## Trust Board Meeting: Thursday 5 July 2012

**TB2012.69**

<table>
<thead>
<tr>
<th>Title</th>
<th>Full Business Case for the Establishment of a Translational Molecular Diagnostic Centre at the Churchill Hospital</th>
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<tbody>
<tr>
<td>Status</td>
<td>A paper for decision.</td>
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<tr>
<td>History</td>
<td>This business case was supported by the Trust Management Executive on 22&lt;sup&gt;nd&lt;/sup&gt; December 2011. An update paper, based on more detailed costing was supported by the Strategic Planning Committee on 14&lt;sup&gt;th&lt;/sup&gt; June 2012.</td>
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<tr>
<th>Board Lead(s)</th>
<th>Mr Paul Brennan, Director of Clinical Services.</th>
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<tr>
<td>Key purpose</td>
<td><strong>Strategy</strong></td>
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Summary

1. **Context.** The following factors are driving the proposed provision of a Molecular Diagnostic Centre.

   1.1. **UK Pathology Consolidation.** Nationally services are consolidating, driven by concentration of specialist services, and commissioner demand for economies of scale and savings.

   1.2. **Technology.** Development of new technologies is causing organisational change, with the move from laboratory disciplines towards shared technological platforms.

   1.3. **Molecular Diagnostics.** This is a key area for modernisation and consolidation as part of personalised medicine, particularly for cancers. To ensure a robust OUH Pathology capability, to support the wider clinical and research functions, post consolidation the OUH must secure designation as one of the limited number of national centres. OUH needs to demonstrate credibility to be designated as a molecular diagnostic hub, and attract further investment.

   1.4. **Profile.** The OUH capability and profile is currently diluted as the high quality molecular diagnostic work is scattered between existing laboratories generating a perceived credibility gap due to the visible lack of a flagship unit.

   1.5. **Translational Pathology.** This requires access to high quality, fully consented and licensed human tissue samples, and pathologist expertise within an accredited, quality controlled and licensed setting.

2. **Current Progress.** The Director of Translational Pathology has been appointed (Prof Runjan Chetty, OxBRC appointment Mar 2011) and is leading the development of translational pathology facilities. Work to consolidate and develop components of molecular diagnostics and tissue banking has been initiated delivering a huge increase in the raw material for research, tighter governance, improved operational efficiency, and development of Oxford Laboratory Medicine (OLM). This brand presents the research and clinical pathology services of the OUH and Oxford University partnership as one, acting as a single source of information and access to services, expertise and BioResources.

3. **Proposal.** The physical consolidation of dispersed functionality and core translational facilities will be achieved by redeveloping Block 4 at the Churchill Hospital. This will include:

   3.1. **Convert the new part of Block 4 into the core consolidated molecular diagnostics unit, biobank, and fresh tissue handling unit.** This will; i) house the cancer molecular diagnostic unit, currently molecular haematology, sharing staff and facilities with the nearby DNA genetics and cytogenetics units, ii) incorporate the Technology Strategy Board funded whole genome sequencing unit, iii) house the fresh tissue handling facility, allowing rapid collection and processing of human tissue from the Cancer Centre theatres, plus the consolidated biobanks, iv) provide demonstrable evidence of OUH’s commitment to molecular diagnostics.

   3.2. **Create a blood sciences department by merging immunology with biochemistry and haematology.** Achieved by moving the immunology labs from the Churchill to the space vacated by molecular haematology at the John Radcliffe. Allowing greater automation, sharing of staff with similar skills, and longer term...
cost savings.

3.3. **Decommission the dilapidated histopathology diagnostic archive (Sheep Station, JR).** Access to parts of this archive has been stopped by OUH Clinical Risk Management due to Health and Safety reasons. It is anticipated that inspection by Clinical Pathology Accreditation would result in major non-compliance.

4. **Finance - Capital.** Using existing and TSB funded equipment, the proposal’s non-recurrent costs, beyond the capital investment, will be minimal. The total Scheme Cost is £2,143,438. Funding of £877,000 will be secured from the Oxford Biomedical Research Centre capital funding and £1,266,438 from the OUH capital budget.

5. **Finance - Revenue.** Costs will be met from within current operational budgets for the departments which will occupy the centre. NHS and BRC funded staff will transfer into the unit. The revenue opportunities and bedside savings from molecular diagnostics are hard to quantify as data is still immature.

6. **Timeframe.** The project is time sensitive as a result of commitments made by the Trust to the National Institute for Health Research during the OxBRC funding application and to fully exploit the opportunity presented by the TSB award. OxBRC will be required to demonstrate return on investment in the FY12/13 annual report to the NIHR (due Q1 2013) requiring the rapid delivery of the project given the delays to date.

7. **Future Opportunities.** This proposal will create an enduring integrated facility. Future development building upon the success of the initial phase could allow:

7.1. **Strategic consolidation of pathology laboratories.** Closer to the new clinical areas without occupying valuable clinical space and adjacent to an off-site transport route enabling pathology service support to other sites.

7.2. **Relocation of the DNA and cytogenetics laboratories.** Medium term, by developing the remaining Block 4 foot print, the DNA and cytogenetics laboratories will be able to relocate from very poor infrastructure.

7.3. **Release of space within the JR 1 site.** Longer term, if a suitable financial model can be identified, the location is well placed for relocation of Cellular Pathology, microbiology and non-acute blood sciences into a single building, vacating large areas of potentially clinical space at the JR.

8. **Recommendations.** It is recommended that the refurbishment of Building 4 at the Churchill is delivered as per Option 2c and the Trust Board authorise the associated capital investment.

9. **Actions.**

9.1. The Trust Board is requested to authorise refurbishment of Block 4 as per Option 2c.

9.2. The Trust Board is requested to authorise capital investment of £2,143,438.
## Final Business Case for the Establishment of a Translational Molecular Diagnostic Centre at the Churchill Hospital

<table>
<thead>
<tr>
<th>Strategic Planning Committee Reference</th>
<th>SPC2012-047</th>
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| Appendices                             | Appendix A - Site Location and Refurbishment Plans  
                                         | Appendix B - Refurbishment Options and Appraisal  
                                         | Appendix C - Management of Proposal Implementation Risks |
| Background papers (if any)             | Establishment of a Translational Molecular Diagnostic Centre at the Churchill Hospital (SPC2011.024) dated 22 Dec 2012. |
| Action/decision required from SPC      | Agreement to recommend to the Trust Board that authorisation is given to proceed with the refurbishment of Block 4, Churchill, with a total capital investment of £2,143,438. |
| Strategic Objective(s) that the case will help deliver | SO2 To provide high quality specialist services to the population of Oxfordshire and beyond.  
                                                     SO3 To be a patient-centred organisation providing high quality and compassionate care - “delivering compassionate excellence”.  
                                                     SO4 To be a partner in a strengthened academic health sciences system with local academic, health and social care partners.  
                                                     SO5 To meet the challenges of the current economic climate and the changes in the NHS and become a resilient, flexible and successful Foundation Trust. |
| Proposed date that revenue spend will begin: | March 2013 |
| Proposed date that capital spend will begin: | July 2012 |
| Conclusion of Equality Analysis        | An equality analysis has not been undertaken for this business case. |
| Review Date                            | 12 months post user occupation. Occupation planned for 7 ½ post approval. |
Acronyms and abbreviations used

| CPA - Clinical Pathology Accreditation. |
| NIHR - National Institute for Health Research. |
| OUH - Oxford University Hospitals NHS Trust. |
| OxBRC - Oxford Biomedical Research Centre. |
| TSB - Technology Strategy Board. |
| UKAS - United Kingdom Accreditation Service. |

Author(s)

Dr Derek Roskell, Directorate Director Pathology & Labs.
James Shepherd, Programme Director Tissue Banking & Cohorts OxBRC

Lead Finance Manager

Mr Kevin Davis, Senior Finance Business Partner

Introduction

1. This paper sets out the next step in the translation of the Partnership’s various molecular diagnostics capabilities into a dedicated NHS Translational Molecular Diagnostic Centre. World leading molecular diagnostics research and its application have taken place across the Partnership. The opportunity now exists to achieve increased patient benefit by initiating a process of consolidating the clinical components within a NHS facility.

2. This development is integral to the Trust establishing itself as a recognised and ultimately designated centre for the provision of molecular diagnostic services. In turn this will strengthen the Trust’s position as a BRC and aspiring Academic Health Sciences Centre in partnership with the University.

Strategic Context and Case for Change

3. Personalised Medicine. Molecular diagnosis is a key area for both modernisation and consolidation as part of the development of personalised medicine, particularly for cancers. Where the detection of specific mutations, gene expressions or other phenotypes allows more tailored treatments to be applied for individual patients. The reduction in whole genome sequencing costs and turn around time, as technology improves, is increasing the viability of translating this capability into clinical service provision (Corporate Objective (CO) 5b). OUH and University of Oxford play a significant role in this field (Oxford 500 genome project1 / Strategic Objective (SO) 2). Recognition of this has resulted in a £2.4m TSB Stratified Medicine award (Dr Jenny Taylor et al) to translate genome sequencing capability into a platform technology for clinical services.

1 See http://www.ox.ac.uk/media/news_stories/2011/110803_3.html.
4. **National Consolidation of Molecular Diagnostics.** Molecular diagnosis medicine is a key interface between clinical and research pathology. Success in molecular diagnosis will be defined by OUH being recognised as one of the limited number of centres which will be designated for providing this service in the UK. The OUH needs to demonstrate sufficient credibility in this area to be designated a molecular diagnostic hub, and attract further investment. Failure to achieve this would be a significant blow to Academic Health Sciences Centre status aspirations and OxBRC weakening our partnership with Oxford University.

5. **OUH Profile.** Currently, the high quality molecular diagnostic work is scattered between existing laboratories, and there is a credibility gap due to the lack of a flagship unit from which this service can be seen to operate. Molecular diagnostics units need to be consolidated into a recognisable entity, for research and operational efficiency and to provide the requisite profile to receive future investment.

6. **Partnership Buy In.** The strategic requirement for this infrastructure has been recognised by the OUH Chief Executive and Head of the Medical School (NIHR OxBRC application dated 14 Jun 2011 / CO4b).

7. **National Pathology.**
   - **7.1. Consolidation.** UK Pathology services are going through a period of consolidation, driven by concentration of specialist services and commissioner demand for economies of scale and savings.
   - **7.2. Organisation Reconfiguration of Pathology.** Concurrently, ongoing changes in laboratory technologies are causing traditional service organisation around laboratory disciplines to evolve into organisation around shared technological platforms.

8. **OUH Pathology.** Clinical pathology is provided by Pathology and Laboratories Directorate with the exception of neuropathology (Neuroscience). Research is distributed across these departments as well as a number of University departments (Wellcome Trust Centre for Human Genetics, Nuffield Department of Clinical Laboratory Science, Weatherall Institute of Molecular Medicine etc). Cellular pathology demand from the Churchill is provided from the JR. To meet research demand access to very fresh diseased tissue a very limited capability has to be regenerated utilising the blood sciences lab in Block 4 to provide space, CPA and management. Connectivity to the theatres via a pneumatic tube is an additional benefit. Research demand ultimately requires a full frozen section service.

   8.1. **Location.** The current geographic relationships between the OUH pathology departments are not operationally efficient in terms of clinical services and research. The benefit of collocation of clinical and research functions within a clinical field has been proven (OCDEM, Neuropathology, Cardiovascular).

   8.2. **Standard of Laboratories.** The current standard of laboratories ranges from newly refurbished to requiring refurbishment.

   8.3. **Translation Pipeline.** Translational pathology requires access to high quality, fully consented and licensed human tissue samples, and pathologist expertise. Early / medium stage research to clinical service translation currently occurs in University space with late stage handover to the appropriate clinical
department. When tests are to be used clinically accreditation, quality control and appropriate licensing CPA is required. Acquisition of CPA by UKAS will bring about more stringent application of this requirement.

8.4. **Diagnostic Archive.** Cellular pathology’s archive is mandated to hold any clinical diagnostic samples for a minimum of 30 years. The current storage facility, the Sheep Station JR, has reached capacity and is not fit for purpose. It is not weather proof and lacks the required access controls. Access to parts of this archive has been stopped by OUH Clinical Risk Management due to Health and Safety reasons. It is anticipated that an inspection by CPA would result in a major non-compliance.

**Future Service Configuration / Capability Vision**

9. **Integration of Translational Pathology.** The long term vision is to consolidate the Partnership’s clinical and research pathology, including molecular diagnosis, in one main location. It is anticipated that this will take place in 2 further phases; i) Relocation of Genetics Laboratories and ii) relocation of the other Pathology Departments where appropriate. This will create a cost effective, fully accredited, core facility which provides laboratory testing services for both diagnostic and research purposes, and facilitates the translation of research tests into routine diagnostic practice, making it a strong contender for any regionalisation of these services. The sites adjacency to off-site transport routes would enable pathology services to support other OUH sites and elsewhere.

10. **Interim Alignment.** The proposed Centre will deliver functional and physical core of this vision built around molecular diagnostics and tissue banking. Further operational alignment will be determined at a later date based on the ability to generate investment, and designation as a genetic testing hub. The proposed development will be constructed to last 20 years in recognition of the time required to plan, finance and deliver the integrated long term vision.

10.1. **Molecular Diagnostics.** The Centre’s specification will see the consolidation of the research capability derived from the TSB award within a clinical department (Molecular Haematology, Dr Schuh). This Department will manage the lab and provide CPA.

11. **Wider Pathology Reconfiguration.** Provision of refurbished space within the Centre will enable the reconfiguration of other pathology departments into improved facilities. The Immunology Department will relocate from the Churchill into the vacated Haematology Laboratory (JR Level 4), forming along with Biochemistry and routine Haematology, a consolidated Blood Sciences Department.

12. **Trust Profile.** The Centre will provide, through modest investment and reconfiguring of existing capabilities, a visible statement of OUH’s commitment to personalised medicine. A successful pipeline of translated molecular tests will differentiate the Trust to the local and regional population. This is urgently needed so that OUH can compete for designation as one of a few centres for this work in the UK, accruing further benefits in terms of leveraged funding and clinical revenue.

12.1. **Physical Infrastructure.** The Centre will be a headquarters where all OUH lab services and tissue banks can be accessed so that they are seen as a core
facility for research / clinical trials as well as standard and specialist
diagnostic testing. This will focus not only on translational molecular
diagnostics but also the wider translational and clinical pathology lead by the
Director of Translational Pathology (Prof Chetty).

12.2. Test Developmental Pipeline. There is a significant track record in
developing platform assays through the Partnership2. The Director of
Translational Pathology will champion this record and provide the focus to
actively develop the translational pathway. The Wellcome Trust Centre for
Human Genetics is developing diagnosis, prognosis or response to treatments
assays (Prof Tomlinson) for future translation3.

Risks of Maintaining the Status Quo


13.1. Weakening of Cancer Networks Hub. OUH position as the hub is weakened by
inability to provide an integrated diagnostic service. If molecular tests are
referred elsewhere by regional hospitals the patient flow is at risk of
following.

13.2. Reduced Perception. Perceived weakness in the area of molecular diagnosis
leads to University researchers looking to other providers, depriving OUH of
much needed revenue and investment. In turn this limits OUH patient access
to translated molecular diagnostics and improved outcomes.

13.3. Loss of Existing Activity. OUH’s existing profitable molecular diagnostic
activity may become non-viable.

13.4. Patient Benefits not leveraged from Research. By not being able to compete
with other world leading medical centres, OUH will be less favourably placed
to secure the latest technologies for patients as a test site for commercial
providers. This would reduce the ability to support clinical trials resulting in
patients having reduced access to cutting edge treatments.

13.5. Service Inefficiencies. The fragmented nature of the molecular diagnostic
services and the physical separation from research labs will continue to
hamper the development of optimal patient care. Immunology would be
unable to relocate to best clinical advantage and laboratories remain in
substandard facilities. Duplication and uncoordinated investment by the
Partnership will continue.

13.6. Accreditation. Failure to have a plan completed to provide CPA compliant
storage for the Cell Pathology archive could result in loss of CPA status for the
department. This would adversely impact upon wider clinical services reliant
on diagnosis performed by the department and organisational reputation.
Commercial provision has an annual revenue cost of £20,4024.


2 Nuffield of Clinical Neurology and ORH Neuroimmunology have translated 14 diagnostic tests into clinical service
since 2000.

3 The translational pipeline has the following candidates: i) BRAF, NRAS, ERBB4, Akt for melanoma (drug response), ii)
VEGF as a marker of response to anti-angiogenesis therapy for melanoma, iii) KRAS, ploidy, microsatellite instability
for diagnosis of colorectal cancer, iv) Array-based comparative genomic hybridisation for melanoma
(diagnosis/prognosis), and v) Next generation sequencing for oesophageal, melanoma cancers and gliomas.

14.1. **NIHR.** The Trust has made a commitment, signed off by the OUH CEO / Head of Medical School to deliver this infrastructure within the original OxBRC, which ended 31 Mar 2012, as part of its NIHR BRC application5. Failure to deliver will damage the creditability of the Partnership with the potential to harm future applications to the NIHR.

14.2. **Technology Strategy Board.** The absence of infrastructure to support and exploit the TSB award would place its outcomes at risk. This has the potential to make the Partnership less attractive to TSB in future applications resulting in the University seeking other partnerships to secure this funding stream.

14.3. **Funders.** The current dislocation of research and clinical networks may prove to be unattractive to funding bodies resulting in the OUH not being the preferred regional centre for molecular diagnostic provision leading to the loss of new revenue streams.

14.4. **AHSC.** The current dislocation of research and clinical networks may impact on future AHSC applications.

15. **Financial.**

15.1. **BRC Capital.** The OxBRC capital funding grant (£877,000) is available until 31 Mar 2013. If not spent or committed by this date the capital is lost, leading to financial management and reputational implications with the NIHR potentially impacting on application for future awards.

15.2. **Revenue.**

15.2.1. **Regionalisation.** Without provision of a credible regional specialist testing capability, the OUH may not remain a preferred regional centre as part of wider pathology modernisation initiatives, leading to loss of current revenue streams. Currently, the regional cancer network contract for Her 2 testing in breast cancer and regional molecular and genetic testing for haematological and other malignancies are delivered by OUH.

15.2.2. **Future molecular diagnostics revenue.** Currently, through the TSB award OUH sits at the forefront of this service the failure to build on it may result in revenue streams being lost to other centres either directly or via regionalisation.

15.3. **Estate Restructuring.** Pathology & Laboratories’ ability to reorganise remains limited; financial benefit of real estate release and consolidation laboratory equipment and staffing would not be realised.

15.4. **Partnership.** The University may look to other strategic pathology partnerships leading to the loss of future investment.

**Potential Opportunities**

16. **Organisational Improvements.**

16.1. **Rationalisation of staffing.** Across a consolidated blood sciences department and through Molecular Genetics, Cytogenetics, and Molecular Haematology departments.

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5 The Partnership’s NIHR BRC application stated that a Molecular Diagnostic Centre would be delivered as part of the current BRC (Page 14).
16.2. Optimisation of Churchill Estate. Reorganisation will enable the release of the Immunology Lab and the long term decommissioning of this building subject to the relocation of the clinical department on the 1st floor. In the interim, it could generate rental income as a research lab although its condition is very poor.

17. Impact on SHA Centralisation of Pathology Provision. OUH is already a regional and supra-regional centre for genetic testing. Consolidation around this facility is in accordance with the national pathology modernisation agenda, and strengthens our position as the natural centre for a specialist testing network.

18. Impact on a future AHSC application. The ability to demonstrate very clearly that OUH is committed to personalised medicine through the provision of this centre would strengthen any bid to become an AHSC.

19. Commercial Clinical Trial Sponsorship. The presence of a focal point for molecular diagnostic research with a plan to deliver a translational clinical and research pathology infrastructure, would address the pathology issues arising from the Cancer Research UK Stratified Medicine Collection Centre call. By delivering a signature centre additional research and commercial funding could be leveraged. This can be seen in the strategic relationship that Illumina, a Next Generation Sequencing company, is developing with Oxford. The opportunity for them to translate their technology into a clinical platform would result in the Partnership being at the forefront of delivering patient benefit in this area.

20. Commissioner Income. Through the provision of molecular diagnostics for the region subsidised by investment from trials and other research, OUH would be in the position to secure revenue in this field from NHS commissioning.

Objectives and Benefit Criteria.

21. Provide CPA space for translational research activity. CPA accredited lab space plus associated offices delivered, against the specification document, to house translation molecular diagnostic research initial focused around the TSB award delivery. Outcome: Space delivered within Pathology & Laboratory Directorate by Dec 2012.

22. Provide improved Cellular Pathology capability on the Churchill site. CPA accredited pathology capability plus associated offices, against the specification document, in support of clinical, research and biobanking activity. Outcome: Space delivered within Pathology & Laboratory Directorate. Basic Churchill pathology grossing and limited reporting relocated from the JR. Delivered by Dec 2012.

23. Provide the hub for Oxford BioResource activity. Laboratory, storage and administrative capability, against the specification document, in support of clinical and research activity. Outcome: Space delivered. Research and clinical storage users identified for relocation, saving clinical and laboratory space in proportion to number of units consolidated. Delivered by Dec 2012.

CPA status. Increased research activity exploiting resource measured by increase access requests processed by Oxford Laboratory Medicine. Delivered by Dec 2012.

25. **Deliver signature facility, promoting the Partnership’s capabilities in pathology, supporting the leveraging of other revenue streams.** A headquarters through which marketing and promotion activity can be undertaken through the Oxford Laboratory Medicine initiative. Outcome: Increased profile measured through increased use of existing capabilities by researchers, increased leveraged funds and exploitation through Oxford Laboratory Medicine’s communication plan. Delivered by Dec 2012 and ongoing.

26. **Deliver on commitments to the NIHR.** Operational translation molecular diagnostic centre operational by Dec 2012. This time frame not possible. Outcome: A clear plan to deliver on this commitment, protecting NIHR capital grant, with delivery by Dec 2012.

27. **Consolidate translational pathology activity within a clinical department.** Piloted through the TSB award being housed within Haematology. Outcome: Improved Partnership coordination of translational pathology research. Increased collaboration between research groups and corresponding Pathology Department. Delivered by Dec 2012. Reported through OxBRC.

28. **Enable the long term strategic vision: Consolidation of research and clinical pathology.** Deliver an enduring stand alone facility, which provides strategic space to enable the development and delivery of this long term vision through focusing Partnership activity (organisation, infrastructure, workflows / estate / communication). Outcome: Reconfiguration achieved. Organisational and operational working identified and delivered. Delivered by Aug 2013.

29. **Enable the reorganisation of the Pathology & Laboratories Department.** Outcome: Molecular Haematology moves to block 4, Immunology moves into the vacated JR space. Immunology fully utilises of the Core Automated Laboratory, with shared technologies and staff and reduced turn around times.

**Selected Option.**

30. **Plans.** The Churchill site and building plans are at Appendix A.

31. **Options Decision.** The option appraisal is at Appendix B. The preferred option is Option 2c. Option 2c delivers the laboratory space, cellular pathology including diagnostic archive and Oxford BioResource, plus associate requirements, to specification. Providing; i) some ability is accommodating further expansion, ii) the strategic space and opportunity to deliver against the strategic vision, and iii) provides demonstrable proof of the Partnership’s commitment to molecular diagnostics translation enabling protection and leverage of current and future clinical and research revenue.

**Financial Analysis.**

32. **Capital - Project Costs.** Total scheme cost after detailed planning (pre-measure and supplier quotations) for Option 2c is £2,143,438.
33. **Capital - Secured Funding.** Funding to meet the Total Scheme cost has been secured as follows:

<table>
<thead>
<tr>
<th>Source</th>
<th>Amount</th>
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<tbody>
<tr>
<td>OxBRC capital budget</td>
<td>£877,000</td>
</tr>
<tr>
<td>OUH FY 11/12 Capital Programme</td>
<td>£200,000</td>
</tr>
<tr>
<td>OUH FY 12/13 Capital Programme</td>
<td>£1,066,438</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£2,143,438</strong></td>
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34. **Capital - Relocation.** Part of the project entails moving existing services into the upgraded Building 4 at the Churchill; it is planned that Haematology will transfer from Level 4 at the John Radcliffe Hospital and Immunology from their current location at the Churchill to the vacated laboratory on JR Level 4. If these moves facilitate the transfer of other services, and contribute towards meeting wider Trust goals as agreed within its Estates strategy, then the Trust Board might consider it appropriate for NHS capital monies to contribute towards the cost of the scheme.

35. **Revenue - Capital Charges.** Assuming asset life of 20 years, the initial capital charge per annum for Options 2c would be a maximum of £180,317. It is extremely unlikely that full capital charges will be incurred as this is a refurbishment project. As most of the planned work is to renew and upgrade existing space (rather than build new facilities). It is likely that when the District Valuer next assesses Building 4 post refurbishment there will be only a marginal increase in its value. If this is the case there will then be a one-off impairment charge against the Trust’s income & expenditure account and the recurrent capital charges will be much lower than those quoted above.

35.1. **Offset.** If upgrading Building 4 results in other Trust-owned buildings being vacated completely, and these buildings can be moth-balled or demolished, capital charge savings would be seen on these properties which could offset (in part, at least) any increase in capital charges arising on Building 4.

36. **Revenue - Other Estates Costs.**

36.1. **Utilities.** As there is little new build and the project mainly entails the refurbishment of existing space, there should be little significant change to other estates-related costs such as utilities and rates. Electricity and gas may increase as a result of the more intensive use of Building 4, but this might be offset by lower use of utilities in the areas being vacated by the departments moving into the Molecular Diagnostics Centre.

36.2. **Double-running Costs.** There may be a small amount of double-running costs if Building 4 comes into use and the planned transfers from Haematology and Immunology do not happen immediately. However these will be non-recurrent and should be kept to a minimum if departments prepare in advance for the moves.

36.3. **Relocation.** There will also be non-recurrent costs incurred in actually moving staff and equipment from their existing locations into Building 4. Unless specialised equipment needs to be transferred then, again, these should be relatively small.

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6 FY 11/12 Capital Charge (£170,510) updated to FY 12/13 figures.
37. **Revenue - Staff Costs.** The plan is to consolidate existing OUH pathology departments and to move current staff into the new facility. There should be no additional staff employed resulting from approval of the business case and therefore no additional pay costs incurred.

38. **Revenue - Molecular Diagnostics.** Analysis of three NICE approved cancer genes (K-RAS, EGFR and C-KIT sequencing) indicates a projected annual income of £25,8007. The CRUK 9 gene test, on validation by the TSB award, will generate £300 per test price in line with CRUK pricing structure8. As further gene tests within the 9 gene test panel receive NICE approval sample numbers will increase with a projected annual income of £103,2009.

**Market Assessment.**

39. **First Adopters.** Molecular diagnostic provision is fundamental in realising the clinical benefits for patients and the financial saving from personalised medicine. The lack of a signature facility in this field places the Partnership as a significant disadvantage when competing for future research and clinical resources. First adopters investing in this field include:


   **UCL Cancer Research UK Centre**11. This centre has lead to an additional £1m per year CR-UK investment.

   **Imperial College Healthcare NHS Trust**12. A pathology and molecular diagnostic capability already established (Jan 2011).

   **Institute of Cancer Research**13. Dedicated Centre for Molecular Pathology (equivalent to the Partnership’s desired end state) set to be completed in 2012.

   **University of Belfast**14. Collaborating with Belfast Health and Social Care Trust, complementing the Belfast ECMC, are delivering the equivalent to the preferred interim solution by Dec 2011.

   **Harvard Medical School**15. A state-of-the-art new facility, the Centre for Advanced Molecular Diagnostics, has been opened.

**Management of Proposal Implementation Risks.**

40. See Appendix C.

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7 40 samples per month at £150 per sample (data from Dr Schuh).
8 Validation anticipated by Aug 2012.
9 NICE approval expected by Aug 2012 leading to demand increasing to 80 samples per month.
15 See: [http://www.brighamandwomens.org/Departments_and_Services/pathology/services/MD/Molecular_Diag.aspx](http://www.brighamandwomens.org/Departments_and_Services/pathology/services/MD/Molecular_Diag.aspx).
Implementation Plan.

41. The process and proposed timeline (See Table 1), derived from feasibility programme, is below. Due to the detailed work already undertaken Stage 3 (Tender / Contract) may be reduced bringing the occupation date forward. Stage 3 will provide more detailed timings for Stages 4 to 7.

42. The project will be delivered through MTC11 due to its time sensitive nature. This is as a result of commitments made by the OUH as part of the BRC funding competition and the ongoing nature of the TSB award. Delays in procurement would prevent leveraged benefit from the TSB award and lead to issues surrounding commitment of the capital from the first iteration of OxBRC with the NIHR.

43. Dr Derek Roskell (Clinical Director Pathology & Laboratories) will be the senior user with input from Dr Taylor (TSB), Dr Schuh (Haematology), Gemma Marsden (Oxford Radcliffe Biobank), Sharon Roberts-Gant (Cellular Pathology). Project Management: James Shepherd (OxBRC). Estates: Richard Muldoon.

<table>
<thead>
<tr>
<th>Action</th>
<th>Timeline</th>
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<tr>
<td>Stage 0 - Identification, Consideration, and Appraisal of Options at</td>
<td>Complete Dec</td>
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<tr>
<td>Stage 1 - Provisional Business Case. Approval at Divisional Board.</td>
<td>Complete 2 Dec 2011.</td>
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<tr>
<td>Stage 1 - Provisional Business Case. Approval by TME/SPC.</td>
<td>Complete Dec 2011.</td>
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<tr>
<td>Stage 1 - Provisional Business Case. Discussion with SHA.</td>
<td>Complete Jan 2012.</td>
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<tr>
<td>Stage 1 - Full Business Case. Approval by SPC.</td>
<td>Jun 2012.</td>
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<tr>
<td>Stage 2 - Full Business Case. Approval by Trust Board</td>
<td>July 2012</td>
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<tr>
<td>Stage 3 - Design. Target Planning Approval Date.</td>
<td>July 2012</td>
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<tr>
<td>Stage 4 - Tender / Contract. Place Order with Contractor.</td>
<td>Approval +2½ mths.</td>
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<tr>
<td>Stage 5 - Construction / Implementation.</td>
<td>Approval +3 mths.</td>
</tr>
<tr>
<td>Stage 6 - Technical Commissioning &amp; Handover.</td>
<td>Approval +6½ mths.</td>
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<tr>
<td>Stage 7 - Post Completion Work.</td>
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<tr>
<td>Stage 8 - Commissioning of Area. Occupation by Users.</td>
<td>Approval +7½ mths.</td>
</tr>
</tbody>
</table>
Table 1: Implementation Time Line

<table>
<thead>
<tr>
<th>Action</th>
<th>Timeline</th>
</tr>
</thead>
</table>

Impact and Intended Effect Reviewed and Reporting.

44. Molecular Diagnostic Activity. Benefit realisation measured against the Objectives and Benefit Criteria. Laboratory activity will be reported as Pathology & Labs Directorate / Critical Care Divisional reporting mechanisms.

45. Molecular Diagnostic Translation. Benefit realisation measured against the Objectives and Benefit Criteria. Scientific reporting by projects through OxBRC Theme annual reporting mechanisms.

46. BioResource. Benefit realisation measured against the Objectives and Benefit Criteria. Oxford Radcliffe Biobank activity reporting annually to the Trust via the Clinical Governance Committee and to the University via the Medical Sciences Division.

Equality Impact Assessment

47. Not Applicable.

Conclusion

48. World leading molecular diagnostic research, which will directly lead to patient benefit, is currently being conducted within the partnership. However, the ability to fully realise the potential patient benefits is being constrained by the lack to infrastructure to support its clinical translation. Other comparable centres are already investing in the infrastructure to realise these benefits. This proposal provides the initial step against the long term vision to enable the Trust to deliver patient benefits and realise revenue resulting from this capability while also protecting it position as a regional centre in pathology.

Recommendations

49. The Trust Board is requested to authorise refurbishment of Block 4 as per Option 2c.

50. The Trust Board is requested to authorise capital investment of £2,143,438.

Mr Paul Brennan, Director of Clinical Services
Dr Derek Roskell, Clinical Director Pathology and Laboratories
James Shepherd, Programme Director BioResources OxBRC
June 2012
Appendix A - Site Location and Refurbishment Plans

Figure 1: Block 4 location in respect to the Churchill site.
Figure 2: Option 2c General Refurbishment Plan (dated 21 Feb 2012).
Appendix B - Refurbishment Options and Appraisal

The following Options and Appraisal was presented as part of the provisional business case.

1. **Option 1 - Do nothing.** Research and Clinical activity associated with each department remains geographically and organisationally separated.

2. **Option 2 - Refurbish Block 4 (Churchill).** Block 4 (See Appendix A Fig 1 for orientation), the only identified available estate able to deliver the project, is refurbished to deliver against specification. Refurbishment is focused in the best quality buildings, with the high cost refurbishments in locations able to be retained in any further redevelopment of the site. A feasibility study has already been completed against specification (Options 2a - c). A further Option 2d delivers the full functionality against a reduced specification. This study has indicated that the refurbishment is feasible with a projected timeframe of 7 months from authorisation.

   2.1. **Option 2a.** Limited provision against full specification; laboratories, and limited associated office space only. Fails to meet specifications against the projected life of the interim solution.

   2.2. **Option 2b.** Limited provision against full specification; laboratories, limited BioResource requirements and associated office space only.

   2.3. **Option 2c Full provision against specification; laboratories, BioResource, cellular pathology diagnostic archive and associated office space.**

   2.4. **Option 2d.** Provision against reduced specification. This brings together components in Options 2a - c providing; laboratories, BioResource, cellular pathology diagnostic archive and associated office space. Functionality not included is not absolutely essential but could be provided later if resources become available.

3. **Option 3 - Develop another location at the Churchill.** Other locations have been explored as part of historical plans. This included refurbishment of Ward 7 which was stopped as it failed to deliver against specifications, including insufficient laboratory space. Option not taken forward.

4. **Option 4 - New build.** An equivalent new build on the Building 4 site against the specification would be in the region of £3 - 3.5m. Option not taken forward as unviable in current financial climate.
## Objectives & Benefit Criteria

<table>
<thead>
<tr>
<th>Objectives &amp; Benefit Criteria</th>
<th>KPI</th>
<th>Option 1 - Do nothing 1 - 5 weighting (poor - excellent)</th>
<th>Option 2a - Refurbishment Block 4 1 - 5 weighting (poor - excellent)</th>
<th>Option 2b - Refurbishment Block 4 1 - 5 weighting (poor - excellent)</th>
<th>Option 2c - Refurbishment Block 4 1 - 5 weighting (poor - excellent)</th>
<th>Option 2d - Refurbishment Block 4 1 - 5 weighting (poor - excellent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Provide CPA space for translational research activity.</td>
<td>Haematology / TSB teams relocated and operating as a coherent translational pipeline. CRUK 9 gene test validated and available as clinical diagnostic generating revenue.</td>
<td>1 - No space available across the Partnership. TSB award, plus future activity, conducted in isolation from clinical departments.</td>
<td>2 - Sufficient lab space. Insufficient associated office space.</td>
<td>3 - Just meets specification. Some constrains imposed by the change in functional use of the building. Long term space issues require delivery of the strategic end state.</td>
<td>4 - Sufficient space against specification potential to absorb some expansion. Some constrains imposed by the change in functional use of the building. Long term space issues require delivery of the strategic end state.</td>
<td>3 - Just meets reduced specification. Some constrains imposed by the change in functional use of the building. Long term space issues require delivery of the strategic end state.</td>
</tr>
<tr>
<td>2. Provide basic Cellular Pathology capability on the Churchill site.</td>
<td>Capability present at Churchill process clinical / research requests.</td>
<td>1 - Very basic clinical service provision through exist Biochemistry facilities in building 4.</td>
<td>3 - Sufficient lab space against specification. Constrained office space requiring hot desking.</td>
<td>3 - Sufficient lab space against specification. Constrained office space requiring hot desking.</td>
<td>4 - Sufficient space against specification. Constrained office space requiring hot desking.</td>
<td>3 - Sufficient lab space against reduced specification. Constrained office space requiring hot desking.</td>
</tr>
<tr>
<td>3. Provide the</td>
<td>Capability</td>
<td>0 - Nil. No</td>
<td>0 - Nil. No</td>
<td>2 - Able to</td>
<td>5 - Sufficient</td>
<td>2 - Able to</td>
</tr>
<tr>
<td>Objectives &amp; Benefit Criteria</td>
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</tr>
<tr>
<td>hub for Oxford BioResource activity.</td>
<td>relocated. Storage users identified and relocated into facility. Increased requests by researchers.</td>
<td>relocation. Activity continues in current insufficient space constraining activity continues.</td>
<td>relocation. Activity continues in current insufficient space constraining activity continues.</td>
<td>relocate if sufficient office space remains after Haematology / TSB workforce allocated space.</td>
<td>space against specification provided. Room for expansion.</td>
<td>relocate if sufficient office space remains after Haematology / TSB workforce allocated space.</td>
</tr>
<tr>
<td>4. Provide a CPA compliant cellular pathology diagnostic archive.</td>
<td>• CPA inspection passed.</td>
<td>0 - Nil. Archive remains in sheep station risking CPA compliance failure.</td>
<td>0 - Nil. Archive remains in sheep station risking CPA compliance failure.</td>
<td>0 - Nil. Archive remains in sheep station risking CPA compliance failure.</td>
<td>4 - Sufficient space against specification provided. Some constrains imposed by the change in functional use of the building. No room for expansion.</td>
<td>3 - Sufficient space against specification provided. Some constrains imposed by the change in functional use of the building. No room for expansion.</td>
</tr>
<tr>
<td>5. Deliver signature facility, promoting the Partnership's</td>
<td>• Leverage research funding and diagnostic revenue realised.</td>
<td>0 - Nil.</td>
<td>2 - Minimum Translational lab functionality for promotion. No associated</td>
<td>3 - Sufficient facility provided. Suboptimal as Oxford BioResource and Director of</td>
<td>5 - Consolidation of a range of activity in signature facility. Able to point to long</td>
<td>3 - Sufficient facility provided. Suboptimal as Oxford BioResource and Director of</td>
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</tr>
<tr>
<td>Capabilities in pathology, supporting the leveraging of other revenue streams.</td>
<td>Fundraising sufficient to resource strategic vision.</td>
<td>1 - 5 weighting (poor - excellent)</td>
<td>functionality demonstrating a coherent capability.</td>
<td>Director of Translational Pathology not consolidated alongside.</td>
<td>term strategic plan.</td>
<td>Translational Pathology not consolidated alongside.</td>
</tr>
</tbody>
</table>

6. Deliver on commitments to the NIHR.
- Able to demonstrate delivery of facility.
  - 0 - Nil.
  - 4 - Minimum delivered.
  - 5 - Delivered.
  - 5 - Delivered.
  - 5 - Delivered.

7. Enable the strategic vision: Consolidation of research and clinical pathology.
- Operational evidence of Partnership working to realise strategic vision.
- Plan to realise vision produced.
- Fundraising sufficient to resource strategic vision.
- Fully
  - 0 - Nil.
  - 1 - Minimal research / clinical service linkage in single discipline. Limits timeframe to deliver full vision.
  - 3 - Suboptimal as Oxford Bioresource / Director of Translational Pathology not consolidated alongside. Location supports collocation on neighbouring estate footprint future new build.
  - 4 - Delivered. Location supports collocation on neighbouring estate footprint future new build.
  - 3 - Suboptimal as Oxford Bioresource / Director of Translational Pathology not consolidated alongside. Location supports collocation on neighbouring estate footprint future new build.
### Objectives & Benefit Criteria

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<th>Option 2d - Refurbishment Block 4</th>
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<tbody>
<tr>
<td>1 – 5 weighting</td>
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<td>1 – 5 weighting</td>
</tr>
<tr>
<td>(poor - excellent)</td>
<td>(poor - excellent)</td>
<td>(poor - excellent)</td>
<td>(poor - excellent)</td>
<td>(poor - excellent)</td>
</tr>
</tbody>
</table>

**KPI**

- integrated clinical service / research pathology facility opened.
- build.

#### 8. Consolidate translational pathology activity within a clinical department.

- Translational pipeline physically integrated into one department.
- CRUK 9 gene test validated and available as clinical diagnostic generating revenue.
- 0 – Nil. Research and clinical activities continue to be physically separated.
- 3 – Molecular Diagnostics and Haematology functions collocated. Able to point to long term strategic plan.
- 3 – Molecular Diagnostics and Haematology functions collocated. Able to point to long term strategic plan.
- 3 – Molecular Diagnostics and Haematology functions collocated. Able to point to long term strategic plan.

#### 9. Enable the reorganisation of the Pathology & Laboratories Department.

- Immunology relocated to JR / higher quality laboratory.
- 0 – Nil. Immunology remains at the Churchill. General improvement to the general standard of
- 5 – Immunology able to relocate. General standard of laboratories in the Directorate improved.
- 5 – Immunology able to relocate. General standard of laboratories in the Directorate improved.
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<th>Option 2d - Refurbishment Block 4 1 - 5 weighting (poor - excellent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Score (highest possible score 45)</td>
<td></td>
<td>2</td>
<td>20</td>
<td>27</td>
<td>39</td>
<td>30</td>
</tr>
</tbody>
</table>

laboratories in the Directorate not delivered.
### Appendix C - Management of Proposal Implementation Risks

<table>
<thead>
<tr>
<th>Risk</th>
<th>Impact</th>
<th>Likelihood</th>
<th>Mitigating Action</th>
<th>Residual Risks</th>
<th>Contingency plan to address risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time. Completion of development to time.</strong></td>
<td>1</td>
<td>2</td>
<td>Feasibility study already completed. 8 month construction programme plan drafted</td>
<td>Unforeseen issue(s) identified during refurbishment delay completion date.</td>
<td>Contingency budget factored into the feasibility estimates. Able to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>and review by OUH estates team. Progress against this plan will be subject to</td>
<td></td>
<td>accept limited delays.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>consistent and regular review.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Construction. As a refurbishment and change in functional use,</td>
<td>3</td>
<td>2</td>
<td>Contingency budget factored into the project estimates by both the quantity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>additional issues may arise during construction programme.</td>
<td></td>
<td></td>
<td>surveyor and OUH estates team.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Finance. Loss of BRC Capital funding. Funding to be committed or</td>
<td>5</td>
<td>2</td>
<td>OUH and other stakeholders to commit funding to demonstrate OxBRC capital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>spend no later than 31 Mar 2012.</td>
<td></td>
<td></td>
<td>committed to NIHR.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Finance. Funding Streams not secured. This will place the project</td>
<td>4</td>
<td>3</td>
<td>Severely limited refurbishment carried out against secured funding.</td>
<td>Benefits severely limited.</td>
<td>Additional sources of funding being investigated.</td>
</tr>
<tr>
<td>delivery at significant risk as significant underlying mechanical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and electrical work require no mater level of refurbishment due to</td>
<td></td>
<td></td>
<td>Functional requirements / specifications reduced to accommodate available funds.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>change in functional use and period of non occupancy.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>