

Trust Board Meeting in Public: Wednesday 11 November 2015

TB2015.140

Title	Research and Development Governance and Performance Report
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Status	For information
History	This is an Annual Report

Board Lead	Dr Tony Berendt, Medical Director			
Key purpose	Strategy	Assurance	Policy	Performance

Executive Summary

<p>1. This paper presents the Research and Development Governance and Performance Report.</p>
<p>2. Clinical research is of major strategic and reputational importance to the Trust. OUH is highly active in clinical research, with ongoing clinical research studies in all Divisions. The Trust has a close partnership with the University of Oxford in clinical research, exemplified by the NIHR Biomedical Research Centre (BRC) and Biomedical Research Unit (BRU), and hosts the NIHR Local Comprehensive Research Network and the Academic Health Sciences Network. Through the recently-designated Academic Health Sciences Centre the NHS Trust has formal joint working agreements with the University of Oxford and with Oxford Brookes University.</p>
<p>3. The NIHR Oxford BRC submitted its Annual Report 2014/15 to the NIHR, with excellent performance indicators and an impressive scope and scale of translational research. Preparations for the anticipated BRC and BRC new funding competition in early 2016 are now underway, but there is the expectation that NIHR budgets across the BRCs and BRUs will be under intense pressure and may be reduced.</p>
<p>4. Health Economics is a main focus for the BRC, work is underway to build evidence of Oxford BRC's impact on patient health, NHS costs and the UK economy, in time for inclusion in the BRC bid in 2016.</p>
<p>5. OUH and OU continues to play a central role in the 100,000 genome project, working alongside both NHS England and Genomics England, and building on the designation of the Genomic Medicine Centre (GMC). Clinical informatics remains a strategic priority and a challenge to bring together EPR data in support of the GMC and clinical research in other areas.</p>
<p>6. The OUH hosts more than 1500 clinical research studies, including approximately 300 clinical trials. OUH R&D activities are supported by annual revenues approaching £50m. Operationally, the Joint Research Office, comprising over 80 members of staff from both OUH and University, supports all joint research across the partnership. There is a need to develop a strategic plan for the future development of the JRO, and urgent decisions about future provision of office accommodation.</p>
<p>7. The focus on clinical research performance by the NIHR remains an important priority for the OUH and OU. OUH R&D has significantly reduced the time taken to grant NHS Permissions (TMA) as well as achieving the first recruitment to such trials within the target timelines. Our recent performance in the 70-day study initiation benchmark has improved substantially, with OUH is now ranked first nationally out of the most research-active NHS Trusts, with a 100% record in the most recent quarter. However, additional performance targets for commercial trials, BRC & BRU studies and LCRN.</p>
<p>8. Recommendation</p> <p>The Trust Board is asked to receive this report for information.</p>

1. Strategic Importance of Research to Oxford University Hospitals

Enabling and undertaking research in Oxford University Hospitals (OUH) aligns the Trust with regional and national agendas to deliver evidence-based medicine in the NHS, and to create health and wealth through research and innovation. Supporting clinical research meets the obligations placed on NHS organisations to promote research and the use of research evidence when providing their services. Moreover, the scale, scope and quality of clinical research activity across the Trust adds national profile to the OUH as one of England's leading University Hospital Trusts, and has important beneficial impacts on clinical services, quality of care, and the recruitment and retention of clinical staff.

OUH is a highly active research organisation, with clinical research taking place in every Clinical Division – including both OUH-initiated studies and studies in close partnership with the University of Oxford. OUH receives a wide spectrum of funding to support clinical research, and either hosts or is a partner in key local and regional research infrastructure. The OUH R&D revenues, approaching £50m per annum, come from a variety of sources including charities, industry and public sector funders and this budget is proportionately distributed across the clinical divisions. The budget supports clinicians, nursing staff and allied health professionals across the organisation. Maintaining a vibrant and growing research environment within OUH is central to our involvement in the initiatives listed above and to securing a leading position in the region. Moreover, the scale of our activities attracts world-class clinicians, clinician scientists and other clinical and non-clinical staff to Oxford, and contributes significantly to retention and career development.

Key partnerships for OUH in clinical research include:

The NIHR Oxford Biomedical Research Centre (BRC). The Oxford BRC is hosted by OUH in partnership with Oxford University and was awarded £98m over five years (2012-2017) following the NIHR competition in 2011. The BRC supports 'translational research', taking laboratory research into a clinical setting. The BRC supports research across many clinical areas, spanning all OUH Divisions, focussing on innovations to improve diagnosis, treatments and healthcare delivery for the benefit of NHS patients.

The NIHR Oxford BRC includes 21 NIHR Senior Investigators, 255 NIHR Investigators employed by the BRC, 186 NIHR Associates and 255 NIHR Trainees with specific BRC funding.

During 2014/15 the NIHR Oxford BRC attracted £262 million of external grant income, representing a leverage ratio of more than 11 fold. The BRC Themes have published >500 papers acknowledging the NIHR Oxford Biomedical Research Centre in peer reviewed journals during 2014-15.

Furthermore, the NIHR Oxford BRC has continued to expand existing and secure new industrial relationships with strong engagement across all sectors from small medtech SMEs to large pharma, including a range of industrial consortiums targeted at specific unmet technology, therapeutic and healthcare needs. Agreements have ranged from strategic alliances to early collaborations and technology access agreements (241 agreements with Industry).

The BRC held its first Health Economics Symposium on the 16th April 2015. Oxford Hospitals NHS Trust and University of Oxford researchers met to evaluate the impact of BRC-supported research on NHS care and health economics. Discussions included how the use of barcode patient identification, bedside handheld computers and electronically controlled blood fridges have improved the safety and efficiency of transfusion and how electronic blood ordering and decision support are cutting blood transfusion costs at Oxfordshire hospitals.

The BRC has provided key funding to the equal opportunities and Athena Swan agendas and has continued to support the activities of the University's Athena Swan Committee.

Following the BRC Mid-term review in late 2014, preparations are now underway for the anticipated **bid for BRC and BRU funding in the next 5 years (2017-2022)**. It is expected that the announcement of the new funding competition will be in early 2016, with an initial qualifying part of the application followed by a full application deadline in Spring 2016 and interviews in early Summer 2016.

Informal indications from NIHR strongly suggest that all NIHR budgets, including the BRCs and BRUs, will be under intense pressure and may be liable to reduction across all successful applicants, particularly if additional new BRCs and BRUs are funded.

The BRC Steering Committee will hold an Away Day in late November 2015 to bring together new proposals from the BRC Themes (working in 'clusters' of related themes), and incorporating a substantial number of new proposals arising from a call for Expressions of Interest to contribute to the new BRC bid, announced in early September 2015.

A BRC bid writing group will be convened to work with the BRC Director and the BRC Steering Committee. It is requested that contributors from the OUH and OU MSD are made available to contribute to the substantial work involved in collating the information required for the bid, and to ensure that the coordination of the work packages are completed in accordance with the deadlines.

The BRC Annual Report for 2015, submitted to NIHR is provided as an accompanying paper for the Board.

The NIHR Oxford Musculoskeletal Biomedical Research Unit (BRU). The Oxford BRU is hosted by OUHT in partnership with Oxford University and was awarded £9.8m over five years from 2012-2017 and undertakes translational research in three key musculoskeletal areas: (a) epidemiology and risk factors for osteoarthritis and osteoporosis; (b) orthopaedic surgery; and (c) inflammatory arthritis (rheumatology).

The BRU works closely with the BRC in preparation and strategy for the new BRC/BRU funding competition in 2016.

The Thames Valley and South Midlands Local Comprehensive Research Network (LCRN).

The new LCRN replaces the former Thames Valley Local Comprehensive Research Network (TVCLRN) and topic-specific networks in Diabetes, Stroke, Cancer and Neurodegeneration (DENDRON), incorporating these activities in to 6 new clinical research divisions covering all therapeutic areas. The OUHT was successful in the 2013 competition to host the new LCRNs, and was awarded £13.5m/year for 5 years, from April 2014, to support the LCRN activity across the Region. The LCRN depends on participation from all NHS Trusts across the LCRN region, which is coincident with the Oxford AHSN, but the governance and responsibility for the management and performance of the LCRN rests with the Board of Host Organisation, working through a designated Executive Director (the OUH Medical Director), and the recently-appointed LCRN Clinical Director and Chief Operating Officer.

The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Oxford. Although hosted by Oxford Health Foundation Trust, OUHT is a partner in, and contributor to, the Oxford CLAHRC. Through strong collaborative leadership, the NIHR CLAHRC Oxford aims to address areas of high importance and relevance for patients as well as key NHS priorities: delivering the most effective and best value services and focussing on those with greatest need – the frail elderly presenting to acute medical services, people with dementia in care homes, and those with chronic enduring illnesses and comorbidities; the highest users of NHS services.

The Oxford Academic Health Science Centre (AHSC). The Oxford AHSC received its designation in 2013 and was launched in early 2014. The AHSC is a partnership comprising OUHT, Oxford Health Foundation Trust, University of Oxford and Oxford Brookes to bring together research, teaching and clinical care activities in the four organisations to address some of the greatest strategic challenges to health care systems here in the UK and globally. Core to this programme will be six 6 interconnected themes that will focus on strategic issues which the partners believe are central to sustaining a successful healthcare system:

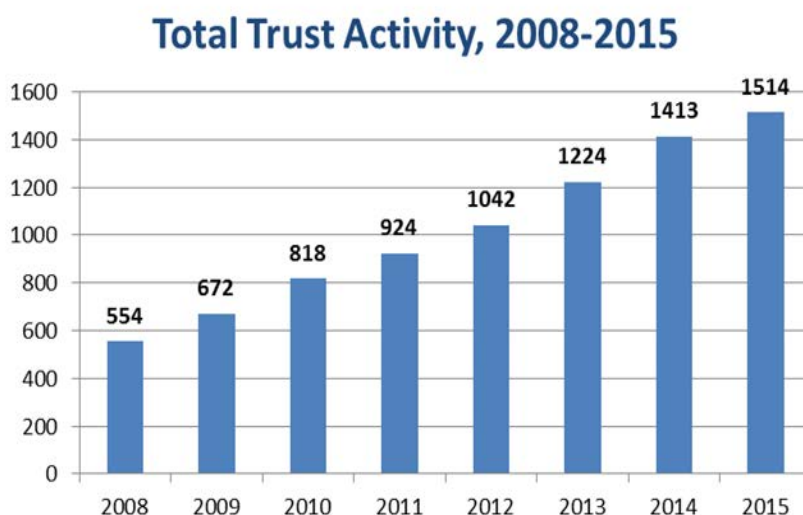
- Big Data: Delivering the Digital Medicine Revolution
- Building Novel NHS, University and Industry Relationships
- Modulating the Immune Response for Patient Benefit
- Managing the Epidemic of Chronic Disease
- Emerging Infections and Antimicrobial Resistance
- Cognitive Health: Maintaining Cognitive Function in Health and Disease.

The Oxford Academic Health Science Network (AHSN). The Oxford Academic Health Science Network is one of 15 AHSNs licensed for five years by NHS, with the vision of 'Best health for our population and prosperity for our region'. The Oxford AHSN will support collaboration, research and innovation across the NHS, universities and business, building on our strengths to deliver exemplary care and create the strongest life science cluster. The Oxford AHSN area covers a population of 3.3 million living in Berkshire, Buckinghamshire, Milton Keynes, Oxfordshire and Bedfordshire. The NHS spends £5bn a year in this region and employs 65,000 people. The Oxford AHSN will:

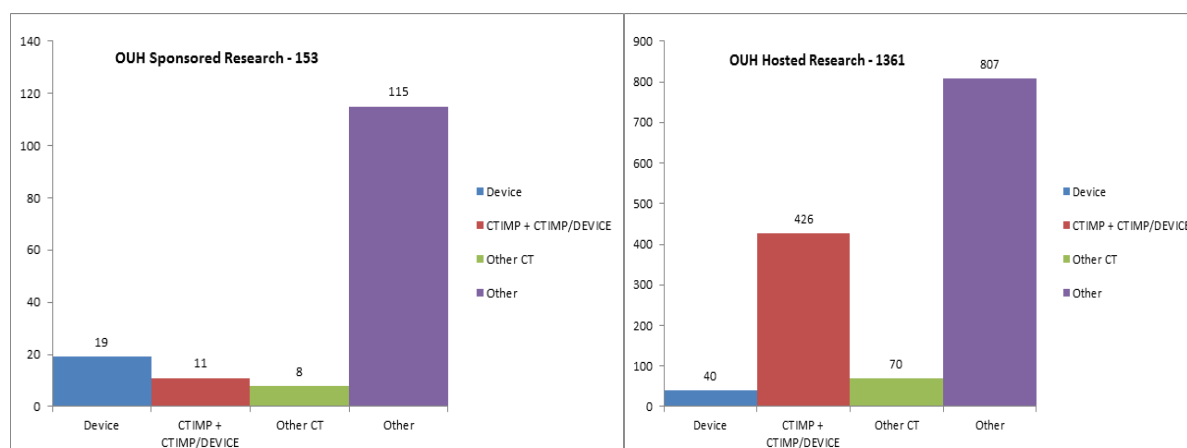
- Focus on the needs of patients and local populations – support and work in partnership with commissioners and public health bodies to identify and address unmet health and social care needs, whilst promoting health equality and best practice.
- Speed up adoption of innovation into practice to improve clinical outcomes and patient experience – support the identification and more rapid uptake and spread of research evidence and innovation at pace and scale to improve patient care and local population health.
- Build a culture of partnership and collaboration – promote inclusivity, partnership and collaboration to consider and address local, regional and national priorities.
- Create wealth through co-development, testing, evaluation and early adoption and spread of new products and services.

2. OUH Clinical Research Activity

The volume of active research studies has increased progressively in recent years, with a tripling of research studies of all types, since 2008, such that OUH now hosts more than 1500 active research studies. These figures are summarised in the graph below:



This number of studies can be analysed according to the nature of the research and whether it is **hosted** (i.e. OUH is the NHS organisation providing the clinical environment, capabilities and patient care) or **Sponsored** (i.e. OUH takes legal responsibility for the conduct of the study, as well as hosting), and whether the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP), or is a non- interventional study. These are shown in the graphs below. The majority of OUH hosted studies are not CTIMPs, and are sponsored by organisations other than OUH (e.g. University of Oxford, commercial partners, other NHS Trusts, other universities).



The OUHT sponsored CTIMPs are the most resource intensive to the Governance team; with all interventional trials (sponsored and hosted) being the primary focus for reporting of OUHT performance to NIHR.

3. Clinical Research Performance

3.1 Background

The Government's Plan for Growth, published in March 2011, aims to increase efficiency in initiation and delivery of clinical research, focusing on recruitment of the first patient to clinical trials within 70 days of receiving a valid protocol; and delivery of commercial clinical trials to time and target.

Since June 2012, the NIHR has required that the Trust report on performance to these targets on a quarterly basis. Attainment of key metrics is a requirement for NIHR funding, including BRCs/BRUs, and comparative performance metrics are published for each NHS Trust receiving NIHR funding. The Trust is also required to publish its own performance to these metrics on a readily accessible page on the website.

The current assessment of performance indicates that the Trust is now achieving the standards set by the National Institute for Health Research for initiation of research with 100% of evaluable trials meeting the target. Improvement is still required in meeting the standards of delivery of research to time and target.

The Department of Health threatened the imposition of financial penalties on Trusts failing to meet the initiation targets by withholding NIHR funding. Due to consistent improvement in performance, it has been confirmed Oxford University Hospitals will not be suffering any financial penalty for 15/16.

The Department of Health has stated that similar financial penalties will still be a possibility for the 2016/17 RCF allocation, though this remains unconfirmed.

3.2 NIHR Clinical Trials Performance Indicators

3.2.1 70 day Benchmark for initiation of clinical trials:

This metric applies to all interventional trials and relates to the time taken to set up a study and grant permission within a Trust; and, once that permission has been granted, the time by the research team to recruit the first patient (with a combined target of no more than 70 calendar days).

Data submitted is assessed and 'adjusted' according to the reasons provided for not meeting the benchmark. For example, if a trial involving rare diseases fails to recruit to the benchmark, this reason is deemed by NIHR to be acceptable and is therefore 'adjusted' out of the performance data. This 'adjustment' serves to ensure that there is no pressure on the Trust to avoid undertaking research into rare diseases; thus maintaining our reputation as a centre of excellence for the treatment of, and research into, rare diseases.

R&D staff work with study teams to ensure that they recruit within the required timescale prior to each NIHR submission. A summary table of OUH 70 day performance figures is shown below:

	Unadjusted % of trials meeting 70 day benchmark	Adjusted % of trials meeting 70 day benchmark
Q2 13/14	19.4	-
Q3 13/14	21.7	34.7
Q4 13/14	25.9	42.4
Q1 14/15	30.6	53.3
Q2 14/15	42.2	70.3
Q3 14/15	54.2	95.0
Q4 14/15	55.1	100
Q1 15/16	64.9	Data awaited from NIHR

The most recent two Quarters' analysis has seen all 'delay reasons' offered by OUH deemed acceptable. This contrasts with the national landscape which saw well over 500 such reasons queried by the NIHR. This is indicative of the data quality now being provided by R&D as well as

the enhanced communication channels, opened and maintained across departments, and the diligence with which these reasons are verified.

For the year to Q4 2015 (1st April 2014 – 31st March 2015) **OUH-hosted clinical trials analysed by NIHR showed a 100% achievement in the 70 day clinical trial initiation metric.** Of the 127 trials analysed in this quarter, the time taken to recruit the first patient ranged from 1 to 69 days, with a median of 34.5 days.

In 'League 1', consisting of the most research-active NHS Trusts, **OUH is the only Trust to have achieved 100% compliance with the 70 day target, in any reporting period to date.**

Whilst this achievement is unlikely to be repeated in each Quarter, a consistently high percentage, such as that achieved in each of the last two reporting periods, is considered to be sustainably attainable; a reflection of the processes and tools which have driven the observable improvement.

As a result of careful streamlining of processes, the average timelines from valid research application to granting trust management approval of an interventional trial have been reduced to a current mean in June of 2.6 days. This provides researchers with more time to achieve first patient recruitment.

3.2.2. Commercial Trials Recruitment to Time and Target

This delivery metric is based specifically on commercially-sponsored clinical trials, which must recruit to time and target; calculated from the total number of patients and the duration of the recruitment period, as set out in the study contract.

The number of trials achieving their target recruitment by or before the target date now shows a steady improvement, as shown in the table below, although much remains to be achieved.

	Number of reported trials	% of evaluable trials meeting recruitment target
Q3 12/13	150	46.6
Q4 12/13	157	52.3
Q1 13/14	162	50.5
Q2 13/14	191	47.4
Q3 13/14	198	46.0
Q4 13/14	181	40.5
Q1 14/15	186	49.0
Q2 14/15	176	55.0
Q3 14/15	171	59.2
Q4 14/15	204	64.7

Accurate feasibility assessments optimize the chance of successful recruitment to target. Early involvement with the research teams is used to ensure achievable recruitment targets are agreed in workable timelines, reflecting OUH capacity and capability.

R&D teams maintain robust communication channels with research teams, to monitor ongoing recruitment figures and review feasibility, where significant changes have been made to trial arrangements; whether through substantial amendment to the protocol or arising from resource challenges.

4. Strategies to Enhance and Accelerate Clinical Trials Performance

A number of measures have been implemented, and are being further developed, to improve the OUH performance in respect of the NIHR metrics for the initiation and delivery of clinical research:

4.1 Measures to improve rapid data management and tracking

The very large scale of the OUH clinical research portfolio requires systems that can track and alert both R&D teams and investigators within the short timelines required by the NIHR metrics. The Research Portfolio Manager (RPM) system continues to be developed and is proving to be an invaluable tool for the management of clinical research performance, by more rapidly highlighting timelines in the performance of the JRO and clinical research teams. The RPM facilitates a proactive approach to the management of data, so that outliers can be identified and addressed, within a time period that will impact upon the data submitted to NIHR.

The RPM is subject to on-going development, with the intention to expand access to relevant data across the Trust, so that real time data can be monitored and potential breaches of time targets highlighted promptly to the relevant PI and Divisional Director. Thus, prompt action to rectify the situation can be implemented by the research teams. This will affect both the 70 day benchmark and the recruitment to time and target metric. Such a development will also serve to create a shared sense of ownership of clinical research performance across the Trust.

The R&D staff have developed a proactive and outward facing approach to research; the JRO ethos is of an integrated team to support clinical research across the Trust. R&D team members attend steering committees and individuals are identified as key contacts for the various Divisional groups and Clinical Trials Units.

Further work is being undertaken to enable the Thames Valley Clinical Research Network to adopt the system as their 'Local Portfolio Management System'. This will further enhance communication and sharing of data, with the aim of avoiding duplication of effort, wherever possible.

4.2 Prioritising Clinical Research Performance in the OUH Clinical Divisions

The OUH Clinical Divisions are crucial to effective clinical research management, governance and performance, since the clinical activity and patient flows are embedded within Divisions, and research study PIs work as either substantive or Honorary Contract holders within the Clinical Division. Work is underway to appoint Divisional R&D Managers, who will take responsibility for coordinating the Divisional clinical research portfolio and ensuring overall satisfactory performance in feasibility, study initiation and recruitment. Embedded within, and professionally accountable to the Divisions, there will be a reporting line into the Joint Research Office. One such manager has been appointed and is in post in Surgery and Oncology. The prioritisation of clinical research performance by the OUH is reflected in the recent decision by TME to receive a formal report of OUH Clinical research performance every quarter. All performance data are summarised by Division and Directorate, which will allow individual Divisions/Directorates to review and act on their performance data in the context of core audit and performance activities.

4.3 Incorporation of Clinical Research Performance in Statutory & Mandatory Training, and in Consultant Appraisal

The R&D Team provide both face-to-face and on-line training modules in Good Clinical Practice (GCP) for all clinical research PIs and for other researchers, to be undertaken in accordance with OUH policies. Greater 'visibility' for GCP training, and the opportunity to introduce specific aspects of clinical research performance that are relevant to both PIs and to wider groups of OUH clinical staff, could be achieved by including research training modules in the OUH

Statutory & Mandatory Training requirements. Work has begun to establish what area should be covered within the mandatory training undertaken by all new OUH staff.

OUH local requirements for consultant medical appraisal have incorporated some aspects of reporting and assessing clinical research activity, for example evidence of up-to-date training in GCP. Working with the Medical Director, there is an opportunity to modify these local requirements to include more systematic and objective information on clinical research performance for all consultants who are PIs in research studies, for example by a requirement to include listings of all studies, with performance metrics, which are made available through the JRO's Portfolio Management System.

4.4 Improved Communication of Research Performance Priorities

Much effort is put into communication of the importance of Trust performance to these metrics. Where training of any kind is delivered to researchers; whether formal in good clinical practice training and audits or informal in the course of business, the issues of both first patient recruitment and recruitment to time and target is highlighted.

However, more systematic work can be done. Opportunities include: introducing clinical research into staff induction briefings; highlighting clinical research performance at clinical team meetings, within Clinical Research Facilities and Clinical Trials Units, BRC Themes, and in collaboration with University Departments, through the University's MSD Research Committee and the MSD Board. These communications will be made through letters, papers and presentations from the OUH Director of R&D, and more widely by other members of the R&D teams and JRO, for example through 'road shows' and workshops to reinforce the message with PIs, research teams and clinical staff.

5. Forthcoming challenges

5.1 Additional requirements in metrics reporting

Recent communication from the NIHR has indicated the creation of a new metric for studies receiving financial support from NIHR Biomedical Research Centre (BRC); NIHR Biomedical Research Unit (BRU) and from the NIHR Clinical Research Facility (CRF). This will require each such study to report Quarterly on their recruitment *that quarter*. The most appropriate way to manage this, given it does not align with current metric reporting, is still under discussion.

5.2 Maintaining good research practice

Successful recruitment must not be at the expense of good and ethical research practice, ensuring that approach and recruitment is always appropriate. The R&D Governance team undertakes monitoring, risk based audits and more brief compliance checks on interventional trials and research studies, to ensure this.

5.3 The Health Research Authority Approvals process

The Health Research Authority (HRA), established in December 2011, began a phased roll-out of the HRA Approvals process in May 2015. HRA Approval is a new process, whereby national NHS permission will be granted for clinical research studies to be conducted throughout all participating NHS Trusts. The process involves NHS Research Ethics Committee review as well as a research governance review to assess compliance with the relevant legislation; such reviews hitherto having been undertaken by individual R&D departments, along with Local Clinical Research Networks for NIHR portfolio studies.

Currently, the R&D team undertakes a governance review of all research studies applying to be hosted by the Trust, and grants permission, on behalf of the Trust, for the research to be carried out. This review involves an assessment of compliance with the relevant legislation; assessment of safety; appraisal the information provided to patients, to ensure that this adequately covers

the research protocol, along with the risks and benefits of participation; along with assessment of capacity, capability and feasibility for the conduct of the study.

It is envisaged that, when the HRA process has been fully implemented, there will be no formal requirement for NHS Permission to be granted by individual Trusts. Trusts will, however, be required to assess their capacity and capability to deliver the proposed research; such assessment will be completed by indication of “readiness” to the Sponsor.

HRA have indicated that this process will be fully operational by the end of 2015. The Trust, therefore, needs to be ready to adapt the processes within the Joint Research Office, in order to ensure that duplication of review is avoided wherever possible, whilst maintaining a level of oversight of the process to ensure that the interests and safety of recruited participants is safeguarded and that the research being undertaken within the Trust is compliant and appropriate.

Whilst it is understood that the HRA will undertake all the necessary checks to ensure that the research study is compliant with the relevant national guidance and legislation, the Trust still retains a duty of care to its patients when enabling them to participate in research studies.

Regardless of whether a mature and reliable process is established by HRA, the Trust will continue to have regulatory responsibilities for the conduct of Clinical Trials of Investigational Medicinal Products (CTIMP) and will be inspected in relation to compliance with the Medicines for Human Use (Clinical Trials) Regulations. Accordingly, the OUH R&D teams will continue to maintain requirements from all PIs in respect of the appropriate capability, standards and performance of OUH clinical research studies, and that these are maintained as key aspects of OUH policies and standards in clinical research.

6. Research Management and Governance

6.1 Background – NHS Research Governance

Research governance refers to the framework in OUH to manage the research process from end to end, to ensure that research is undertaken in a safe, appropriate and ethical manner, in accordance with national guidance and applicable laws to ensure that maximum benefit is derived from research of public and patients. These include:

- **The Health Research Authority (HRA)** that has responsibility for the National Research Ethics Service (NRES), which is responsible for all Research Ethics Committees (RECs).
- **The NHS Research Governance Framework (RGF)** that sets out a framework for the governance of research in health and social care. This includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. The HRA intends to replace the RGF late 2014 with a new simplified framework.
- **EU Clinical Trials Directive (2001/20/EC)** provides a framework which sets out how clinical trials investigating the safety or efficacy of a medicinal product in humans must be conducted. The EU Clinical Trials Directive was transposed into UK Law as the Medicines for Human Use (Clinical Trials) Regulations 2004 and came into force on 1st May 2004, forming the basis for the UK Clinical Trials Regulations 2004.

6.2 Local Frameworks for R&D Governance, Training and Monitoring

Locally, clinical research is governed by a number of OUH Trust polices:

- Safety Reporting in Clinical Research
- Sponsorship of Clinical Research Studies
- Trust Management Approval for Clinical Research
- Research Protocol Amendments

- Monitoring and Audit of Research Studies
- Research Grants Policy and Procedures
- Management of Intellectual Property
- Integrity in Research
- Receipt, Storage and Handling of Investigational Medicinal Products

These policies are underpinned by a suite of Standard Operating Procedures (SOP) within R&D. Policies and SOPs are updated in response to national and local developments.

The policies are all available on the OUH website and specific attention is drawn to them during Good Clinical Practice (GCP) training. The content and requirements of the policies are also covered within this training. Through collaboration with the University of Oxford Clinical Trials and Research Governance team (CTRG), GCP training is provided to cover all research-related legislation and GCP; courses being designed for both staff new to trials and an update for experienced researchers. GCP training is a legal requirement of the Regulations and the Research Governance Framework. All researchers, in the Trust and the University, are required to have undertaken this training every three years as a minimum.

A training course is provided for clinical researchers, specifically designed for those not engaged in the conduct of a CTIMP. Informal training is provided in the form of advice and support to researchers and their teams.

The R&D Governance team ensure that all Clinical Trials of Investigational Medicinal Products (CTIMP) and device trials, for which the Trust has taken on the role of Sponsor, are monitored, to assure the Trust of compliance with the relevant regulations. In addition, a number of hosted CTIMPs are selected for audit, either where concerns have been raised, or according to a risk assessment.

6.2 Strengthening Research Governance in OUH

OUHT has a very large research portfolio and has established a robust approach to governance in accordance with national standards.

Despite this positive environment there is a need for all members of staff involved in research to maintain a high level of awareness of the need to comply with the policies and procedures for research governance in the Trust. This is most easily achieved by ensuring that R&D activities are fully integrated, reported and monitored in the Clinical Divisions. Currently, the OUHT Director of R&D is in discussion with Divisional Directors and the OUHT Board to establish the roles of Divisional R&D directors supported by a senior R&D manager/coordinator.

These dedicated individuals would be mandated to promote research, oversee performance and ensure that research active staff have adequate training to undertake trials and studies in a safe manner. This effective local/divisional implementation and monitoring of governance policies will promote patient safety in OUHT.

Greater awareness of R&D governance, for training in GCP and the requirements of R&D SOPs and policies could be achieved through Statutory and Mandatory Training, through Appraisal and through Divisional audit and training activities, the goal being to ensure that the vast majority of clinicians are able to support well governed research by understanding the processes that should be demonstrable by investigators in the clinical environment.

7 Research Management and the Joint Research Office (JRO)

7.1 R& D Finance

7.1.1 Year End Financial Position

The OUH R&D financial position for the 2014-15 financial year, including major joint OUH-OU NIHR infrastructure programmes (BRC, BRU, etc) reported a break even position. In total for Research and Development across the Trust, actual income of £47.453m was recovered and expenditure of an equal amount was committed (£47.453m).

7.1.2 Financial Planning for 2015-16

For the financial year, the Trust is planning for an annual R&D income of £44.9m. The total overall funding represents a reduction in income and spend from the previous year which reflects:

- The 2014-15 budget and spend was inflated by in-year and non-recurrent allocations from the NIHR which have been wholly committed against planned spend.
- Changes in funding levels for LCRN to reflect the move of Heatherwood and Wexham Park hospitals from Thames Valley network.
- Reduction in levels of RCF funding allocations to the Trust (see below).

7.1.3 Research Capability Funding

An annual allocation for RCF is made to the Trust in respect of major OUH-OU NIHR programmes, and for NIHR Senior Investigators who are OUH employees or OUH honorary contract holders (£75k/year RCF for each of 21 NIHR Senior Investigators). The Trust has received a total of £5,787k for the financial year 2015-16. This funding allocation has been reduced by circa 10% compared with previous years. This reduction was not, in any part, due to any performance metric or benchmark, but reflects the pressure on NIHR budgets leading to a reduction in all RCF awards from NIHR this year.

Funding decisions and commitments have already been made for RCF for 2015-16. The reduced funding allocation will result in a need to review and revise any outstanding calls for funding. This may result in less flexibility and less certainty for the Research and Development team to support in-year emerging issues.

The Trust, as the Host Organisation to Thames Valley and South Midlands Clinical Research Network, is also in receipt of Network RCF. For 2015-16, the network funding allocation has also been reduced to £317k, from £667k in 2014-15.

7.1.3 R&D Recruitment

R&D has successfully appointed the first R&D Divisional Manager who took up the post in July 2015 and is based within the Division of Surgery and Oncology and line managed by the Divisional Director. The R&D Divisional Manager will manage the delivery of research within their Division, collaborating with Research Investigators to prioritise clinical research studies and clinical trials. They will work closely with the Director of R&D and the R&D team to ensure clinical research performance targets are met and maintained. It is expected that 'up to' 4 further posts will be recruited and will be based within each of the OUH Divisions.

The role of Associate Director of R&D remains vacant following Dr Glenn Well's departure in December 2014. Despite extensive recruitment, there have been difficulties in finding a suitable replacement and therefore recruitment continues. It is proposed to link an OUH Deputy Director of R&D role with an additional role as COO for the Oxford AHSC.

Recruitment is currently underway for a Head of R&D Operations. This role will be directly responsible for the OUH R&D management functions through the Joint Research Office and will oversee the delivery of services to facilitate and support high quality clinical and translational research within the OUH – University of Oxford Partnership and its collaborators.

7.1.4 Accommodation for the Joint Research Office

The current space within the JRO remains over-crowded, housing >80 Trust and University employees and on a number of grounds a less than ideal working environment.

The Trust Estates continues to explore possible ways of making the current space more acceptable on a temporary basis and possibly increasing capacity slightly.

The University has a licence from the Trust to occupy the JRO until March 2018. The indications are that the OUH may not wish to renew the licence due to future uncertainty over part of the hospital where the JRO is based. A plan for accommodation of the R&D teams, co-located with each other and with University colleagues, is crucial to maintaining the scale, scope and

performance of OUH clinical research. The need for the Trust and the University to work together and re-provide space for the JRO teams is becoming increasingly crucial.

7.1.5 ISO Accreditation

The BRC operations team achieved renewal of the ISO9001 designation in 2014-15 and is currently using the NIHR hub to disseminate information to the Themes. The BRC website provides comprehensive and up to date information including details of the BRC Open Day, public lectures, events, the Health Economics Symposium and the Mid-Term Review process.

8. Conclusions

Continued focus on clinical research activity and delivery will be achieved through the OUH's key research programmes and programmes. The Joint Research Office has established a research governance and support plan with prioritised objectives to include:

1. Working with all OUH Divisions and partner University Departments to provide support for clinical research
2. Continuing review and setting of standards in research design, approval and conduct of all clinical research studies, including the need to provide timely performance data in near 'real time'.
3. Development, through consultation, of a research governance and delivery scorecard based on key performance indicators, and its incorporation into Divisional and Trust performance review processes
4. Development of a learning package to disseminate broad understanding of basic principles of research governance (and how ethically to promote and support clinical research) among the vast majority of front line clinical staff
5. A programme of audit of compliance with key policies and standards
6. Quarterly reporting to TME and annual reporting to the Board

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