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UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT BY TRUST BOARD COMMITTEE TO TRUST BOARD

DATE OF TRUST BOARD MEETING: 7 July 2011

COMMITTEE: UHL RESEARCH AND DEVELOPMENT COMMITTEE

CHAIRMAN: Mr M Hindle, Trust Chairman

DATE OF COMMITTEE MEETING: 13 June 2011

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

- There were no specific recommendations for the Trust Board arising from the Research and Development Committee meeting held on 13 June 2011.

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

- The Planned Care Research Strategy (Minute 71/11 refers);
- Development of a Paediatric Cardiac Surgery Research Strategy (Minute 72/11 refers);
- UHL R & D Strategy and Divisional Engagement (Minute 73/11 refers);
- MHRA Action Plan (Minute 74/11 refers), and
- Human Tissue Authority Inspection (Minute 75/11 refers).

DATE OF NEXT COMMITTEE MEETING: 11 July 2011.

**Mr M Hindle, Trust Chairman
1 July 2011**

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

**MINUTES OF A MEETING OF THE UHL RESEARCH AND DEVELOPMENT COMMITTEE,
HELD ON MONDAY 13 JUNE 2011 AT 2.30PM IN THE LESLIE LEWIS TUTORIAL ROOM,
CLINICAL EDUCATION CENTRE, 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
Professor B Morgan – Professor of Cancer, Imaging and Radiology
Professor D Rowbotham – Director of Research and Development
Mr S Sheppard - Assistant Director of Finance
Ms A Tierney – Director of Strategy
Dr A Thomas - Reader and Consultant in Medical Oncology

In attendance:-

Professor R Baker - LNR CLAHRC Director
Mrs G Belton – Trust Administrator
Mr A Lotto – Consultant Cardiac Surgeon and Director of Research, East Midlands Congenital Heart Centre (for Minute 72/11 only)
Mr A Palmer – Research Service Manager, Acute Division (for Minute 72/11 only)
Mr P Panchal - Non-Executive Director

RESOLVED ITEMS

ACTION

68/11 APOLOGIES AND WELCOME

Apologies for absence were received from Professor C Brightling, Professor of Respiratory Medicine; Professor D Field, Professor of Neonatal Medicine; Professor N Samani, BRU Director; Mrs J Wells, Patient Adviser; Professor D Wynford-Thomas, UHL Non-Executive Director and Dean of the University of Leicester Medical School and Mr M Wightman, Director of Communications and External Relations.

The Chairman welcomed Professor R Baker, LNR CLAHRC Director to his first meeting of the UHL R & D Committee.

69/11 MINUTES

Resolved – that (A) the Minutes of the Research and Development Committee meeting held on 9 May 2011 (paper A refers) be confirmed as a correct record, and

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

TA

70/11 MATTERS ARISING FROM THE MINUTES

70/11/1 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 42/10 (of 10 May 2010) relating to the provision of an update on the relationship between MIT/Harvard and health service management – the Director of Strategy confirmed that she was progressing a number of avenues, and would notify the Trust Administrator when she had further information to report to the Committee in order that this could be scheduled on a future agenda as appropriate;

DS/TA

- Minute 44/11 (of 11 April 2011) relating to actions arising out of Professor Mellon's presentation to the Committee on Urological Research within UHL – the Assistant Director of Research and Development confirmed that he had spoken to the University's Innovation Office and alerted them to potential issues relating to Intellectual Property arising from Professor Mellon's presentation, and would provide further updates at future Committee meetings as appropriate. Particular discussion took place regarding information which was provided to UHL clinicians concerning Intellectual Property, noting the importance of clinicians undertaking research being fully aware of such issues. Whilst information regarding this issue was not currently issued directly by the Trust's R & D Office, clinicians were recommended to attend talks at the University on this issue. However, it was noted that the Research and Development website was currently being re-designed, and when re-launched, would include information regarding intellectual property;
- Minute 59/11 (Quarterly R & D Scorecard and Agreement of UHL Target):
 - in response to a query raised at the previous meeting, the Assistant Director of Research and Development confirmed that sub-categories included within 'Other' research studies included non-NHS, and non-NIHR studies (e.g. Department of Transport or other Government Departments, and also other Trusts or Universities);
 - with regard to the target to be applied against the Grant Applications and Grant Awards indicator, the Director of Research and Development recommended a target of 20%, which was agreed by the Committee;
 - in respect of the issues raised at the previous meeting relating to actions designated to the Director and Assistant Director of Research and Development (namely, discussing the issue of tracking publications relating to UHL-led research in the media with the Communications Team, and giving consideration as to how to give credit for publishing papers to emerging newcomers) the Director of Research and Development confirmed that discussions had commenced with the Communications Team regarding these matters. No firm plans had yet been agreed, so it was agreed that this item would remain on the Committee's Matters Arising report with verbal feedback regarding progress given at future meetings, as appropriate;
- Minute 64/11/1 (BRU Applications) – further to a query raised at the previous meeting, the Chief Executive confirmed that the interview date for the Trust in respect of its BRU Applications would be 22 July 2011. A maximum of five people (comprising both Trust and University staff) were to attend and discussions were currently underway as to identifying the most appropriate staff for this purpose, and
- Minute 65/11/1 (Scheduling of Strategic Discussion) – the Trust Administrator confirmed that the R & D Committee meeting scheduled for 5 September 2011 was to be given over for a three-hour strategic discussion regarding R & D as per the Committee's request to have time devoted specifically for this purpose.

ADRD

DRD

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

(B) the Director of Strategy be requested to notify the Trust Administrator when she had further information to report back to the Committee in respect of Minute 42/10 of 10 May 2011 (as referenced above) in order that this could be scheduled on a future agenda, as appropriate, and

DS/TA

(C) the actions relating to the third bullet point of Minute 59/11 above remain on the Committee's Matters Arising report, and the Director of Research and Development be requested to provide verbal updates regarding progress at future Committee meetings, as appropriate.

DRD/TA

71/11 PLANNED CARE RESEARCH STRATEGY

Dr Thomas, Reader and Consultant in Medical Oncology gave a presentation to the Committee regarding the R & D Strategy for the Planned Care Division, the contents of which were detailed in paper C. The Director of Research and Development expressed his gratitude to Dr Thomas for giving this presentation at short notice, and note was made of the wish of the Divisional Director of Planned Care, who could not be present at today's meeting, to attend a future meeting of the Committee to expand further on the Division's research strategy.

Dr Thomas particularly highlighted the following points within her presentation:

- (a) the findings that patients who were involved in research studies tended to do better than those who were not. Such patients underwent more follow-ups than patients who were not involved in research studies and there was a need to ensure that all patients were able to participate in research studies if they wished to do so;
- (b) the need to effectively cascade messages regarding the importance of research and development given the apparent perception sometimes at grass roots level that research was not a priority for the Trust;
- (c) various strengths (e.g. the links within R & D), and also weaknesses that currently existed. A particular issue was raised in relation to HR turnaround times and support, which the Chief Executive undertook to progress outwith the meeting; CE
- (d) a specific issue regarding the changing of letter templates utilised for patients (relating to the aim to get research embedded into everyday practice). The Chief Executive undertook to highlight this specific issue at the 100 Meeting due to be held that evening, and CE
- (e) the excitement clinicians felt about the development of the Hope Unit, which would be a dedicated space for patients to attend to receive their therapies.

In discussion on this item, members:

- (i) debated any apparent 'rising stars' of research noting the strong links between the R & D Strategy and the analysis of the Trust's services which was currently being undertaken by the Strategy Directorate. Note was made of some research work being undertaken within General Surgery and Musculo-Skeletal, however the majority of the research work within the Planned Care Division related to Cancer Services;
- (ii) made note of the genetic studies being undertaken, as well as the wider engagement work planned with the public – it was considered that the Trust should be ambitious in terms of its five year plan and also be conscious of the relevance of its research to the wider community (particularly when making investment decisions), making note also of any particular issues relating to NICE and with regards to PCT commissioning. Whilst there was no current link with CLAHRC, there existed wider links with others, and there also existed the practical link of translating research into practice;
- (iii) considered it important to set the national context, in order not to proceed insularly;
- (iv) agreed that the Reader and Consultant in Medical Oncology (and relevant others) in conjunction with the Dean of the University of Leicester Medical School should ensure that the Planned Care Research Strategy was congruent with the University's Research Strategy (with appropriate dovetailing of definitions); RCMO/
DUoL
- (v) agreed that the Reader and Consultant in Medical Oncology would review the scope for further contributions from others within Planned Care, as appropriate, and RCMO
- (vi) considered that it may prove helpful to have information from the Director and Assistant Director of Research and Development relating to collaborations

being undertaken with other Trusts / Academic partners, particularly in respect of strategic collaborations as opposed to short-term collaborations. In light of the Trust's current on-going work relating to its BRU applications, it was agreed appropriate to consider the issue of developing strategic links further in August / September 2011.

**DRD/
ADRD/
TA**

In conclusion, the Chairman thanked Dr Thomas for her presentation.

Resolved – that (A) the contents of this presentation (paper C refers) and the additional verbal information provided be received and noted,

(B) the Chief Executive be requested to look into those issue raised under points (c) and (d) above,

CE

(C) the Reader and Consultant in Medical Oncology be requested to undertake the actions identified in points (iv) and (v) above, and

**RCMO/
D,UoL**

(D) the Director and Assistant Director of Research and Development be requested to schedule an agenda item regarding the issue covered under point (vi) above at a future meeting of the Research and Development Committee (in August or September 2011).

**DRD/
ADRD/
TA**

72/11 DEVELOPING A PAEDIATRIC CARDIAC SURGERY RESEARCH STRATEGY

Mr Lotto, Consultant Cardiac Surgeon and Director of Research for East Midlands Congenital Heart Centre and Mr Palmer, Research Service Manager (Acute Division) attended to give a presentation to the Committee regarding the development of a Paediatric Cardiac Surgery Research Strategy.

The recent amalgamation of congenital heart disease services into the EMCHC had unveiled the necessity for the EMCHC to develop a research strategy in line with the broader UHL strategy. In this way the EMCHC would also be fully recognised into the Trust's R & D Strategy and create a structure within the EMCHC which was able to help and support clinicians dealing with research. The contents of Mr Lotto's presentation, and the supporting paperwork (paper D refers) outlined the vision for the EMCHC research strategy and detailed the work undertaken to-date.

Following the presentation, in discussion on this item, members:

- (i) noted that the Safe and Sustainable Review had identified a gap currently with regard to the Centre's Research Strategy, which was being addressed through the work described;
- (ii) commended Mr Lotto on the work undertaken around the infrastructure, and requested that he included information relating to areas of research focus (both current and future areas) within the next draft of the strategy for discussion and agreement by the EMCHC Research Board;
- (iii) made note of links to the Trust's Cardio-Respiratory BRU application, and of the assistance offered by Professor Samani and Professor Williams in initial discussions of the EMCHC Research Board;
- (iv) in response to a query, noted that a number of individuals had already been identified, and agreed, to become members of the EMCHC Research Board. In terms of how the EMCHC Research Board would operate, it was agreed that the Director of Strategy would assist Mr Lotto in the convening of the Research Board in terms of defining the terms of reference etc, and
- (v) agreed that Professor Baker and Mr Lotto would meet further outwith the meeting to discuss issues raised relating to perinatal mortality studies and the congenital register.

CCS

DS

RB/CCS

In conclusion, the Committee congratulated Mr Lotto on the progress made to-date (noting his gratitude to Mr Palmer in terms of the support he had offered to Mr Lotto) and extended their full support to him in the achievement of his vision. The Committee requested that Mr Lotto returned to attend a meeting of the UHL Research and Development Committee in six months' time to report on progress.

CCS/TA

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

(B) Mr Lotto, Consultant Cardiac Surgeon and Director of Research for East Midlands Congenital Heart Centre, be requested to include information relating to areas of research focus (both current and future areas) within the next draft of the strategy for discussion and agreement by the EMCHC Research Board,

CCS

(C) the Director of Strategy be requested to assist Mr Lotto in the convening of the Research Board in terms of defining the terms of reference etc,

DS

(D) Mr Lotto, Consultant Cardiac Surgeon and Director of Research for East Midlands Congenital Heart Centre and Professor Baker, LNR CLAHRC Director be requested to meet further outwith the meeting to discuss the issues raised under point (v) above, and

RB/CCS

(E) Mr Lotto, Consultant Cardiac Surgeon and Director of Research for East Midlands Congenital Heart Centre, be requested to attend a meeting of the UHL Research and Development Committee in six months' time to report on progress.

CCS/TA

73/11

UHL R & D STRATEGY AND DIVISIONAL ENGAGEMENT

The Director of Research and Development reported verbally, confirming that discussions had now concluded with Professor Wynford-Thomas, Non-Executive Director and Dean of the University of Leicester Medical School and that the Trust's R & D Strategy was congruent with the University of Leicester Research and Development Strategy.

It was agreed that the Director of Research and Development and the Director of Strategy would now finalise the UHL Research and Development Strategy for submission to, and endorsement by the Research and Development Committee in July 2011 for onward recommendation to the Trust Board for formal approval at its meeting in August 2011. In terms of embedding the strategy within the Divisions, it was agreed appropriate thereafter to issue a set of metrics around R & D development to the Divisions.

DRD/DS

Note was made of the need for the final version of the strategy to include details of the 'rising stars' the Trust would be investing in. It was agreed that the Director of Strategy would pick up any additional relevant issues with Professor Baker, LNR CLAHRC Director outwith the meeting.

DS/
LNR,CD

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

(B) the Director of Research and Development and Director of Strategy be requested to finalise the UHL Research and Development Strategy for submission to, and endorsement by the Research and Development Committee in July 2011 for onward recommendation to the Trust Board for formal approval at its meeting in August 2011 (thereafter issuing a set of metrics around R & D development to the Divisions), and

DRD/DS

(C) the Director of Strategy be requested to pick up any relevant issues relating to the R & D Strategy with Professor Baker, LNR CLAHRC Director.

DS

74/11 MHRA ACTION PLAN

The Director of Research and Development presented paper 'E', which related to the Medicine and Healthcare Products Regulatory Agency's (MHRA) Statutory Routine GCP Systems Inspection at the Trust between 14th and 17 March 2011. The Inspection Report detailed the findings and recommendations by the Inspectors. There were no "critical" findings identified during the inspection, which was welcomed, however there were findings identified in the areas relating to informed consent and trial management, the full categorisation of and details relating to which were as detailed within paper E. The Trust was required to respond to each of the findings by providing a brief summary of planned corrective and preventative actions along with an estimated timeframe for completion, and this was returned to the MHRA within the permitted timeframe (appendix 1 to paper E refers).

The MHRA Inspections could accept the response to the report findings or seek further information or clarification from the R & D Department. Once the responses had been deemed satisfactory, the MHRA would issue an Inspection Statement with an accompanying Closing Letter.

In discussion, it was noted that where studies had now been archived, any issues arising from these as identified in the report, would be addressed through the implementation of action to prevent any recurrence in future studies.

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

75/11 HUMAN TISSUE AUTHORITY INSPECTION

The Assistant Director of Research and Development reported verbally to advise of a HTA (Human Tissue Authority) Inspection undertaken on 24 May 2011, the findings of which had been released on 10 June 2011. No critical, major or minor findings had been identified. The systems of governance and oversight were commended, and the audit programme was specifically highlighted as an example of good practice. The inspectors gave advice on the destruction of long held tissue samples, and recommended addition of more detail to the Standard Operating Procedures (SOPs) should the University begin research tissue bank operations. The Assistant Director of Research and Development particularly commended Mr G Hewitt, University of Leicester Research Governance Manager for the work he had undertaken in preparation for the inspection.

The Committee noted this excellent outcome, and formally recorded their thanks to the staff involved.

Resolved – that this verbal information be noted.

76/11 EXTERNAL ACADEMIC REVIEW

The Chief Executive reported verbally to advise that Professor Wynford-Thomas, Dean of the University of Leicester Medical School was currently considering inviting one or two people from a number of recommended names to undertake a review of the Academic Strategy. Terms of reference for the review were to be agreed, and invitations would then be issued.

Resolved – that this verbal information be noted.

77/11 PROGRESS ON BRU APPLICATIONS

The Director of Research and Development reported verbally on progress with the Trust's three BRU applications, noting that the deadline for submission of the applications was the

end of the current week.

During discussion on this item, members:

- (i) noted that the Director of Research and Development would oversee the final submissions of all three applications to ensure their coherence and congruence;
- (ii) noted the potential staff members (both Trust and University-based) who could possibly be asked to attend the interviews on 22 July 2011;
- (iii) noted that the Director of Research and Development would be facilitating a 'mock interview panel' to be held one week before the interviews. It was agreed that he would circulate the date of the mock panel to relevant R & D Committee members when this had been finalised, and
- (iv) made note of the other Trusts attending the interviews and of their respective portfolios in terms of their BRU applications, and any related links with UHL – it was agreed to hold further discussions regarding this issue at the September 2011 meeting of the UHL R & D Committee, which had been reserved for strategic discussions.

DRD

DRD/CE

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

(B) the Director of Research and Development be requested to circulate the date of the mock interview panel (when finalised) to relevant members of the R & D Committee, and

DRD

(C) further discussions be held regarding the issue raised under point (iv) above at the September 2011 meeting of the UHL R & D Committee, which had been reserved for strategic discussions.

CE/DRD/
TA

78/11 ESTABLISHMENT OF AN ONCOLOGY CLINICAL TRIALS FACILITY

Dr Thomas, Reader and Consultant in Medical Oncology, reported verbally to confirm that the project remained on schedule.

Resolved – that this verbal information be noted.

79/11 MINUTES FOR INFORMATION

79/11/1 Biomedical Research Unit Board

Resolved – that it be noted that the Minutes of the BRU Board meeting held on 11 April 2011 would be submitted to the next meeting of the UHL R & D Committee on 11 July 2011.

79/11/2 CLAHRC

Resolved – that it be noted that a meeting of CLAHRC had not taken place since the last UHL Research and Development Committee meeting held on 9 May 2011.

80/11 ANY OTHER BUSINESS

Resolved – that there were no further items of business.

81/11 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 7 July 2011:

- The Planned Care Research Strategy (Minute 71/11 refers);
- Development of a Paediatric Cardiac Surgery Strategy (Minute 72/11 refers);
- UHL R & D Strategy and Divisional Engagement (Minute 73/11 refers);
- MHRA Action Plan (Minute 74/11 refers), and
- Human Tissue Authority Inspection (Minute 75/11 refers).

67/11 DATE OF NEXT MEETING

Resolved – that the next meeting of the Research and Development Committee be held on Monday 11 July 2011 at 2.30pm in the Leslie Lewis Tutorial Room, Clinical Education Centre, Leicester Royal Infirmary.

The meeting closed at 4.23pm.

Gill Belton
Trust Administrator