

**BOD 62/2021**

(Agenda item: 8)

**Report to the Meeting of the**

**Oxford Health NHS Foundation Trust**

**Board of Directors**

**September 2021**

**Research and Development Report**

**For information**

**Executive Summary**

**R&D Director**

The key staffing change over the past 6 months was the appointment of Dr Karl Marlowe (OHFT CMO) as interim R&D Director as from 1st July.

**Oxford Health Biomedical Research Centre (BRC)**

The current BRC funding award runs until November 2022 and the NIHR has launched a two-stage open competition for the next award (2022-2027).

In early August OHFT received confirmation from the NIHR that all the proposed Themes (11) included in the stage one application had been invited to participate in the second stage of the application, due for submission 20th October

**Oxford Cognitive Clinical Research Facility (CRF)**

The current CRF funding award comes to an end in August 22 and the NIHR has lunched a funding competition for the next award (2022-2027) with a closing date of 29th of September 2021.

**Oxford Applied Research Collaboration Oxford and Thames Valley (OxTV) (ARC)**

The ARC submitted evidence to show the progress against conditions of the award in April 2021, and at the end of June 2021, were notified by the NIHR that the Independent Selection Committee recommended the ARC OxTV should continue to be designated and funded until the end of the contractual period (Sept 24)

**NIHR Community Healthcare MedTech and IVD Co-operative (MIC)**

Following NIHR guidance, OHFT organised a recruitment process for a new Director, which concluded with the appointment of Professor Gail Hayward (formerly MIC Deputy Clinical Director) as the new Clinical Director.

**Consent to discuss participation in research**

OHFT have recently introduced changes to how we inform patients about research, to try and make research more inclusive. The “Count me in” initiative gives all patients the right to hear about research that they may wish to participate in, unless they request to not be informed

**Oxford Joint Research Office (JRO)**

The OU\OUH JRO has been active for several years and reports into the Joint Research and Development Committee (JRDC) at OU\OUH. OHFT now have the opportunity to join the JRO.

The next step is for revised JRO Terms of Reference to be agreed by the JRDC with Oxford Health and Brookes becoming members, thus meeting one of the objectives of the Oxford Academic Health Partner objectives

**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 support these development

**Author and Title:** Bill Wells and Karl Marlowe

**Lead Executive Director: Karl Marlowe**

This is in line with the 4 strategic priorities of the Trust, especially that of Research & Education.

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# Introduction

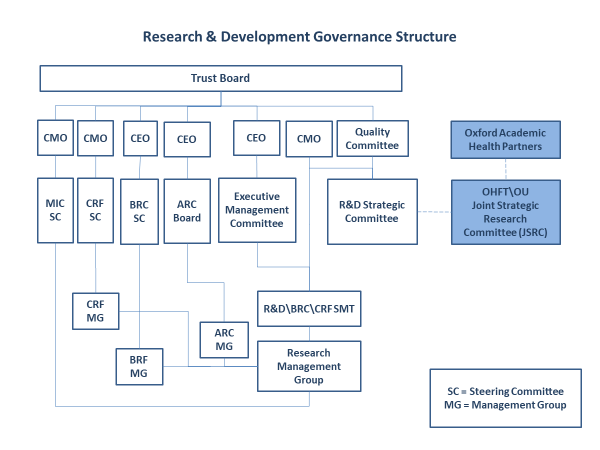
Participation in research produces direct benefits for patients and, more generally, improvements in the quality of care. Organisations can also benefit financially from both cost savings and income generation. Oxford Health NHS FT (OHFT) is a leading research-active mental and community trust with strong strategic research links to both the University of Oxford, which is the top-rated University in the THE World University Rankings and Oxford Brookes University.

## 2021- 2026 Trust Strategy

The OHFT strategy includes a key objective to “Become a leader in healthcare research and education”, where the Trust is committed to integrating research alongside clinical care to allow all patients to benefit from participation in research. Already one of the top two NHS organisations for mental health research, the Trust has strong relationships with world class academic institutions including the University of Oxford and Oxford Brookes University.

## Research Governance Framework

The following R&D governance framework was agreed with the Board in January 2021.



### Research Management Group (RMG)

The RMG was set-up some years ago as a high-level committee to drive a collaborative research strategy across the Trust and local area. Following changes to the governance framework this group is now chaired by the Head of R&D and has taken on a more operational remit across three areas.

1. OHFT NIHR Infrastructure awards – Biomedical Research Centre (BRC), Clinical Research Facility (CRF), Applied Research Collaboration (ARC) and MedTech and In Vitro Diagnostic Co-operatives (MIC)
2. Collaboration with local stakeholders – Oxford Academic Health Partners (OAHP), Oxford University Hospitals\Oxford University Joint Research office, Brookes University, Oxford Academic Science Network (AHSN) and the TV&SM Local Clinical Research Network (CRN)
3. OHFT functions – Community and Forensic Directorates, Oxford Improvement Centre (OHI) and Research Communications

The RMG meets monthly and reports into the R&D Senior Management Team. It is augmented on a quarterly basis with representation and reports from the following research teams

* Study Delivery
* Study Set Up and Management
* Research Informatics and CRIS Management
* Pharmacy
* Research Engagement
* Quality Assurance \ Opt-out
* PPI & EDI
* Finance

### Joint Strategic Research Committee (JSRC)

The JSRC ensures strategic alignment between OH and University partners. It meets quarterly to oversee:

* joint investments in R&D across the partners, including the use of Research Capability Funding (RCF)
* identification of major funding opportunities
* strategic direction of core research infrastructure (BRC, CRF, ARC)

## COVID-19

The pandemic has impacted research locally and nationally in many ways. Initially many studies were put on hold following which vaccine and related studies were developed, set-up and opened. At the same time as COVID-19 studies were being developed the NIHR launched the RESTART initiative aimed at reopening studies previously put on hold. At OHFT studies were reviewed by a prioritisation panel to ensure they were COVID safe. Currently, we are running the following Covid-19 studies, alongside our wider portfolio of research studies:

**Novavax**

Since October 2020, OHFT successfully set up and delivered the urgent public health Novavax vaccine trial. This has required transforming the R&D workforce and responding rapidly to issues relating to training and development, staff resourcing, data management, contracts, finance, working with external partners, equipment, and administrative pressures. This has been a huge challenge for the team due to the extremely short timelines, with recruitment of our first participant only four days after contract sign off. We successfully recruited 463 participants to the trial in only four weeks-this exceeded our recruitment target. Due to a major amendment, we went on to support a Novavax crossover trial design. This meant that participants who received the Novavax vaccine received placebo and vice-versa. A sub-sample of participants took part in the Novavax crossover trial, which was implemented at a national level in response to the number of participants being unblinded due to increasing opportunities to receive the deployed vaccines. In addition, OHFT is also one of only two NHS Trusts in the UK to be supporting the Novavax serology sub-study. Novavax follow up study visits are still in progress, with the study end date anticipated at the end of December 2021.

**PRINCIPLE**

This priority one urgent public health Covid-19 trial was successfully set up at OHFT and opened to recruitment in Jan 2021. It aims to evaluate treatments for Covid-19 in participants over the age of 50, that can be taken at home Recruitment is primarily through the District Nursing teams in the community directorate, with support from R&D and is a great opportunity to further embed research within the community nursing teams. To date, we have not recruited any participants to PRINCIPLE. As a result, we are implementing additional research delivery team support to help the community nurses to identify any potential recruits to the study.

**Virus Watch**

OHFT has successfully supported the Virus Watch study involving over 50,000 participants nationally. Virus watch aims to better understand local and community incidence and transmission of Covid-19 through regular questionnaires assessing incidence, symptom profile, severity, and transmission risk. OHFT supported an immunity subset of the Virus Watch study which involved obtaining blood samples to assess immune response to help establish whether Covid-19 infection led to protective immunity and antibodies. We rapidly set up and delivered various clinics through Oxfordshire and Buckinghamshire in Autumn 2020 and Spring 2021 with various families throughout these localities to help understand the local immune response to Covid-19.

# Research Culture

## Staff Survey

Two of the research questions included in the 2020 staff survey were to test staff awareness of research within the Trust and their confidence in talking to patients about research. While the percentages were similar to 2019 there was an increase in the absolute number of staff responding. The results are shown in the tables below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **How aware are you of the clinical research work undertaken in the Trust?** | **2020** | |  |  | **2019** | |  |
|  |  | **%** |  |  |  | **%** |  |
| No awareness | 1,354 | 42% |  |  | 1,026 | 42% |  |
| Some awareness | 1,670 | 52% |  |  | 1,301 | 53% |  |
| I'm actively involved in research | 166 | 6% |  |  | 142 | 6% |  |
| **Total Responses** | **3,190** | **100%** |  |  | **2,469** | **100%** |  |
|  |  |  |  |  |  |  |  |
| **Would you feel confident discussing clinical research trials with patients?** | **2020** | |  |  | **2019** | |  |
|  |  | **%** |  |  |  | **%** |  |
| Not part of my role | 1,893 | 58% |  |  | 1,439 | 57% |  |
| Part of my role but not confident | 287 | 9% |  |  | 203 | 8% |  |
| Yes, somewhat | 762 | 24% |  |  | 630 | 25% |  |
| Yes, always | 305 | 9% |  |  | 261 | 10% |  |
| **Total Responses** | **3,247** | **100%** |  |  | **2,533** | **100%** |  |

## Communications

Over the last six months research communications have been focussed on supporting the renewal bids for the OHFT Biomedical Research Centre and more recently the Oxford cognitive health Clinical Research Facility. In both cases this has included developing sections of the BRC website to showcase elements of our work critical to the renewal bids.

For the BRC we created [a new COVID-19 research hub page](https://oxfordhealthbrc.nihr.ac.uk/covid-19-research/) neatly bringing together all pandemic related research in a single online location and [a new ‘Our People’ section](https://oxfordhealthbrc.nihr.ac.uk/our-people/) to demonstrate the impressive range of collaborators involved in the BRC. The web pages for the CRF are currently being revised and new photography has been commissioned to better showcase the facility and its capabilities. This is part of a rolling programme to update our research image library that will be ongoing over the coming months.

Alongside this, the changes to research contact implemented by the trust in August 2021 have been another major focus for comms activity. The ‘opt-out’ project has been supported by a detailed communications plan. Activity across a range of channels has been designed to ensure that all stakeholders, internally and externally, are well informed about the process and its implications. We have created a dedicated intranet page containing resources and information for staff, which continues to be signposted with a standing item in the weekly staff bulletin. The changes to research contact were announced publicly on the Trust website and were covered on local news by BBC radio Oxford. Resources for patients and the public are available online and include a Q&A and a digital patient leaflet. Patient leaflets are also being sent out in hard copy with appointment letters. The changes to research contact are being further supported with ongoing social media posts and follow up stories to be published later in the year.

Our internal research comms has benefitted in recent months from a new dedicated section in the weekly staff bulletin issued each Wednesday. This double page spread has enabled us to more effectively promote research related opportunities and events as well as to share key research news stories with staff. In collaboration with the research delivery teams significant and ongoing work has been also been undertaken to update and improve the R&D presence on the intranet. We have provided intranet training to a number of research colleagues so that information can be updated quickly and directly by teams as necessary.

We remain committed to our aspiration to create more multimedia content for use on the web and social media. For International Clinical Trials Day in May we produced [a short video introduction to the CRF](https://youtu.be/Fx_5V8Sq428) which is available to watch on the BRC website, has been shared on social media and is also being used as part of the Trust induction for new staff. We are currently working on a short film about the Brain Health Centre for the Oxford Health NHS Foundation Trust Annual General Meeting in September.

Since March we have published 17 online news items covering topics including children’s and adolescent’s mental health, vaccine hesitancy, PPI projects and the Trust’s opt-out project. We continue to collaborate closely with communications colleagues in the University of Oxford to release stories to national media. All our news stories are supported by posts on the BRC twitter account which has now grown to over 1,200 followers.

# Research opportunities for Patients

## Consent to discuss participation in research

Changes to way we inform patients about research at OHFT have now been implemented in Adult and Older Adult Mental Health services. This means that patients in these services can soon expect to hear about research opportunities unless they say that they do not wish to receive this information.

Information about the change is currently being circulated to patients in relevant services. We will allow at least 30 days for information about the change to be received and considered by patients, before they can be contacted about research opportunities.

The change in approach only relates to patients hearing about research opportunities. The decision to take part in research remains entirely voluntary and this will continue to be stressed to both staff and patients. The main motivation for this change in approach is to be more inclusive by making the opportunity to participate in research available to all our patients.

In preparation for the change. The following actions have been taken:

* Quarterly strategic group meetings have been held to plan the change, inviting representatives for Information Governance, Patient and Public Involvement, the Executive Team, service Medical Directors, the Communications Teams and Research & Development.
* A comprehensive communication plan has been implemented to inform staff and patients about the changes. This includes a campaign across social media channels, press release to local media, news stories on Oxford Health website, a patient facing leaflet (available in a variety of formats), posters displayed in clinic areas, an information campaign within the Trust via the intranet and weekly bulletin, and all staff email to inform staff of the change and equip them to answer questions from patients
* A Trust wide live Information Event with Question and Answer session was provided for staff on Teams, to share information about the change. A recording of the session and a written Q&A piece were shared for those who could not attend.
* A new Intranet site has been launched, to explain the change and to provide staff with relevant information and documents relating to the project ([here](https://ohft365.sharepoint.com/sites/research/SitePages/Changes-to-research-contact---everything-you-need-to-know-about-'opt-out'.aspx))
* A new Research participation form is now live on Carenotes, to capture patient research activity. This includes a space to document if patients ‘opt-out’ of research contact. This should improve data quality around the number of patients who choose to / not take part in research and the impact of research across the Trust.
* Training sessions about the change and use of the new Carenotes forms have been provided for staff and recorded so that it can be accessed by new starters, or those requiring a refresher.
* Research letters and leaflets have been shared with relevant teams ([example here](https://ohft365.sharepoint.com/sites/research/SiteAssets/Forms/AllItems.aspx?id=%2Fsites%2Fresearch%2FSiteAssets%2FSitePages%2FChanges%2Dto%2Dresearch%2Dcontact%2D%2D%2Deverything%2Dyou%2Dneed%2Dto%2Dknow%2Dabout%2D%2Dopt%2Dout%2D%2FOH%2D208%2E20%2DOpt%2DOut%2DPatient%2DLeaflet%2DFINAL%2Epdf&parent=%2Fsites%2Fresearch%2FSiteAssets%2FSitePages%2FChanges%2Dto%2Dresearch%2Dcontact%2D%2D%2Deverything%2Dyou%2Dneed%2Dto%2Dknow%2Dabout%2D%2Dopt%2Dout%2D)), so that information about the change can be incorporated within appointment letters. The research letter has also been added to the appointment letter template on Carenotes to allow for auto-generation of the information if these templates are used. Administrators have been contacted directly, to remind them of the process and to provide contact details should they have any questions.
* Trust letterheads have been amended to include a research strapline. It is hoped that this will help Oxford Health be seen as a research active Trust.
* A dedicated email inbox (researchconsent@oxfordhealth.nhs.uk) and phone line (01865 902013) have been set up for patients and staff to contact the team directly, to ask questions or to let us know of their contact preferences.
* The Trust’s privacy statement has been updated and a DPIA has been written, in consultation with the IG lead.
* To avoid confusion with the national data, opt-out, the change will not be referred to as ‘opt out’ in communications materials.

An evaluation of the change will now be conducted by the core team for this project over the next year. This will include feedback from patients and staff about the change.

Following evaluation, it is expected that this change in approach will be adopted in other areas of OHFT, such as the community directorate in 2022.

## NIHR Clinical Research Network (CRN) performance

The CRN High Level Objectives for 2021-22 have now been approved and are attached.  These focus on efficient study delivery for both commercial and non-commercial studies and increasing participation by provider organisations including those in Primary Care and non-NHS settings.  As a result of the disruption caused by the pandemic, NIHR CRN did not apply a performance-based model to inform the funding allocations for 2021/22 but retained the funding model from the prior year. This resulted in the network receiving a core allocation of £17m which includes an inflationary uplift and some additional delivery monies to support an increase of its directly- managed flexible workforce to develop more capacity to deliver studies across community and non-NHS settings.

The first half of 2021/22 has been as busy, if not busier, than the previous year with a focus now both on delivering the important urgent Covid -19 studies whilst also building momentum on the restart of the non-Covid portfolio. In terms of the Covid-19 research, the network has continued to recruit well locally and is still leading nationally for several of the high profile studies coming from Oxford University, including the RECOVERY and PRINCIPLE platform studies. More vaccine, anti-viral and long Covid-19 studies are still expected.  In addition, DHSC has asked NIHR to work with research funders and partners across the UK’s research system to develop a formal plan to manage the recovery of key non-COVID 19 studies that require specific focus and support over the next 6-12 months. The network has therefore received twice-weekly updates on those studies that have been designated as part of the formal Managed Recovery process and is working closely with stakeholders to ensure that these can be setup and delivered promptly within the region where possible.

The current LCRN contract runs out on 31st March 2024 and stakeholders have started to come together with DHSC to discuss the future priorities and any potential changes in focus.  More work on this is anticipated over the coming months.

### OHFT CRN Portfolio Performance July 21 YTD (4 months)

At the end of July 21 OHFT had recruited 477 participants to 49 portfolio studies across five specialties.

|  |  |
| --- | --- |
| **Specialty Summary** | **FY22 YTD (4 months)** |
| DenDron | 48 |
| Mental Health | 400 |
| Stroke | 26 |
| Children | 1 |
| Public Health | 2 |
| **Total** | **477** |

### As a result, OHFT were ranked 3rd nationally in terms of studies running and 6th for number of participants recruited

**Studies**

|  |  |
| --- | --- |
| **Mental Health Trust** | **FY22 YTD (4 months)** |
| South London and Maudsley NHS FT | 61 |
| Cambridgeshire and Peterborough NHS FT | 54 |
| Oxford Health NHS FT | 49 |

**Recruitment**

|  |  |
| --- | --- |
| **Mental Health Trust** | **FY22 YTD (4 months)** |
| Greater Manchester Mental Health NHS FT | 13,958 |
| Southern Health NHS FT | 6,275 |
| South London and Maudsley NHS FT | 2,457 |
| North East London NHS FT | 649 |
| Berkshire Healthcare NHS FT | 506 |
| Oxford Health NHS FT | 477 |

## Community Directorate

### Summary of Current Research Studies supported

The Community Research Delivery Team has been actively supporting study Delivery in the Community Directorate in the last six months. Currently seven studies are open for recruitment, this includes 2 COVID related trials

**Table 1 Current Research Studies open to recruitment Sept 2021**

|  |  |  |
| --- | --- | --- |
| Study name | Aim of the Study | Recruitment (No. participants) |
| PRINCIPLE | Platform trial of medicines for use in Community treatment of COVID-19 | 0 participants/0 target (limited capacity in the Community Nursing team) |
| Healthtalk online | Qualitative research on the Lived Experience of Disease | Participant Identification Site for Nuffield Department of Primary Care, University of Oxford |
| Embedding Diabetes Education | Randomised Control Trial | Recruitment site for Nuffield Department of Primary Care, University of Oxford |
| OCS Recovery | Stroke Recovery | 78 participants |
| Social communication intervention for Children with Down Syndrome |  | Recruitment target 8 |
| LISHORE | Spirituality interventions to improve wellbeing for staff in Covid (Survey & Focus Groups) | Open to Recruitment |
| Enhancing resilience in the nursing workforce during COVID-19 | Enhancing resilience in the nursing workforce in the COVID-19 environment: transitioning from face-to-face to online learning (Survey & Focus Groups) | Open to Recruitment |

The following three studies are planned to open in the next 6 months.

* A National Survey of Strength Assessment and Training in Pulmonary Rehabilitation
* M-MOST: A Feasibility Study of Strength Training and Nutritional Supplements funded by the NIHR Research for Patient Benefit (NIHR RfPB)
* PALL-UP: A national survey and focus groups study on the access, provision, and Lived Experience of End-of-Life Palliative Care

There are currently a further 6 studies in development in collaboration with Children’s services, COPD nurses, Physiotherapists and Respiratory Therapists in the Community Directorate.

**Funding Proposals**

The CRDT in collaboration with Oxford Brookes University and the OHFT AHPs were invited to submit a second round of the Elizabeth Casson Trust funding, but were unsuccessful

**Rejected Studies**

The team have screened and advised on 10 proposed studies for the Community Directorate. These included 4 audits, and 6 rejected studies. Of the rejected studies, three were due to a lack of capacity in the clinical teams or lack of suitable Principal Investigators in the Community Directorate. The remained three were rejected due to lack of suitable patients, lack of practical support from the external commercial company and one mental health study which was redirected.

## Equality, Diversity, and Inclusion (EDI)

A group including the Research Delivery & CRF Manager, Patient and Public Involvement (PPI) Manager and Head of R&D meet regularly to identify practical steps which can be taken to improve access to research. The areas of focus are staffing (the mix of staff within R&D), research participation and PPI Involvement identifying geographic areas of interest and running community events

Recent updates include

* *Florence Nightingale Programme:* one of the CRF Nurses was admitted to the FN programme will be undertaking a quality improvement project where she is planning to undertake an EDI based project. This project is targeting inpatient clinical staff and raising awareness of research via educational participatory sessions to increase inclusivity of inpatient service users in research.
* *The Listen, Share, Hold, Respond* (LiSHoRe) project: This will be a multi-site, participatory consultation project to understand the psycho-spiritual experiences and support needs of BAME NHS workers during the Covid-19 pandemic and has been funded by NHS England (CI: Guy Harrison; PI: Cathy Henshall).
* *Introduction of an Equality Monitoring Form*: developed an EMF based on the OHFT-endorsed EMF. The plan is to attach this to Case Report Forms for studies (where appropriate) and collect and analyse data to establish a baseline of participant composition. This will be used to help identify populations we could target in our diversity outreach. We will also compare this data to staff baseline demographics (where appropriate) to check for representativeness and potential patterns. This pilot is currently underway and has been recently implemented for all relevant / feasible studies within the three delivery teams. This process will be reviewed in January 2021.
* *Community Participatory Action Research (CPAR*) project: applied to a Health Education England programme to train three volunteer researchers from BAME communities in CPAR and for them to deliver a project to understand barriers to getting involved in research for BAME communities in OHFT regions. We have worked with the Community Research Lead, Head of Inclusion, and the Head of Charity Involvement to develop the proposed project. The application outcome is expected March, and if successful the project will begin April 2021.
* *Literature Review:* partnering with local NIHR organisations to carry out a literature review on successful approaches to engaging seldom heard groups in research. The literature review will be co-produced with patient and public involvement contributors from seldom heard groups. March - September 2021.
* *Equality Impact Assessment (EIA)*: planning an EIA of our Patient and Public Involvement work, linking with Mo Patel, and reaching out to the NIHR Applied Research Collaborations who have implemented EIAs in a research setting. (Timeline tbc)

OHFT are developing a link with University Hospitals of Leicester, regarding their CRF and in particular opportunities to enhance our EDI work

# National Institute for Heath (NIHR) Infrastructure awards

## NIHR Oxford Health NIHR Biomedical Research Centre (BRC)

**A copy of the FY21 Annual return is attached for reference**

**Summary update**

The NIHR supports 20 Biomedical Research Centres (BRCs) nationally: they are collaborations between world-leading universities and NHS organisations that bring together academics and clinicians to translate lab-based scientific breakthroughs into potential new treatments, diagnostics, and medical technologies. The NIHR created the BRCs to transform discovery science into new treatments which will deliver personalised, precision care. The OHFT Biomedical Research Centre (OHBRC) is a partnership between OHFT and the University of Oxford and is one of the only 2 centres nationwide dedicated to mental health research. The aim of the OHBRC, is to bring the best science to the complex problems of mental disorders and dementia. The OHBRC is currently composed of 3 major Research Themes and 5 cross-cutting Themes, including PPI (Patient and Public Involvement) and Education and Training.

https://oxfordhealthbrc.nihr.ac.uk/research

|  |  |
| --- | --- |
| OHBRC Themes | Theme Lead |
| Adult Mental Health | Prof Paul Harrison |
| Older Adults and Dementia | Prof Clare Mackay |
| Precision Psychological Therapies | Prof Anke Ehlers |
| Informatics and Digital Health [CC] | Prof Andrea Cipriani |
| Clinical Research Infrastructure and Experimental Medicine [CC] | Prof Cath Harmer |
| Neuroimaging and Cognitive Neuroscience [CC] | Prof Kia Nobre |
| PPI [CC] | Prof Ilina Singh |
| Education and Training [CC] | Ass Prof Elizabeth Tunbridge |

CC=cross cutting Theme

**Recent hight impact publications examples**

* 6-month neurological and psychiatric outcomes in 236 379 survivors of COVID-19: a retrospective cohort study using electronic health records (2021). The Lancet Psychiatry.
* Bidirectional associations between COVID-19 and psychiatric disorder: retrospective cohort studies of 62 354 COVID-19 cases in the USA. (2021). The Lancet Psychiatry.
* Disrupting the power balance between doctors and patients in the digital era. (2021). The Lancet Digital Health
* Cullen AE, Palmer-Cooper EC, Hardwick M, Vaggers S, Crowley H, Pollak TA, Lennox BR. Influence of methodological and patient factors on serum NMDAR IgG antibody detection in psychotic disorders: a meta-analysis of cross-sectional and case-control studies. (2021). The Lancet Psychiatry.
* Risk factors for suicide in prisons: a systematic review and meta-analysis. (2021). The Lancet Public Health.
* Comparative efficacy and acceptability of antidepressants, psychotherapies, and their combination for acute treatment of children and adolescents with depressive disorder: a systematic review and network meta-analysis. (2020). The Lancet Psychiatry.
* Bidirectional associations between COVID-19 and psychiatric disorder: retrospective cohort studies of 62,354 COVID-19 cases in the USA. (2021). Lancet Psychiatry.
* Identifying outcomes for depression that matter to patients, informal caregivers, and health-care professionals: qualitative content analysis of a large international online survey. (2020). Lancet Psychiatry..
* Associations between statin use and suicidality, depression, anxiety, and seizures: a Swedish total-populat cohort study. (2020). Lancet Psychiatry.
* Comparative efficacy and acceptability of psychological interventions for the treatment of adult outpatients with anorexia nervosa: a systematic review and network meta-analysis. (2021). Lancet Psychiatry.
* Challenges and future directions for representations of functional brain organization. (2020). Nat Neurosci.
* Exploring activity levels in physical education lessons in the UK: A cross-sectional examination of activity types and fitness levels (2021). BMJ OSE Med.
* Web-based physical activity intervention for people with progressive multiple sclerosis: application of consensus-based intervention development guidance. (2021).BMJ Open.
* Cohort profile: The Oxford Parkinson’s Disease Centre Discovery Cohort MRI substudy (OPDC-MRI). (2020). BMJ Open.

**OHBRC Activity (2017-2021)**

● 384 studies were initiated in the period

● 33,579 ​participants were recruited to studies this year

● 74 investigators were supported by OHBRCs and 120 associates

● 546 peer reviewed articles were published

● 27 partnerships with UK SMEs were reported and 63 new or continued strategic partnerships

● £53.6m million of leveraged funding

**Renewal**

The current funding period runs from April 2017 to March 2022, plus a costed extension to November 2022 and the NIHR has launched a two-stage open competition for the next awards (2022-2027).

**Stage 1:** NHS/university partnerships in England were invited to submit a short application by 26th May. These were reviewed by an International Selection Committee who made recommendations to the Department of Health and Social Care (DHSC) on which NHS/university partnerships should be shortlisted and invited to submit a full application at Stage 2.

In early August the OHFT received confirmation that all the proposed 11 Themes are invited to participate to the second stage of the application.

**Stage 2:** The stage 2 will require an extended application (deadline: 20/10/2021) with the proposed strategy and research programme and detailed costing. Each Theme will undergo peer review to inform the decision of the International Selection Committee. The stage 2 process will include interviews with applicants and the committee will make recommendations to DHSC as to which partnerships should be awarded NIHR BRC designation, and the level of funding.

**OHBRC 2 (2022-2027) proposed structure (£45m):**

|  |  |
| --- | --- |
| OHBRC 2 Themes | Theme Lead(s) |
| Data Science for Precision Mental Health | Andrea Cipriani |
| Dementia | Masud Husain & Clare Mackay |
| Experimental Medicine: Neurocognitive biomarkers for treatment development | Cath Harmer & Philip Cowen |
| Flourishing, Mental Health and Wellbeing | Ilina Singh & Willem Kuyken |
| Mental Health & Development | Cathy Creswell |
| Novel therapeutic targets and biomarkers for psychiatric disorders | Paul Harrison & John Todd |
| Pain | Irene Tracey & David Bennett |
| Precision Psychological Treatments | Anke Ehlers & Daniel Freeman |
| Prevention of multiple morbidities in whole and high-risk populations | Paul Aveyard & Kamaldeep Bhui |
| Sleep & Circadian Pathways to Better Health | Colin Espie and David Ray |
| Technologies for brain and behaviour diagnostics | Kia Nobre & Heidi Johansen-Berg |

## 

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

**A copy of the FY21 Annual return is attached for reference**

**Summary update**

The NIHR funded OHFT-CRF provides specialist facilities to undertake high intensity clinical studies in mental health and cognition, including dementia, focusing on an experimental medicine design. The CRF delivers a mix of commercially sponsored and non-commercially sponsored studies.

The CRF has developed to enable several specialist activities including undertaking intensive psychiatric rating scales, physical monitoring, sample collection and sampling, lumbar punctures, and IV infusions.

Studies range from an experimental medicine design testing novel compounds (late Phase 1/Phase 2, not ‘first-in-man) and clinical trials to longitudinal cohort studies.

In the past six months the CRF has extended its opening hours flexibly to accommodate the restart of funded activity previously paused due to Covid-19 together (experimental / mechanistic cognitive health research) with Urgent Public Health studies (such as the Novavax vaccine trial and the COVID-CNS study – see attached NIHR annual returns Finance Report 20/21).

In collaboration with the Biomedical Research Centre and OHFT, the CRF has delivered Brain Health Centre clinics. This project aims to develop enhanced, standardised radiology reports, which compare an individual patient’s results to normative data from a large number of healthy brains (the ~40,000 UK Biobank participants). The enhanced reports used for patients attending the Brain Health Centre will provide clinicians with more clinically relevant measures of brain health that will facilitate accurate and earlier diagnosis of memory problems.

This project is a joint enterprise between the BRC and the CRF.Through the BHC, this project is linked with the Older Adults & Dementia and Cognitive Neuroscience and Neuroimaging themes of the OH BRC as well as linking with NIHR D-TRC and OUH BRC.

The CRF has experienced high staff turnover and a severe shortage of nurses so cross cover was provided from the other two delivery teams overseen by R&D (Mental Health Research Deliver Team and Memory and Cognition Research Delivery Team). A Band 7 CRF Team Lead has been appointed and creative efforts are undertaken to recruit the correct skillset (secondments offered, proactive international recruitment, etc.).

**Renewal**

The current CRF funding comes to an end in Aug 22 and earlier this year the NIHR lunched a funding competition for the next five years (2022-2027) with a closing date of 29th of September 2021. The CRF Director is collaborating with the CRF SMT, OHFT R&D, OHFT clinical services, OUH, OH-BRC, and Oxford University to finalise the strategy for a renewed CRF and to write the application. Input will be sought from all relevant stakeholders.

As part of the renewal strategy, the CRF is looking to expand its physical space capacity with support from OHFT by securing additional research space in Abingdon and Didcot. Collaborations are also being developed with other Trusts

## NIHR Applied Research Collaboration Oxford and Thames Valley (OxTV)

**A copy of the FY21 Annual return is attached for reference**

### Summary update

This report provides an overview of activity at ARC OxTV for the last eight months (Jan-Aug 2021).

**Activity**

We submitted the evidence to show the progress against conditions of the award on time (April 2021), and at the end of June 2021, were notified by NIHR that the Independent Selection Committee recommended the ARC OxTV should continue to be designated and funded until the end of the contractual period (30 September 2024).

Projects are progressing well, and we are increasing the information on the website. The ARC Annual Report (attached) captures all the theme activity from the ARC against the objectives from the bid document and new objectives which have arisen from the pandemic but also changing local need.

Our NIHR Finance and Activity report for 20/21 showed substantial progress for the ARC, summary figures are provided in the table below. Next year is already looking stronger with several new DPhils starting in October 2021, and more projects added to the ARC portfolio.

Progress from last year:

|  |  |  |
| --- | --- | --- |
|  | **FY 19/20** | **FY 20/21** |
| **Projects** | 30 | 68 |
| **Participants recruited** | 65 | 34002 |
| **External Funding** | £1,510,608 | £4,268,876 |
| **Publications** | 21 | 132 |
| **DPhils** | 0 | 5 |

We have secured funding from three ARC national priority areas (Ray Fitzpatrick – Adult Social Care, Richard McManus – Multiple Long-Term Conditions and Paul Aveyard – Prevention) which are bringing in an additional £900,000 of funding to the ARC.

**New work and partnerships**

Over the past few months, we have been bringing in new partnerships and will be reviewing the Collaboration Agreement. These include:

New Bucks University, who will be added to the Collaboration Agreement as a funded partner.

Milton Keynes University Hospital NHS FT. There are several opportunities for the ARC to support this agile trust, as they increase their research portfolio. We already fund a midwife who works at this trust. The ARC Senior Manager is a member of the hospital R&D management group and has linked them with Oxford Health for the next NIHR Clinical Research Facilities (CRF) bid as they would like to be a hub.

The ARC is also a member of the Buckinghamshire Combined Universities Healthcare Research Group. We have presented about the ARC and will use this group as an opportunity to find new collaborators and raise awareness of current ARC projects.

We are funding a PPI pilot project with Oxford Academic Health Partners to look at the role of Social Prescribing in the Oxford Brain Health Centre with a view to securing external funding.

The additional funding for the Beneficial Changes Network project, now the NHS Insight Prioritisation Programme, has enabled us to support new projects including SHAPE (Supporting Hospital And Paramedic Employees) (Supporting Hospital and Paramedic Employees during and after Covid) which is focusing on workforce wellbeing one of the key priority areas for the NHS Long Term Plan.

AstraZeneca have funded a study to look at the safety and efficacy of all COVID-19 vaccines using the ORCHID (Oxford- Royal College of General Practitioners Clinical Informatics Digital Hub) platform.

**Capacity Development**

We have appointed two Senior Research Fellows, Dr Esther Williamson, focusing on musculoskeletal research leadership and Dr Sara Shaw, focusing on net-zero across health and care organisations. The second of these is joint funded by the OUH (Oxford University Hospitals) BRC, as sustainability spans both the ARC and BRC portfolios.

For our internship programme, we have recently awarded two internships, one in public health and the other in social care, both are looking to embed research into their everyday practice. We have been capturing any barriers to accessing the programme, for example, public health and social care staff who are not formally registered are not eligible and assessing the demand for such schemes from across the region. This information will enable us to put in a proposal for additional funding from Health Education England to support future capacity development.

The Public Health Practitioner course is in the preliminary stages of development, drawing alignment with their learning needs assessment and standards required for registration. Communications is a key area where the ARC can support capacity development.

A seminar on Interrupted Time Series was held in May 2021 and will form the basis of a training course, which will be delivered locally by the end of 2021 and more widely available early 2022. The training will introduce the different methodologies, when they are suitable and will also include practical training for staff in the AHSN, Commissioning Support Units etc. on the use of R programme to ensure routine data is utilised as effectively as possible.

Finally, John Powell and Nadja Leith have led on the development of a Masters in Digital Health. This is an extension to what we committed to do in providing a module but will be a significant addition to increase capacity and capability around digital health.

**Staffing**

The only key staff change is Professor Paul Aveyard has taken over as Theme 1 lead, as Professor Susan Jebb has been appointed as the [Chair of the Food Standards Agency](https://www.arc-oxtv.nihr.ac.uk/news/professor-susan-jebb-appointed-as-chair-of-the-food-standards-agency), she will remain as the Theme 1 deputy.

The appointment of a Deputy ARC Director is ongoing at the time of authoring the report. Confirmation of ARC funding until 2024 has mitigated against the risk of losing key staff and no significant staff changes are anticipated at this time.

**Reginal Activities**

**Oxford and Thames Valley Strategic Partners**

We are raising awareness of the ARC and its activities with the regional team from NHSE/I and through collaborative working across the South East, with the three AHSNs and ARCs (Kent, Surrey, Sussex, Wessex and OxTV). We are looking to pilot reverse engineering research priorities, working closely with our Integrated Care Systems (ICSs) to identify and address evidence gaps in a responsive manner. The initial proposal is to look at the RESTORE2 work programme that Ray Fitzpatrick is supporting in Care Homes and assess how it may be adapted for informal carers and domiciliary care.

All three Healthcare Trusts in the OxTV region have noted that they have a wealth of community data, and we are looking at the potential of incorporating this into existing data sets. There are many opportunities for the ARC to support capacity development in the trusts and all are open to collaborating on projects and facilitate participant recruitment.

**3.2 Community Involvement**

The University was selected as a pilot site for the NIHR’s new Race Equality Framework, we will be working across the departments and infrastructure to implement this framework over the summer. The ARC suggested we could also look at the applicability for all protected characteristics, not just race, which was welcomed.

Building on the OpenPrescribing platform supported by the ARC, Ben Goldacre and his team engineered the [OpenSAFELY](https://www.opensafely.org/) analytics platform, a new secure analytics platform for electronic health records in the NHS, created to deliver urgent results during the global COVID-19 emergency. OpenSAFELY was one of the three exemplars showcased in the recent citizen’s juries, arranged by Greater Manchester ARC, looking at public perceptions of data sharing in the context of a pandemic. The [report](https://www.arc-gm.nihr.ac.uk/projects/Citizens-Juries-on-Health-Data-Sharing-in-a-Pandemic), has now been released by the juries and there is strong public support for the platform, particularly in comparison to the other two alternatives.

The PPI Leads from the ARC and BRCs are developing a centralized PPI toolkit for all researchers doing medical and social care research. This is due to be completed by early October 2021. It will be hosted by the Division of Medical Sciences website, under a new dedicated section for involvement, rather than just a link through patient/public engagement. The individual PPI sections of the ARC, the BRC and the Department of Primary Care Clinical Sciences will link to this new toolkit under their PPI resources for researchers. We are also in discussions to include a link within the new Researcher’s Hub, which has been developed and will be hosted by the University of Oxford.

**Implementation**

Key activities during the last 6 months include:

* Implementation strategy approved by ARC Strategy Board (March 2021)
* First ARC Implementation Oversight Group meeting held (April 2021). Discussed progress relating to implementation across the ARC, with a high-level overview provided on current position for each theme. Looking to develop several impact case studies.
* Progressed collaboration across ARC, AHSN and Oxford University Innovation (OUI). This will facilitate the smooth progress of research outputs to implementation. A non-disclosure agreement is now in place to enable open discussion and sharing of information across all parties
* First two National ARC Implementation Operational Leads meetings held (ARC OxTV initiative). This new group will provide peer support, networking, potential collaboration opportunities and highlight research outputs for wider implementation

**National Context**

**NIHR Update**

NIHR have released their updated strategy document [Best Research for Best Health: The Next Chapter](https://www.nihr.ac.uk/documents/about-us/Best%20Research%20for%20Best%20Health%20The%20Next%20Chapter.pdf). Diversity week will be 29th of November – 3rd of December 2021, the ARC plan to highlight its activities to increase inclusion.

The ARC has applied for an additional £723,000 funding to increase capacity and capability in high quality mental health research. The application focuses on sharing innovations developed locally with the populations and areas where the need is greatest, through partnership with the four Northern ARCs, we will hear the outcome of this application in September 2021.

The next stage of funding for the NHS Insights Prioritisation Programme (formally Beneficial Changes Network (BCN)) is a competitive process, with AHSNs able to apply for up to £275,000, to implement and evaluate innovations which contribute to NHS Reset and Recovery, fit with ICS and regional needs and are aligned to the fours BCN themes (Remote monitoring, remote consultations, novel approaches to service delivery and health and social care workforce). The Oxford AHSN is working in partnership with the ARC to develop the application and deliver the project if we are successful.

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

**A copy of the FY21 Annual return is attached for reference**

### Summary update

**Extension of the NIHR MIC**

OHFT were advised by DHSC and NIHR of a 6-month extension to the current award in Jun 21, with a new end date of the June 2023. The extension funding was being awarded to either complete original objectives, where the pandemic had resulted in delays or extend or introduce new objectives within the MIC themes

The MIC management and theme leads developed new aims and objectives for completion of an amended business plan together with financial considerations, for submission by the 8th Sept, however DHSC superseded the six-month extension with the announcement of a 12-month extension on the 27th Aug 21 (new end date Dec 23). The extension business plan submission deadline has been scrapped until further notice.

**MIC annual report feedback**

The MIC received feedback on the 2020/2021 annual report on the 16/07/2021, with an overall DHSC RAG (Red, Amber, Green) rating of ‘Green’ for narrative and finance & activity reports (= on track. No risks to delivery identified; minimal comments/recommendations provided by reviewers).

**Change of Director**

* After 3 ½ years as MIC Director, Professor Chris Butler made the decision to step down as MIC Clinical Director.
* Following NIHR guidance, OHFT organised a recruitment process for a new Director, which concluded with the appointment of Professor Gail Hayward (formerly MIC Deputy Clinical Director) as the new Clinical Director. Gail’s appointment was confirmed by the NIHR through a VTC which was fully executed in Sept 21
* Professor Butler will continue to work with the MIC as clinical theme lead of the MedTech theme, which he has led since the start of the MIC funding.

**CONDOR update**

* The MIC has continued its leadership (CI Prof Gail Hayward) of the NIHR-funded CONDOR programme (<https://www.condor-platform.org/>) for the evaluation of diagnostics for SARS-CoV-2 / COVID-19.
* The CONDOR collaborative group has secured a no-cost extension to the award with a new end date of 28/02/2022.
* CONDOR discussions have taken place during the summer to secure a costed extension to fund the group to extend the remit of CONDOR to multiplex tests for respiratory viruses.

**RAPTOR-C19 update**

* Work has continued on the RAPTOR-C19 element of the CONDOR programme (evaluation of diagnostics for SARS-CoV-2/COVID-19 in community settings - <https://www.condor-platform.org/condor_workstreams/raptor>), with the support of the CRN and with approximately 20 GP sites open.
* RAPTOR was extended to Welsh testing centres in Cwm Taf in July, which has brought about a sustained increase in recruitment into the study.
* It is anticipated that evaluation of the first two candidate diagnostics will be completed in early autumn, with results fed back to DHSC (Test Validation Group).
* The RAPTOR team has additional diagnostic candidates under negotiation for inclusion in the study.

**Femtech project initiation**

* The MIC has won external funding for and has initiated a new project to identify clinical needs for women’s health across the life course.
* The project is being carried out in collaboration with colleagues from the Department of Engineering and Obstetrics and Gynaecology.

The OHFT CMO has recently agreed to join the MIC steering committee

# Leadership and Management

## Board and Executive Management Committee

R&D presentations at senior OHFT meetings have included

* April Board, Bill Wells (Head of R&D)
* May Executive Management Committee, Bill Wells (Head of R&D)
* July Quality Committee, Marco Pontecorvi (BRC Manager)
* Sept Trust Leadership Team, John Geddes (BRC Director)

## Staffing

The key staffing change over the past 6 months was the appointment of Karl Marlowe (OHFT CMO) as interim R&D Director as from 1st July.

Earlier this year Julie-Ann Timbrell, HR Business Partner starting meeting regularly with the Head of R&D and wider management Team. This support has made a significant improvement in handling HR related issues. There are further opportunities to develop this link to help promote research across the Trust

## Research Management Team (RMT)

### Background

### Background

The Research Management Team provides support in

* Management, prioritisation, and coordination of studies via the study Pipeline process, based and capacity and capability assessments and regulatory approval
* Ensuring studies are monitored and managed appropriately throughout the study life cycle
* Liaising with the outsourced contracts team at OUH for confidentially agreements and research contracts, obtaining signatures in house
* Reporting validated Trust performance in terms of studies running and participants recruited
* Providing advice on governance, portfolio adoption and sponsorship
* Granting letters of access for research purposes
* Reviewing requests for research sponsorship
* Managing and validating study data via Studyline

### Set Up

Despite the pandemic, a high level of studies was opened in 2020-2021 and we are seeing a significant increase in the level of activity in recent months. The main barrier to set up is the lack of capacity within the team.

We are currently trialling a hub and spoke model of trial set up and delivery that may help us to mitigate this in future by allowing us to draw upon regional staff and centres.

**Number of studies opened**

|  |  |
| --- | --- |
| Year | Number of Studies |
| Opened 2018-2019 | 41 |
| Opened 2019-2020 | 52 |
| Opened 2020-2021 | 46 |
| Currently in Set-up | 21 |

**Breakdown of active studies and studies on hold**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | FY 21 | | FY 22 | | | | |
|  | Apr | Mar | Apr | May | Jun | Jul | Aug |
| active | 50 | 85 | 86 | 85 | 90 | 93 | 93 |
| on hold | 44 | 20 | 16 | 14 | 14 | 12 | 10 |
| open studies in total | 94 | 105 | 102 | 99 | 104 | 105 | 103 |
| % of active studies | 53 | 81 | 84 | 86 | 87 | 89 | 90 |

**Open studies according to type and status**

|  |  |
| --- | --- |
| Type | Number of studies |
| Recruiting site | 84 |
| PIC | 15 |
| other non-recruiting | 1 |
| research database | 3 |
| Grand total | 103 |

|  |  |
| --- | --- |
| Status | Number of studies |
| Active | 16 |
| Awaiting first participant | 25 |
| Recruiting | 40 |
| Follow up | 14 |
| On hold | 9 |
| Grand total | 103 |

**Directorate approved studies**

|  |  |
| --- | --- |
| Directorate | Number of studies |
| Oxfordshire & South West Mental Health | 80 |
| Buckinghamshire Mental Health | 49 |
| Community Services | 5 |
| Specialised Services: Learning Disabilities | 4 |
| Specialised Services: Forensic Services | 1 |

### *Note: some studies will be running in more than one directorate*

### Contracts

The Head of the RMT plays a key role in helping to interpret the legal impactions of potential activities. She is the key contact for Investigators and links with both OUH contracts and the Trust legal team to provide assurance

|  |  |  |
| --- | --- | --- |
|  | FY21 | FY22 (Apr-Jul) |
| Confidentially Agreements | 16 | 4 |
| Trial Agreements | 11 | 1 |
| PIC Agreements | 8 | 4 |
| Collaboration Agreements | 5 | 3 |
| Amendments | 15 | 7 |
| SLAs | 13 | 5 |
| other | 4 | 1 |
| Grand total | 72 | 25 |

### Honorary Contracts

Honorary contracts are required to allow non-OH employed staff to undertake research in the Trust.

There have been delays and confusion recently regarding this process which has identified a need to clarify and simplify its requirements.

The Head of RMT is leading a project to outline a revised process based on a nationally agreed framework to streamline and provide guidance

## Research Informatics (RI)

The RI function plays a key role in the extraction, analysis, and management of research data.

The main areas covered by the team are

* GDPR and information governance
* Extraction and analysis, of data for research and clinical audit purposes
* Managing the CRIS system
* Completion of the NIHR BRC and CRF annual return metrics
* Supporting the development of efficient systems and processes to support research management and delivery

### GDPR and information governance

The Head of RI works closely with the OHFT Head of Information Governance to monitor and support the implementation of Trust best practice in relation to GDPR. This includes reviewing the data element of research studies to identify and mitigate potential risks and identifying where Data Processing Impact Assessments are required.

The review of research studies includes checking the data capture (both direct and indirect) and any processing, storage, transfer, and linkage. Most studies will have been approved by the Health Regulation Authority (HRA) and or a study sponsor, however based on the diligence of the Head of RI a number of studies have required further assurance checks.

Following a recent Digital Strategy Group meeting the Head of RI outlined some of the current limitations our external authorised researchers face in relation to IT, and their subsequent reduced capability to support Trust approved research.

R&D are funding short-term support to try and address some to the issues regarding GDPR and study sponsorship. These issues will need to be addressed to support the expansion of research.

### Managing the Clinical Records Interactive Search (CRIS) system

The RI team use various tools to provide data for research and clinical audit work, these include CRIS

**Oxford CRIS Oversight Group**

The Oxford CRIS Oversight Group is sub-divided into.

* CRIS Operational Oversight Group. A virtual group which reviews all CRIS research applications prior to approval. All linkage projects require approval by the CRIS Oversight Group as well as a Data Protection Impact Assessment (DPIA) and a relevant Data Sharing Agreement
* CRIS Strategic Oversight Group. This group meets four times a year and has a more strategic focus. Its remit includes monitoring the relationship with Akrivia Health, the National Governance Group, CRIS activity and presentations from CRIS researchers

The groups are chaired by the Medical Director and Caldicott Guardian and the voting members include the Head of IG, Patient and Public Involvement (PPI) members and relevant Clinical Service Representation

The Natural Language Processing (NLP) work provides CRIS users with an automatic text reading facility for extracting and providing the context for relevant data currently only available within the free text fields of a medical record. This includes Medications, Diagnosis including the severity, Health Scores, Adverse Effects and Symptoms

**Akrivia Health**

OHFT RI team work closely with Akrivia Health, a company which spun-out of the BRC. The Trust also has a seat on the Akrivia Board.

Akrivia continue to access the high level of expertise within the CRIS team at OHFT and work with them to identify areas of common interest. These include

* Platform Development - OHFT will be involved in reviewing the new CRIS system – the new system is currently undergoing user acceptance testing.
* Consultancy Work – OHFT have delivered a number of pieces of work commissioned Akrivia Health

### Completion of the NIHR BRC and CRF annual return metrics

One member of the RI team supports the production of the finance and activity reports for both the BRC and CRF Annual Returns. This is a contractual requirement and takes places over the period April to June each year. The same team member provides activity data to support capacity planning with the CRF.

### Supporting the development of efficient systems and processes

The RI team support R&D in providing efficient systems and processes, however the time available to do this is limited. As the Trust increases its research activity this is an area which could bring important benefits.

The Head of RI and Head of R&D are members of the BRC digital theme, Trust Digital Strategy Board, and Information Governance Group. They also provide Trust representation on external groups such as the UK Health Data Research Alliance and Health Information Collaborative

## Research Pharmacy

The pharmacy team is a key element of research within OHFT. It currently has 16 trials open for dispensing, a mixture of commercial and non-commercial trials, and 6 in set up. They continue to meet regularly and all QMS criteria are up to date.

They are the central pharmacy for one multi-site trial sponsored by University of Oxford, which involves posting IMP to participants nationwide

The vaccination trials supported during the earlier pandemic are now complete from the pharmacy perspective, and the team are concentrating on getting all trials that were halted during the pandemic restarted according to current restrictions and regulations, opening of the new trials and training of new and existing staff.

The team has struggled with staffing capacity, partly due to the pandemic, so have recruited a further full-time technician which enables our team to be far more robust to staff changes elsewhere in the pharmacy department. Training, procedures, and processes have been put in place for our senior technician to be able to check trial medication, and our newly recruited technician will in time also train for this task, these measures further increase the capacity of our team.

Re Brexit, the transition has created some delays in IMP supply, all of which have been managed so that IMP supply to participants was not disrupted. Going forward further regulation will come into force which should not affect us directly, but we will continue to monitor and manage IMP supply closely.

## Finance & IP Management

### Finance

**Research Income**

The table below shows income received over the last three years along with the FY22 budgeted income.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Research Funding** | **FY19** | **FY20** | **FY21** | **FY22 Budget** |
| Infrastructure | 6.7 | 5.5 | 5.8 | 5.9 |
| Grants | 1.2 | 4.1 | 3.7 | 2.8 |
| RCF | 1.2 | 1.4 | 1.3 | 1.8 |
| Studies | 0.4 | 0.3 | 1.0 | 0.7 |
| CRN | 0.7 | 0.8 | 0.8 | 0.9 |
| Other | 0.4 | 0.5 | 0.4 | 0.5 |
| **Total** | **10.6** | **12.5** | **13.0** | **12.7** |

Infrastructure income has remained fairly consistent over this period. The larger FY19 value included a one-off £1m for CRIS. The fluctuations in grant funding reflects the differing payment profiles on awards over the financial years.

The table below details the infrastructure income

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Infrastructure** | **FY19** | **FY20** | **FY21** | **FY22** |
| BRC | 3.8 | 2.9 | 2.8 | 2.8 |
| CRF | 0.7 | 0.7 | 0.7 | 0.8 |
| CLAHRC \ ARC | 2.0 | 1.7 | 2.0 | 2.0 |
| MIC \ DEC | 0.1 | 0.2 | 0.3 | 0.3 |
| **TOTAL** | **6.7** | **5.5** | **5.8** | **5.9** |

**FY22 Performance**

As at Month 5, R&D reported a small underspend, against a £125k budget. The current forecast assumes a breakeven position at year end, however the treatment of a potential surplus created from vaccine related income is being discussed

**Research Capability Funding (RCF)**

Research active NHS organisations receive RCF to enable them to meet some, or all, of the research-related salaries of their researchers and research support staff. The RCF allocation is based on a percentage of NIHR funding received in the previous calendar year. The FY22 award is £1.85m, split Trust & Dept of Psychiatry (£1.4m) and Dept of Primary Care (£0.45m).

The FY23 Trust & Dept of Psychiatry allocation is estimated to drop from £1.40m to £0.6m.

**CRN Monitoring visit**

Following a visit from the Thames Valley & South Midlands Clinical Research Network Local. Their COO reported having no concerns regarding OHFT’s financial management of their funding

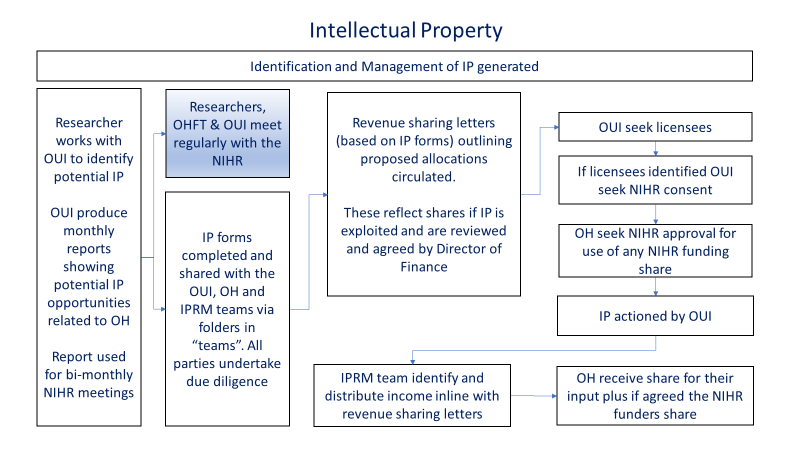
**Leadership**

The Head of R&D is a member of the UKRD finance group which represents 17 organisations across the UK.

He also chairs a small sub-group of 6 Trusts primarily focusing on research income distribution and meets regularly with the Head of Research Finance at OUH.

### Intellectual Property (IP) Management

OHFT has developed an IP Process which is under the control of the Director of Finance. The management process is shown below



For potential IP opportunities arising from NIHR funding, OHFT meet with OUI, the NIHR, NIHR infrastructure managers and researchers on a bi-monthly basis. These meetings provide the NIHR with an update on the current portfolio of IP related opportunities. It also allows them to indicate if they are likely to provide consent to exploit any IP arising

Management of IP is assisted by Oxford University Innovations (OUI) in line with the IP Framework Intellectual Property Agreement. The process has three core elements cores elements.

* Contracting, which is undertaken by OUH contracts under a service level agreement
* Identification and Management, which involves the Head of R&D
* Exploitation, which is manage by Oxford University Innovations under the Framework Intellectual Property Agreement (FIPA)

OHFT are currently exploring with OUI, OU and OUH the possibility of pooling IP related receipts received across Oxford to create a fund (“Turbine Fund”). Researchers will be able to seek support for discrete projects aimed at securing the adoption of technologies in a healthcare setting. Details are being develop and will be shared with the NIHR for approval.

Once the outcome of the BRC and CRF awards are known the FIPA will need to be reviewed. We will look to do this work inline with OUH who have similar arrangements with OUI and the NIHR.

# Research Active Workforce

**NIHR 70@70**

Dr Cathy Henshall was appointed to the NIHR CRN Associate Director of Nursing (interim) position in September 2020. This seconded role involves being Programme Director for the NIHR’s 70@70 Senior Nurse and Midwife Research Leader Programme and leading a robust evaluation of the programme to identify its added value and impact in terms of increasing research capacity and capability in nursing and midwifery research, as well as enabling nurses and midwives to step into research leadership positions. It also involves collaborating with colleagues in national organisations such as NHS-E&I and NHS Engagement to develop strategies, policies and initiatives to embed research into clinical practice.

Other initiatives linked to the 70@70 programme include:

Establishment of Oxford Nursing and Allied Health Professionals Clinical Academic Pathway Development working group. A strategy for developing NMAHP clinical academic pathways was agreed by the Oxford AHP in late 2020. We are currently working with Oxford Health BRC, Oxford Health and Oxford Brookes University with a view to funding two clinical academic NMAHP professorial posts. Postholders research interests will align with the BRC 2’s research themes. Stakeholder involvement includes the Oxford Health BRC Training Lead, OHFT Chief Nurses, the Director of OxINMAHR, OHFT BRC Director, OHFT Chief Medical Officer and the OSNM Director. The strategy aims to enable career pathway progression at pre-doctoral, doctoral, and post-doctoral levels.

A new Oxford & Thames Valley Training Group has been established to pool research training and development resources and make them accessible to early career researchers, with collaborators including the NIHR Research Design Service, Oxford Brookes, OUH, OHFT, the CRF and the two Oxford BRCs.

Bi-annual Academic Writing Retreats for Nurses are co-funded by the OHFT and Oxford BRCs, CRF and OxINMAHR. The last retreat was in April 2021 and was successfully delivered online due to Covid-19. The online retreat evaluated very well and the next one is planned for October 2021. Monthly ‘lunch lab’ clinical research educational sessions for staff are also well established.

Development of an online ‘Research Support Package’ for clinical staff is underway but has been delayed due to Covid-19 pressures. However, the online modules are currently being finalized with a view to launching later this year via the OHFT L&D portal. The two main online modules will be made available to all staff across the Trust.

NIHR James Lind Alliance in Community Nursing: this ARC funded project involves undertaking a priority setting partnership in community nursing to identify the top 10 evidence uncertainties in this area. The two surveys sent out as part of this process were shared with community nurses, patients and carers at a national level. A national steering group, with representation from Chief nurses, community nurses, patients and carers across England was established to guide the process. A final workshop in mid-September will result in the identification of the top 10 evidence uncertainties in community nursing, with project completion shortly afterwards. The process has enabled national collaborations with colleagues at NHS England, the CRN, and NHS Engagement to ensure the research priorities are embedded within the national community nursing agenda. In addition, the NIHR ARC TVSM has committed to hosting a workshop in late 2021 to identify which of the evidence uncertainties can be supported through the ARC in the form of deliverable research projects.

A new Masters level MSc in Professional Practice has been approved and launched in 2021. Dr Henshall is leading the Advanced Research Design module and the module team is made up of experienced research and teaching colleagues across the R&D team. The MSc Programme will be available for all clinicians across the Trust to access through either the Mental Healthcare or Physical Healthcare workstreams. The module will run from October to December 2021.

Over the past year, we have supported two 16-19 year old nurse cadets enrolled on the Thames Valley Nurse Cadets programme, with a view to growing a skilled clinical research nursing workforce pipeline. The band 2 cadets are enrolled on the healthcare worker apprenticeship programme, and work on the CRF four days each week (with one day assigned to study). Following completion of the two year course the cadets can either become band 3 healthcare assistants, enrol on nursing associate training or study for a nursing degree. Our cadets have received mentorship and supervision from the CRF team and have excelled in their roles, acquiring key clinical research skills, benefitting from tailored training and development opportunities and receiving reciprocal support from the wider CRF team.

We have also created secondment opportunities for nurses and allied health professionals working in clinical settings to allow them to spend up to 12 months working within the R&D department. Additionally we are supporting student nurses to undertake their clinical and management placements on the CRF and across the R&D department.

# Collaborations

## Oxford Academic Health Partners (OAHP)

OAHP experienced some constraints during the continued pandemic but remains broadly on track with all its stated objectives. Monthly Board meetings have proved very effective and will continue for the foreseeable future. The partners are currently unpacking specific tasks to deliver mid and long term goals specified at re-designation. The Chief Operating Officer has established a system to monitor operations, and this is now a standing item on the Board agenda.

As planned OAHP support for stage 1 of the BRC renewal process was welcomed. Both NHS trusts were shortlisted in full and work is now underway to deliver to stage 2 in October 2021.

Since the last update, the project to improve data coherence for research and patient benefit has progressed at pace. Reports have been received by several executive and oversight groups. Key deliverables are expected in late 2021.

The Joint Research and Development Committee (JRDC) has received and discussed a statement of the principles required to establish an integrated Oxford joint research office. The necessary updates to governance will follow shortly. This achievement will be fundamentally important as a component of the Joint Working Agreement across the partnership.

Engagement with the Integrated Care System (BOB-ICS) and the Oxford AHSN have been particularly productive. OAHP will contribute to a digital health roadmap facilitating outcomes building on Research and Innovation needs review led for Oxford and the Thames Valley region by AHSN and ARC and also a joint workplan to include:

* Needs assessment and readiness screening
* Identification of stakeholders and test sites
* Evaluation and monitoring (RWE)
* Development of Community Diagnostic Hubs. Target for the first of these Dec 2021

OAHP annual report and case studies [https://www.oxfordahsc.org.uk/wp-content/uploads/2021/08/Paper-4-Oxford-Academic-Health-Partners-AHSC-Annual-Report-2020-2021\_FINAL.pdf](https://protect-eu.mimecast.com/s/ycmaCDq4LijVVKNhWVGSF?domain=oxfordahsc.org.uk)

## Oxford Joint Research Office (JRO)

The OU\OUH JRO has been active for several years and reports into the Joint Research and Development Committee (JRDC) at OU\OUH. The Head of R&D meets with the JRO leads on a regular basis and has had input into their planned objectives.

In August the Head of R&D was invited to join the JRO operational, Heads of Teams group. The next step is for revised JRO Terms of Reference to be agreed by the JRDC with Oxford Health and Brookes becoming members of the JRO, thus meeting one of the objectives of the Oxford Academic Health Partners as mentioned above

## Oxford Institute for Nursing Midwifery and Allied Health Research (OxINMAHR)

### Background

The Oxford Institute of Nursing, Midwifery and Allied Health Research (OxINMAHR) is a unique research institute in the UK with the core aim of producing world-class health-related translational research that will impact upon health and social care delivery and clinical practice.

Our three main Research Centres are:

* **Movement, Occupational and Rehabilitation Sciences (MOReS)** Centre Director: Prof Helen Dawes [hdawes@brookes.ac.uk](mailto:hdawes@brookes.ac.uk)
* **Nursing, Midwifery, Health and Social Care Research** Centre Co-Directors: Prof Eila Watson [ewatson@brookes.ac.uk](mailto:ewatson@brookes.ac.uk) and Dr Mary Malone: [mmalone@brookes.ac.uk](mailto:mmalone@brookes.ac.uk)
* **The Centre for Nutrition and Health Centre Director: Dr Jonathan Tammam;** [**jtammam@brookes.ac.uk**](mailto:jtammam@brookes.ac.uk)

### OxINMAHR Research Governance and Commercial Research Manager

Mr Boki Savelyich has been appointed to the post of OxINMAHR Research Governance and Commercial Research Manager (starts Nov 21). Boki comes with over 15 years of research governance and management experience. He has most recently held a senior management role in a large integrated care NHS Trust, ensuring continuous specialist support for research systems and processes, particularly regarding regulatory duties and Quality Management Systems, operational management, and customised research training.

### OxINMAHR submission to REF2021 Unit of Assessment 3

* Doubling of submission FTE compared to 2014 (n = 25)
* 56 publications of 3\* and 4\* quality submitted
* 3 impact case studies (a) Improving quality of life for people living with and beyond a diagnosis of cancer (Watson et al); (b) Condition Informed Frameworks for exercise and physical activity (Dawes et al), and (c) Children’s missed healthcare appointments and   
  increasing safety: The “Was Not Brought” approach (Appleton)
* 39 PhD awarded in REF period
* 15 page environment statement

### Oxford Health BRC application

OxINMAHR senior researchers are an integral part of 2 nominated BRC themes

* Prevention, population and individual approaches
* Flourishing, Mental Health and Well being

### Oxford Partnership projects

* Oxford Clinical Academic Pathways for NMAHPs
* Pan-Oxford NIHR Clinical Masters Programme (application)
* HEE/NIHR Internships (hosted by OxINMAHR) for 3 years
* OxINMAHR and Institute of Public Care project(s)

### Recent grant highlights

* *An exploration of registered nurses’ experiences and perceptions of patient safety in critical care during the COVID-19 pandemic.* Burdett Trust For Nursing
* *COA allocation - computer-aided vision* (Led By Good Boost Wellbeing Technology). Strategy Board (Innovate UK)
* *Health-Related Quality of Life and Aging: Measuring what Matters to Older People* (with McGill University). Canadian Institutes of Health Research
* *Listen, Share, Hold, Respond* (led by Oxford Health NHS Foundation Trust). NHS England
* *Bionics+: User Centred Design and Usability of Bionic Devices* (with University of Warwick). Engineering & Physical Sciences Research Council (EPSRC)
* *Transforming older adult disability through virtual, peer-led community rehabilitation:* led by MSK charities. Technology Strategy Board (Innovate UK)

### Oxford Health representation of External Advisory Group (for information)

Prof John Geddes and Marie Crofts (or deputy) sit on the OxINMAHR External Advisory Board which meets 3 times a year

## Research Network

**The OHFT research contacts include**

**Berkshire Healthcare**

OHFT continue to maintain a productive relationship with Berkshire Healthcare. We are reviewing where we have similar objectives or complementary interests and are looking to put ourselves in a position to exploit any joint opportunities.

Areas we have shared information on recently are ICO audits, GDPR and Opt-Out

Both Trusts are part of the Buckinghamshire, Oxfordshire, Berkshire Integrated Care System and will work together to align our clinical research priorities with the wider system priorities.

**University Hospitals of Leicester NHS Trust**

OHFT are developing a link with University Hospitals of Leicester, regarding their CRF and in particular opportunities to enhance our EDI work

**Birmingham and Solihull Mental Health Foundation Trust**

OHFT are looking to deliver a study involving Birmingham and Solihull Mental Health FT on a hub and spoke basis.

**Buckinghamshire Healthcare and Milton Keynes**

Both of these local trusts reached out to OHFT to make contact and discuss opportunities within the last six months. This will continue on a quarterly basis

# Risks

Key risks to OHFT are

|  |  |  |
| --- | --- | --- |
| **Risk** | **Detail** | **Potential Impact** |
| Non-renewal of the CRF from Aug 22 | The current award funds OHFT study deliver and support staff | Lack of funding for OHFT employed staff  OHFT are contracted to deliver studies which finish beyond the end date of the existing award funding. |
| Non-renewal of the BRC from Dec 22 | The current award funds OHFT study deliver and support staff | Lack of funding for OHFT employed staff  Loss of staff expertise on the CRIS system |
| Large amount of OHFT participant recruitment from one study | In FY21 the Oxford Monitoring system for attempted suicide recruited 1,067 participants from a total of 2,635 reported for OHFT.  Note: a further 463 people were recruited for the Vaccine trial which is not expected to be repeated | Lower participant recruitment could lead to reduced Clinical Research Network funding |

**Authors and Title:** Dr Karl Marlow Interim Director of R&D

Bill Wells, Head of R&D

**Lead Executive Director:** Dr Karl Marlowe

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*