

Paper P

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT BY TRUST BOARD COMMITTEE TO TRUST BOARD

DATE OF TRUST BOARD MEETING: 2 June 2011

COMMITTEE: UHL RESEARCH AND DEVELOPMENT COMMITTEE

CHAIRMAN: Mr M Hindle, Trust Chairman

DATE OF COMMITTEE MEETING: 9 May 2011

RECOMMENDATIONS MADE BY THE COMMITTEE FOR CONSIDERATION BY THE TRUST BOARD:

- Approval of the R & D Operational Capability Statement (Minute 55/11 and associated appendix refers).

OTHER KEY ISSUES IDENTIFIED BY THE COMMITTEE FOR CONSIDERATION BY THE TRUST BOARD:

- The current status of the Trust's BRU Applications (Minute 64/11/1 refers).

DATE OF NEXT COMMITTEE MEETING: 13 June 2011.

**Mr M Hindle, Trust Chairman
26 May 2011**

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

**MINUTES OF A MEETING OF THE UHL RESEARCH AND DEVELOPMENT COMMITTEE,
HELD ON MONDAY 9 MAY 2011 AT 2.30PM IN THE BOARD ROOM, VICTORIA BUILDING,
LEICESTER ROYAL INFIRMARY**

Present:-

Mr M Hindle – Trust Chairman (Chair)
Dr K Harris - Medical Director
Dr D Hetmanski – Assistant Director of Research and Development
Mr M Lowe-Lauri – Chief Executive
Mr P Panchal - Non-Executive Director
Professor D Rowbotham – Director of Research and Development
Professor N Samani - BRU Director (from Minute 58/11/1 onwards)
Dr A Thomas - Reader and Consultant in Medical Oncology
Mrs J Wells – Patient Adviser
Professor D Wynford-Thomas - UHL Non-Executive Director and Dean of the University of Leicester Medical School

In attendance:-

Mrs G Belton – Trust Administrator

RECOMMENDED ITEMS

55/11 R & D OPERATIONAL CAPABILITY STATEMENT

Members approved the content of the Research Support Services Operational Capability Statement (paper D refers) for recommendation (as an appendix to these Minutes) onto the Trust Board for approval, subject to the Assistant Director of Research and Development including additional wording within the section of the document entitled; 'Escalation Process' (page 10 of the report refers) with regard to the role of the Chairman of the R & D Committee and the R & D Committee itself.

ADRD

Members noted the dynamic nature of this document, and the fact that any minor changes to the document would be submitted to the R & D Committee for approval on behalf of the Trust Board, with the Trust Board subsequently notified of any such changes by the Chief Executive via the Minutes of the R & D Committee.

Recommended – that (A) the R & D Operational Capability Statement be supported, subject to the above referenced addition, and submitted to the Trust Board for formal approval (as an appendix to these Minutes), and

(B) any minor amendments to this document be submitted to the R & D Committee for approval on behalf of the Trust Board, with the Trust Board subsequently notified of any such changes by the Chief Executive via the Minutes of the R & D Committee.

CE

RESOLVED ITEMS

ACTION

56/11 APOLOGIES

Apologies for absence were received from Professor R Baker, LNR CLAHRC Director, Professor C Brightling, Professor of Respiratory Medicine; Professor D Field, Professor of Neonatal Medicine; Professor B Morgan, Professor of Cancer, Imaging and Radiology, Mr S Sheppard, Assistant Director of Finance, Dr A Tierney, Director of Strategy and Mr M Wightman, Director of Communications and External Relations.

57/11 MINUTES

Resolved – that (A) the Minutes of the Research and Development Committee meeting held on 11 April (paper A refers) be confirmed as a correct record, subject to:

- point (ii) of Minute 45/11 be amended to read: ‘noted that a recent MHRA Inspection had identified some issues relating to Pharmacy, none of which were critical’, and

TA

(B) the contents of the associated action plan (paper A1 refers) be confirmed as a correct record.

58/11 MATTERS ARISING FROM THE MINUTES

58/11/1 Matters Arising Report

Members reviewed the contents of the Matters Arising report (paper B refers) and members provided the following verbal updates in addition to the information already listed:

- Minute 44/11 – the Assistant Director of Research and Development had a meeting scheduled to take place on Wednesday 11 May 2011 with the University’s Intellectual Property and Commercialisation Team;
 - the Director of Research and Development had met with Professor Mellon both before and after the last meeting of the R & D Committee and would continue to pursue the exploration of potential fundraising opportunities with Professor Mellon on an on-going basis;
 - the Director of Research and Development had now spoken to a number of key people and was progressing the convening of a session specifically regarding surgical research;
- Minute 46/11 – the Director of Research and Development had now met with the Dean of the University of Leicester Medical School to discuss the latest iteration of the R & D Strategy. This document would be re-submitted to the R & D Committee for final review when completed;
- Minute 49/11 – the Chief Executive undertook to arrange a meeting with Mr Sheppard, Assistant Director of Finance, prior to the next meeting of the Research and Development Committee, and
- Minute 17/11 (of 7 February 2011) – it was agreed appropriate for Professor Samani (BRU Director) to include relevant information regarding the Trust’s planned re-appointment to the post of Chair of Medical Physics within the BRU application.

CE

Resolved – that (A) the contents of paper B, and the additional verbal information provided, be received and noted, and

(B) the Chief Executive be requested, prior to the next meeting of the Research and Development Committee, to arrange a meeting with Mr Sheppard, Assistant Director of Finance.

CE

59/11 QUARTERLY R & D SCORECARD AND AGREEMENT OF UHL R & D TARGET

The Assistant Director of Research and Development presented paper ‘C’, which detailed the quarterly R & D scorecard covering January to March 2011, and reported as follows on the content of this report:

- The Trust was on target in terms of the total number of research studies which were being undertaken. Particular discussion took place regarding ‘Own Account’ work and the fact that this was a requirement for certain NIHR applications. Members noted that the largest increase in research activity had taken place in respect of the category of ‘Other’ and the Assistant Director of Research and Development was requested to confirm the sub-categories included within ‘Other’

- at the next meeting of the Research and Development Committee;
- office performance was on par with that reported for the previous quarter. The Director of Research and Development advised members of a change to the system originally set-up whereby the figure now reported (for percentage of projects approved within 60 days) covered the whole time taken to approval and not just those aspects within the direct control of the R & D team;
- in respect of 'Governance', the Trust was in advance of its target against this indicator;
- with regard to the indicator relating to 'Recruitment to Studies', the Trust was currently on target to achieve a 20% increase on 2009/10 figures;
- the indicator relating to 'Portfolio' was expected to show an increase by June 2011;
- with regard to 'Publications' the Trust was currently above its 2009 level and within 15% of its own target;
- additional information had been included against the 'Grant Applications' indicator which members agreed was useful. Members also requested that, in future iterations of the quarterly R & D scorecard, the Assistant Director of Research and Development included the name of the Principal Investigator in the section relating to grants, and
- in response to a question raised in relation to research publications, it was agreed that the Assistant Director of Research and Development would discuss, with the Communications Team, the issue of tracking publications relating to UHL-led research in the media.

ADRD

ADRD

ADRD

With regard to the agreement of R & D related targets for the 2011/12 financial year, these were agreed as follows:

- (1) Recruitment to Studies – a 20% increase was agreed with regard to portfolio studies (in line with the national target) with a recognition that this would be a challenging target and a 10% increase was agreed in respect of non-portfolio studies (note being made that an increasing number of studies were likely to be portfolio studies);
- (2) Research Activity – a target of 10% increase was agreed;
- (3) Office Performance – it was agreed to set a stretch target of a median of 28 calendar days (against a challenging national target of a median of 30 calendar days) recognising the inherent challenges this target posed, and the potential need to take a pragmatic approach to realising this target if required (e.g. by agreeing a different standard for 'Own Account' studies);
- (4) Governance – a target of 10% increase was agreed (as per the recommendation from the Research Governance Framework);
- (5) Publications – previously the Trust had set its own arbitrary target of 10% increase on the previous year and was within 15% of target. Particular discussion took place regarding the wish to focus on the quality of publications rather than the number of publications. Following discussion, it was agreed that the following information would be collated and published on an annual basis: the number of papers published and the average impact factor of every publication. It was also agreed that the reporting of this figure would note this information for the current and also previous year. In discussion, it was also agreed that the Director and Assistant Director of Research and Development would give consideration as to how to give emerging newcomers credit for publishing papers, and
- (6) Grant Applications and Grant Awards – note was made that the Trust had not previously set a target against these indicators, and views were sought from members as to whether such a target should be set. It was agreed that the Director and Assistant Director of Research and Development would give consideration as to a possible target that could be applied against this particular indicator, reporting back at a future Committee meeting for agreement.

DRD/
ADRD

DRD/
ADRD

Resolved – that (A) the contents of this report, and the additional verbal information provided, be received and noted,

- (B) the Assistant Director of Research and Development be requested to:**
- (i) confirm the sub-categories included within 'Other' (Research Studies) at the next meeting of the Research and Development Committee, and** ADRD/TA
 - (ii) discuss, with the Communications Team, the issue of tracking publications relating to UHL-led research in the media, and** ADRD
- (C) the Director and Assistant Director of Research and Development be requested to:**
- (i) give consideration as to how to give emerging newcomers credit for publishing papers, and**
 - (ii) give consideration as to a possible target that could be applied against the Grant Applications and Grant Awards indicator, reporting back at a future Committee meeting for agreement.** DRD/ADRD/TA

60/11 PARTNERSHIP WITH QUINTILES

The Assistant Director of Research and Development reported verbally in respect of the Trust's partnership with Quintiles, noting that Quintiles had been pleased with the Trust's performance in the first year of the partnership. Quintiles had 25 sites in the United Kingdom and inducted partners to the scheme by recruiting them to participate in studies.

The Assistant Director of Research and Development reported that he was due to meet with Quintiles in the next month, at which time he would seek further figures from them to present at a future meeting of the Research and Development Committee for members' information.

ADRD

Resolved – that (A) this verbal information be noted, and

- (B) the Assistant Director of Research and Development be requested to seek further figures from Quintiles at his forthcoming meeting with them, for presentation at a future Research and Development Committee meeting.** ADRD/TA

61/11 NIHR FLEXIBILITY AND SUSTAINABILITY FUNDING ALLOCATIONS – 3 MONTH PROGRESS REPORT

The Director of Research and Development presented paper 'E', which detailed information regarding NIHR Flexibility and Sustainability Funding Allocations for 2011/12. Members' attention was particularly drawn to section 2.1 which detailed the Trust's (and CLAHRC's) FSF allocation for the past year (2010/11) and current year (2011/12) along with the percentage increase in funding received. Section 3.2 of the report also provided a comparison of the Trust's FSF funding compared to other comparable teaching Trusts.

Particular discussion took place regarding the following points:

- (i) the need to heighten awareness of FSF amongst University staff;**
- (ii) the benefit in transparency regarding where the FSF funds were utilised – it was agreed that the Director of Research and Development would present this information to a future meeting of the Research and Development Committee;** DRD/TA
- (iii) the need to agree a policy by which the Trust would deploy the FSF in any given year, and**
- (iv) regulations concerning FSF spend in Foundation Trusts (FTs) compared to NHS Trusts which were not Foundation Trusts.**

Resolved – that (A) the contents of this report be received and noted, and

- (B) the Director of Research and Development be requested to present information regarding FSF spend to a future meeting of the Research and Development Committee.** DRD/TA

62/11 ESTABLISHMENT OF AN ONCOLOGY CLINICAL TRIALS FACILITY

Dr Thomas, Reader and Consultant in Medical Oncology, reported verbally on this item, advising that there was now a proposed opening date of 24 February 2012 for the Oncology Clinical Trials Facility. An appropriate timeline for the project was in place, and relevant tender documentation was being drawn up. A meeting of the project group had been scheduled for May 2011 to work through the relevant data sheets. Further discussions were planned with the HOPE Foundation on 12th July 2011, and note was made of the desire of all involved to ensure that the 'finish' of the facility was as patient friendly as follows.

Resolved – that this verbal information be noted.

63/11 UPDATE ON PATIENT ADVISER LIAISON

Mrs Wells, Patient Adviser, reported verbally in respect of the Outreach into Schools Project, advising that she had met with Dr Pandya on 5 May 2011, and was pleased to report that the project; 'Opportunities for All: Exciting and Challenging Careers in Health and Science' would be going ahead, and would be held from 4 – 8 July 2011. The principle supervisors would be Dr Pandya and Dr Luyt, and the students who would participate would all be 16 years old. Mrs Wells circulated, for members' information, one copy of the draft modules already agreed, noting that most of the spare modules had now been filled. The response from the staff approached to participate had been very enthusiastic, and the course was to be written up by a Clinical Academic Trainee. Mrs Wells was currently developing two questionnaires; one to be completed by the student participants at the beginning of their course, and one to be completed at the end of the course. They would also receive a diary to complete contemporaneously as well as documentation concerning Health and Safety, confidentiality etc. The main aim of the course was to create a partnership between schools, colleges and universities. It was also hoped that the course would raise awareness of opportunities that existed for young people and also encourage leadership amongst the students. This was to be a pilot study which, if successful, would provide a model for future work.

Funding for the project remained an issue. It was estimated that the costs would be in the region of £500, which included provision for a very basic food allowance. The Director of Research and Development noted that the nature of the project, in terms of its patient and public involvement, should be viewed favourably by the NIHR.

In further discussion on this item, Mr Panchal, Non-Executive Director, sought assurances that the students invited to participate would be as representative as possible in terms of their communities and geographical location, noting the need to ensure that those students in vulnerable and marginalised communities were not put at a disadvantage. Mrs Wells, whilst noting the intention to select students based on their interest in taking part, undertook to pass Mr Panchal's comments onto Dr Pandya, and request that Dr Pandya replied directly to Mr Panchal regarding these specific points.

JW

Resolved – that (A) this verbal information be noted, and

(B) Mrs Wells, Patient Adviser, be requested to contact Dr Pandya regarding the issue raised in terms of ensuring that children from marginalised and vulnerable communities were not disadvantaged in the selection process employed with regard to this project, and to request that Dr Pandya replied directly to Mr Panchal on these points.

JW

64/11 MINUTES FOR INFORMATION

64/11/1 Biomedical Research Unit Board

It was noted that the Minutes of the BRU Board meeting held on 11 April 2011 would be presented at the next meeting of the R & D Committee.

TA

The Chief Executive and Professor Samani, BRU Director, reported verbally to advise that all three of the Trust's BRU applications had been short-listed, and significant work would now be undertaken within the Trust in order to submit full applications by the July 2011 deadline. In response to a query from Professor Samani as to whether interviews would be held with short-listed Trusts as part of the next stage of the application process, the Chief Executive undertook to seek clarification at the next meeting of the NIHR Board and to confirm the outcome, via email, to relevant staff.

CE

Resolved – that (A) this verbal information be noted,

(B) the Chief Executive be requested to seek clarification at the next meeting of the NIHR Board as to whether interviews will be held for those Trusts who had been successful in having their BRU applications short-listed, and to confirm the outcome, via email, to relevant staff members, and

CE

(C) the Minutes of the BRU Board meeting held on 11 April 2011 be submitted to the next meeting of the Research and Development Committee.

TA

64/11/2 CLAHRC

Resolved – that it be noted that the next CLAHRC meeting was due to be held in June 2011.

65/11 **ANY OTHER BUSINESS**

65/11/1 R & D - Strategic Discussion

In response to a suggestion made by the Chief Executive, members agreed the periodic scheduling of a three-hour strategic R & D discussion within the calendar of business for the Research and Development Committee. The Trust Administrator was requested to schedule such a strategic discussion for the R & D Committee in September 2011.

TA

Resolved – that the Trust Administrator be requested to schedule a three hour discussion in the calendar of business for the Research and Development Committee in September 2011.

TA

66/11 **IDENTIFICATION OF KEY ISSUES THAT THE COMMITTEE WISHES TO DRAW TO THE ATTENTION OF THE TRUST BOARD**

Resolved – that the following items be brought to the attention of the Trust Board at its meeting on 2 June 2011:

- R & D Operational Capability Statement (Minute 55/11 refers), and
- The current status of the BRUs (Minute 64/11/1 refers).

67/11 **DATE OF NEXT MEETING**

Resolved – that the next meeting of the Research and Development Committee be held on Monday 13 June 2011 at 2.30pm in the Leslie Lewis Tutorial Room, Clinical Education Centre, Leicester Royal Infirmary.

The meeting closed at 4.02pm.

Gill Belton - Trust Administrator

NIHR Guideline B01

R&D Operational Capability Statement

Version History

Version number RDOCS 001	Valid from 01/07/2011	Valid to 31/06/2012	Date approved 01/07/2011	Approved by xxx	Updated by rrr
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 Organisation Services
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 Organisation R&D Planning and Investments
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 Other Information

Organisation R&D Management Arrangements

Information on key contacts

Organisation Details	
Name of Organisation	University Hospitals of Leicester NHS Trust
R&D Lead / Director (with responsibility for reporting on R&D to the Organisation Board)	Professor David Rowbotham
R&D Office details:	
Name:	R&D Office
Address:	Leicester General Hospital, Gwendolen Road, Leicester LE5 4PW
Contact Number:	0116 258 8351
Contact Email:	
Other relevant information:	Fax: 0116 258 4226
Key Contact Details e.g. Research Governance Lead, NHS Permissions Signatory contact details	
Contact 1:	
Role:	Assistant Director of R&D
Name:	Dr David Hetmanski
Contact Number:	0116 258 4199
Contact Email:	david.hetmanski@uhl-tr.nhs.uk
Contact 2:	
Role:	R&D Manager
Name:	Mrs Carolyn Maloney
Contact Number:	0116 258 4109
Contact Email:	carolyn.maloney@uhl-tr.nhs.uk
Contact 3:	
Role:	
Name:	
Contact Number:	
Contact Email:	

Add further contacts by selecting and then **copying** the five Excel **rows** (ie 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
Assistant Director R&D	1 WTE	
R&D Manager	1 WTE	
Clinical Trials Monitor & Trainer	1 WTE	
Senior RM&G Facilitator	1 WTE	
RM&G Facilitator	2 WTE	
R&D Administrator	1.6 WTE	
Portfolio Coordinator	1.5 WTE	
Senior Finance Manager	1.0 WTE	
Assistant Research Accountant	0.8 WTE	
Governance Manager	1.0 WTE	University of Leicester
Governance Officer	1.0 WTE	University of Leicester

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
Trust R&D Committee (monthly): Chaired by the Trust Chairman, attended by the Chief Executive, Director of R&D, Director of Strategy, Director of Communications and External Relations, Assistant Director of Finance, Patient Advisor, Researcher from Acute Division, Researcher from Planned Care Division, Researcher from Women's & Children's Division, Researcher from Clinical Support Division, Dean of the University of Leicester Medical School, Assistant Director of R&D. Minutes of the meeting are reported to the Trust Board. Recommendations and key issues are drawn to the attention for of the Trust Board for consideration at its next meeting.

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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 eg host Organisation
Leicestershire, Northamptonshire & Rutland Comprehensive Local Research Network	Host Organisation
Trent Stroke Research Network	Host Organisation
South East Midlands Diabetes Local Research Network	Host Organisation
Leicestershire, Northamptonshire & Rutland Cancer Research Network	Host Organisation
Trent Local Research Children's Network	Satellite Office

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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 (eg	Contact Name	Email address	Contact Number
University of Leicester	Main academic research partner; Joint R&D Office;	Graham Hewitt	gjh13@leicester.ac.uk	0116 223 1262 or 0116 258 8241

Leicester Cardiovascular Biomedical Research Unit	Collaboration with the University of Leicester; funded by the NIHR	Tim Skelton, BRU Manager	ts144@leicester.ac.uk	0116 250 2429
Leicestershire, Northamptonshire & Rutland Collaboration for Leadership in Applied Health Research & Care	Collaboration with the University of Leicester and NHS Trusts in the LNR region; funded by the NIHR	Martin Williams, CLAHRC manager	mjw48@leicester.ac.uk	0116 252 5419
Respiratory Therapeutic Capability Cluster	As a centre with the University of Leicester in a collaboration between Pharma, academia and the NHS	Prof Chris Brightling	ceb17@leicester.ac.uk	0116 258 3340
Leicester Clinical Trials Unit	Based at the University of Leicester; collaboration between the University and the Trust; awarded provisional registration by the United Kingdom Clinical research Collaboration (UKCRC)	Dr Linda Porter	lp173@leicester.ac.uk	0116 249 4536
University Hospitals of Nottingham NHS Trust	Agreement for provision of PET Scanning by the InHealth PET Centre, Nottingham City Hospital	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351
University of Nottingham	Research collaboration in Respiratory Medicine and Oncology	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351
Loughborough University	Research collaboration in Sports & Exercise Medicine, Health Services	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351
De Montford University	Research collaboration in Nursing, Imaging Technology	Contact via UHL R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351

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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	II, II, IV	✓	✓	✓	✓	✓	
As Participating Organisation	I, II, II, IV	✓	✓	✓	✓	✓	
As Participant Identification Centre	✓	✓	✓	✓	✓	✓	

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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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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	The University and Trust Jointly hold an HTA Licence for Research, (Licence Number: 12384) under Section 16 (2) (e) (ii) of the Human Tissue Act 2004. The licence authorises the storage of relevant material for the following scheduled purposes: Establishing after a person's death the efficacy of any drug or other treatment administered to him; Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); Public display; Research in connection with disorders, or the functioning of the human body; Clinical audit; Education or training relating to human health; Performance assessment; Public health monitoring; Quality assurance;		The Licence is renewed on a rolling basis each July 14th, and remains in place until revoked

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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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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 (eg number/type of scanners)	Contact Name within Service Department	Contact email	Contact number	Details of any internal agreement templates and other comments
<i>Pathology</i>	UHL pathology services offer an extensive range of tests for all disciplines to both Leicestershire patients and beyond. We are a reference facility for a number of specialised tests including toxicology, Haematological Malignancy disorders, Renal Calulus analysis and Renal Biopsy histopathology to name a few. In the small number of cases where UHL pathology does not offer a test in house, then we are normally able to arrange this testing through an accredited laboratory with whom we hold a service level agreement	Mr Andrew Folwell	andrew.folwell@uhl-tr.nhs.uk	0116 204 7802	
<i>Radiology</i>	The UHL Imaging Department provides all the scanning and imaging facilities expected for a trust of this size including six CT systems (full body), five MRI systems (full body, superconducting magnets), five Gamma Camera systems and numerous basic, fluoroscopic and mammographic X-ray systems. Provision of all the above categories are provided across the three hospital sites of the Trust.	Prof Bruno Morgan	bruno.morgan@uhl-tr.nhs.uk	0116 258 6898	
<i>Pharmacy</i>	UHL Pharmacy has Trials Pharmacists covering all three hospitals of the UHL Trust, supported by a team of dedicated Trials Technicians.	Mr David Lovett	david.lovett@uhl-tr.nhs.uk	0116 258 5462	
<i>Cardiac Imaging</i>	UHL was awarded funding by the NIHR for a new dedicated 3 Tesla research scanner for Cardiovascular Magnetic Resonance (CMR) imaging. The instrument was installed at a new build on the Glenfield Hospital site in February 2011.	Dr Gerry McCann	gerry.mccann@uhl-tr.nhs.uk	0116 258 3476	

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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>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	
<i>Contracts</i>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	
<i>Data management support</i>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	
<i>Finance</i>		Abdul Ismail	abdul.ismail@uhl-tr.nhs.uk	0116 258 8241	
<i>Information Technology</i>		IM&T	caroline.hughes@uhl-tr.nhs.uk	0116 258 8521	
<i>Legal</i>		Steve Murray	steve.murray@uhl-tr.nhs.uk	0116 258 8960	
<i>HR</i>		Nicola Junkin	nicola.junkin@uhl-tr.nhs.uk	0116 258 5540	
<i>Statistical support</i>		R&D Office	rdadmin@uhl-tr.nhs.uk	0116 258 8351	

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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
Cardiovascular	Genetics of coronary heart disease and development of new treatments; management of hypertension; novel therapeutic interventions for heart disease; cerebrovascular disease and stroke; cardiovascular imaging; causes and treatment of cardiac arrhythmias; cardiovascular imaging; measurement and monitoring of cardiovascular system; haemostatic mechanisms in atherothrombotic diseases; management of heart failure; vascular surgery techniques and outcomes; cardiovascular disease in ethnic minority groups.	Prof Nilesh Samani	njs@leicester.ac.uk	0116 258 3236
Diabetes	Prevention, early diagnosis, patient education and self-management; assessment of new therapies; diet, nutrition, sedentary behaviour; service development; ethnic minority groups.	Prof Melanie Davies	melanie.davies@uhl-tr.nhs.uk	0116 258 6481
Respiratory	Pathophysiology, genetics and treatment of asthma and COPD; pulmonary rehabilitation; tuberculosis; viral infections, vaccines and antiviral agents; ciliary dyskinesia (primary and chronic disease); chronic cough; emphysema surgery; extracorporeal membrane oxygenation.	Prof Chris Brightling	chris.brightling@uhl-tr.nhs.uk	0116 258 3340
Oncology	Clinical trials and development of novel chemotherapeutic agents (including those developed in our Experimental Cancer Medicine Centre laboratory); prevention of cancer; novel imaging techniques; new therapies for B cell malignancies; diagnosis and treatment of bladder and prostate cancer; novel surgical techniques.	Dr Anne Thomas	at107@leicester.ac.uk	0116 258 7602
Renal Disease	Translational, clinical and epidemiological studies in proteinuric renal disease, tubular injury, IgA nephropathy, and diabetic nephropathy; mechanisms of progressive renal injury; preventing renal disease; management of renal transplantation.	Prof Nigel Brunskill		

Child Health	National and regional infant mortality and morbidity of the fetus, infant, and child related to pregnancy, delivery, and intensive care; paediatric pharmacokinetics and pharmacodynamics; respiratory disease.	Prof David Field	df63@leicester.ac.uk	0116 258 5522
Transforming research evidence into practice	This work is conducted through the LNR CLAHRC which is hosted by UHL and includes several UHL employees as programme leads and investigators. Its purpose is to: conduct applied health research in new ways that can more rapidly inform practice; increase research capacity in the NHS so partner NHS organisations are better able to generate, and make use of, new research evidence; develop systems and structures for the application of knowledge and for the translation of research evidence into more effective and efficient health care policy and practice.	Prof Richard Baker	rb14@leicester.ac.uk	0116 252 3277
Women's Health	Urogynaecology, pre-term birth, hypertension in pregnancy; fetal-placental growth.	Mr Marwan Habiba	mah6@leicester.ac.uk	0116 258 3170

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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	Age & Aging		<i>Dr Simon Conroy</i>	spc3@leicester.ac.uk	0116 252 5878
National	Age & Aging		<i>Prof Tom Robinson</i>	tom.robinson@uhl-tr.nhs.uk	0116 252 3182
Local & National	Cardiovascular		<i>Prof Nilesh Samani</i>	njs@leicester.ac.uk	0116 258 3236
Local & National	Genetics		<i>Prof Liz Draper</i>	msn@leicester.ac.uk	0116 252 3200
Local & National	Critical Care		<i>Dr Jonathan Thompson</i>	jt23@leicester.ac.uk	0116 258 5658
Local & National	Dermatology		<i>Dr Anton Alexandrov</i>	anton.alexandrov@uhl-tr.nhs.uk	0116 258 7562
Local & National	Ophthalmology		<i>Prof Irene Gottlob</i>	ig15@leicester.ac.uk	0116 258 5041
Local & National	Gastroenterology		<i>Prof Janusz Jankowski</i>	janusz.jankowski@uhl-tr.nhs.uk	0116 204 7864
Local	Infectious Diseases & Microbiology		<i>Dr Adrian Palfreeman</i>	adrian.palfreeman@uhl-tr.nhs.uk	0116 258 5859
Local & National	Injuries & Emergencies		<i>Prof Tim Coates</i>	tc61@leicester.ac.uk	0116 252 3263
Local & National	Paediatrics (non-medicines)		<i>Dr Monica Lakhonpaul</i>	ml103@leicester.ac.uk	
Local & National	Renal		<i>Prof Nigel Brunskill</i>	nigel.brunskill@uhl-tr.nhs.uk	0116 258 8043
Local & National	Urogenital & Urogynaecology		<i>Mr Masood Khan</i>	masood.khan@uhl-tr.nhs.uk	0116 258 4449
Local & National	Reproductive Health & Childbirth		<i>Mr Marwan Habiba</i>	mah6@leicester.ac.uk	0116 258 3170
	Respiratory		TBA		

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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
Respiratory	Refurbishment to provide additional clinical trial / research facilities	£300k	Autumn 2011
Diabetes	Refurbishment of two existing ward areas for a Diabetes Centre of Excellence	£600k	Summer 2011
Oncology	Refurbishment of existing an existing theatre area to provide further clinical research capacity	£350k	Autumn 2011
Cardiovascular Research Centre	University of Leicester are building and equipping a new four story research facility on the Glenfield Hospital Site	£12.6M	Spring 2012

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Organisation R&D Standard Operating Procedures Register

Standard Operating Procedures				
SOP Ref Number	SOP Title	SOP Details	Issue Date / Amendment Date	Review Date
UHL SOP CLIN/101	Preparation, Approval, Distribution, Amendment and Storage of Standard Operating Procedures		March 2006 Superseded September 2010	31/03/2012
UHL SOP CLIN/102	Informed Consent to include process of assessment for Non Medic, AHP & Nurses		March 2006 Superseded January 2010	31/03/2011
UHL SOP CLIN/104	Clinical Trials Authorisation		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/105	Study Specific R&D Files		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/106	Preparation of Clinical Trial Protocols and Procedures for Amendments		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/107	Protocol Amendments		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/108	Site Management (Monitoring) for Trust as Sponsor		March 2006	31/03/2011
UHL SOP CLIN/109	Processing and Reporting of Serious Adverse Events/Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions		March 2006 Superseded 30/11/2010	31/03/2011
UHL SOP CLIN/110	Inspection by Regulatory Agencies		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/112	The review of Clinical Trials involving Pharmacy		March 2006	31/03/2011
UHL SOP CLIN/113	Sourcing a Supplier of a Placebo for In-House studies		March 2006	31/03/2011
UHL SOP CLIN/114	Research Agreements		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/115	Clinical Trials Management for In-house Sponsored Trials		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/116	Indemnity for Negligent/Non-negligent Harm		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/117	Suspected Fraud/Malpractice in Clinical Research		March 2006 Superseded January 2010	31/03/2011
UHL SOP CLIN/118	Laboratory Procedures		March 2006	31/03/2011
UHL SOP CLIN/119	Research Governance/ Sponsor Audit Policy		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/120	Data Protection Policy		March 2006 Superseded April 2009	31/03/2011
UHL SOP CLIN/121	Training in Staff Engaged in Clinical Trials		March 2006 Superseded January 2010	31/03/2011
UHL SOP CLIN/122	Equipment Maintenance/Calibration		March 2006	31/03/2011
UHL SOP CLIN/123	R&D Approval Process		March 2006 Superseded 18/09/2009	31/03/2011
UHL SOP CLIN/124	CI/PI Responsibilities		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/126	Tissue Bank Guidelines		March 2006 Superseded March 2009	31/03/2011
UHL SOP CLIN/127	Procedure in event of Non-Compliance		March 2009	31/03/2011
UHL SOP CLIN/128	Procedure for Transfer of Human Tissue		March 2009	31/03/2011
UHL SOP CLIN/129	Pre-approval of Studies involving Genetically Modified Materials and / or Gene Therapy		May 2009	31/03/2011
UHL SOP CLIN/130	Access to Patient Notes for Research		May 2006	31/03/2011
UHL SOP CLIN/131	Peer Review for studies under review for Sponsorship by University Hospitals of Leicester NHS Trust		November 2009	31/03/2011

UHL SOP CLIN/132	Risk Assessment of Clinical Trials of Medicinal Products and Device Trials		November 2009	31/03/2011
UHL SOP CLIN/133	Essential Study Documentation. Trial Master Files/Site Files		February 2010	31/03/2011
UHL SOP CLIN/134	Review of Research Proposals requiring University Hospitals of Leicester NHS Trust Sponsorship		February 2010	31/03/2011
UHL SOP CLIN/135	Self-Monitoring Procedures for Research Activity at University Hospitals of Leicester NHS Trust		March 2010	31/03/2011

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Information on the processes used for managing Research Passports

Indicate what processes are used for managing Research Passports

The process is as described in the Trust's Research Passport Policy (Trust ref B1/2010), approved by the Policy & Guideline Committee 18/01/10.

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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

Projects are processed by the RM&G Team in the Joint Trust and University R&D Office. Weekly project meetings provide a forum to flag any issues that may become a problem. Potential issues are escalated to the R&D Manager in the first instance, then to the Assistant Director, the Director and then to the R&D Committee for review. Where an expedited response is required, issues may be directly referred to the highest level within the Trust including the Chief Executive and within the University of Leicester to the Dean of the College of Medicine, Biological Sciences and Psychology.

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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 collaborate in.

Comments

All research activity is entered onto the ReDA Research Management Database. We have access to CSP intelligence from the CLRN.

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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 activity may be found on the Trust's website (www.uhl-tr.nhs.uk/ourservices/rd) and on the University of Leicester College of Medicine, Biological Sciences and Psychology website (www2.le.ac/colleges/medbiopsych/research).

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