

**BOD 113/2018**

(Agenda item: 13)

**Report to the Meeting of the**

**Oxford Health NHS Foundation Trust**

**Board of Directors**

**27 September 2018**

**Research and Development Report**

**For information**

**Executive Summary**

Oxford Health NHS FT continues to host and support the Oxford Academic Health Science Network programs related to mental health, specifically Anxiety and Depression, Dementia and Early Intervention in Psychosis.

The last six months has seen the submission of annual report to the National Institute of Health Research (NIIHR) for the Oxford Health Biomedical Research Centre (BRC) following its first year of operations. Significant progress has been made during the first year, where we have received 50% of the funding, including establishing robust governance structures, publication of a Patient and Public Involvement strategy, supporting over 80 studies and over £16 million leveraged funding.

An annual report for the NIHR Clinical Research Facility has also been submitted highlighting that we have supported 43 studies and published 64 peer reviewed articles. Occupancy of the CRF is at 62% across three sites, with the 90% occupancy at the Warneford CRF. The team continues to work with OUH to identify space at the John Radcliffe site to support the expansion of the CRF.

The Oxford NIHR Collaboration in Leadership in Applied Health Research and Care (CLAHRC) led by Professor Richard Hobbs continues to make good progress against its objectives and generate impact in the form of academic publications, patient benefit and cost savings within the NHS. This infrastructure funding stream is to be replaced by the ARC for which Oxford Health has supported the submission of a robust application for funding due to start in 2019.

The NIHR Community Healthcare MedTech and IVD Co-operative (MIC) is continuing to make progress against it objectives and has had 11 formal company interactions/consultations in the last six months, covering sepsis, haematology, detection of bladder cancer, liver health, remote monitoring of patients, and multi-function diagnostic platforms. Consultations are one channel through which the MIC delivers support to the diagnostics and medtech industries.

A Research Management Group is providing a value asset in steering the strategic and scientific direction of research undertaken within Oxford Health NHS FT and its partners by bringing together key stakeholders from the various NIHR infrastructures, AHSC, AHSN, University of Oxford, Oxford Brookes University, clinical services on a monthly basis.

The Trust continues to provide robust research support to enable researcher to conduct studies within OHFT, with regular pipeline meetings to establish feasibility for each study taking into consideration scientific and strategic importance to patients, the organisations and its partners.

Work has commenced rolling out the consent for recontact process within the Trust whereby clinicians will discuss with patients whether they are interested in being contacted about research. This will be documented in CareNotes with a specific form. This will then link to CRIS to establish who meets a research studies criteria and has also indicated they are happy to be contacted.

CRIS is continuing to support researchers undertaking studies within the organization in addition to increasing the support for clinical audit within the Trust.

It is expected that R&D will meet its expected contributions to overheads and break even on external funding streams.

**Governance Route/Approval Process**

The is a biannual update report to the Board for Research and Development taking place or being hosted within the Trust and is for information

**Statutory or Regulatory responsibilities**

Research and Development is aligned to its regulatory responsibilities in undertaking research and is compliant with contractual obligations

**Recommendation**

The Board is asked to note the report.

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**Lead Executive Director:** Mark Hancock

1. ***Strategic Objectives*** *– this report relates to or provides assurance and evidence against the following Strategic Objective(s) of the Trust [OR N/A – no Strategic Objectives apply] (****please delete as appropriate****):*

*1) Driving Quality Improvement*

*(Goals: patients will be safe from harm; patients will achieve the clinical outcomes they want; and patients and carers will have an excellent experience)*

*2) Delivering Operational Excellence*

*(Goals: our services will be effective and efficient; information will be translated into knowledge; and our planned surplus will be delivered)*

*3) Delivering Innovation, Learning and Teaching*

*(Goals: the impact of the AHSN, AHSC and CLAHRC will be maximised; we will collaborate in research and innovation; and we will deliver high quality teaching)*

*4) Developing Our Business through Collaboration and Partnerships*

*(Goals: we will work in collaborative partnerships; we will maintain and grow our services where we add value; and we will have strong relationship with our stakeholders)*

*5) Developing Leadership, People and Culture*

*(Goals: staff satisfaction will be in the top 20% of Trusts nationally; our staff and teams will be high-performing; and we will recruit and retain an excellent workforce)*

*6) Getting the most out of Technology*

*(Goals: our patients and staff will have the right technology available; our workforce will have the necessary IT skills to do their jobs well; and an outstanding IT service will be delivered)*

*7) Using our Estate efficiently*

*(Goals: patients and staff will benefit from safe and appropriate environments; our estate will be sustainable and environmentally-friendly; and our estate will be cost-effective)*

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# Introduction

Participation in research produces widespread benefits for patients and, more generally, improvements in quality of care. A Censuswide comsumer poll of 3,000 people in England, commissioned by the NIHR published data in September 2014 saying that 95% of those as responding stated that it is very important that the NHS carries out clinical research, with 85% or people agreeing that they would be very or somewhat willing to take part if they were diagnosed with a medical condition or disease. This accounted for the main factor that was most likely to motivate them into taking part, along with if a friend/family member was taken seriously ill and didn’t have the treatment they needed. The majority of those surveyed said that clinical research takes place within the NHS, Universities and Clinical Trials Units. Oxford health NHS FT has strong links to the University of Oxford, which has been rated as the world’s best university for clinical, pre-clinical and health subjects for the past 5 years (2011- 2016 THE World University Rankings), top ranked in the Research Excellence Framework 2014 for research quality in Psychology, Psychiatry and Neuroscience and third highest University in the areas of mental health and dementia in the RAND report commissioned by NIHR in 2015. In addition Oxford Health NHS Foundation Trust was the top ranked mental health Trust in the Mental Health Highlight Area in the NIHR RAND report

# Networks and Collaborations

## Oxford Academic Health Science Network (OAHSN)

### Oxford AHSN Mental Health - Introduction

Fran Butler continues in the new Oxford AHSN Mental Health Programme Lead role, working across the AHSN’s three programmes – Innovation, Improvement and Industry - and liaising with local stakeholders to develop a sustainable mental health programme connected with mental health priorities and planning in the health system.

As the AHSN covers the Thames Valley and Milton Keynes areas, we are able to spread good practice in Mental Health services from within this area as well as from other AHSNs nationally.  Additionally we are also able to connect those with ideas for innovations within CCGs/Trusts/ICSs to potential sources of funding.

Clinical Networks Up to March 2018, the Oxford Health NHS FT hosted three Oxford AHSN clinical networks – Anxiety and Depression, Dementia and Early Intervention in Psychosis (EIP). The work of the Anxiety and Depression network continues at a similar level and is described below, however the AHSN investment in Dementia and EIP has reduced with a refocussing of mental health work. The AHSN continues to run dementia webinars for a wide range of stakeholders, and its Best Practice Care Homes network for in-reach mental health teams (including participation of members of OHFT’s Care Home Support Service) also continues. We are currently discussing involvement of the AHSN’s Patient Safety Collaborative with EIP teams in a project to improve safety of transfers between services across the Thames Valley – we anticipate this linking in with the OHFT Improvement Centre though this is still to be discussed.

Other mental health innovations within the AHSN which are being implemented or explored include:

**Sleepio** – see below

**Integrated mental health care and policing teams (SIM) –** a national initiative in which police are integrated within a mental health team so that the team can provide a combination of nursing care and behavioural management. We are currently exploring whether this is an initiative that could be rolled out within Oxford AHSN’s area.

**Mental Health Care for Emergency Department Frequent Attenders – a Regional Collaborative** We are aiming to support a collaboration in the Thames Valley region, which will enable us to share best practice for frequent attenders requiring mental health care, to better understand patient flow and to design collaborative strategies based on collective knowledge across the different localities. This project, which was initiated by Dr Deon Louw, a consultant in the Emergency Department at OUHT, has been shortlisted for funding from the Q Exchange initiative (part of the Health Foundation).

### Oxford AHSN Anxiety and Depression (A&D) Network

This existing network is hosted by OHFT with Professor David Clark as Clinical Lead and Ineke Wolsey as Network Manager. Building on the last report to the Board when much detail was provided on the various projects the Anxiety and Depression Network can report the following progress:

**Continuous performance improvement:** All Thames Valley IAPT services continue to hold good recovery rates (on average 57%, which is 6% higher than the national average).The Integrated IAPT services recovery rates are, as expected because of increased complexity patients presenting with long term conditions and co-morbid depression/anxiety, slightly lower on average. Numbers of patients completing treatment are up from 1807 (April) to 2117 (July) and numbers achieving recovery up from 1054 (January) to 1101 (July).

**Relapse prevention:** the A&D Network has started detailed work on identifying and understanding patients who present for re-admission following a course of treatment. The aim is for early identification of this patient group so that an improved treatment package and/or more intensive post-discharge support can be offered to minimise the risk of relapse.

**The health economics evaluation** of the Integrated IAPT programme is well underway with Cohort 1 pre and post Integrated IAPT evaluation now completed. Reports for the national team and our Thames Valley commissioners due mid-September. Further analysis to include Cohort 2 will take place during September for sign off early October. The paper for publication will be based on the latter which will include 3 months pre and post healthcare utilisation (primary and secondary care) for Cohort 2 and 6 months pre and post healthcare utilisation (primary and secondary care) for Cohort 1.

**The therapy support and follow app**: the project kick-off meeting was held on 28th August with the appointed app developers. The Expert Reference Group and Patient Forum have met on a number of occasions to determine final functionality.

### 1.1.3 National IAPT Database

This is a further project related to IAPT within the AHSN. There has been acknowledged difficulty in processing IAPT data submissions at a national level with NHS Digital, with particular concern over data quality. Discussions between NHS Digital and Professor David Clark have led to a commitment to release this national dataset for restricted research and service evaluation purposes with a view to helping identify and overcome the persistent data quality issues associated with the consolidation of local extracts. To this end the Oxford AHSN Informatics Team is providing the infrastructure, expertise and access to the data for use by the Oxford University Department of Experimental Psychology (under David Clark; Professor and Chair of Experimental Psychology) and the University College London department of Clinical, Educational and Health Psychology (under Professor Stephen Pillings; Head of Clinical Education and Health Psychology & Professor of Clinical Psychology and Clinical Effectiveness) to conduct research.

### Sleepio

Innovate UK have funded a collaborative partnership which will enable free direct access to Sleepio, an evidence-based sleep improvement programme, for 2.7 million adults across the Oxford AHSN footprint.  This project (the ‘Sleepio project’) is jointly delivered by Oxford AHSN and Big Health, and is supported by NHS England.

The project aims to provide a blueprint for the adoption of digital medicine at scale and to produce two outputs: (1) a guide to enabling access and promoting the uptake of digital medicine and (2) a sustainable commissioning model, based on NHS savings and clinical outcomes.  These outputs will assess the engagement delivered by two different approaches:

* Primary care engagement, where healthcare professionals refer patients in to the service.  Primary care engagement activities will be focused on six ‘core’ GP practices in Buckinghamshire and will be led Dr Michael Mulholland.  These ‘core’ practices will be asked to refer patients to Sleepio, promoting Sleepio within their practice, undertaking training on the impact of insomnia and providing data for the health economic evaluation component of the project.  Core practices will be reimbursed for their participation.
* Population engagement, where employers and institutions are asked to raise awareness and signpost access to the service amongst their staff and members.  As part of this workstream, we will engage with NHS Trusts and other programmes, such as IAPT and Live Well Stay Well, to explore opportunities for their users to benefit.

## Oxford Academic Health Sciences Centre (AHSC)

The ASHC will submit a separate report to the Board regarding activity across the four partner organization in Oxford. These reports will be on a biannual basis

## Oxford Institute of Nursing, Midwifery and Allied Health Research

The Oxford Institute of Nursing, Midwifery and Allied Health Research (OxINMAHR) is an Oxford Brookes University led partnership between key stakeholders to lead and participate in world-class research and evidence-based practice. We have a particular interest in innovation and best practice at the point of care.

OxINMAHR researchers take a broad, holistic view of health, to encompass physical, psychological, emotional, spiritual, cultural and social elements; and, consider health and illness to occur in the context of family life. Thus, health issues and challenges are viewed as being concerns for individuals, as well as their families and communities. OxINMAHR has a specialist focus on research that; (i) Enhances patient safety and well-being; (ii) Enhances health equity and social justice; and, (iii) Promotes health workforce resilience and sustainability.

OxINMAHR is currently in a state on transition while the process of recruitment of a new Institute Director is ongoing; presently Prof Helen Dawes is interim Director.

Within OxINMAHR, research activity continues to contribute to both strategic and operational objectives for Oxford Health Foundation Trust. OBU are keen to continue to collaborate with OHFT to create and develop clinical academic appointments for nurses and AHPs. Work is underway to identify areas within OHFT/OBU where these appointments may be created and successfully sustained.

Across OxINMAHR, public involvement (including patients, carers and families) is viewed as a key aspect of research, which is encouraged at each stage of the research process. There are two distinct areas of Public Involvement to meet both AHP and Nursing programmes of research.

For AHP, the MOReS team has two vibrant groups for children and adults and include an ideas factory. Activities include a registered Freestyle Project (led by Dr Shelly Coe) which follows the recently launched National Standards for Public Involvement. For Nursing, the PPI group is co-chaired by Cathy Henshall and Jo Brett and seeks to engage and involve patients and the public from a diverse range of backgrounds in research. CH and JB are hosting an OxINMAHR PPI research event in early November to shape ideas for future PPI involvement in research moving forward.' These activities make significant contribution to ensure that research themes, topics and studies are developed from a range of sources and from the bottom up to improve the quality of care.

Many joint collaborations and research projects are ongoing with members of Oxford Health including Dr Beatrix Ruckli working with Dr Johnny Collett on a CRIS data project. Early findings indicate that patients who have a diagnosis of Autistic Spectrum Disorder, Personality Disorder and Asperger’s are likely to have a higher risk of self-harm when compared to patients with other mental disorders, admitted to local acute mental health in-patient wards. This is a clinical significant finding and their collaborative work aims to inform the development of staff training sessions to improve patient care. MOReS affiliate Dr Richard Baskerville is currently involved in exercise and self-management for diabetes care with regular organised walks around Oxford with patients and has been very recently appointed as Oxford City Locality Diabetes Coordinator for Oxfordshire Clinical Commissioning Group with huge potential for developing strong relationships to create a positive impact on patient care and research.

Ongoing project work with the Oxford Centre for Spirituality and Wellbeing led by Prof Debra Jackson and Dr Guy Harrison relates to supporting leaders to maintain positive culture for clinical team through a survey of senior clinicians within the Thames Valley region. The purpose of this survey is to assess the need for training/ CPD in spiritually integrated patient care.

The recently formed Nursing and Midwifery Excellence UK (NAME-UK) is an informal network of UK health care organisations and individuals (including OHFT) who are interested in pursuing Magnet® or Pathway to Excellence® recognition with the American Nurses Credentialing Center for quality patient care, nursing and midwifery excellence and innovations in professional nursing and midwifery practice.

The International Dementia and Culture Collaborative (IDCC) is led by Dr Joanne Brooke and was set up with current projects to consider the impact of culture on nurses understanding dementia and how this may impact on their provision of person-centred care.

Research from the Children and Families Research Group led by Jane Appleton, involves children within the prenatal period, up to age 18. It includes areas such as safeguarding, child protection, child health, looked-after children, and the role of the family unit including parenting, school, and community influence on child wellbeing.

Current projects with a focus on patient care include: i) stand up for cerebral palsy ii) occupational therapy and young people with emerging mental health issues iii) movement, physical activity and mental and physical health and wellbeing iv) factors relating to safe driving performance and mental health.

Across OxINMAHR a wide range of research degrees are undertaken and supervised through the involved Centres and research groups in collaboration with both OHFT

The Centre for Movement, Occupational and Rehabilitation Sciences (MOReS) led by Prof Helen Dawes has developed strong research links with teams across the Trust and have been named in a draft of ‘ A strategy to develop the capacity, impact and profile of Allied Health Professionals in Oxford Health NHS Foundation Trust 2018-2023’. This documents a commitment to recruit and retain high quality staff to embrace and embed new ways of working to enhance clinical practice and maximise the health and wellbeing of Trust staff. The team work in close contact with OHFT (Rebecca Kelly and Dr Beatrix Ruckli) to develop and evaluate staff training workshops.

Possible areas of strategic direction being considered are

* Recruitment of AHP to PhD studentships
* Exploring the potential for clinical academic roles
* Engagement of clinical staff in research and support from management teams
* Developing the theme of adolescent/young people mental health
* Developing AHP and Nursing research (from BSc to Fellow) and translation into practice

# National Institute of Health Research Infrastructure

## NIHR Collaboration in Leadership in Applied Health Research and Care (CLAHRC) Theme Updates

### Operations

All projects funded through the CLAHRC are on track to complete as planned or have been extended to accommodate delays and are targeted for completion by the revised end date.

A number of BRC pull through projects have been agreed by the Programme Management Board. These are listed by theme with updates where appropriate:

### Theme 1: Early intervention and service redesign led by Professor Belinda Lennox

* Measuring the fidelity of Early Intervention in Psychosis interventions using Natural Language Processing to improve the prediction of relapse in First Episode Psychosis started 1 Sep 2018
* “Fat & sane or skinny & mad”: Investigating the interplay between physical and mental health in patients with psychosis started 1 Sep 2018
* Ketamine registry refinement and evaluation started 1 June 2018. Activities so far include a PPI conference at Wellcome collection on 22nd August, leading the collaboration which also involves the Oxford, UCLH and SLAM BRCs and Exeter; Developing and refining documentation for the Patients Know Best platform-based ketamine registry.
* Improving Clinical Decision Making in Ambulatory Emergency Care (ACE); A feasibility study of performance coaching using Extended Supervised Learning Events (ELSE) for peer supported learning starts 1 Jan 2019

### Theme 2: Behaviour Change: Exercise and Rehabilitation led by Professor Sallie Lamb

* Re-purposing anti-TNF therapy for fibrotic and inflammatory conditions started April 2018

### Theme 3: Patient Experience and patient reported outcomes led by Professor Ray Fitzpatrick

* Assessment of decision-support (PRO-MAPP) for patients with musculoskeletal problems starts Jan 2019

### Theme 4: Better management of medical-psychiatric multimorbidity

* no additional projects ongoing

### Theme 5: Patient management of chronic disease led by Professor Richard McManus

* Development of an intervention: kidney age, not kidney disease starts Sep 2018
* Mechanistic insights into the long-term effects of self-management of hypertension following a hypertensive pregnancy: The SNAP-HT extension study. started July 2018
* Harnessing data from electronic health records to predict risk of adverse events associated with antihypertensive therapy in multi-morbid patients with hypertension starts October 2018

### Theme 6: Behaviour Change: Diet and Obesity led by Professor Susan Jebb

* Developing a mobile application for tracking and improving the quality of food purchased : 'SwapShop' started June 2018
* Tracking respiratory exchange ratio (RER) during weight loss started June 2018
* Understanding food swap behaviours in the PCSHOP study started June 2018

### Summary Forward Look

**CLAHRC Extension:** Confirmation from the NIHR CCF of 9 months pro-rata extension funding (Jan, 2019 to Sept, 2019) on the 9th of January, 2018. Allocation of funding to themes/projects currently being finalised by CLAHRC Executive group.

A list of CLAHRC extension projects is available separately; operational updates will be included in future reports to the Trust Board.

**CLAHRC Annual Stakeholder Symposium:** Postponed from November 2018 to 15 February 2019 at Saïd Business School. An organising committee comprising theme representatives will develop the programme and is due to meet 11 Sep 2018.

**National CLAHRC Directors’ meeting** will be hosted by the Oxford team at Pembroke College on 25 and 26 September 2018

## Applied Research Collaboration (ARC):

NIHR call for the CLAHRC successor scheme was announced in mid-June. Oxford and Thames Valley ARC proposal (£9m) was submitted 17 August 2018 by Professor Richard Hobbs – Director, hosted by Oxford Health NHS FT. Decisions expected in December 2019

Research Themes are more broadly defined than in the CLAHRC and implementation is a key feature:

* Disease Prevention through Health Behaviour Change led by Professors Susan Jebb and Paul Aveyard
* Patient Self-Management led by Professor Richard McManus
* Mental Health across the Lifecourse led by Professors Cathy Creswell (Reading) and Andrea Cipriani
* Community Health and Social Care led by Professors Ray Fitzpatrick and Sarah Lamb
* Applied Digital Health led by Professor John Powell

Cross cutting theme:

* Novel methods to aid and evaluate implementation led by Professor Rafael Perera-Salazar

Implementation Lead will be Professor Gary Ford, AHSN

## NIHR MedTech and In Vitro Diagnostic Co-operatives (MIC)

The NIHR Community Healthcare MedTech and IVD Co-operative has had 11 formal company interactions/consultations in the last six months, covering sepsis, haematology, detection of bladder cancer, liver health, remote monitoring of patients, and multi-function diagnostic platforms. Consultations are one channel through which the MIC delivers support to the diagnostics and medtech industries.

The MIC team has had the following key industry-relevant paper accepted for publication, which will provide additional evidence to support prioritization of diagnostic tests on multiplex systems for use in the community: Fanshawe TR, Ordóñez-Mena JM, Turner PJ, Shine B, Hayward GN. Frequencies and patterns of laboratory test requests from general practice: a service evaluation to inform point of care testing. Journal of Clinical Pathology (accepted)

Professor Dan Lasserson (MIC theme lead – Acute Adult Ambulatory Care) has written an analysis for a NICE Medtech Innovation Briefing (MIB), which is due to be published in full later this year.

Innovate UK Small Business Research Initiative Phase II project: The MIC is continuing to support Mologic Ltd in their development of a point-of-care diagnostic test to stratify patients to the most appropriate treatment during acute exacerbations of their condition.

NIHR i4i funded collaborative projects: The MIC has begun work on a project together with the Bristol Urological Institute, University of the West of England and the NIHR Devices for Dignity MIC. This Product Development Award (PDA) project concerns the development and evaluation of a novel diagnostic for urinary tract infection, with the MIC providing health economic and clinical input. Work on a second PDA project is about to begin with Cambridge Respiratory Innovations Ltd and the University of Portsmouth to evaluate the performance of the CRiL N-Tidal platform in asthmatics.

The NIHR HTA funded METRIC (MEasuring TempeRature In Children) study, which is a methods comparison study of different thermometry devices completed recruitment in August, with the project now in the analysis phase.

The MIC Diagnostic Evidence Workshops will take place between the 26th and 28th September at Worcester College Oxford. These workshops will build on the success of the DEC Diagnostic Evidence Workshop, with an introductory day complemented by two additional days which will cover more advanced health economics and statistics for diagnostic medicine. All three workshops are now fully booked, with high representation from the diagnostics industry.

The first MIC clinical theme workshop will take place in Birmingham in November. Led by Professor Dan Lasserson, this workshop ‘Ultrasound – delivering the diagnostics strategy of the future’ will focus on the point-of-care use of ultrasound technology in acute settings by non-specialist clinicians (i.e. non-radiologists/sonographers). The workshop will be attended by clinicians, academics and developers of point-of-care ultrasound systems.

The MIC Acute Paediatric Ambulatory Care theme will shortly start a service evaluation in paediatric ED at the John Radcliffe to examine the impact of two point-of-care tests on the pathway for children presenting with suspected appendicitis. The foci of this evaluation will be length of stay and time to clinical decision.

## NIHR Oxford cognitive health Clinical Research Facility (CRF)

The CRF is a single managed entity hosted by OUH in partnership with OHFT. The CRF provides a flexible and integrated neuroscience resource that facilitates the efficient and timely conduct of experimental neuroscience including high intensity early phase experimental medicine research and early phase clinical trials. The CRF’s aim is to be fully aligned with the strategies of both the NIHR BRCs based in Oxford to enable, encourage and facilitate high intensity research in neuroscience and to work with principal investigators and commercial partners both established and new to achieve this aim.

The main research areas include; Adult Mental Health Disorders, Dementia and Neurological Conditions.

### Outputs

Data submitted for the annual return on activity between 1st April 2017 and 31st March 2018 shows that 43 studies were undertaken and 64 peer-reviewed articles were published where either CRF staff were contributing authors or the research was carried out on the CRF.

The CRF provides specialist clinical research study and trial support for a range of studies, including commercial and non-commercial sponsors’ studies, with a focus on experimental medicine.

Key examples of studies currently active:

* The Oxford calcium channel antagonist study: exploration of the role L-type calcium channels in cognition and sleep (OxCaMS) compares effects of a calcium channel blocker, nicardipine, versus placebo; results may help decide whether calcium channel blockers benefit individuals with mood instability and bipolar disorder and may facilitate the search for medicines that are more effective, safer and easier to tolerate. OxCAMS opened in late 2017; we have recruited 9 participants.
* PREVENT’s (Alzheimer’s Society) aim is to describe the interaction of AD risk (based on genetics and family history) and biological markers of AD in middle age. PREVENT will establish a trial-ready cohort to test the benefit of an intervention program based on multiple risk factors. The study may result in the identification of intermediary biomarkers of AD risk in middle age and will enable further targeted research. The study has recruited to target (n=68). Participant assessments and lumbar punctures are undertaken on the CRF.
* EPAD investigates new treatments that aim to prevent or delay the onset of clinical symptoms of AD. It involves >36 organizations across Europe, including universities, pharmaceutical companies and patient organizations, and is supported by the European Innovative Medicines Initiative. It works closely with other, similar initiatives worldwide, including the US-based Global Alzheimer’s Platform. EPAD opened to recruitment in 2018 and has recruited 22 participants to date.
* SINAPPS2 is an MRC funded, randomised, phase II, double-blinded, placebo-controlled trial aiming to test the efficacy and safety of intravenous immunoglobulin (IVIG) and rituximab versus placebo treatment for antibody-associated psychosis in addition to the current psychiatric standard of care. Patients with antibody positive psychosis will receive either IVIG and rituximab, or placebo infusions. The primary outcome is time to remission sustained for six months. The main SINAPPS2 site is OUHFT; however, IVIG/placebo infusions are delivered at the CRF. All registered nurses and medics are trained to deliver IV medications.
* The MRC funded RESTAND (Research on Emotional effects of SeroTonin Agonism in Non-medicated Depression) and RESTART (Research on Emotional effects of SeroTonin Agonism in ResistanT depression - medicated) studies investigate the early effects of activating serotonin-4 (5HT4) receptors on emotion processing in depressed patients, to further understanding of the mechanisms underlying antidepressant treatment. RESTAND/RESTART uses a randomised experimental medicine design, with some participants allocated to receive a drug which activates 5HT4 receptors. Restand opened on the CRF in July 2018 and 7 participants have been screened.

### Studies in set up and due to open within the next 6 months include:

* New Therapeutics in Alzheimer’s disease (NTAD) This is a highly-focused biomarker study combining both established and novel markers to identify a marker set for measuring outcomes in prodromal disease proof of concept trials and in addition, to establish a sample bank for further exploratory studies.
* Deep and Frequent Phenotyping (MRC). DFP will track and predict change over time in preclinical AD and healthy controls by measuring pathology using a number of different methods (brain imaging, CSF collection, cognition change). We predict the study data will be the largest, openly available dataset on preclinical AD, thereby providing a rich data source for research into understanding AD better and informing treatment trials for new drug development.

### Occupancy

The FY18 occupancy of 62% reflects the average resource utilisation across three sites, the Oxford cognitive health CRF (OHCRF), FMRIB Centre Functional magnetic resonance imaging and the Acute Vascular Imaging Centre (AVIC). 90% of the occupancy took place at the OHCRF with the balance occurring equally across the other two sites. The OHCRF occupancy increased during the year from 64% in Q1 to 71% in the final quarter underpinned by a full staffing complement for the first time in the year and a high level of set-up activity in relation to new studies. The average for the year was 64% compared to 59% in FY17.

Occupancy at the OHCRF is reviewed and planned each month to ensure best use of available resources.

### Renewal of CRF funding

The NIHR Oxford cognitive health CRF was awarded renewal of NIHR funding (3.7M over 5 yrs) commencing April 2017, hosted by OUH. The CRF renewal included resource to expand the facilities at the JRH. The CRF team has been working with AVIC, Nuffield Dept of Neurosciences, and the OUH Executive Team and R&D Department to determine the best way to achieve this aim. However, an appropriate location for the CRF expansion at the John Radcliff Hospital has not yet been identified; we will continue to work with colleagues at OUH to seek clarification on this.

### Strategy and Research Objectives

Primary objective: to deliver new therapies tailored to individual patient needs by breaking down disciplinary boundaries, capitalizing on scientific, technical and infrastructural capabilities that cut across disorders.

Short-term objectives: To build further our capability in translational neuroscience, to facilitate the objectives of OH-BRC, to expand facilities at the JRH.

Medium-term objectives: To realise plans for purpose built integrated and coordinated neuroscience research and clinical facilities across Oxford. Work has been initiated for a joint University-NHS Masterplan to develop the Warneford as a Brain Health Centre for translational neuroscience. The Masterplan is driving the joint development, the first stage of which is the £4.5 million upgrade of the Oxford Centre for Human Brain Activity, now part of the newly opened Wellcome Centre for Integrative Neuroimaging.

Long-term objective: To deliver an efficient translational pipeline fueled by Oxford’s unrivalled scientific infrastructure and expertise and deploying the very best science to deliver new therapies for patients’ mental, cognitive and neurological disorders.

## NIHR Biomedical Research Centre (BRC)

The successful Oxford Health BRC, a partnership between OHFT and University of Oxford has commenced with funding started in April 2017, £12.8 million over 5 years

The hub of the new center is at OHFT Warneford Hospital site. The site also houses the University of Oxford’s Department of Psychiatry and its associated research centers and facilities.

The strategy is to bring the best science to the complex problems facing research into mental disorders and dementia with the aim to use digital and other new technologies to produce scalable solutions with global application and transform our discovery science into new treatments and diagnostic tools, delivering precision care that is strongly informed by patient involvement, ethical and economic consideration

### Overview of Activity

We have:

* created formal governance and reporting structure to embrace the new BRC for mental health in partnership between Oxford Health NHS FT and the University of Oxford
* created the **BRC steering committee** to oversee the strategic direction of the BRC.
* continued with the *BRC theme leaders* meeting, established during the BRC application process and established theme and cross cutting theme operational groups to increase collaboration and synergies across themes, which facilitates staff to be funded and managed across themes.
* developed processes to enable appropriate adoption of research studies to benefit from BRC infrastructure and enable the leverage of additional research funding.
* supported 83 studies during this first year, 15 are currently in set up, with 23 closed and 45 open
* supported the submission of 36 approved grants with a further 9 applications pending.
* leveraged and received £16,371,358 in-year project funding as a result of the infrastructure and vision provided by the BRC
* undertaken considerable work developing the Patient and Public Involvement and Engagement (PPIE) strategy, which has been co-produced with involvement from the Patients And Research (PAR) group, Oxford Health BRC and Oxford cognitive health CRF.
* published in the public domain the PPIE strategy following favourable review by the NIHR <https://oxfordhealthbrc.nihr.ac.uk/patient-and-public-involvement/ppi-strategy/>.
* commenced the operationalisation of the PPIE Strategy
* supported the infrastructure within the NIHR Oxford cognitive health CRF (CRF), including the development of Treatment Resistant Depression (TDR) clinics to increase opportunities for patients to become involved in translational research
* enabled increased sample collection with the CRF and increased lithium monitoring of participants
* been working with BRCs nationally (Maudsley, Cambridge, Bristol, and Nottingham) and NOCRI to establish a NOCRI Mental Health Translational Research Collaborative (TRC) to drive the exceptional work in the mental health arena across the country through the BRC network.
* Worked in partnership with NIHR Maudsley BRC and the European College of Neuropsychopharmacology Networks for Bipolar Disorder and Experimental Medicine, by holding an event - Experimental medicine in mood disorders - innovation in methods and targets; and development of standards to drive global collaboration in drug development in mental health. This will lead to two strategic vision papers, in collaboration with Lancet Psychiatry

Top Three Achievements

* Prof Andrea Cipriani's Network Meta-Analysis comparing the efficacy and tolerability of 21 antidepressants versus placebo (Lancet, 2018) provided the most thorough assessment yet of the relative efficacy and acceptability of currently available antidepressants, in comparison with both placebo and between drugs. This large scale research synthesis clarifies much of what is currently known about these drugs and will help guide clinical practice and target future research. By working closely with communications and media colleagues, the publication of the article has already had a constructive impact in what is often a controversial field and should help remove the stigma and misinformation surrounding the appropriate use of antidepressants. The work has been welcomed both nationally and internationally.
* Professor Daniel Freeman, an Oxford Health clinical psychologist, and collaborators won the first NIHR i4i Challenge Award in Mental Health to support a £4 million project to make virtual reality treatments for mental health problems available to NHS patients. NIHR MindTech Healthcare Technology Co-operative is a key collaborator. This technology will increase dramatically the number of people who can access the most effective psychological therapies through the delivery of automated treatments and inexpensive VR kit, enabling widespread use in the NHS. The application was strongly supported by the Oxford Health BRC and CRF, and is working in collaboration with the Precision Psychological Treatments Theme, led by Prof Anke Ehlers.
* Our collaboration with Johnson and Johnson (Dopamine and choice in depression) at the time of the BRC award has been consolidated and strengthened. As a direct result of BRC funding we were able to complete a study validating a cognitive biomarker for anhedonia in depression and with antidepressant drug treatment. This work has been published and incorporated in subsequent Phase 1 clinical trials. Additional areas of work are being established including digital health technologies. An oversight group, chaired Prof Ilina Singh is being established to consider this developing partnership with Johnson and Johnson, including ethics and PPI.

### BRC Themes

#### Adult Mental Health: Innovation in Diagnosis and Treatment (Theme Lead: Professor Paul Harrison)

We have started implementing standardised assessments, although this is still in its early stages we have adapted procedures in the research mood disorder clinic, for example adding standardised recording of physical health parameters and use of questionnaires; standardised specific cognitive tests and imaging sequences between studies to reduce unnecessary heterogeneity

We have expanded the use of biosensor data, with collection of several data streams originating from smartwatches, Fitbits, ECG patches, and smartphones, being central to three of the publications arising from this theme

We have continued to work with the informatics theme and others to maintain and grow the biosensor data capabilities in our research. We are also working with our PPIE cross-cutting theme to ensure we address the many ethical and acceptability issues which these approaches raiseWe completed OxLith, an intensive and multimodal double-blind RCT of the acute responses to lithium therapy in bipolar disorder. Remarkably little is still known about how this ‘old’ drug works, and what the initial markers of response or harm might be. OxLith included clinical and cognitive ratings, collected via apps and iPads, biosensors, biochemical data, and MRI and MEG scans to assess brain structure, connectivity and activity. Initial analyses show that lithium has very early effects on mood stability, and on brain activity, and more analyses are underway. OxLith also showed unexpected tolerability and acceptability of lithium and we also plan to undertake qualitative analyses of the user experience.

The ‘AMOSS’ study addressed the relationship between bipolar disorder and borderline personality disorder and is now complete. Using innovative devices and designs, AMOSS showed striking differences in the pattern and correlates of unstable mood between the two conditions. It showed that adding biosensor data (e.g. circadian variation in heart rate; GPS data) enabled the two conditions to be distinguished much better than could have been anticipated. The lessons learned from AMOSS are already feeding into new studies within this theme.

#### Older adults and dementia (Theme Lead: Professor Clare Mackay)

A key aim of the Older Adults and Dementia theme is the establishment of a Brain Health Centre (BHC), which has progressed substantially in recent months. Members of the BHC working group have held a number of meetings with key stakeholders, including BRC-CRF director, BRC steering committee, CRF manager, University Department Governance Officer, OHFT Governance Lead, OUH Neuroradiology, Health economists, OH Chief Operations Officer, OH Caldicott Guardian, as well as others with experience of setting up integrated clinical-research programmes (e.g. OCMR – Oxford Centre for Clinical Magnetic Resonance Research, AVIC – Acute Vascular Imaging Centre). Application of ethical approval to create a BHC research database is underway, and meetings to establish the necessary University and Trust contracts to provide a clinical service in the BHC are being arranged. A PPI (participant and patient involvement) working group representative will be appointed in the next few weeks, and a PPI panel will also be established to provide input to the set up of the BHC.

A key new appointment has been Project Manager Gary Gibbs, who is supporting the development of the Brain Health Centre. Other recent appointments include Delia Gheorghe, EPAD (European Prevention of Alzheimer’s Disease) National Coordinator, and Shona Forster, EPAD National Communications Officer, both of whom are based in the Department of Psychiatry.

Of the ongoing studies include the PREVENT study has recently completed recruitment for baseline assessments, whilst the DPUK (Dementias Platform UK) Clinical Studies Register (CSR) has recently been granted ethical approval to provide a register of highly characterised individuals for recruitment to clinical trials. The Deep and Frequent Phenotyping (DFP) study is still yet to commence, having been delayed due to challenges in establishing the governance arrangements for use of existing cohort members. The Friends of OxDARE (Oxford Ageing and Dementia Research) registry is currently looking to appoint several Friends of OxDARE ambassadors to help promote OxDARE and attend OxDARE meetings to provide a PPI perspective. The Friends of OxDARE registry has been promoted to relatives of attendees of Oxford Health memory clinics, and a number of public engagement events are also planned to increase sign-ups to the registry.

#### Precision Psychological Treatments (Theme Lead: Professor Anke Ehlers)

The PIs are working on several studies of internet-delivered psychological treatments. Two of the programmes (for social anxiety disorder and PTSD) are being evaluated in collaboration with Oxford Health IAPT Services in Oxfordshire and Buckinghamshire in two research studies. The cognitive therapy for social anxiety disorder programme (iCT-SAD) will be delivered by nominated IAPT therapists, with training and supervision from therapists at the Oxford Centre for Anxiety Disorders and Trauma (OxCADAT), and an audit of treatment results is being conducted. The cognitive therapy for PTSD programme (iCT-PTSD) is currently being evaluated in a randomized controlled trial, and the IAPT services refer patients with PTSD to the trial. After completion of the trial, IAPT therapists will be trained in iCT-PTSD for the next study. Several other internet-delivered treatment programmes are in development. There are initial conversations about the possibility of a spinout company to ensure the maintenance and further development of the programmes as it has not been possible to recruit suitable Web developers for the advertised posts. Currently, the programmes are being maintained by two collaborating IT companies who developed the websites for the therapy programmes, FRY-IT and Whiskered Wizard.

A post for a virtual reality (VR) developer (Aitor Rovira) was created within the Trust, and a VR laboratory has been established at the Warneford site. This is being used by several PIs in research projects on a range of disorders (eating disorders, anxiety disorders, response to bullying, paranoia). There is an established link with the spin out company Oxford VR.

* + 1. **BRC Cross Cutting Themes**

#### Informatics/digital health (Theme Lead: Professor Simon Lovestone)

We have received additional funding for UK-CRIS this financial year and are establishing an expert advisory group to oversee the national UK-CRIS platform and provide national leadership in information governance for real world clinical data.

We have established a core group of informaticians at Oxford which is becoming fully trained in the analysis of complex multi-modal biomolecular data for biomarker studies. This group is working with others on a test data set (AddNeuroMed) and has successfully established pipelines for metabolomics QTL analysis to nominate target biomarkers. A paper is in generation. We are now assembling a wider collaborative group for replication and extension studies across other datasources

We have made progress in establishing, testing and refining a suite of apps for use on smartphones for assessment of cognition in preclinical Alzheimer’s. These will be implemented in clinical studies in 2018/19

We are working with Johnson and Johnson and have completed an agreement to work together to establish a centre for mental health and dementia to encompass the BRC Digital theme and other initiatives. As part of this agreement we have received funding for three programmes of work from Johnson and Johnson, one on drug development for Alzheimer’s disease, one on experimental medicine for treatment resistant depression and one on informatics for dementia risk and mechanism.

The BRC has provided a platform for the successful Pathfinder grant (£1 million starting in April 2018) in the Mental Health Data Platform programme. This will enable us to establish a very exciting programme of infrastructure development and projects using both clinical and molecular data in studies that will help us to understand, find biomarkers for, nominate targets for therapeutics and establish platforms for clinical trials. We will have a strong focus on mood disorders

UK-CRIS has been used as an example of real world observational data, to understand the relationship between cardiovascular, metabolic disease and Alzheimer’s Disease onset and progression with a view to nominating targets for development.

#### Neuroimaging and Cognitive Neuroscience (Theme Lead: Professor Kia Nobre)

A key infrastructural development for the Neuroimaging and Cognitive Neuroscience theme is the installation of a new MEG (magnetoencephalography) scanner at OHBA, which is due to be completed in 2019. This new scanner will include a helium-recapture function that will remove the need for weekly helium fills.  Recently, equipment has been installed in the OHBA MRI scanner to allow for hypercapnic MRI, which involves breathing gas with slightly lower than normal levels of oxygen in the MRI scanner. This new equipment is currently being used in a pilot study to assess the association of cerebrovascular health and risk of Alzheimer’s disease. The NTAD (New Therapeutics in Alzheimer’s disease) study is aiming to start recruitment in October, contingent on ethical approval being finalised. Progress has also been made in establishing standardised MRI protocols that will be used nationally in the DFP (Deep and Frequent Phenotyping) study. In relation to the Brain Health Centre (BHC), connections have been established with OUH consultant neuroradiologists, who will report on clinical MRI scans conducted in the BHC, and the clinical and research MRI protocols have been established. Piloting of sensitive cognitive tests that will be adapted into web-based tests for ‘waiting-list’ assessment and remote longitudinal follow-up of BHC patients is about to start.  Additionally, plans are in progress for a national meeting of clinicians to establish the optimal set of memory clinic cognitive assessments. A meeting with members of the NIHR MedTech and In Vitro Diagnostics Co-operative (MIC) is also being arranged to discuss potential evaluations of patient benefits of novel app-based cognitive assessments.

#### Clinical research infrastructure and experimental medicine (Theme Lead: Professor Catherine Harmer)

With continued expansion of the theme’s infra-structure support, we have adopted 39 studies in total jointly with the Adult Mental Health theme. These studies have received support in various forms, including pharmacy assistance, statistical and ethics advice, help with experimental design and analysis, access to Standard Operating Procedures (SOPs) and to the Clinical Research Facility (CRF). We have also jointly funded 5 pilot studies on the pathway to fellowship or larger scale funding applications.

Closely working with the Quality Assurance Manager - Joy Wiles, hired from our budget on a part-time basis -, we have expanded our library of SOPs (13 currently in place).

We have close connections with the PPI theme. One of our members (Dr. Liliana Capitao) is the staff co-chair of the Patient and Research (PAR) group and PPI liaison for our theme, as part of our ongoing commitment to the development and delivery of the PPI Strategy for the OH BRC. We have also successfully incorporated PPI into some of our BRC-adopted studies and we plan to expand on this work.

We co-organised the BRC/CRF open day with other themes. This event took place in May 2018 and it was very well attended. There was a widespread interest from both the scientific community and the wider public.

We recruited an additional staff member in April 2018 - Dr. Cassandra Gould van Praag -, who provides neuroimaging analysis support for experimental medicine studies particularly. We are continuing to engage with industry to facilitate experimental medicine studies. Our research programme funded from UCB Pharma focused on the use of implicit cognitive biomarkers has started; our experimental medicine probe of stress has been incorporated into J&J novel therapeutics pathway and we are in the planning stages of an Oxford based research programme on glutamatergic novel compounds with J&J.

#### Patient and Public Involvement and Ethics (Lead: Professor Ilina Singh)

The BRC Patient and Research Group (PAR) are developing a set of shared value statements that inform how Patient and Public Involvement is approached at the BRC. The objective is to improve the impact of PPI and the experience of both public contributors and researchers. These will be informed by the experience of public contributors and researchers, and the NIHR National Standards for Public Involvement.

We are developing a network of patients, carers and public members interested in PPI in mental health and dementia, and the BRC PPI theme has been represented at the Cowley Road Carnival and Healthfest.

We are working with the Oxford BRC and CLAHRC to deliver a series of 8 seminars for PPI contributors, on the research cycle, with the aim of improving the confidence of patients, carers and public members to get involved in research. These will take place over the autumn and winter.

Working with PPI colleagues at Maudsley Biomedical Research Centre and University College London Hospitals Biomedical Research Centre, the Oxford Health BRC (led by Rupert McShane) delivered a patient and public consultation day on the prescribing and monitoring of ketamine as a treatment for depression (22 August 2018). A report from the event will be published in the autumn.

#### Education and Training (Lead: Professor Elizabeth Tunbridge)

We have focussed primarily on developing the bespoke training courses that form the core of the capacity development plans outlined in our application, and which were highly commended by the panel. These are the Oxford Certificate in Experimental Medicine for Mental Health (OxCEMM) and the MSc in Translational Neuroscience. ,. OxCEMM is a short course designed to provide trainees with the practical information they need to design, conduct and analyse experimental medicine studies. The application process is currently open with the first course being run in early 2019 and the MSC cou

The other central component of our capacity development plan is the development of the Experimental Medicine Network (EMN). The EMN will provide all relevant local staff and trainees with access to continued training, and a forum to share experiences and ideas. Progress in this area has focused on beginning a scoping exercise in consultation with our local partners (including the newly-established Education Research Collaboration, described further below, and, in particular, with Oxford BRC, and other local stakeholders [e.g. the Oxford Institute for Nursing, Midwifery and Allied Health Research]) to identify currently-available training, and gaps in this provision.

## NIHR Clinical Research Network (CRN)

Building on the success seen since FY 2015/16, in FY 2017/18 Oxford Health NHS Foundation Trust was the 5th highest recruiting mental health trust across all specialties, with 2349 participants recruited to a total of 62 portfolio studies. In FY 2017/18 OHFT was the 2nd highest recruiting trust to studies on the Mental Health portfolio with 2093 participants recruited to 42 studies. In FY 2017/18, OHFT was ranked 31st out of all NHS trusts reporting recruitment to the Dementia and Neurodegenerative diseases portfolios with 206 participants recruited to 13 studies. There is a small Primary Care portfolio.

In FY 2017/18 Thames Valley and South Midlands CRN was ranked 8th out of 15 CRNs in terms of participant recruitment to the Mental Health and Dementia and Neurodegeneration portfolios. This includes activity across all trusts in the region.

This trend continues in FY 2018/19 to date with Oxford Health currently being the 5th highest recruiting trust to the Mental Health portfolio. This year OHFT is ranked 19th out of all NHS trusts reporting recruitment to the Dementia and Neurodegenerative diseases portfolio with 101 participants recruited to 7 studies. There is a small Primary Care portfolio.

The CRN are proud of their achievement in meeting participant recruitment targets. There are a range of studies, commercial drug trials, non-commercial trials including repurposed medications, tele-care, patient and carer surveys and genetic studies.

Drs Andrew Molodynski and Rohan Vanderputt continue in their respective roles as CRN Mental Health lead and CRN Dementia lead across the Thames Valley region. Helen Collins, CRN Research Delivery Manager continues to work with the Prof Andrea Cipriani as Associate Director of R&D support NIHR portfolio studies.

A number of new PIs are supporting the portfolio: three Old Age Psychiatrists have recently become actively involved as PIs or Sub-investigators.

# Research Set Up, Management and Governance

## Pipeline Group Meetings

The Pipeline Group, chaired by Prof Andrea Cipriani, Associate Director of R&D, meets regularly to determine whether studies are of scientific, strategic, patient value and whether there is capacity to undertake the study in the Trust and where the study could take place. It is key that a Principal Investigator (PI) is identified early in the process that can lead the study set up and delivery. The Pipeline Group aims to establish whether the study is appropriate to be developed in terms of undertaking costings, contract negotiations, capacity and capability (completion of HRA Statement of Activities) as part of the set up process thus enabling a more transparent and collective approach to research to ensure study targets can be met and that there is no overburdening of certain patient populations. The Research Support Team have adapted their process to ensure that the Pipeline meetings can be as effective as possible.

A Mini Pipeline Group has been established to meet bi-monthly to discuss expressions of interest coming in to the Trust and potential Oxford Health NHS Foundation Trust sponsored studies.

## Health Research Authority

Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments’ Research Ethics Service. Since its introduction in April 2016 the changes have been embedded within the Research Support Office HRA Approvals

## Capacity and Capability

One aspect of HRA Approval is ensuring that there is clarity on the resource implications for participating NHS organisations and others delivering research within an NHS care setting.

For non-commercially sponsored studies a Schedule of Events and Statement of Activities forms are used to capture all information around study activities being undertaken at a local level as part of the approvals process.

For commercially sponsored studies a completed NIHR Industry Costing Template and template agreement are used prior to local NHS approvals to confirm that the sponsor intends to use with host organisations.

The Research Support Team work with researchers and sponsors to ensure a swift process of confirming the Trust’s capacity and capability to deliver the study to time and target. The team require that authorisation has been obtained from the appropriate Service Director, responsible for the Directorate where the research activity will take place before Trust Management Approval is provided to the research team. Directorate contact is now required before the study is presented to the Pipeline Group.

## Contracts and Confidentially Disclosure Agreements

An agreement between OHFT and OUH to undertake the review of research contracts and contracts Confidentially Disclosure Agreements (CDA) from a legal perspective to ensure the Trust obligations are appropriate is ongoing and working effectively.

Recently concerns were raised regarding the terminology within legal agreements over the liability. The Trust has agreed a preferred approach that no contract or CDA should have unlimited liability without a complete risk assessment. Internal processes, aligned with OUH are ongoing to assess and monitor risk, with agreed internal processes for sign off. A standard operating procedure is being drafted by OUH and once approved will be adopted in OHFT with an appendix detailing local Trust requirements

A Framework Intellectual Property Agreement (FIPA) has been agreed and signed between Oxford Health NHS FT, University of Oxford and Oxford University Innovations. The Trust and the University have for many years collaborated in research projects and other activities under individual projects and the FIPA provides a platform which will govern the management and exploitation of intellectual property and materials arising from such activities. The FIPA will be used to support the ventures such as spin out companies using therapies and technologies developed between the partner organisations.

## Costings

The Head of R&D Finance leads the costings process and works closely with research and clinical teams to provide accurate information on the timing and cost of undertaking specific protocol driven activity, including the set up and management of studies to ensure that the studies are run in a cost neutral manner within the NHS.

## Study Data Capture

The Research Support Office received a database system called Studyline in May 2017. Studyline runs on the OXNET server, a secure NHS server system. The updated database has some new and enhanced functions and will be used to its full potential to provide reports and data on research activity, including recruitment, to ensure a more robust and accurate understanding of research activity taking place within the Trust and surrounding Trusts Studyline has recently been linked with the NIHRs Central Portfolio Management System (CPMS) where data is uploaded overnight. The Research Support Team have begun work with the Data Manager to streamline the recruitment reporting process.

## Monitoring and Auditing of Research Projects

The R&D Support Team audited four hosted studies in 2017/18 and one study has been audited so far in 2018/19. The study was selected due to a complaint from a study participant. No serious breaches were found during the audit but some actions were requested.

The Research Support Team will continue to react to any issues that arise and will implement routine monitoring and auditing as soon as staffing is back to full capacity later in 2018.

## Studies and Participant Recruitment

The NIHR publishes league tables on an annual basis for NIHR portfolio adopted studies. There may be slight discrepancies in the data when comparing to internally data capture due to reporting differences and potential lag time.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2014/2015** | **2015/2016** | **2016/2017** | **2017/2018** |
| Number of Open Studies | 40 | 48 | 77 | 74 |
| Number of Participants | 2012 | 2576 | 1994 | 2456 |

### NIHR Metrics and Targets

As of Quarter 1 2018-19 the Health Research Authority have stated that improvement in clinical trial performance and reducing site set up and participant recruitment time will no longer be assessed with a 70 day benchmark. A renewed focus will be placed on transparency, accuracy, and meeting sponsor expectations. The Research and Development Department are still working to ensure that delays getting patients in to studies are minimised.

# Research Support

## Pharmacy

The clinical trials pharmacy team has implemented a new system for identifying errors made during the dispensing of clinical trials. The error rate and content are now reviewed regularly at team meetings.

Berkshire Mental Health trust has approached our pharmacy team to ask for support in developing their clinical trials pharmacy service, following the resignation of their research pharmacist, discussions are ongoing regarding this collaboration.

The air conditioning facility at CPSU failed during the heat wave and IMP products were at risk of a temperature deviation. We made the decision to move all stock to Oxford Pharmacy Stores (a wholesaling company next door) temporarily to protect it whilst awaiting engineering works on the system. The stock was returned within 24 hours and the system has been working effectively since. All sponsors were informed. No temp deviations occurred during the process.

The clinical trials pharmacist (CRF) has resigned and the job share post will be advertised and recruited to, this will reduce flexibility in the team in the short term

## Case Records Interactive Search (CRIS)

The Oxford CRIS Oversight Group meetings are held bi-monthly to discuss submitted applications and monitor the audit of CRIS searches. The group is chaired by the Medical Director and Caldicott Guardian and is attended by the CRIS Coordinator, Director of IT, Head of Information Governance, Head of R&D, a carer/patient representative, representatives from the trust Clinical Directorates, Trust Audit Team, Trust Pharmacy team and academic leads from the University.

To date the CRIS Oversight have approved 31 UK CRIS applications, 14 of which were research questions, 6 service evaluation, 11 clinical audit questions. We currently have 20 active CRIS searches and 29 active CRIS users.

We are progressing well will with our natural language processing (NLP) capabilities and further collaborations are also in progress. These will provide the CRIS users with an automatic text reading facility for extracting and bringing into context relevant data from free text fields within CRIS.

All authorised non Trust staff researchers are provided with a virtual desktop environment, created by the Trust IT department, which restricts both access to the data and prevents the data from being removed from the Trust firewalls. This will soon move to a facility at Swansea University - UK Secure Research Platform - UK SeRP which will provide additional analysis and NLP tool facilities.

The CRIS Manager and Digital Theme Leader of Ox-CRIS for NIHR Oxford Health BRC – Tanya Smith will be undertaking a 6-month secondment with the UK CRIS team to lead on and nationally promote the effective use of CRIS within other NHS organisations. This has included the recent training day held at the Said Business School, where representatives from 9 other NHS Trusts attended.

## Consent for re-contact

The Trust is initiating a Consent for Recontact Process within the organisations, whereby clinicians will discuss with patients whether they are interested in being contacted about research. This will be documented in CareNotes with a specific form. This will then link to CRIS to establish who meets a research studies criteria and has also indicated they are happy to be contacted. This is currently being piloted within three clinical teams, but is not exclusive and others are being encouraged to get involved.

A new register for non-patient citizens will be created (Oxford Mental Health Register (OxMenHD) and will link with an existing register for non-patient citizens interested in dementia research – Oxford Dementia and Aging Research (OxDare). The register can then be used by the researchers who require health volunteers for a study.

# Trust Governance and Reporting Mechanisms

## Reporting and Governance

The Research Management Group (RMG) is a high level committee established to drive the collaborative research strategy across the Trust. It is responsible for the strategic and scientific direction of the research undertaken with or in partnership with OHFT.

The RMG oversees and monitors the financial position of research where there is involvement of the Trust and receive reports from the Head of R&D Finance which will highlight major areas of expenditure, anticipated changes or impacts on budgets and related funding. In addition it is accountable for the assurances made to the Trust to ensure fulfilment of its responsibilities as a host organization.

The meetings have been recently restructured to bring bring together academics and clinical services with mutual interest in particular projects or work streams to increase engagement between clinical services and research for open discussion about the synergistic and collaborative working to deliver patient benefit through research endeavors. One example presented was the development of the Brain Health Centre. A working group has been established with academic and clinical representatives from psychiatry, neuroscience and radiography, who are exploring how a Brain Health Assessment could best integrate research to benefit the memory clinic service, and identify which memory clinic patients would be best served. It is hoped that key outcomes are to reduce time pressures on doctors in clinic, and facilitate access to quality standardized longitudinal assessments, as well as provision of clinician training and opportunities for joint clinical-research roles

The RMG receives information and assurances from the various research activities undertaken in conjunction with OHFT, including dashboard reports on the OHFT BRC, CRF, CLAHRC, DEC, TV&SM CRN, Case Records Interactive Search (CRIS), Research Feasibility, Set-Up, Delivery and Management (including quality assurance), Pharmacy and Research Finance.

A summary of these reports is submitted to the Quality Sub Committee: Effectiveness on a quarterly basis.

## Information Governance related to Research

With the implementation of the EU General Data Protection Regulation in May this year R&D have worked hard to understand the implications and requirements related to research. This is being lead by Helen Jones (Research Delivery Manager) and Tanya Smith (CRIS Manager), who are drafting a guideline for research staff on the implications of GDPR in relation to the set up, delivery and maintenance of research studies hosted by Oxford Health NHS FT. This document will apply to anyone working in the research arena in addition to clinical staff and patients. The guideline will include details of the research IG Assets with their lawful basis for processing under the new GDPR, template documents, action plans and timelines which are currently being implemented across the research teams.

## Research on the Care Quality Commission Agenda

In January 2018 a partnership was formed between the National Institute of Health Research (NIHR), Health Research Authority (HRA), Medicines and Healthcare Products Regulatory Agency (MHRA) and Care Quality Commission (CQC) to develop new research indicators for use as part of the CQC’s monitoring and inspection programme. Members of the NHS R&D community also took part in the work to support the partnership in taking this forward. This was based on the increasing evidence that patients have better outcomes at research active hospitals, regardless of whether they took part in research studies. The new indicators aim to provide NHS organisations the opportunity to showcase research as part of their assessments by the CQC, thus demonstrating their commitment to high quality patient care. Initially NHS organization will be able to demonstrate their commitment to promoting research awareness within the organization, how research is facilitated and the equity of research undertaken.

# Staffing

Over the past six months changes have been made to the management structure of the three research delivery teams (CRF, Adults, Older Adults) within R&D. The Research Delivery Management Team (RDMT) is led by Andrea Cipriani (Associate Director of R&D) and Cathy Henshall (Nurse Lead for Research/CRF Manager), who are responsible for the strategic direction and oversight of the three teams and who work closely with the NIHR and CRN to ensure that their requirements are met. A new Research Delivery Manager (8a) role is being developed and Helen Jones is currently acting up into this post on an interim basis (managed by CH). A permanent appointment to this post is expected to be made later this year.

One of the primary aims of the RDMT is to more fully integrate and streamline the work of the three research delivery teams to ensure that activities, policies and processes are aligned, and to promote greater efficiency and effectiveness across the teams in terms of study set-up, recruitment and delivery. Work is being done to facilitate cross team working, knowledge sharing and consistent documentation across the teams. This requires a collaborative, joined-up approach, and is supported by Helen Jones with the provision of line management to the three Band 7 operational managers across the teams.

Cathy Henshall has joined Prof. John Geddes (R&D Director), Emma Stratful (Deputy Director of Research Strategy and Operations), Prof. Andrea Cipriani (Associate Director of R&D),and Bill Wells (Head of R&D Finance) as a new member of the Senior Management Team.

# Estates

Earlier in 2018 a business case was approved for work to be carried out to modify the ECT Suite at the Whiteleaf centre to support the undertaking of research studies, in particular late phase commercial studies. This will relieve the pressure on the CRF due to the increased number of BRC studies it is supporting in addition to providing increased opportunities to staff and patients in Buckinghamshire. Work is expected to be completed in September 2018 with a study expected to started shortly thereafter.

Work has been initiated between R&D, Estates and Clinical Services to look for additional opportunities across the geographical area of the Trust to be able to conduct research.

# Communications

The patient involvement and engagement section of the NIHR Oxford Health website has been significantly expanded, with more signposting for anyone wanting to get involved in research, and the release of a very well received short animation film summarising our patient and public involvement in research strategy (https://youtu.be/PCz7dtZ4YiU)

The Trust communication team supported the PPI team hosting a very successful stall at the Cowley Road Carnival, getting feedback on how best to communicate about research with the general public.

The communication team has extensively advertised the first Oxford Health BRC short course, on social media, to Oxford Health staff, to the Clinical Commissioning Group’s readers, and more widely within the Medical Sciences Division at the University of Oxford.

The research team, including the consent for recontact project, will also have a stand at the Oxford Health annual general meeting.

The toolkit section on the Oxford Health R&D website has been revised to make it easier for clinicians interested in research to find the right support.

The communications team supported media handling for a study by Daniel Freeman showing that automated virtual reality could successfully provide therapy to treat fear of heights: this again got extensive media coverage.

# Finance

## Research Income

During the last ten years, OHFT income generated from research activity has grown from just over £1m in FY09 to an FY19 budget of £12.1m.

Income over the period FY10 to FY14 was largely from a small number of grants but over the last five years these have been replaced by infrastructure awards providing the opportunity to support more research activity and generate leveraged income.

The FY19 income budget has benefitted from a non-recurrent £1m award for the development of UK CRIS as part of the BRC. FY20 will see the existing CLAHRC award come in an end in October resulting in a £1m reduction although it is hoped that the bulk of this will be mitigated by a successful ARC application.

## FY19 Income Budget

The FY19 Income budget of £12.1m is made-up and managed as follows:

|  |  |  |
| --- | --- | --- |
| **FY19 Income Budget**  | **Management of Funds** | **£k** |
| **Source**  | **R&D SMT *(note 1)*** | **Primary Care**  | **Other**  | **Total** |
| **National Institute for Health Research (NIHR)** |  |  |  |  |
| Biomedical Research Centre (BRC) | 3,846 |  |  | 3,846 |
| Collaboration in Leadership in Applied Health Research & Care (CLAHRC) |  | 2,000 |  | 2,000 |
| Research Capability Funding (RCF) | 672 | 534 |  | 1,206 |
| Study income | 111 | 967 |  | 1,078 |
| Clinical Research Facility (CRF) | 744 |  |  | 744 |
| I4I | 1,100 |  |  | 1,100 |
| MIC |  | 249 |  | 249 |
| **Total** | **6,473** | **3,750** | **-** | **10,223** |
| **Other Funding** |  |  |  |  |
| Clinical Research Network: Core Funding | 792 |  |  | 792 |
| Clinical Research Network: Hosting of Network staff |  |  | 314 | 314 |
| Study Delivery | 349 |  |  | 349 |
| Other Grants | 391 |  |  | 391 |
| **Total** | **8,005** | **3,750** | **314** | **12,069** |

Note 1: The R&D SMT is made up of Prof. John Geddes (R&D Director), Emma Stratful (Deputy Director of Research Strategy and Operations), Prof. Andrea Cipriani Associate Director of R&D), Dr Cathy Henshall (CRF Manager) and Bill Wells (Head of R&D Finance)

## Performance

R&D performance for FY18 resulted in a contribution to overheads of £63k compared to a budgeted cost of £3k generating a £66k favourable variance. This variance was due to greater then budgeted study income and vacancies and was after directly funding its finance support (£153k), CRF estates and facility costs (£45k), contract support (£20k) and work at the Whiteleaf Centre (£34k) to allow later phase research studies to take place in Buckinghamshire.

The FY19 YTD period 4 position was a £24k contribution to overheads compared to a £12k expenditure budget generating a £36k favourable variance. As with FY18 this is primarily due to greater than budgeted study income.

## Collaboration in Leadership in Applied Health Research & Care (CLAHRC)

The CLAHRC commenced in January 2014 and following a successful extension application it will now run until September 2019. It is led by Professor Richard Hobbs from the University of Oxford, Department of Primary Care. Following a mid-term review the themes are Service Redesign, Behavioral change (exercise & rehab), Patient Reported Outcome Measures (PROMS), Multi-morbidity, Patient self-management and Behavioral change (weight & obesity). FY19 Funding is £2m and FY20 reduces to £1m due to the award coming to an end in 2019. It is hoped that the CLAHRC will be replaced by the ARC where funding of £9m over five years would start in October 2019. The ARC application was recently submitted with interviews taking place in October 2018 and the Department of Health and Social Care confirming selected NIHR ARCs in December 2018.

## Medtech and In vitro diagnostic Co-operative (MIC)

The NIHR funded MIC started in January 2018 and is led by Gail Hayward from the Department of Primary Care (£1.2m, FY19 250k)

## Clinical Research Facility (CRF)

CRF funding commenced in April 2017 (£3.7m, FY19 £744k). This award is hosted by OUH but managed in its entirety by OHFT with the bulk of the funding being used to activity at the Warneford. Funding was planned to be used for development of CRF facilities at the OUH however due to problems in identifying suitable space funding was reallocated to other areas selected as part of a completion in FY18. A similar process took place recently with £27k awarded to NDCN to develop Oxford Health’s CRF capacity for nuclear imaging and £45k awarded to the Acute Vascular Imaging Centre at OUH to support innovative new areas of work requiring intensive nursing inputs.

## Biomedical Research Centre (BRC)

The BRC commenced in April 2017 and is led by Professor John Geddes from the University of Oxford, Department of Psychiatry. It contains three themes, Adult Mental Health, Older Adult Mental Health and Psychological Therapies and three cross-cutting theme Neuroimaging & Cognitive Neuroscience, Informatics & Digital and Infrastructure & Experimental Medicine which includes an element of the Clinical Research Facility. There are also PPI and Training elements. FY18 expenditure was in line with the £1.4m funding awarded. The original FY19 funding of £2.8m has been increased to £3.8m by the NIHR to support the development of UK CRIS as noted above.

## Clinical Research Network: Thames Valley and South Midlands (CRN)

The FY19 core CRN budget of £791k funds Service Support Activity (primarily patient recruitment). It is currently predicted that only £708k will be utilised by OHFT with the balance being returned to the CRN.

CRN Network staff such as the Thames Valley Primary Care Research Partnership are hosted by the Trust but not under the management of the R&D Senior Management Team. All costs are recovered on a direct costs basis from the CRN (FY19 budget £314k)

## Research Capability Funding (RCF)

Research active NHS organisations receive RCF to enable them to meet some, or all, of the research-related component of the salary of their researchers and research support staff. The annual RCF allocation combines a percentage of NIHR funding received in the previous calendar year with an allowance for each Senior Investigator associated with Trust.

The FY19 RCF allocation of £1,205m showed an increase of £168k on FY18 with an extra £88k driven by higher infrastructure awards and £80k driven by increased grant related income.

The FY19 allocation was split between the Trust & Department of Psychiatry (including CLAHRC) £672k and the Department of Primary Care £533k.

## Grant Income

The NIHR study income is received for three awards, these are:

* Professor Richard McManus (Department of Primary Care). “Optimising the monitoring and management of raised blood pressure during and after pregnancy” (£2.5m, FY19 £503k)
* Professor Andrew Farmer (Department of Primary Care). “Supporting people with type 2 diabetes in effective use of their medicine through a system comprising mobile health technology integrated with clinical care” (£2.5m, FY19 £463k)
* Dr. Valeria Frighi (Department of Psychiatry) “Fractures in people with intellectual disabilities” (£152k, FY19 £111)

In addition to several small sub-contracted applications four have been submitted with OHFT as lead, these are detailed in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigator | Organisation | Study Title | Funder | Funding |
| Paul Stallard | OHFT | A comparison of usual care versus usual care plus a smartphone self-harm prevention app (BlueIce) in young adolescents aged 12-17 who self-harm | NIHR | 269,001 |
| Claire Friedman Smith  | Dept. of Primary Care, University of Oxford  | Safety Netting in Primary Care: A realistic review of the contexts and mechanisms of its effectiveness | NIHR | 149,803 |
| Ben Goldacre | Dept. of Primary Care, University of Oxford  | 0418-10135 Explaining and reducing incorrect prescribing of methotrexate in primary care | NIHR | 292,793 |
| Ben Goldacre | Dept. of Primary Care, University of Oxford  | 0418-10130 Identifying, explaining and addressing unwarranted variation in GP prescribing | NIHR | 327,743 |

## I4I

The I4I award “Immersive virtual reality to transform the lives of patients with psychosis” (£3,9m, FY19 £1.1m) commenced in June 2018, will run for three years and is led by Professor Daniel Freeman (Department of Psychiatry).

## Study Delivery

The Study delivery function is led by Prof. Andrea Cipriani (Associate Director of R&D), Dr. Cathy Henshall (CRF Manager) and Helen Jones (Study delivery manager). This brings together commercial and non-commercial study income generated from resources funded by the CRN, CRF and BRC. The NIHR funders expect income generated to be recycled for the benefit of research. This area is under new management and provides the opportunity for greater utilisation of resources and the development of new investigators.

## Oxford Academic Health Science Network (OAHSN)

The OASHN is a clinical development rather than research and is reported separately in the finance report to the Board with the Medical Director as the executive lead. OHTF hosts the Dementia (FY19 £19k), Early Intervention in Mental Health (including the Preparedness funding) (FY19 £164k) and Anxiety and Depression OAHSN Clinical Networks. The Anxiety and Depression network will be funded in FY19 by the AHSN & others £69k and CLAHRC £61k with a further £27k available from the CLAHRC in FY20.

## Infrastructure Funding Timeframes

|  |  |  |
| --- | --- | --- |
| **Infrastructure or Award** | **Current funding timeframe** | **Total Value** |
| CLAHRC | Jan 2013 to Sep 2019 | £10.5m |
| MIC | Jan 2018 to Dec 2022 | £1.2m |
| CRF | April 2017 to March 2022 | £3.7m |
| BRC | April 2017 to March 2022 | £13.5m |

## National Involvement

During FY18 R&D Finance provided input into national consultations on proposals for a single costing and contracts model for England and the current and future use of Research Capability Funding. It also responded to a paper based NIHR audit request and if selected will receive a visit from the NIHR in the autumn as part of the follow-up exercise.

FY19 activity will potentially include testing the new NIHR annual return portal (required for the BRC, CRF, MIC & CLAHRC) and further involvement in the national single costing and contract initiative.

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1. *A risk assessment has been undertaken around the legal issues that this paper presents and there are no issues that need to be referred to the Trust Solicitors.*
2. *This paper (including all appendices) has been assessed against the Freedom of Information Act and the following applies:*
* *THIS PAPER MAY BE PUBLISHED UNDER FOI*
1. *This paper provides assurance and evidence against various Care Quality Commission Outcomes*