper@uhb.nhs.uk T: 0121 371 14181</p>

<p>NIHR Health Technology Co-operative (HTC)</p>	<p>The NIHR infrastructure funding for HTCs enables NHS Organisations to act as centres of expertise that focus in clinical areas or themes of high morbidity and unmet need for NHS patients. Working collaboratively with industry, they develop new medical devices, healthcare technologies or technology-dependent interventions, which improve treatment and quality of life for patients.</p> <p>Working with key partners the Birmingham HTC is concentrating on the clinical area of trauma and is under the clinical directorship of Dr Tom Clutton-Brock</p>	<p>Daljeet Bansal daljeet.bansal@uhb.nhs.uk 0121 371 14209</p>
<p>NIHR Liver Biomedical Research Unit</p>	<p>The Birmingham NIHR Liver BRU at UHB, in partnership with University of Birmingham, is part of a multi-million pound scheme to prevent, diagnose and treat ill-health. It is one of 16 BRUs in England funded by the National Institute for Health Research that focus on translational research. The funding supports people, infrastructure, equipment and running costs, allowing a team of scientists to undertake challenging and complex translational research to develop new therapies for liver disease.</p>	<p>Please visit our contacts page on our website www.uhbresearch.co.uk</p>

<p>NIHR Surgical Reconstruction and Microbiology Research Centre</p>	<p>The NIHR SRMRC is a joint venture between the Ministry of Defence, UHB and University of Birmingham to innovate in, and share, medical research and advanced clinical practice in battlefield medicine to benefit all trauma patients in the NHS at an early stage of injury.</p> <p>The centre carries out world-leading research to help people recover better and faster from severe injuries helping to make the NHS leaders in the world of trauma care. Its clinical director is Professor Sir Keith Porter, who is the UK's only Professor of Clinical Traumatology and has been leading a team to develop world-class treatment for injured military servicemen and women for the past 10 years.</p>	<p>Karen Piper karen.piper@uhb.nhs.uk 0121 371 14181</p>
<p>Research Design Service for the West Midlands (RDS WM)</p>	<p>Research Design Service for the West Midlands (RDS WM) provide advice and practical support to help NHS researchers, and others working in partnership with the NHS, in the West Midlands area who have a 'good idea' and want to turn that into a research proposal for submission to peer-reviewed funding programmes in applied health and social care. The RDS WM comprises of three 'hubs' based in the Universities of Birmingham, Keele and Warwick. Each Hub has a team of staff who can advise on all aspects of preparing grant applications and specialist expertise in statistics, quantitative and qualitative research techniques, clinical trials, evidence synthesis, health economics, epidemiology, public and patient involvement, and ethics and governance.</p>	<p>Melanie Guthrie rdscentre@contacts.bham.ac.uk Tel: 0121 414 8533</p>

<p>Wellcome Trust Clinical Research Facility</p>	<p>The Birmingham Wellcome Trust Clinical Research Facility is a joint venture between University Hospitals Birmingham NHS Foundation Trust (UHB), Birmingham Children's Hospital NHS Foundation Trust, the University of Birmingham and the Wellcome Trust.</p> <p>The Clinical Research Facility at the Queen Elizabeth Hospital Birmingham is situated on the first floor of the Wellcome Building and has a direct corridor link to the New Hospital. It is also in close proximity to the University of Birmingham's Institute of Biomedical Research, reinforcing the collaboration between the UHB and the University of Birmingham Medical School.</p> <p>Under the leadership of the Programme Director and Clinical Manager, a team of trained personnel work with Principal Investigators from both the Trust and the University to develop, implement and evaluate research protocols.</p>	<p>Joanna Gray joanne.gray@uhb.nhs.uk 0121 371 3159</p>
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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			√	√	√	√	
As participating organisation	√ (Phase 1,2,3,4)	√	√	√		√	
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)	Licence end date (if applicable)
Human Tissue Authority Research Licence	The Trust makes use of the Human Biomaterials Research Centre at the University of Birmingham which has an HTA Research Licence (12358)		N/A

ARSAC licences	To permit use of radioactive materials for research. Separate site-specific licence required to be held by appropriate consultant for every research trial	N/A
Tissues and Cells for Patient Treatment Licence	Licence number 11100 (distribution, procurement, storage and testing)	N/A

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

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
Pathology	The Trust can provide Biochemistry, Haematology, Microbiology/Serology, Immunology, Microbiology and Cellular Pathology services. There are specialist laboratory facilities such as category three rooms, chromatography and tandem Mass spectrometry, specialist radio-immunoassay and a molecular suite shared by all disciplines. All laboratories are consultant led, CPA Accredited and staffed by appropriately, qualified, registered and experienced medical, scientific and support personnel.	Dr Kirsty Gordon	kirsty.gordon@uhb.nhs.uk	(0)1213715996	N/A

Radiology	<p>MRI - 6 Scanners: - 5 x 1.5T (4 Siemens and 1 GE) and 1 x 3T Siemens Vario (one of which is short wide bore) Brain Lab available CT - 5 scanners (All Siemens): Power injectors available Interventional Suite: 5 Interventional rooms in total, 4 are single plane Philips Allura FD20's and one Siemens bi-plane Neuro unit PACs - GE and upgrading to AGFA May 2013 Radiology System (CRIS): Healthcare Software Systems Outpatient Imaging (Plain film rooms – all digital) - 3 Carestream and 1 Philips (with tomography), OPG machine with Lateral Cephalogram available Inpatient Imaging (Plain film rooms – all digital) - 3 Carestream and 1 Philips (with tomography) AE Imaging (Plain film rooms – all digital): 3 Carestream and OPG machine Ultrasound Imaging Inpatient – 9 scanners in total and Probes – Transvaginal, linear etc Fluoroscopy Imaging - 5 rooms, Various Mobile Imaging machines</p>	Karen Isaacs	karen.isaacs@uhb.nhs.uk	(0)1213712589	N/A
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Pharmacy	<p>A dedicated staff resource is available to support the development, implementation and delivery of a trials dispensing service.</p> <p>Infrastructure and staffing capability is available to deliver aseptic trials within a dedicated facility. A new gene therapy facility is being commissioned and will be available to support gene therapy trials in the very near future.</p> <p>A new radiopharmacy unit is at the design stage and will be commissioned in 2014. It will be licensed to undertake clinical trials and thereby provide the Trust scope to expand upon trial activity in nuclear medicine.</p>	Amisha Desai	Amisha.Desai@uhb.nhs.uk	(0)1216272315 Ext: 8056	N/A
Nuclear Medicine	3 gamma cameras inch 2xSPECT/CT, PET/CT, DXA, radioactive sample counting, radionuclide therapy suite	Chris Boivin	chris.boivin@uhb.nhs.uk	1213712281	N/A

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
R&D Operations	The R&D Operations teams are divided into Cancer and Non-cancer for management, reporting and allocation of support. Clinical researchers can request support for portfolio studies and commercial studies to assist feasibility, set up, co-ordination and implementation of study visits to ensure recruitment targets are delivered and if necessary address any operational issues that may arise during the study.	Joanne Plumb	joanne.plumb@uhb.nhs.uk	0121 371 13702	N/A
Finance	Provides financial management support within the research department	Asha Kanith	asha.kanith@uhb.nhs.uk	0121 371 2000 ext 53130	N/A

Protocol Development Service	The Protocol Development Service (PDS) provides specialist support to clinicians to help facilitate research grant applications. Services include; developing the research idea, identifying funding streams, arranging meetings, assisting with finances, identifying support and providing advice on sponsorship and governance.	Victoria Aldridge	PDS@uhb.nhs.uk	0121 371 14028	N/A
Contracts	Standard model agreements are handled by the Clinical Trials Manager or the Head of R&D Governance. Non standard agreements and confidentiality agreements are handled by the Research Contracts and Governance Manager	Chris Counsell Kabir Mohammed Louisa Bailey	chris.counsell@uhb.nhs.uk kabir.mohammed@uhb.nhs.uk louisa.bailey@uhb.nhs.uk	0121 371 14185	N/A

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
Burns and plastics	UHB is home to the Healing Foundation UK Burns Research Centre, which is investigating a range of areas, including the use of nanotechnology to create a polymer-based skin substitute, face and hand transplantation, and trailing new drugs to neutralise chemical burns.	Mr Naiem Moiemem	clinicalresearchfeasibility@u hb.nhs.uk
Cancer	UHB is one of the country's leading cancer research institutions, and is home to Birmingham Centre for Clinical Haematology, Cancer Research UK (CRUK) Technology Hub and Experimental Cancer Medicine Centre. Major areas of research interest include blood, breast, urological, brain, colorectal, head and neck, and neurological cancers.	Prof Nick James	clinicalresearchfeasibility@u hb.nhs.uk
Cardiology	The Queen Elizabeth Hospital Birmingham is a national centre for heart and lung transplant and a regional centre for specialist cardiac services including electrophysiology, adult congenital heart disease, cardiac imaging, percutaneous cardiac intervention including valve replacement, inherited cardiac syndromes, cardiac and thoracic aortic surgery and cardiomyopathy. Research is underway into cardio-renal disease, cardiac device development, aortic surgery, atrial fibrillation, outcomes after cardiac surgery and congenital heart and aortic disease.	Dr Jonathan Townend	clinicalresearchfeasibility@u hb.nhs.uk
Critical Care	UHB has one of the world's largest single critical care units, treating and researching a wide range of conditions. Current research includes wound care, acute lung injury, trauma and infection.	Dr Tony Whitehouse	clinicalresearchfeasibility@u hb.nhs.uk

Dermatology	UHB is a national centre of excellence in researching skin cancer, led by Dr Jerry Marsden. Important work is also underway in psoriasis and pyoderma gangrenosum.	Dr Jerry Marsden	clinicalresearchfeasibility@u hb.nhs.uk
Diabetes	UHB is a regional and national centre for diabetes research, supported by the Chronic Disease Research Centre. Work is underway on types 1 and 2 diabetes, including drug and lifestyle therapies	Dr Parth Narendran	clinicalresearchfeasibility@u hb.nhs.uk
Gastrointestinal	UHB works closely with the University of Birmingham, research researching biomarkers to predict cancer risk for IBD patients. There is also research into the role of iron in cancer and IBD, and collaborative work on idiosyncratic reactions to drugs.	Dr Tariq Iqbal	clinicalresearchfeasibility@u hb.nhs.uk
Liver medicine	UHB is a world-renowned centre for liver medicine research out of the NIHR Liver Biomedical Research Unit, and working with the hospital's busy liver transplant programme, one of the biggest in Europe. Research is underway into immune mediated liver disease, viral liver disease, cell therapy, metabolic liver disease, hepatocellular carcinoma, portal hypertension and vascular liver disease hypertension and transplantation outcomes, amyloidosis, clinical and transplant hepatology	Dr Gideon Hirschfield	clinicalresearchfeasibility@u hb.nhs.uk
Liver surgery	UHB is one of the world's pioneering institutions for developing liver transplant surgery. Current research includes the ethical issues around transplant, scanning technologies, and artificial means of maintaining the liver's condition in a deceased patient before transplant.	Mr Simon Bramhall	clinicalresearchfeasibility@u hb.nhs.uk

Medical physics	UHB's medical physics department has a close relationship with the University of Birmingham to carry out important research. This includes increasing X-ray efficiency and exploring the effectiveness of proton beam therapy.	Prof Stuart Green	clinicalresearchfeasibility@u hb.nhs.uk
Microbiology	UHB operates one of the most modern and sophisticated microbiology departments in Europe and is active in many areas of research. This includes epidemiology, management of complicated infections, non-culture diagnosis, equipment and facilities evaluations	Dr Beryl Oppenheim	clinicalresearchfeasibility@u hb.nhs.uk
Neurology	UHB, in conjunction with the University of Birmingham, is carrying out world leading work on Alzheimer's disease, Parkinson's disease, motor neurone disease, multiple sclerosis, and degenerative problems associated with stroke.	Prof Adrian Williams	clinicalresearchfeasibility@u hb.nhs.uk
Ophthalmology	UHB is a regional and national centre for treating and researching a range of ophthalmic conditions. This includes neuro-ophthalmology, glaucoma, retinal disease and inflammatory eye disease.	Dr Timothy Matthews	clinicalresearchfeasibility@u hb.nhs.uk
Renal medicine	UHB is at the cutting edge of renal medicine research, working closely with surgical colleagues and the University of Birmingham. Research includes immune mediated renal disease, paraprotein related renal diseases, chronic kidney disease (CKD) (including epidemiology), transplantation (immune and non-immune-mediated aspects), cardiovascular disease in CKD, dialysis and acute kidney injury	Dr Paul Cockwell	clinicalresearchfeasibility@u hb.nhs.uk

Respiratory medicine	UHB has a busy respiratory medicine research programme covering both cancer and non-cancer conditions. As well as lung cancer, research focuses on alpha 1-antitrypsin efficiency, COPD and lung function testing.	Dr Ian Woolhouse	clinicalresearchfeasibility@u hb.nhs.uk
Rheumatology	UHB is a regional centre for treating rheumatological conditions, and is carrying out research on Sjögren's syndrome, lupus, early arthritis, and is also active in developing models of transitional care.	Dr Simon Bowman	clinicalresearchfeasibility@u hb.nhs.uk
Sexual health	UHB is responsible for delivering sexual health services across Birmingham and is carrying out research into HIV, pelvic inflammatory disease and health service delivery.	Prof Jonathan Ross	clinicalresearchfeasibility@u hb.nhs.uk
Trauma	UHB hosts the NIHR Surgical Reconstruction and Microbiology Research Centre, working with the Ministry of Defence and the University of Birmingham. Research includes work on acute response to injury, traumatic brain injury, catabolic state after injury, surgical management of abdominal injury, managing blast injury, non-culture diagnosis, fungal pathogen diagnostics, micro-organism spread, ocular trauma, cranial-facial reconstruction.	Prof Sir Keith Porter	clinicalresearchfeasibility@u hb.nhs.uk

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

Specialty group membership (local and national)
<p>Details of the Locality Speciality Leads can be found on the link http://www.crnc.nihr.ac.uk/NR/rdonlyres/BE4C2C98-16FA-4992-AE2B-737D29FCB20D/0/LocalSpecialtyGroupLeadContactDetails220113.pdf</p>

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
Set up and co-ordination of studies	2 new posts have been requested to support the delivery of the 70 day benchmark and to also support service departments in the tracking of studies on this tracker.	£40k
Senior trial co-ordinator / practitioner	A new post has been created to support the trial co-ordinators based within the R&D ops team this team is growing and requires a career structure to support and professional develop this service which is becoming more demanding as the skill mix for delivering study is required to be more efficient and cost effective	Cost neutral

<p>Significant investment has been made to support the Ophthalmology research team (PI Alastair Denniston)</p>	<p>PI support along with research nurse and clinic support has been provided to increase recruitment to portfolio studies. A capital bid for the upgrade of an OCT machine has also been supported to deliver additional specialist autofluorescence investigations required for trial study protocols</p>	<p>£18k</p>
<p>Institute of Translational Medicine</p>	<p>The ITM is intended to capitalise on Birmingham’s growing role in Life Sciences which forms a key component of the city’s growth strategy. The proposed ITM will provide further capacity for clinical trials and could play a significant role in generating growth locally and nationally.</p>	<p>£24m (£12million from Birmingham Health Partners and £12m from the Department of Business, Innovation and Skills (BIS) and the Department of Health</p>

Organisation R&D standard operating procedures register

Standard operating procedures

Research policies, procedures and SOPs are developed by the R&D departments and controlled in accordance with the Trusts Controlled Document system. All R&D policies, procedures and SOPs will be recorded on our web pages at www.uhbresearch.co.uk

Information on the processes used for managing research passports.

Indicate what processes are used for managing research passports

Applications for honorary research contracts and letters of access are channelled through the R&D Governance Office. A completed Research Passport or NHS to NHS confirmation of pre-employment checks, as appropriate, along with supporting documents is submitted to the office. Letters of Access are issued by the R&D Governance Office, while applications for Honorary Research Contracts are forwarded to the Human Resources Department to process.

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

Escalation process

Initial queries are addressed by the R&D Administrator or Clinical Trials Manager as appropriate. More complicated issues are escalated to the Head of R&D Governance or Head of R&D Operations. If the matter remains unresolved after negotiation it is further escalated to the Deputy Director of Delivery.

Planned and actual studies register

The organisation should maintain or have access to a current list of planned and actual studies which its staff leads or in which they are involved.

Comments

All planned and actual studies are recorded in full on the R&D Governance database. In addition recruitment data is captured for all studies active within the Trust via PICS.

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)

For further information please see our website www.uhbresearch.co.uk