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UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST REPORT BY TRUST BOARD COMMITTEE TO TRUST BOARD

DATE OF TRUST BOARD MEETING: 6 October 2011

COMMITTEE: UHL RESEARCH AND DEVELOPMENT COMMITTEE

CHAIRMAN: Mr M Hindle, Trust Chairman

DATE OF COMMITTEE MEETING: 12 September 2011

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

 Proposed additional membership of the UHL Research and Development Committee (Minute 94/11 refers).

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

 NIHR Biomedical Research Unit Awards: The Next Steps (Minute 103/11 refers)

DATE OF NEXT COMMITTEE MEETING: 10 October 2011.

Mr M Hindle, Trust Chairman 30 September 2011

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

MINUTES OF A MEETING OF THE UHL RESEARCH AND DEVELOPMENT COMMITTEE HELD ON MONDAY 12 SEPTEMBER 2011 AT 2.00PM IN CONFERENCE ROOMS 1A AND 1B, GWENDOLEN HOUSE, LEICESTER GENERAL HOSPITAL

Present:-

Mr M Hindle – Trust Chairman (Chair)
Professor C Brightling – Professor of Respiratory Medicine
Dr D Hetmanski – Assistant Director of Research and Development
Mr M Lowe-Lauri – Chief Executive (from Minute 101/11)
Professor B Morgan – Professor of Cancer, Imaging and Radiology
Professor D Rowbotham – Director of Research and Development
Professor N Samani – BRU Director (from Minute 98/11)
Dr A Thomas – Reader and Consultant in Medical Oncology
Mrs J Wells - Patient Adviser (from Minute 101/11)

In attendance:-

Mrs S Khalid – Chief Pharmacist (for Minute 98/11 only) Mr P Panchal – Non-Executive Director Mrs K Rayns – Trust Administrator

RECOMMENDED ITEMS

94/11 RESEARCH AND DEVELOPMENT COMMITTEE MEMBERSHIP

Further to discussion under Minute 96/11 below, members supported the appointment of Mr P Panchal, Non-Executive Director, as a full voting member of the UHL Research and Development Committee for Trust Board approval.

Following discussion regarding progress of Pharmacy clinical trials support (Minute 98/11 below refers), the Committee supported the appointment of Mrs S Khalid, Chief

Chair

Pharmacist, as a full voting member of the UHL Research and Development Committee for

Trust Board approval. The Trust Administrator was requested to forward the schedule of meeting dates to the Chief Pharmacist.

The Chairman undertook to seek Trust Board approval for both of the above appointments, via the presentation of these Minutes to the Trust Board meeting on 6 October 2011. Subject to the Board's approval, the Director of Corporate and Legal Affairs would be requested to update the UHL R & D Committee membership and terms of reference.

<u>Recommended</u> – that (A) Mr P Panchal, Non-Executive Director be appointed to the UHL Research and Development Committee as a full voting member;

(B) Mrs S Khalid, Chief Pharmacist be appointed to the UHL Research and Development Committee as a full voting member;

(C) the Trust Administrator be requested to forward the schedule of meeting dates to the Chief Pharmacist;

(D) Trust Board approval for the above appointments be sought on 6 October 2011, (via the presentation of these Minutes), and

(E) subject to Trust Board approval, the Director of Corporate and Legal Affairs be requested to update the UHL R&D Committee membership and terms of reference accordingly.

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RESOLVED ITEMS

95/11 APOLOGIES

Apologies for absence were received from Professor R Baker, LNR CLAHRC Director; Professor D Field, Professor of Neonatal Medicine; Dr K Harris, Medical Director; Mr S Sheppard, Assistant Director of Finance; Dr A Tierney, Director of Strategy; Mr M Wightman, Director of Communications and External Relations, and Professor D Wynford-Thomas, UHL Non-Executive Director and Dean of the University of Leicester Medical School.

96/11 MINUTES

Mr P Panchal, Non-Executive Director, queried why the Minutes of previous meetings showed him as being "in attendance" rather than "present" and members noted (in response) that Mr Panchal had not yet been appointed as a formal member of the R & D Committee. The Chairman sought members' views on the potential appointment of Mr Panchal to the R & D Committee membership, which was strongly supported. A formal recommendation for seeking appropriate Trust Board approval to amend the membership and terms of reference is provided at Minute 94/11 (above).

Resolved – that (A) the Minutes of the Research and Development Committee meeting held on 11 July 2011 (paper A refers) be confirmed as a correct record, and

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

97/11 MATTERS ARISING FROM THE MINUTES

97/11/1 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 83/11 the Chairman confirmed that the Trust Board had approved the R&D Strategy (as presented to the 1 September 2011 Board meeting), although the strategy had since been overtaken by the positive achievement of the three BRU awards. The Chairman noted that he had formally recorded his appreciation to everyone involved in supporting the BRU awards at that Board meeting;
- Minute 86/11 the Director of Research and Development confirmed that no preliminary meeting date for the EMCHC Research Board had yet been set;
- Minute 89/11 the Patient Adviser confirmed (at a later point in the meeting) that she would provide a verbal update on liaison with the Schools Outreach Project to the R & D Committee on 10 October 2011;
- Minute 70/11/1 of 13 June 2011 (regarding an issue previously raised under Minute 42/10 of 10 May 2010) in the absence of the Director of Strategy, the Chairman undertook to investigate this matter arising in order that an appropriate update on the relationship between Harvard/MIT, Health Service Management and Nottingham University could be provided via the Matters Arising Report to the 10 October 2011 meeting;
- Minute 71/11 of 13 June 2011 members noted the intention to schedule a follow-up presentation from the Planned Care Division at the earliest opportunity. It was confirmed that the Women's and Children's Division would present at the R & D Committee meeting in October 2011 and Clinical Support would present to the November 2011 meeting, and
- Minute 44/11 of 11 April 2011 (regarding progressing the issue of intellectual property)

 the Assistant Director of Research and Development confirmed that he had nothing specific to report at that time.

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Chair/ DS

DR&D/

ADR&D

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

(B) progress against the matters listed under Minutes 86/11, 89/11, 70/11/1, and 44/11 continue to be monitored via updates to the Matters Arising Report, as appropriate, and

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(C) the Director of Research and Development be requested to schedule the followup presentation by the Planned Care Division, and presentations by the Women's and Children's and Clinical Support Divisions as detailed above. DRD/TA

98/11 EXTERNAL REVIEW OF PHARMACY SERVICES

Further to Minute 45/11 of 11 April 2011, the Chief Pharmacist attended the meeting to present paper C, which provided an update on progress with the action plan for Pharmacy clinical trials support, following the external review by Kings Health Partners. During discussion on this item, members particularly noted:-

(a) that the investment costs of setting up a full manufacturing facility at UHL for clinical trial investigational medicinal products (CTIMPs) would be prohibitive and that a full scale production operation was not considered a sustainable model. Discussions continued regarding potential collaboration with NUH (which already had its own fully licensed production facility) in respect of this and a range of other Pharmacy-related issues. In addition, competitive quotations were routinely invited for contracted out production facilities to ensure that the best value-for-money costs were built into the baseline costs of any research trials;

(b) additional Pharmacist staffing (0.4wte) had been obtained to support clinical trials for Oncology and Haematology and a bid for additional R&D FSF funding (0.8wte) had been submitted to the vacancy management panel to support increased activity levels in Diabetes research:

- (c) opportunities to redesign the current Pharmacy provision were being explored in depth with a view to increasing the available space for clinical trial facilities.

 Architectural plans had been prepared for re-modelling the existing space and providing a small extension, but further issues in respect of logistics, temperature monitoring and scheduling of clinics/reactive prescriptions would require resolution before the final model could be taken forward for development, and
- (d) the scope to provide additional Pharmacy presence at the increasing number of Divisional, CBU and Specialty based R & D meetings was restricted by the small numbers within the Pharmacy team and their availability. As an overarching solution, the Chairman proposed that the Chief Pharmacist be appointed to the UHL Research & Development Committee to enhance Pharmacy input into R & D workstreams. The Chief Executive strongly supported this proposal and the Committee agreed the appointment. Minute 94/11 (above) provides the formal recommendation for seeking appropriate Trust Board approval to amend the membership and terms of reference.

Chair

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<u>Resolved</u> – that (A) the progress update on Pharmacy clinical trials support (paper c) be received and noted, and

(B) the Chief Pharmacist be requested to continue to explore opportunities for collaboration with NUH in respect of CTIMP manufacturing facilities, and a range of other Pharmacy-related issues.

CP

99/11 FSF FUNDING

The Director of Research and Development briefed members on the outline process for allocating funding against the detailed FSF spending plans and advised that a presentation on this process would be provided to the R & D Committee on 10 October 2011. He

ADR&D

stressed that transparency in the arrangements for future allocations would remain key. The Assistant Director of Research and Development noted the importance of thorough spending plans and suggested that a report for the 2012-13 allocations be scheduled on the R & D Committee agenda in either January or February 2012.

ADR&D

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

(B) the Assistant Director of Research and Development be requested to:-

- provide a presentation on FSF funding to the 10 October 2011 meeting, and
- present detailed FSF spending plans to the January 2012 or February 2012 meeting.

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100/11 PARTNERSHIP WITH QUINTILES

Further to Minute 86/11/1 of 11 July 2011, the Assistant Director of Research and Development provided an update on progress with obtaining the previously-requested data from Quintiles. Members noted that following an internal restructuring exercise by Quintiles, a meeting had now been arranged with their new area manager. The UK lead site manager had agreed to forward some data to inform a report to the R & D Committee on 10 October 2011. Verbal feedback received to date from Quintiles indicated that UHL was an excellent and well-performing Trust.

ADR&D

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

(B) the Assistant Director of Research and Development be requested to provide a written report on Quintiles data to the 10 October 2011 meeting.

ADR&D

101/11 ESTABLISHMENT OF AN ONCOLOGY CLINICAL TRIALS FACILITY

Dr A Thomas, Reader and Consultant in Medical Oncology, reported verbally on the recent and unexpected departure of the previous project manager and challenges surrounding the messaging arrangements with the project Architects. However, the plans had now been signed off for the tender process to commence and the facility was expected to open before the start of the 2012-13 financial year. Responding to a query by the Chief Executive, the Reader and Consultant in Medical Oncology confirmed that the project remained on schedule and there was considered no scope for any slippage.

Resolved – that this verbal information be noted.

102/11 R & D SCORECARD

The Assistant Director of Research and Development introduced the Research and Development Scorecard (paper D refers) and detailed discussion took place regarding the following aspects of the scorecard report:-

- (a) research activity and the number of trials were RAG rated as green and performance was broadly as expected in these areas;
- (b) office performance for non-portfolio projects stood at 11.5 (median time in days) against the target of 30:
- (c) governance arrangements (audit and monitoring performance) were on schedule and RAF rated as green;
- (d) recruitment to studies performance continued to be disappointing (RAG rated as red) and a thorough investigation of the reporting system and any other factors affecting the recruitment rates was underway. The data was being further validation process was also being carried out. Appropriate action plans to mitigate the declining position would be reported to the 10 October 2011 meeting;

ADR&D

(e) Professor N Samani, BRU Director, challenged the accuracy of the non-portfolio recruitment data, suggesting that 800 patients had been recruited to one study in a

- single quarter and this had not been reflected in the data. Professor Samani also queried the process for adopting studies and whether the arrangements for peer review and ethics applications could be streamlined in any way. In response the Director of Research and Development advised that the criteria had already been amended recently;
- (f) the Director of Research and Development highlighted his concerns regarding the likely impacts upon the Trust's reputation and the research income arising from significant reductions in recruitment rates noted over the last three to four months;
- (g) Mr P Panchal, Non-Executive Director, queried whether the reduction in recruitment to studies arose from lack of take up by patients, or lack of opportunities being created for patients to volunteer for studies. In response, the Director of Research and Development confirmed that detailed tracking arrangements were in place and that any under-performing areas would be subject to appropriate investigation;
- (h) Professor N Samani, BRÜ Director, sought further information regarding the arrangements to reflect the quality and impact of publications within the performance metrics. In response, the Director of Research and Development advised that he currently reviewed all publications on an annual basis for input into the Trust's annual report and that he would easily be able to assess and record the impact of each paper within this annual review process. Dr A Thomas, Reader and Consultant in Medical Oncology, queried how the impact would be defined and the Director of Research and Development suggested that a pragmatic approach would be adopted based upon criteria laid down by the National Review Committee, alongside particular weighting factors for the significance of the study, the type of journal and the likely readership of each publication.

DR&D

Resolved – that (A) the R & D Scorecard and the verbal information be noted.

(B) the Assistant Director of Research and Development to present an updated R&D Scorecard to the 10 October 2011 meeting, and

ADR&D

- (C) The Director of Research and Development to:-
- report to the 10 October 2011 meeting on the factors affecting recruitment rates to R&D studies and appropriate action plans to mitigate the declining position, and

DR&D

 monitor the impact of publications on an annual basis (as part of the work for the annual report) and capture this data within the R&D Scorecard. DR&D

103/11 NIHR BIOMEDICAL RESEARCH UNIT AWARDS: THE NEXT STEPS

Paper E provided the updated position statement following the announcement of the NIHR BRU awards for Cardiovascular Disease, Respiratory Disease and Nutrition, Diet and Lifestyle including Obesity to UHL and its partner Universities. The paper also reflected upon the governance arrangements for the BRUs and opportunities to be considered in respect of working towards becoming a Biomedical Research Centre (BRC) in the future. The Director of Research and Development introduced a discussion around the proposed arrangements to establish a single overarching BRU Board, in place of the need to establish three separate BRU Boards. Suggestions for the membership of such a BRU Board were provided in appendix III to paper E.

The Chief Executive noted two general types of BRC (specialist and comprehensive) and he suggested that a candid assessment of UHL and competitor Trusts would be prudent. He stressed the importance of protecting the individual BRUs, and demonstrating their robust performance against plan and good use of investment. He advised that some BRU awards had been lost by other organisations as a result of performance related issues.

Professor N Samani, BRU Director, voiced his view that an overarching BRC would be out of UHL's league for the next three to five years, until a large number of excellent areas of research had been developed. He also queried the advantage of becoming a BRC in

specialist areas. Members suggested that intellectual synergies between the BRUs would be developed as a concept, but opportunities for exploring BRC status would be reconsidered in approximately 12 months' time (September 2012). The Chief Executive recommended that the advantages of seeking external support at an early stage in this process also be considered.

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DR&D

Professor C Brightling, Professor of Respiratory Medicine, highlighted his concerns regarding the availability of clinical space and suggested that such issues be explored as part of the work to agree any strategic and intellectual synergies between the BRUs. The Chief Executive also considered the implications and opportunities that would be created for other clinical sciences within UHL and the Universities of Leicester and Loughborough. The Chief Executive undertook to review the proposed membership of the overarching UHL BRU Board and provide feedback to the Director of Research and Development (outside the meeting).

CE

Finally, Dr A Thomas, Reader and Consultant in Medical Oncology, expressed concern that the success of the Trust's three BRU applications had not been widely communicated and suggested that there was a lack of awareness of this good news both within the Trust and externally. The Chairman undertook to provide this key feedback to the Director of Communications and External Relations (outside the meeting).

Chair

<u>Resolved</u> – that (A) the report on the BRU awards and the subsequent discussion on strategy and management be noted;

(B) the Chief Executive be requested to review the proposed membership of the overarching UHL BRU Board and provide feedback to the Director of Research and Development (outside the meeting);

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(C) the Chairman to provide members' feedback regarding a perceived lack of external and organisational awareness of the success of UHL's three BRU applications to the Director of Communications and External Relations (outside the meeting), and

Chair

- (D) the Director of Research and Development be requested to:-
- initiate a further review of the opportunities for exploring BRC status in 12 months' time (September 2012), and

DR&D

 consider the advantages of seeking external adviser support early in this process. DR&D

104/11 STRATEGIC ISSUES

The Chief Executive introduced a discussion on the exploration of strategic collaborations with other Trusts and academic partners in relation to R & D issues, noting the relevance of the preceding discussion on BRUs in this respect (Minute 103/11 above refers). Members considered the diverse ethnicity of the local population and expressions of interest received from several prospective commercial and academic partners in developing collaborative arrangements to attract investment and strengthen constituents.

Mr P Panchal, Non-Executive Director, highlighted opportunities for the Trust to link up with Leicestershire partnership sub-regional partnerships in order to raise the profile for attracting investment and welcomed the notion of pre-investment in diverse community engagement. He queried whether the Trust's R & D Strategy would require a refresh in the light of recent developments. The Director of Research and Development confirmed that this was already under consideration.

Professor N Samani, BRU Director, sought additional information regarding how the model with large commercial institutions would work, noting that historically such models had not proven to be very long-lasting. The Chairman confirmed that such discussions were

consistent with the Trust's 15 year strategic plans, in identifying key areas of interest and locating sources of expertise. The Chief Executive advised that UHL would welcome the approach to creating opportunities based upon the key respective strengths of the Trust and its strategic partners.

Professor C Brightling, Professor of Respiratory Medicine, noted the importance of translational research and opportunities to create super-clusters driven by early phase disease management and pre-clinical studies conducted with like-minded institutions. The Chief Executive voiced concern that the super-cluster model might prove to be overly fragmented for this purpose.

<u>Resolved</u> – that (A) the detailed discussion regarding potential strategic collaborations with other Trusts and academic partners be noted, and

(B) the Chief Executive be requested to collaborate with other key Universities and Trusts in a shared review of key strategic strengths (shared governance approach) and provide feedback accordingly to the UHL R&D Committee in October or November 2011.

105/11 R & D COMMITTEE MEETING DATES IN 2012

Paper F provided the proposed R & D Committee meeting dates for 2012. All members were requested to review their availability and feedback any concerns regarding particular dates to the Trust Administrator (outside the meeting). Subject to any concerns being raised, the Trust Administrator would seek appropriate meeting venues and advise these accordingly.

Resolved – that (A), subject to any concerns being advised to the Trust Administrator, the following R & D Committee meeting dates be agreed for 2012:-

Monday 9 January 2012 (from 2.30pm to 4.30pm); Monday 6 February 2012 (from 2.30pm to 4.30pm);

Monday 5 March 2012 (from 2.30pm to 4.30pm);

Monday 2 April 2012 (from 2.30pm to 4.30pm);

Monday 14 May 2012 (from 2.30pm to 4.30pm);

Monday 11 June 2012 (from 2.30pm to 4.30pm);

Monday 9 July 2012 (from 2.30pm to 4.30pm);

Monday 13 August 2012 (from 2.30pm to 4.30pm);

Monday 10 September 2012 (from 2.30pm to 4.30pm);

Monday 8 October 2012 (from 2.30pm to 4.30pm);

Monday 5 November 2012 (from 2.30pm to 4.30pm);

Monday 10 December 2012 (from 2.30pm to 4.30pm), and

(B) the Trust Administrator be requested to seek appropriate meeting venues and notify members accordingly.

106/11 MINUTES FOR INFORMATION

106/11/1 Joint UHL / UL Research and Development Committee

Members noted that in view of the termly meeting structure of the Joint UHL / UL Research and Development Committee, no meeting had taken place sine 1 July 2011. At the Chief Executive's suggestion, the Chairman undertook to review of the tiered meeting structure with the Dean of the Medical School, in the light of UHL's BRU awards and provide feedback to the UHL R & D Committee, as appropriate.

Resolved – that the Chairman and the Dean of the Medical School be requested to review the Joint UHL /UL Research and Development meeting structure in the light

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of UHL's BRU Awards and provide feedback to the UHL R&D Committee as appropriate.

106/11/2 Biomedical Research Unit Board

<u>Resolved</u> – that the Minutes of the Biomedical Research Unit Board meeting to be held on 26 September 2011 be presented to the R & D Committee (when available).

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106/11/3 CLAHRC

Resolved – that the Minutes of the LNR CLAHRC Management Board meeting held on 26 July 2011 be presented to the R & D Committee on 10 October 2011.

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107/11 ANY OTHER BUSINESS

107/11/1 Contact Details for the University of Leicester "Med Reach" Scheme

The Patient Adviser advised that she had not yet received the relevant contact details for the University of Leicester "Med Reach" scheme from the Director of Research and Development, as suggested under Minute 89/11 of 11 July 2011.

DR&D

<u>Resolved</u> – that the Director of Research and Development be requested to forward the appropriate contact details to the Patient Adviser (outside the meeting).

DR&D

Chair

107/11/2 Cardiac Surgery Chair – Applications Process

Professor N Samani, BRU Director, highlighted the application process for a Cardiac Surgery Chair, which was due to close by the end of October 2011. He updated the Committee in respect of a named interested candidate and advised that a decision would be made by the end of December 2011.

Resolved – that the information be noted.

108/11 IDENTIFICATION OF KEY ISSUES THAT THE COMMITTEE WISHES TO DRAW TO THE ATTENTION OF THE TRUST BOARD

<u>Resolved</u> – that the following items be brought to the attention of the Trust Board at its meeting on 6 October 2011:

• UHL Research and Development Committee membership (Minute 94/11 above refers).

109/11 DATE OF NEXT MEETING

<u>Resolved</u> – that the next meeting of the Research and Development Committee be held on Monday 10 October 2011 at 2.30pm in the Board Room, Victoria Building, Leicester Royal Infirmary.

The meeting closed at 4.03pm.

Kate Rayns
Trust Administrator