

**BOD 24/2021**

(Agenda item: 14)

**Report to the Meeting of the  
Oxford Health NHS Foundation Trust  
Board of Directors  
APRIL 2021**

**Research and Development Report**

**For information**

## **Executive Summary**

### **COVID-19**

Most studies were initially put on hold in March and April 2020.

In the summer the NIHR launched the RESTART initiative aimed at reopening studies. OHFT studies were reviewed by a prioritisation panel to ensure they were COVID safe prior to reopening.

### **National Institute of Health Research (NIHR)**

NIHR feedback has been received on the FY20 annual returns for the following awards with no concerns raised.

- Oxford Health Biomedical Research Centre (BRC)
- Oxford Cognitive Clinical Research Facility (CRF)
- Oxford Applied Research Collaboration Oxford and Thames Valley (OxTV) (ARC)
- NIHR Community Healthcare MedTech and IVD Co-operative (MIC)

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

The BRC award has been extended by eight months to allow time for the renewal competition to take place.

The competition will launch on **14 April 2021**, with a submission deadline for Stage 1 applications of the **26 May 2021**. Shortlisted applicants will be invited to submit a full application at Stage 2 of the competition. This stage will launch on **4 August 2021** and will close on **20 October 2021**. Applicant interviews are expected to take place in **April 2022**.

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

In May 2020 the CRF was made available to the Oxford Vaccine Group to support the Oxford-AstraZeneca vaccine trial

In October the Novavax vaccine trial opened at the CRF. This was supported by staff across the region and recruited 463 participants.

The CRF was also used as a vaccination hub by the Trust

In April 2020 the CRF contract was novated from Oxford University Hospitals to Oxford Health

The CRF award has been extended by five months to allow time for the renewal competition to take place.

The funding competition will launch on **23 June 2021**, with a submission deadline for applications of the **29 September 2021**.

Application outcomes are to be announced **mid-January 2022** and the awards will start **September 2022**

### **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.

**Author and Title:** Bill Wells and John Geddes

**Lead Executive Director:** Mark Hancock

- **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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## 1 Introduction

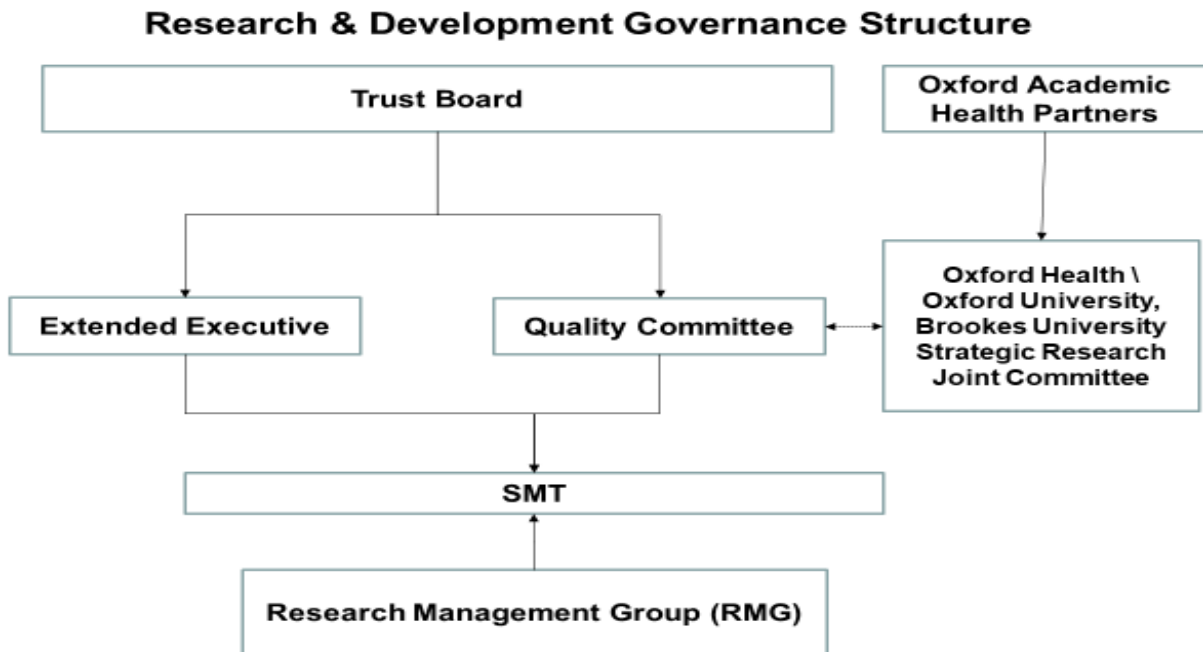
Participation in research produces direct benefits for patients and, more generally, improvements in the quality of care. Organisations can also benefit financially from both cost savings and income generation. Oxford Health NHS FT (OHFT) is a leading research-active mental and community trust with strong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

### 1.1 2021- 2026 Trust Strategy

The latest draft Trust 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.

### 1.2 Research Governance Framework

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



#### 1.2.1 Research Management Group (RMG)

The RMG was set-up some years ago as a high-level committee to drive the collaborative research strategy across the Trust and local areas. Following changes in the governance framework this group will now take on a more operational remit across three areas.

- Operation and Management of 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)

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- Collaboration with local stakeholder – 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)
- Internal OHFT functions – OHFT Community Research, Oxford Improvement Centre (OHI), Research Communications and Finance

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 \ Opt-out
- PPI & EDI

### **1.2.2 Oxford Health\Oxford University\Brookes University Strategic Research Joint Committee**

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

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

## **1.3 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.

### **Covid-19 studies**

#### **Novavax**

Since October 2020, OHFT have 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 recent major amendment we are now being asked to support a Novavax crossover trial design. This change to study design means that participants who received the Novavax vaccine will receive placebo and vice-versa and has been 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 one of only two NHS Trusts in the UK to be supporting the Novavax serology sub-study.

#### **PRINCIPLE**

This priority one urgent public health Covid-19 trial has been 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

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directorate, with support from R&D and is a great opportunity to further embed research within the community nursing teams.

## 2 Research Culture

### 2.1 Staff Survey

Two of the research questions asked to staff as part of the 2020 staff survey were to test their 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.

The survey also provided useful staff comments which we hope to respond to later this year

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%
<b>Total Responses</b>	<b>3,190</b>	<b>100%</b>	<b>2,469</b>	<b>100%</b>

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%
<b>Total Responses</b>	<b>3,247</b>	<b>100%</b>	<b>2,533</b>	<b>100%</b>

### 2.2 Communications

Since our last report in March 2020, R&D communications and engagement has adapted to accommodate the requirements and limitations of COVID-19. There has been significant focus on sharing and showcasing the way research at the Trust and the Oxford Health BRC has responded to the challenges of the pandemic, including mental health impact and our support for vaccine trials. Although some events and activities, such as our planned open day, have had to be postponed, the situation has enabled us to explore virtual events and develop our online presence. Overall there has been good progress in raising the profile of research at the Trust in both external and internal communications. New easy-to-access links to R&D have been created on the OHFT homepage and the intranet and a new dedicated R&D section has been added to the weekly staff news bulletin.

The last twelve months has seen significant growth and improvement in the BRC website. This has included the ongoing development of microsites for specific areas of the BRC's research. A major piece of work was undertaken at the end of last year to build a new microsite for Oxford Dementia and Ageing Research (OxDARE), bringing this under the umbrella of the BRC. The Oxford Precision Psychiatry Lab's microsite has expanded significantly in order to host their evidence-based guidance on COVID-19 and mental health. This important project has also been supported by social media activity and the production of a short film about the project early in the first lockdown.

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We have published 35 online news items over the year covering diverse topics, including a BRC supported event at the Oxford Asian Cultural Centre to mark International Women’s Day, the opening of the Oxford Brain Health Centre, and frequently updated coverage of the BRC’s COVID research. Some examples of stories we have covered are listed on the next page. A major review was undertaken in 2020 to bring the website into line with new accessibility laws. Work on the site’s accessibility is ongoing in advance of further deadlines in September 2021.

Collaboration with communications colleagues across NIHR infrastructure has continued to be central to our R&D communications activity. The two Oxford BRCs have recently entered into a shared agreement with In2Science to mentor disadvantaged young people and encourage them to explore STEM careers. We have just begun work on planning our rescheduled joint open day to take place later this year, either online or in person as guidance permits.

In October 2020 the Oxford Health BRC participated in a series of NIHR online talks as part of the Oxford IF Festival alongside the TVSM CRN, ARC OxTv and the Oxford BRC. Professor Cathy Creswell’s talk on managing childhood anxiety was attended by 224 virtual participants making it one of the two most popular talks in the series. Research was also prominent at the Trust’s first online Healthfest event. The R&D tent was among the five most popular areas of the festival’s virtual site and was celebrated on twitter by Oxford MP Annelise Dodds as a highlight of the event.

Working closely with the Department of Psychiatry communications officer and the University of Oxford press office, we have released a number of key stories to the media. This collaborative approach has enabled us to benefit from the resource and reputation of the University to leverage maximum media coverage. The media release of Professor Paul Harrison’s November paper on COVID-19 and adverse mental health outcomes is a case in point and received widespread coverage across print and broadcast media both nationally and internationally.

Throughout the year R&D communications have been closely involved with planning for the Trust’s introduction of an opt-out approach to research recruitment. A communications plan has been created to ensure that all stakeholders are well informed about the implications and benefits of the new policy and this will be launched when opt-out is rolled out later in the year.

With the approach of the BRC renewal process, we have begun initial conversations with production companies to produce the film required as part of the application. This project will also be collaborative, with the two Oxford BRCs working closely together to create films which remain distinct while highlighting the synergies between the two centres.

The following are some of the stories published on the Oxford Health BRC website:

- [2.2.1 Opt-out approach to research benefits patients and staff](#)
- [2.2.2 Oxford Brain Health Centre celebrates high levels of research participation and positive feedback from patients](#)
- [2.2.3 20% of COVID-19 patients receive a psychiatric diagnosis within 90 days](#)
- [2.2.4 COVID-19 and mental health research at Oxford Health BRC](#)
- [2.2.5 Study to explore mental health benefits of online cultural experiences](#)
- [2.2.6 Supporting mental health and resilience in first responders – operational training is most effective](#)
- [2.2.7 Genetic risk factors for mental illness affect how children’s brains are wired up](#)
- [2.2.8 Lack of comparative data on new therapeutic agents poses a challenge to health care systems](#)

### **3 Research opportunities for Patients**

#### **3.1 Consent to discuss participation in research**

Approval was received from the Executive Management Group and the Board of Directors in March 2020 to move to an ‘opt-out’ system of contacting patients about research. It was anticipated that this change would

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be implemented by September 2020. The COVID pandemic and subsequent shifting of priorities, most notably Oxford Health being the lead site for delivering the Novavax vaccine study locally, resulted in a delayed implementation date.

It is anticipated that this change in research approach will now be launched within the mental health directorate at the beginning of May 2021.

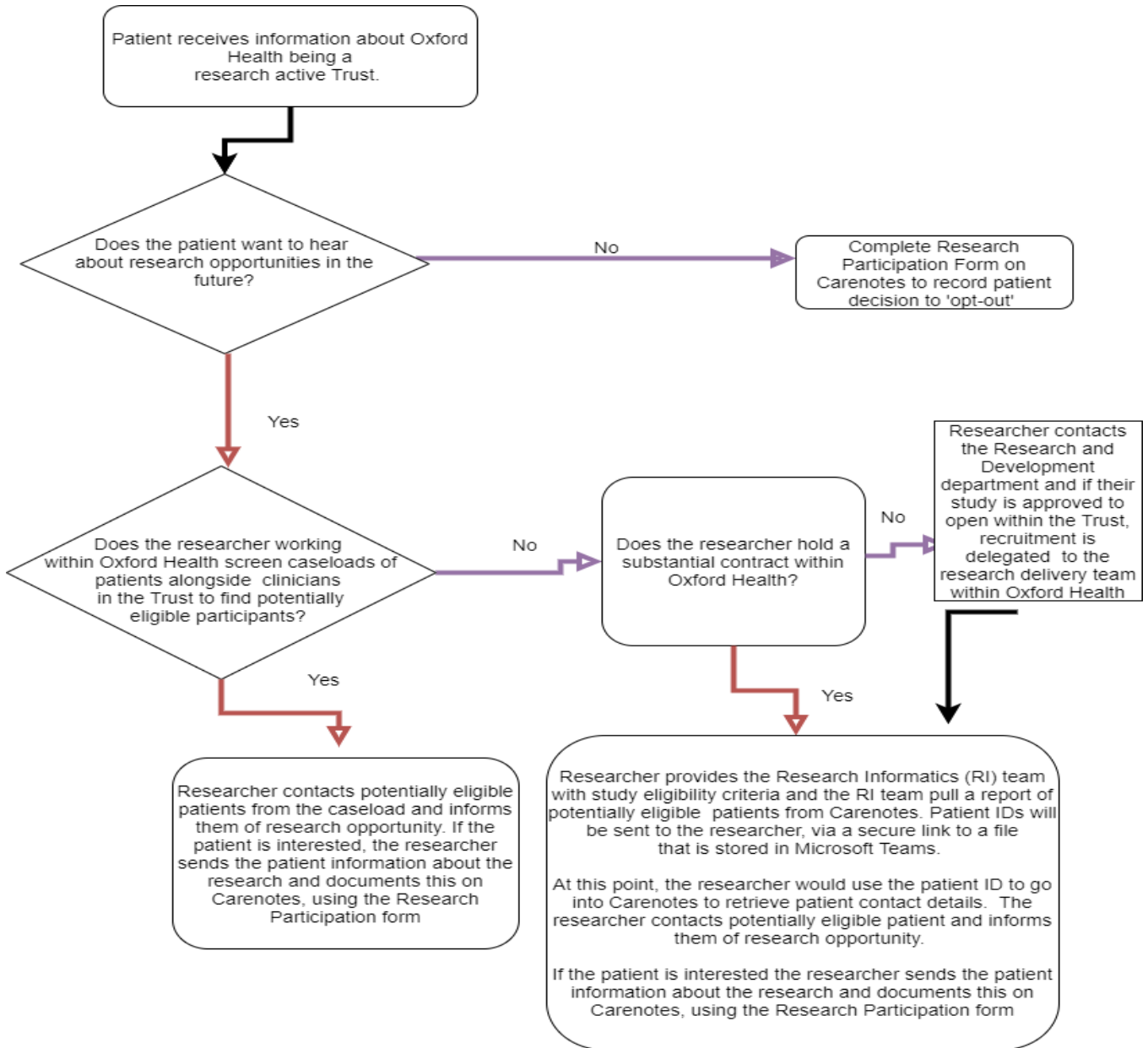
- To avoid confusion with the national, opt-out it was decided that this project shall be launched under the banner of: 'Today's research, tomorrow's care: changing how we inform patients about research'
- A request has been made to amend Trust letterheads with the above strapline, but with the additional sentence of 'For more information see: [www.oxfordhealth.nhs.uk/research](http://www.oxfordhealth.nhs.uk/research)'. It is hoped this will help Oxford Health be seen as a research active Trust
- A new Research participation form is being developed in consultation with the IM&T team that shall be used to capture all patient research activity, including when they 'opt-out'. 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
- Members of R&D plan to attend staff meetings throughout the second half of March and April to brief clinical staff on this project and what this means for patients and staff
- A comprehensive communication plan has been drafted, which includes a campaign across social media channels, press release to local media, news stories on Oxford Health website, a patient facing leaflet (see below), an information campaign within the Trust via the intranet and all staff email to inform staff of the change and equip them to answer questions from patients
- The Trust's privacy statement has been updated and a DPIA has been written, in consultation with the IG lead

It is worth stressing that this change in approach is only about hearing about research opportunities. The decision to take part in research remains entirely voluntary and this shall 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.

It is expected that the 'opt-out' approach will be adopted by the community directorate later in the year, and discussions have already taken place with the Clinical Director.

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The diagram below summarises patient recruitment via the new system



Note: Where a study protocol explicitly states *that screening can only happen by a member of a clinical team*, we would need the study team to submit a minor amendment to allow access to R&D staff to use our opt-out database. Alternatively, a member of the clinical team could email the Research informatics team, to pull a list of eligible participants to screen.

Patient Leaflet



**Today's research,  
tomorrow's care.**  
Take part now to improve care in the future

Research & Development

Oxford Health NHS Foundation Trust is a research active trust.

It is our goal to improve patient care by developing and discovering new treatments and interventions.

Research & Development

As part of your care, we will inform you about opportunities to participate in relevant research unless you ask us not to.

To ensure that everyone who uses our services hears about research opportunities we will sometimes contact you about research you may be eligible to take part in.

You do not have to take part. It is up to you to decide whether to find out more about the research we contact you about.

Research at Oxford Health NHS Foundation Trust

Our research is conducted to the highest standards and is informed by our patients, their carers and our clinical colleagues.



Research studies at Oxford Health look at a range of different conditions, interventions, therapies and treatments. You can find a list of current research studies on our website

<https://www.oxfordhealth.nhs.uk/research/about/trials/>

Being involved in research may involve completing a questionnaire, talking to us about your experiences as a patient, trying out a new medication or testing a new therapy.

2 Oxford Health NHS Foundation Trust | [www.oxfordhealth.nhs.uk](http://www.oxfordhealth.nhs.uk)

Today's research, tomorrow's care.

What if I do not want to receive information about research?

If you do not want to hear about research opportunities, you can tell us:

By telephone: 01865 902013 to leave a message  
By email: [researchconsent@oxfordhealth.nhs.uk](mailto:researchconsent@oxfordhealth.nhs.uk)  
By post: complete and return the below form

I do not want Oxford Health NHS Foundation Trust to access my records or contact me about relevant research opportunities.

Signature

Date \_\_/\_\_/\_\_

Name \_\_\_\_\_

Address \_\_\_\_\_

Post code \_\_\_\_\_

Date of birth \_\_\_\_\_

Once completed, please return to an Oxford Health member of staff involved in your care or post it to:

Research and Development, Oxford Health NHS Foundation Trust, Warneford Hospital, Warneford Lane, Oxford, OX3 7JX

[www.oxfordhealth.nhs.uk](http://www.oxfordhealth.nhs.uk) | Oxford Health NHS Foundation Trust 3

Research & Development

Please contact us if you would like the information in another language or different format.

Arabic يُرجى الاتصال بنا إذا كنتم ترغبون في الحصول على المعلومات بلغة أخرى أو بتسيق مختلف.

Bengali আপনি এই তথ্য অন্য ভাষায় বা আলাদা আকারে পেতে চাইলে অনুগ্রহ করে আমাদের সাথে যোগাযোগ করুন।

Urdu اگر آپ یہ معلومات دیگر زبان یا مختلف فارمیٹ میں چاہتے ہیں تو برائے مہربانی ہم سے رابطہ کریں۔

Chinese 若要以其他語言或格式提供這些資訊，請與我們聯繫

Polish Aby uzyskać informacje w innym języku lub w innym formacie, skontaktuj się z nami.

Portuguese Queira contactar-nos se pretender as informações noutra idioma ou num formato diferente.

Oxford Health NHS Foundation Trust  
Trust Headquarters  
Warneford Hospital, Warneford Lane  
Headington, Oxford OX3 7JX

Switchboard 01865 901 000  
Email [enquiries@oxfordhealth.nhs.uk](mailto:enquiries@oxfordhealth.nhs.uk)  
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### **3.2 NIHR Clinical Research Network (CRN) performance**

The NIHR CRN remains focused on delivering Urgent Public Health (UPH) research in response to the Covid-19 pandemic. As at 5th February, the region had recruited to a total of 34 UPH studies (including 2 non-consenting studies). Several of these are sponsored by Oxford University including the multi-site Recovery, Principle and Condor platform studies. The LCRN is therefore the Lead Network on more UPH studies than other regions and is very closely involved with their set up and ongoing recruitment across the country.

Across the country, the LCRNs have been tasked with developing regional approaches for the delivery of major vaccine and prophylactic trials. A number of these have now been delivered locally and more are at the planning stages. The Novavax vaccine study is of particular note, which was led from OHFT, successfully meeting its recruitment target with a total of 462 participants. Interim results from the trial were published on 29th January 2021 which found that the vaccine was 89.3% effective at preventing the virus, including new variants. The data will now be submitted to regulators for independent scrutiny and product approval.

In terms of planning for 2021/22, the formal HLOs and priorities for the LCRNs have not yet been confirmed but it is expected that there will be an ongoing need to support UPH Covid-19 research for some time whilst also increasing the focus on resuming and increasing recruitment to non-Covid-19 studies as circumstances develop.

#### **3.2.1 OHFT CRN Portfolio Performance February 21 YTD (11 months)**

At the end of January OHFT had recruited 2,301 participants to studies across various specialties.

<b>Specialty</b>	<b>FY20/21 YTD (11 months)</b>
DenDron	26
Mental Health	1,885
Primary Care	2
Stroke	41
Children	3
Health Services Research	3
Public Health	89
Infection	462
<b>Total</b>	<b>2,511</b>

#### **3.2.2 National Rankings**

At the same point OHFT were ranked first in terms of studies open with 39 and 9<sup>th</sup> in terms of the number of participants recruited

<b>Mental Health Trust</b>	<b>FY20/21 YTD (11 months)</b>
Southern Health NHS Foundation Trust	37109
Cambridgeshire and Peterborough NHS Foundation Trust	7044
Nottinghamshire Healthcare NHS Foundation Trust	4523
South London and Maudsley NHS Foundation Trust	4351
Devon Partnership NHS Trust	3066
Tees, Esk and Wear Valleys NHS Foundation Trust	2950
Cumbria, Northumberland, Tyne and Wear NHS FT	2677
Greater Manchester Mental Health NHS Foundation Trust	2518
Oxford Health NHS Foundation Trust	2511

Note: These figures are subject to validation before the year end

### **3.3 Community Directorate**

#### **3.3.1 Developing a Community Research strategy for OHFT**

The ongoing COVID-19 pandemic has demonstrated the need for community research at Oxford Health NHS Foundation Trust to be developed to support patients and clinical staff. This is important as, in 2019, within the Trust’s research portfolio only 1.2% of staff in the Community Services were actively involved in Research, compared with 6-8% in the Mental Health Directorates (2019 OHFT staff survey).

The Community Directorate aims to improve the opportunity for patients to participate in clinically significant research with the ability to improve lives in line with OHFT Trust and the National Institute of Health Research (NIHR) strategic priorities. We also seek to improve our links with other research partners including Oxford Brooked University, University of Oxford, Oxford Universities NHS Foundation Trust, Applied Research Collaboration, Biomedical Research Centres and Academic Health Sciences Network. Our aims are to:

1. To improve the opportunity to participate in research for patients in the Community Directorate
2. To increase involvement in research for staff in the Community Directorate
3. To develop a Community Research portfolio and links between R&D and the Community Directorate

The strategy has been sent to Dr Ben Riley and Professor John Geddes for review, Feb 2020

#### **3.3.2 Governance**

In order to manage Community Directorate research, a strategic management group will meet quarterly to provide organizational oversight, with representation at directorate and board levels. A core operational working group will meet monthly to monitor existing projects and research opportunities. As involvement and engagement with patients, the public, staff, and our research partners are a key objective, six monthly meetings are planned with a wider audience.

Key participants in the Core Group:

Bill Wells	Head of Research and Development
Brandy Coote	Head of Research Management
Cathy Henshall	Head of Research Delivery, NIHR Associate Director of Nursing
Jennifer Potts	Research Engagement Lead (Maternity Leave)
Amanda Colston	Community Research Manager
Pete McGrane	Clinical Director, Community Services
Jeanne Fay	Associate Medical Director, Community Services
Sara McKelvie	Community Ambulatory Medical Lead, Community Research Lead

#### **3.3.3 Community Research Manager**

The team are pleased to announce that Amanda Colston has been appointed as full time Community Research Manager for the R&D department. Her role will include overseeing Covid-19 vaccine trials and managing the Community Research portfolio.

#### **3.3.4 COVID research**

The Trust is currently delivering the Novavax vaccine trial. Delivery was supported within the Clinical Research Facility at the Warneford Hospital with medic and nursing support provided at a regional level. The Trust is a participant identification site for PRINCIPLE working with the Community Nursing Team. The Trust is also participating in Virus Watch.

#### **3.3.5 Projects in development**

Dr Cathy Henshall has been working with the NIHR 70@70 Programme and the James Lind Alliance to deliver a community nursing priority setting partnership. The 70@70 programme is for senior nurse and midwife clinical research leaders with experience of building a research-led care environment for patients, and a record of developing existing practice and contributing to a research rich environment. She has also been working to

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develop Clinical-Academic Pathways for nurses, midwives and AHPS, in partnership with OUHFT, OBU and the BRCs.

Dr Henshall has also received funding to work as Principle Investigator on LiSHORE, an NHS E-funded project with Guy Harrison as project. This project aims to undertake national consultation meetings to explore the unmet needs of BAME workers during Covid-19 to enable recommendations to be made to develop a spirituality toolkit. The project is due to start in April 2021 and OHFT is the Lead site.

Dr Sara McKelvie has applied to Public Health England/Health Education England for training support for BAME volunteers to work within their communities to support Participatory Action Research. The aim of this project is to understand barriers to vaccine uptake in BAME groups. This has been in collaboration with Claire Murray, PPI Lead for the BRC and Head of Inclusion Mo Patel.

Oxford Brookes and OHFT have been collaborating to increase Allied Health Professionals participation in research. This group plans to submit an Expression of Interest to the Elizabeth Casson Trust in May and has a research workshop planned. This work is being led by Dr Sara McKelvie and Sara Bolton, AHP Director at OHFT.

Dr Sara McKelvie and Brandy Coote have been mentoring two Community projects:

- 1) Personality Disorder Positive Outcomes Programme (PDPOP) – An Oxford Health education programme for primary care, delivered by the Complex Needs Service Training unit (TVI) in partnership with Luther Street Medical Centre (Community Directorate) Dr Rob Schafer
- 2) Virtual Pulmonary Rehabilitation – Understanding the effectiveness of virtual pulmonary rehabilitation compared to face to face classes. Chris Swindale, Respiratory Physiotherapist, Integrated Respiratory Team

### **3.3.6 Achievements**

Our 2020-2021 aims were to map out research activity in the Community Directorate, start a Community Research Group and write a Community Research Strategy. These have been achieved. The team have also identified barriers and facilitators to participation in research for staff at OHFT.

Our 2021-2022 aims are to:

- Increase the number of Good Clinical Practice trained staff
- Increase the Community Research Portfolio projects and secondments to R&D
- Improve links with Patient and Public Involvement
- Implementation of the adoption Trust policy of an 'Opt Out' approach to research in the Community Directorate

### **3.4 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
- *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).

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- *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. Currently developing guide for implementation in collaboration with the Research Informatics team
- *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)

## **4 National Institute for Health (NIHR) Infrastructure awards**

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

The Oxford Health Biomedical Research Centre (OH-BRC), a partnership between OHFT and the University of Oxford commenced in April 2017 with funding of £12.8m until March 2022. An additional one-off £1m was awarded in FY19 to provide a sustainable solution to UK-CRIS. The award has recently been extended to Nov 2022 with additional funding of £1.9m.

The hub of the new centre is at the Warneford Hospital site which also houses the University of Oxford's Department of Psychiatry with associated research centres and facilities, and a Clinical Research Facility (CRF) hosting a wide portfolio of active studies for the OH-BRC, the TRUST and the University.

The OH-BRC is a strategic collaboration designed to identify and support the best science to understand the complex problems facing research into mental disorders and dementia, with the aim to translate this understanding into actual, scalable solutions to improve healthcare and to transform our discovery science into new treatments and diagnostic tools, delivering precision care that is strongly informed by patient involvement, ethical and economic considerations.

### **Renewal**

The NIHR BRC funding competition will launch on **14 April 2021**, with a submission deadline for Stage 1 applications of the **26 May 2021**.

Shortlisted applicants will be invited to submit a full application at Stage 2 of the competition. This stage will launch on **4 August 2021** and will close on **20 October 2021**. Applicant interviews are expected to take place in **April 2022**.

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### **4.1.1 Progress towards short term objectives:**

Progress towards mid-long-term objectives:

- The BRC Steering Committee includes strong patient involvement and continues to provide strategic direction and oversight
- Planned an externally chaired, peer-reviewed, mid-term review to ensure the BRC continues to deliver world class research meeting mental health research priorities.
- The BRC Theme Leaders meetings identify collaboration opportunities and facilitate cross-theme funding of staff delivering high levels of efficiency and value for money.
- The BRC has continued to support initiatives within the NIHR Oxford cognitive health CRF, including the development of Treatment Resistant Depression (TRD) clinics to increase opportunities for patients to become involved in translational research.
- The BRC has worked with the CRF to increase the services provided within the CRF to include IV infusions for experimental immunotherapy of psychosis.
- We have scientifically and financially supported the Mental Health Translational Research Collaborative (MH-TRC) to drive effective collaboration in experimental medicine across the UK via the NIHR BRCs, the CRF, NOCRI and a network of similar infrastructures in Wales and Scotland.
- The BRC provided the project lead (Dr Michael Browning) for Treatment Resistant Depression as part of the Mental Health Translational Research Collaborative (MH-TRC).
- The BRC contributed to the Psychosis element of the Mental Health Translational Research Collaborative (MH-TRC).

Progress towards mid-long-term objectives:

- The Oxford Brain Health Centre is now ready to open its doors (the pandemic has temporarily delayed this moment): a joint clinical-research service which will be fully functional in Year 3 (starting in September 2020 and pending additional lockdowns).
- We have developed processes to enable appropriate adoption of research studies to benefit from BRC infrastructure and enable the leverage of additional research funding.
- The BRC has supported 242 studies (156 in year 2, 83 in year 1)
- We have leveraged £12m of project funding in year 3 as a result of the infrastructure and
- We have recruited 12k patients across a variety of studies (5k in year 2)

Longer term objectives include

- Realise our vision of a Brain Health Centre on the Warneford site
- Deliver high level of leveraged funding and value for money from NIHR investment
- Transform research in psychiatry by incorporating the full potential of biomedical concepts and advances.

### **4.1.2 Significant developments in implementing the strategy**

**Alignment and co-location of research and clinical service: an integrated new home for the Brain Health Centre:**

The University of Oxford and Oxford Health NHS FT are working jointly to redevelop the Warneford hospital site as a world class clinical research centre, combining excellence in research and clinical care for people with mental disorders and dementia. The proximity of the site to the University's Old Road Campus – the biggest biomedical research campus in Europe will align and integrate mental health research with the University's research institutes. Harnessing this research power will increase research progress into mental disorders and dementia – as well as tackling key challenges such as multimorbidity

The plans for the development of the Warneford site are continuing apace with the signing of a joint Memorandum of Understanding between NHS, University and Donor and the creation of a Joint Vehicle (JV).

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The JV will develop Warneford Park with integrated clinical services, research, and commercial space – and a new Oxford College.

### **Translation of new targets and methods creating an efficient translational pipeline:**

We continue to work productively across Oxford and with external partners to develop the translational pipeline. A key development – led jointly with NIHR Maudsley BRC - was the development of the NIHR Mental Health Translational Research Collaboration a national network of centres of excellence in mental health translational and clinical research that facilitates collaboration with charities and industry partners. The MH-TRC will build collaborative infrastructure across the NIHR-supported sites in England and equivalent in Scotland and Wales.

### **Creating innovative solutions using informatics, big data and digital technology:**

We have continued to build national collaboration with UK-CRIS, including (in consultation with NIHR) the development of a sustainability plan for this world-leading asset. The spin-out of CRISTAL Health – a new company, now Akrivia Health - was complete in May 2019. We continue to build links with Big Data Institute, Alan Turing Institute and have attracted international leaders such as Prof Stephen Friend (ex-Apple, now Visiting Professor of Connected Medicine) to Oxford. Our local CRIS team

### **Building experimental medicine power by Partnerships and Recruitment:**

Major partnerships with industry are being developed. We continue to build involvement of patients and public in our research. Recruitment and development of staff continues – all three current mental health NIHR Research Professors (Creswell, Freeman, Cipriani) are based in Oxford with Prof Cathy Creswell being recruited in 2019 from Reading to lead development of child and adolescent psychological treatments. Dr Catherine Henshall, Senior Nursing Research Fellow, was successful in the NIHR 70@70 competition and we will use this success to further build academic nursing.

#### **4.1.3 TOP THREE ACHIEVEMENTS OF BRC in 2019-2020**

- Development of The Oxford Brain Health Centre
- Creating a sustainable model for UK-CRIS through spinning out of CRISTAL HEALTH/AKRIVIA <https://akriviahealth.com/about/>. The BRC received NIHR funding in 2018-19 to develop UK-CRIS as a sustainable national platform. Cristal Health Ltd is now a private company, partly owned by the NHS, and works in partnership with the Department of Psychiatry at the University of Oxford. OHFT were allocated equity based on the NIHR investment and the OHFT Director of Finance holds a seat on the Board.
- Development of a sustainable model and business plan for True Colours and implementation in the clinical service and as a standard method of outcome assessment in mental health and chronic physical disorders

#### **4.1.4 Leadership**

- International, independently chaired (Prof Trevor Young, Toronto) mid-term review conducted October 2019 to review progress towards objectives
- OH CEO Stuart Bell retired 2020 (delayed until June because of pandemic) – new CEO Dr Nick Broughton recruited who will chair BRC SC ensuring strategic importance of BRC to OH

### **PROGRESS MADE IN EACH RESEARCH AND CROSS-CUTTING THEME**

#### **4.1.5 RESEARCH THEME: ADULT MENTAL HEALTH, Prof Paul Harrison**

The theme adopted 10 new studies, providing them with advice on statistics, ethics, experimental design, data analysis, and providing infrastructure support on sample processing, and lab assays. We produced 3 new SOPs, and published 58 papers, many in leading journals, spanning the range of the theme's objectives.

A few areas are highlighted here:

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- Mood instability – its basis, correlates and treatment potential: Using UK Biobank we showed its genomic basis and continue to investigate the remote monitoring of mood instability; completed experimental medicine study showing how mood instability and its underlying brain activity vary within/across individuals.
- Calcium channels – programmatic investigation of involvement in mental disorders and as potential therapeutic targets. This topic has remained a central focus of our discovery-to-translation approach. We completed a high-intensity experimental medicine study of calcium blockers. We made important discoveries about brain calcium channels in the brain and are in discussion with a major pharma to take this work further. We are the first to have access to TriNetX, a global electronic health network (66 million patients) demonstrating that calcium blockers affect rates of delirium, neurodegeneration, and depression.
- Autoimmune factors in psychosis. SINAPPS ([www.sinapps.org.uk](http://www.sinapps.org.uk)), an MRC-funded trial of immunotherapy for antibody-positive cases of psychosis continues, and recently passed its interim milestone. It has been found that specific antibodies are associated with a distinct blood metabolome; this is of major mechanistic interest and may be of diagnostic utility.
- Identifying novel psychiatric drug targets. Two new projects have begun. First, the 5-HT4 receptor, with agonists being tested for antidepressant and pro-cognitive properties (in collaboration with the Experimental Medicine theme). Second, we have identified a novel genomically-informed target for schizophrenia for study (see below).
- Multimodal approaches to adult mental health. Our multimodal approach has been enhanced by Professor Helen Dawes, Head of the Movement Science Group at Oxford Brookes University who is now part funded by our theme, enabling us to add her innovative research on exercise and fatigue to our studies.

### **Challenges**

Covid-19 has impacted greatly on all ongoing studies and has led to a significant shift in theme priorities for the coming year as outlined below.

### **Leadership**

The leadership remains unchanged and is well supported by two research managers. The lab manager left last year but was replaced by an experienced person who has fitted well into the role. We have also benefitted from appointment (part funded by our theme) of Parisa Mansoori as Operations Manager of the Mental Health TRC Collaboration. Dr Mansoori has been instrumental in linking our studies with other BRCs and across the TRC. We will shortly appoint a theme Deputy Lead who will help us deliver on the objectives for the remainder of this BRC and the preparations for renewal.

### **Progress of the theme's strategy**

Our objectives and progress were reviewed at the BRC mid-term review in October 2019. All were endorsed and will continue, but there was enthusiasm to increase the emphasis on using genomics and other 'big data' to drive discovery of novel drug targets. This reflects the progress made in the calcium channel work (serving as exemplar), and the great strength in this area across Oxford departments and institutes. We have created a senior research post to take this work forward. The appointee, Dr Arne Mould, started in June 2020 and will work on a new target, and which has already included in the first Psychiatry Catapult grant, involving six pharma companies.

### **COVID-19 RESPONSE**

We are also urgently and substantially modifying our strategy in response to the mental health need of the Covid-19 pandemic.

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- We have established a 'Covid Brain Health Centre', linked to the overarching Brain Health Centre developed by the BRC Ageing and Dementia Theme; This provides Covid-19 survivors a clinical service and a research opportunity.
- We are part of the Covid-19 neurology and psychiatry cohort utilising the NIHR Bioresource.

More COVID-related activities have been initiated but these fall outside the reporting window of this report. To compensate for these two growth areas, the theme will reduce its involvement in the digital and remote sensor aspects of its original objectives. This work still remains at the heart of the BRC, but is now better led from the Digital cross-cutting theme, as described elsewhere.

### **4.1.6 CROSS CUTTING THEME: Clinical research infrastructure and experimental medicine, Prof Cath Harmer**

One of our first objectives was to enhance our capability in leading experimental medicine studies:

- BRC infrastructure has transformed our ability to conduct our core experimental medicine studies and to complete them in a high standard and in a timely manner. This makes us much more attractive to industry. The Theme currently supports 34 studies. Assistance and support for neuroimaging analysis has been provided to 7 ongoing studies, each of which has involved training in the application of state-of-the-art imaging and neuroinformatics techniques, with a focus on reproducible analysis and reporting.
- Our publications and study adoption metrics show a continued increase year on year (publications – 7, 13 and now 23; studies adopted – 14, 23 and now 34).
- We identified the need for a dedicated clinical trials unit to support our early clinical trials. In the last year we have helped to set up the Oxford Brain Health Clinical Trials Unit (OBHCTU). OBHCTU includes a Director Dr Vanessa Raymont, QA manager, statistician as well as bespoke IT and IG support. It also provides an integrated platform for clinical trial managers on specific trials and studies. The OBHCTU obtained ISO 9001:2015 accreditation and Royal Charter status for its quality management system (QMS) in February 2020 and is also in the process of applying for UKCRC registration.
- This increased capacity and capability has allowed us to make good progress on our next objective to validate experimental medicine models across disorders (short term aim) and to implement novel biomarkers in treatment discovery (medium term aim). In particular we have:
- Set up our MRC-Johnson & Johnson funded experimental medicine study characterising the effects of the fast-acting antidepressant ketamine on human emotional processing, to develop experimental medicine models for future treatment discovery (Harmer/Murphy/Cowen)
- Completed phase 2 of our UCB-alliance funding developing novel experimental medicine markers for cognitive impairment in Parkinson's Disease (Harmer/Murphy)
- Completed 2 separate studies examining the impact of noradrenergic transmission (manipulated with reboxetine) and cholinergic transmission (manipulated with rivastigmine) on uncertainty estimation during learning (Browning)
- Completed an experimental medicine study investigating the impact of Pramipexole on a series of learning and decision-making tasks (Browning/Harmer/Cowen)

We have applied experimental medicine models to new treatment discovery:

- In the TIDE study, exploring the effects of a novel anti-inflammatory target for treatment resistant depression, supported by an MRC programme grant (Cowen/Harmer).
- To explore novel treatments for mood stabilisation in bipolar disorder, MRS was used in healthy participants to select a dose of the drug ebiselen that demonstrated target engagement (IMPase inhibition) in the human brain. Subsequently ebiselen was studied in a phase 2a clinical trial in 60 Trust patients with hypomania/mania. Ebiselen was more effective than placebo and is being pursued as a treatment in bipolar disorder in collaboration with an Industrial partner.

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- In the MRC funded RESTART and RESTAND studies exploring the potential for a 5HT4 partial agonist in the treatment of depression using an experimental medicine approach (Harmer/Cowen/Murphy)
- In the IBLT study we have investigated the impact of a computationally defined training intervention on currently depressed patients.
- NIHR EME-funded multicentred RCT looking at the effect of Pramipexole augmentation of treatment resistant depression (PAX-D study; Browning/Geddes/Harrison/Cowen). This includes a mechanistic outcome derived from the experimental medicine study of Pramipexole described above.
- A further key objective was to work to integrate psychological and pharmacological treatment research and to harmonise frameworks and methods for assessment.
- Obtained funding from the Sloane Robinson foundation to explore the effects of combining an antidepressant treatment with a psychological therapy informed by an experimental medicine approach in depression.
- Completed and published a study showing the beneficial effects of combining the NMDA partial agonist d-cycloserine on one session CBT for panic disorder using experimental medicine markers (Reinecke et al 2020)

### **Long term aim:**

to use experimental medicine markers to predict and personalise treatment packages more successfully. We have now finished the final follow up to the Predict study (Browning/Harmer) which compared the effects of antidepressant drug treatment which was either informed (predict group) or not informed by early change (control group) in experimental medicine markers. There was no effect on the primary outcome of change in depression. However, the predicted treatment showed a beneficial effect on anxiety symptoms and on functional recovery (i.e. ability to return to work and everyday function). This provides support for the idea of using experimental medicine to enhance timely treatment response in depression and provides a platform for future studies exploring the effects of different treatments and their combination

### **Leadership**

We hold bimonthly meetings with the leads of the adult mental health, older adults and imaging cross-cutting themes to optimise joint working. We are also part of the informatics theme supported by the MRC pathfinder work and have integrated experimental medicine markers in linkage studies.

### **Challenges faced**

Our midterm review feedback was very positive. However, one referee commented that we could benefit more from the excellent base of preclinical animal science in Oxford (across departments). We have supported a new scheme to provide funding for pilot studies to preclinical scientists to enable this translation and commenced joint meetings to enhance collaboration.

#### **4.1.7 RESEARCH THEME: OLDER ADULT MENTAL HEALTH, Prof Clare Mackay**

Overarching theme aim: Refine and streamline our experimental medicine strategy for cognitive health in ageing.

We have streamlined the subthemes as follows:

#### **Brain Health Centre (BHC) – planned launch (April 2020) postponed due to COVID-19:**

Significant progress towards launch of BHC clinical service includes:

- agreement with CRF that BHC will operate as ‘satellite’ of CRF on clinic days,
- established operational team consisting of Trust and University employees,
- staff training and necessary honorary contracts obtained,
- database, installed within OH IT systems, to track clinical pathway and produce clinical reports developed and tested,
- established NHS MRI safety screening workflow with OUH neuroradiology,

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- delivered talks to clinicians about potential of MRI in memory clinics at Old Age Psychiatry CPD and Clinical Psychology meetings.

Progress of BHC research:

- obtained ethical approval to establish BHC Research Database (RD),
- established BHC RD within OU IT system,
- incorporated existing OxDARE database systems into BHC RD to manage patient re-contact,
- submitted funding applications for harmonisation of BHC and UK Biobank scans (see Cog Neuro theme),
- started qualitative research to assess expectations and experiences of OH clinicians with the BHC.

### **Pharmacological interventions:**

Existing studies: Deep and Frequent Phenotyping (DFP) opened recruitment via TrialSpark platform and UK Biobank participants; PREVENT follow-up visits in progress; recruitment and study visits begun for 'Amyloid Imaging in PREVENT' (AIP) sub-study; Microglial CSF1R in Alzheimer's Disease'

(MICAD) in final set-up, aiming to open in year 4; DPUK GreatMinds has launched and now has over 3000 participants registered; European Prevention of Alzheimer's Disease (EPAD) study closed early in March 2020 due to funding.

Several new large-scale projects are being set up, including 'Brain health through action on insulin resistance' (BEAR), an Oxford study measuring tau accumulation in APOE positive, type 2 diabetic patients receiving GLP-1 receptor agonist; an Oxford site is opening for DPUK Tau PET, acquiring Tau PET imaging in PREVENT cohort; several data-based projects (linked with Informatics theme) underway, e.g. investigating association of anti-inflammatories and Alzheimer's disease (AD). Newly launched Oxford Brain Health Clinical Trials Unit, led by Dr Vanessa Raymont, will support the set-up of pharmacological studies in year 4.

### **Non-pharmacological interventions:**

Existing studies: REtirement in ACTion (REACT) Main study now completed; Mobile Technologies for Assessment of Cognition (MTAC) sub-study follow-up visits complete and data analysis underway; Heart-Brain study started recruitment from Whitehall-II cohort to assess association of cardiovascular health in mid-life and cerebrovascular reactivity in older age; LifeBrain consortium's qualitative research led to Global Brain Health survey aiming to gather large-scale international information about public awareness/interest in brain health.

Several new projects in preparation: ENCRYPT, a Cambridge-run PREVENT sub-study using VR navigation and 7T MRI to study brain regions affected earliest in AD; RADAR-AD, testing remote measuring in amyloid-positive patients with early AD; effects of diet on brain structure and function, and dementia risk measures in UK Biobank.

DPUK has recently been renewed for a further 5 years, including funding for a trial delivery framework to work alongside existing NIHR recruitment and trial delivery mechanisms to deliver the right trial to the right patient.

Patient and Public Involvement (PPI; further details in PPIE section of report):

BHC PPI advisory panel expanded, including patients from OH memory service. The panel provided feedback on BHC patient journey, research questionnaires and cognitive testing. Planned 'mock' BHC appointments with panel members postponed due to COVID-19. Pre- and post-appointment questionnaires developed to obtain feedback from BHC attendees, linking with OH experience and involvement manager and existing patient feedback processes.

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OxDARE conducted wide range of PPIE in year 3: producing COVID-19 guidance for older adults and their families; won Department of Psychiatry award for Public Engagement with Science Communications; more detailed in PPIE. Friends of OxDARE registry continues to support research within this and other BRC themes.

### **Leadership, personnel, strategy, and challenges:**

- Leadership is provided by the theme lead, Gallacher, Koychev, Raymont, Suri
- During year 3, BHC team expanded to include joint clinical-research roles: BHC clinical co-ordinator: OH R&D research nurse; 3 CRF nurses/clinical Ras; Hon contracts for 3 University RA; 2 CRF medics
- New appointments include OxDARE RAs. Two further RAs recruited, starting later in the year.

### **Challenges:**

Participant recruitment/testing postponed due to COVID-19. We look forward to the BHC launch when it is safe to do so in year 4.

### **Major new grants, awards, and achievements:**

- Wellcome Institutional Strategic Support Fund (PI), Open Science Co-ordinator- 2020-2022 £89,600.
- Wellbeing and health research for people with dementia shortlisted for Times Higher Education STEM best research awards.
- Suri was expert witness at House of Lords enquiry on UK Government's healthy ageing policy.
- Theme staff organised several national dementia meetings, including 4th UK Dementia MRI conference (July 2019), DPUK 5-year celebrations (July 2019), EPAD England conference (July 2019).

### **4.1.8 CROSS-CUTTING THEME: Neuroimaging & Cognitive Neuroscience, Prof Kia Nobre**

Short-term: Develop suite of sensitive fine-grained cognitive and imaging measures of brain structure and function

- Continued to develop and refine further sensitive cognitive measures of spatial memory, sustained attention, timing, and emotional deficits, which are currently being applied in a range of patient populations. First phase of testing for theme-developed VR cognitive testing platform is complete, and data is being analysed.
- Recruitment opened for Heart-Brain study (HBS), part of Sana Suri's fellowship. HBS uses multimodal MRI, Doppler ultrasound, arterial pressure measurement and cognitive testing to evaluate emerging role of CVR as biomarker in dementia clinical trials and inform personalised strategies for managing cardiovascular health to delay dementia.

Short-term: Establish apps- and web-based platform for cognitive testing

- Standardized battery of sensitive cognitive measures developed for the Brain Health Centre (BHC) has been piloted in healthy older adults and received PPI feedback from the BHC advisory group.

Short-term: Apply magnetoencephalography (MEG) methods for charactering functional connectivity in brain networks and dynamics of brain states.

- Installation of new MEG Triux Neo scanner, the first of its kind in Europe, with better signal quality and zero helium boil-off, was completed at OHBA in Oct 2019. Using the new scanner, MEG has continued to be applied to clinical populations including mood disorders and dementias. DFP and NTAD (both MEG projects) have begun recruiting participants with mild cognitive problems and healthy controls (HCs). Data collection is complete for the MEG PD study and data is now being analysed.

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- Work is ongoing to establish novel analysis methods for exploring spontaneous and task-modulated features of neuronal oscillations in a range of psychological and clinical disorders. In year 3 we have applied the Hidden Markov Model to describe the temporal dynamics underlying electrophysiological power spectra and are working to apply the Empirical Mode Decomposition to describe the finegrained structure of oscillatory signals.

Medium-term: Applying cognitive-phenotyping tests to large populations for validation and identification of cognitive markers of risk and progression of disorders of mental health

- Manuscript accepted describing the cognitive-phenotyping tests developed by this theme to characterise changes with age, applied to over 2000 participants.
- Data collection has finished for project testing Oxford Biobank participants with mobile phone-based cognitive tests of working- and long-term memory; data analysis is in progress.
- Members of large-scale DPUK GreatMinds (Older Adults) are completing a range of web-and appbased questionnaires/cognitive tests, including CANTAB and Mezurio.

Medium-term: Establish pipeline for integrating imaging measures into clinically relevant tools

- Methods for harmonising MRI measures developed through DPUK by Griffanti (fellowship application) to apply these methods in the BHC, enabling integration of quantitative brain information into enhanced clinical radiology reports. A standardised template including semi-quantitative visual ratings, drafted in collaboration with OUH Neuroradiology and NIHR Oxford BRC Imaging CrossCutting theme will be implemented in NHS radiology reporting systems for the BHC.

Ethical approval being sought to scan HCs using BHC MRI protocol to facilitate use of UK Biobank data as normative data against which to compare individual BHC scans for future quantitative radiology reports.

- Presentations delivered to clinicians, including Old Age psychiatrists and Older Adult Clinical psychologists, about MRI and potential benefits to memory clinics.

### **Leadership, personnel, challenges, and strategy:**

Theme leadership is provided by Dr Nahid Zokaei, Professor Mark Woolrich and theme lead. Key appointments include Pitt (RA NTAD), and Brosnan (post-doctoral researcher)

Challenges:

- Recruitment and data collection for most studies is paused due to COVID, although online testing of several cognitive tasks continues.
- Several regular seminars have been run to promote the theme work: 'Why & How imaging methods meeting', co-organised with the WIN, provides monthly opportunity to share knowledge on novel brain imaging methods, and 'In Translation', involving presentations of current/planned research, highlighting benefits from BRC, and promoting knowledge sharing and collaboration.

The overall strategy remains unchanged, we look forward to continuing the momentum into year 4.

### **Major new grants, awards, and achievements:**

- EU Innovative Training Network - Oct 2019-Oct 2023, €3,966,875 (Oxford ~€300,000)
- Oxford-Berlin Collaborative funding - Jan 2020-Dec 2020, €25,000 (Oxford €12,500)
- WIN Seed Grant – Mar 2020-Feb 2021 – £11, 480

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- Marie Skłodowska-Curie Postdoctoral Fellowship to Dr Méadhbh Brosnan, 2019-2021, €212,934 – Project: Prefrontal plasticity underpinning resilience against cognitive ageing - Nobre: Supervisor and mentor
- German Research Foundation Fellowship to Dr Anna-Katharina Bauer, 2019-2021, ~€60,000 – Project: The role of neural oscillations in cross-modal perception - Nobre: Supervisor and mentor
- Kia Nobre was awarded the 2019 Broadbent Prize, European Society for Cognitive Psychology.
- Theme researcher Professor Mark Woolrich was in the top 1% of the 2019 list of Highly Cited Researchers

### **4.1.9 RESEARCH THEME: PRECISION PSYCHOLOGICAL TREATMENTS (Prof Anke Ehlers)**

Short-term aims:

To build a digital platform for delivering psychological therapies via the internet (a).

To develop and pilot novel internet implementations of a range of psychological therapies developed by the key researchers that have been shown to be effective when delivered as face-to-face interventions (b).

- a. Virtual reality (VR) lab and digital platform for psychological therapies
  - The BRC-funded virtual reality laboratory (Dr. Avitor Rovira) facilitates the use of VR in the treatment of psychological problems. Current projects include Freeman's work on VR in psychosis, Stein's work on parental training, and Murphy's work on binge eating.
  - We have continued to use the platforms for online treatment delivery developed by Clark and Ehlers in Wellcome Trust funded research. We continue to work with two IT companies (FRY-IT and Whiskered Wizard) in maintaining and improving the platforms. In addition, we have worked with another company, Global Initiative, an Oxford based software firm, to develop digital CBTe for binge eating disorder (Murphy and Fairburn).
- b. Development of novel internet implementations of psychological therapies. We have made good progress with developing a range of new online treatments:
  - A therapist-assisted version of digital CBTe for binge eating disorder (Murphy and Fairburn) has been programmed and is ready for piloting.

Freeman's group worked with patients to design a range of new VR interventions for patients with psychosis.

An internet-delivered cognitive therapy for PTSD in military populations (Ehlers, Murray and Wild) is being piloted.

Medium-term aims:

To conduct randomised controlled trials of the new treatments, identify mediators and moderators of treatment response using the large databases and to further enhance the effectiveness of the treatments by refining their content (a).

To develop internet-based therapist training to support dissemination of the programmes.

- a. Randomised controlled trials (RCTs). The theme supported several RCTs of digital interventions:
  - Murphy and Fairburn completed a trial of "Digital CBTe," a novel digital treatment for those eating disorders characterised by recurrent binge eating (i.e., bulimia nervosa and binge eating disorder) and found that binge was reduced by 55%.
  - Leigh and Clark are conducting the OSCA trial of therapist-assisted digital cognitive therapy for social anxiety disorder for adolescents.
  - Freeman's group is running several VR treatment trials. The THRIVE trial of automated therapy for patients with psychosis who have persecutory delusions, focusing on dropping defence behaviours in social situations. The GAMECHANGE trial aims to increase patients' confidence in everyday life with automated VR treatment. The POWER POSING trial found positive effects

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- Ehlers’s STOP-PTSD trial compares the efficacy of internet-delivered cognitive therapy for PTSD, internet-delivered stress management therapy for PTSD, and a wait-list condition.
- Wild’s PREVENT-PTSD trial investigates the efficacy of online resilience training in the prevention of PTSD and depression in student paramedics.
- Analyses to identify moderators and mediators of outcomes: Ehlers and Clark’s group are investigating processes of change in cognitive therapy for social anxiety disorder and PTSD and have completed three studies.

### b. Development of internet-based therapist training

- Clark’s and Ehlers’s groups are developing an online training site for the implementation of effective treatments for anxiety disorders (<https://oxcadatresources.com>). So far, 9921 therapists from 120 countries have signed up for the website, as well as 604 researchers and students.

### Long-term aims:

To roll out the internet-delivered therapies in the NHS and evaluate their effectiveness in routine clinical care and to use the results to further refine the treatments.

- Clark and Ehlers have started a study to disseminate internet-delivered cognitive therapy for social anxiety disorder to NHS Improving Access to Psychological Therapies (IAPT) Services. Adaptations have been made on the basis of results from pilot studies.
- Wild’s resilience intervention for emergency workers is being disseminated throughout England and Wales by the mental health charity, Mind, and modified for other at-risk groups, such as isolated older adults, and families of veterans.
- Espie’s group have made the Sleepio and Daylight apps available to support the health and wellbeing of NHS staff during the COVID-19 outbreak.

### NEW GRANTS:

- The BRC helped support a successful NIHR RfPB application “Sleep Well” study and prestigious Wellcome Trust DPhil Training Fellowship on improving confidence in psychosis in the VR lab
- The theme created a new Clinical Academic post in digital psychological therapies, which is partly funded by the BRC and partly by the Trust’s Improving Access to Psychological Therapies (IAPT) Services. Dr Graham Thew was appointed.
- Dr Jennifer Wild was awarded a BRC Senior Research Fellowship.
- Professor Catherine Creswell was awarded a NIHR Senior Fellowship.

### **4.1.10 CROSS CUTTING THEME: Informatics and Digital Health, Prof Andrea Cipriani**

#### Overview:

In 2019 the theme carried out a critical review and redesign of its organisational structure, content and programme aims, leading to change in leadership, appointment of theme coordinator, subtheme leads were defined, and balanced representation of Trust/University personnel.

Core team reviewed the theme’s projects and decided to focus on high impact projects that met relevant criteria (e.g. Innovation/originality; Oxford leadership; Alignment with Trust digital strategy). Five ‘flagship’ projects were selected and presented to the Trust digital strategy board.

#### Programme aims:

Redefined programme were presented during the BRC’s mid-term review in October 2019, during which Digital theme received helpful and positive feedback. Approach now includes: continuous review of projects;

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increased international collaboration (University of Toronto /CAMH); increased industrial collaboration; Integration of the 3 subthemes to achieve a personalised care approach.

### **Key achievements:**

The UK-CRIS initiative continued to expand its collaboration network, augmenting the dataset and sustainability. 12 NHS Trusts are now in partnership with 2.8m deidentified records. The team was established (and continues to grow) to enhance data management and data science. Current projects are described in the section on UKCRIS, and work is underway to link with True Colours and a national primary care database. CRISal Health Ltd was incorporated in May 2019 with private sector investment. A launch of the company's new brand 'Akrivia Health' was held in December 2019.

Development of the True Colours (TC) programme has continued in both research and service contexts. After a 6-month review programme, relevant stakeholders committed to resourcing True Colours sustainably, involving both Oxford NHS Trusts, with a potential long-term outcome of a spinoff company. New leadership team established with Oxford University Innovation to support TC maintenance and development. Aim is to use TC as digital platform supporting patient care across Trust. TC is being deployed as main method of obtaining patient reported outcome measures across PHOSP-COVID study ([www.phosp.org](http://www.phosp.org)) major UKRI/NIHR funded.

PETRUSHKA is developing an internet-based system to help doctors and patients choose the best antidepressant via innovative statistical and artificial intelligence-based analysis of existing CRIS and QResearch data, considering efficacy, adverse events, patient specifics and preferences.

The aim of the eMOTIVE project is to develop personalised intervention and management tools for patients with mood disorders, incorporating automated analysis of passive data collected from facial expressions and speech.

- Developed both an experimental task and a mobile phone app to capture 3D data on mood whilst preserving privacy.
- Collecting multi-modal data from patients and healthy volunteers,
- Working with the Alan Turing Institute to develop techniques to extract structured information on mood that can inform accurate diagnosis and personalised care. This APFEMA has attracted other external funding.

iSAM is developing a platform of real-world data from children and adolescents, with the long-term aim to prevent and reduce mental health problems. We are working with the Trust to link several data sources to facilitate both research and patient care. We have also collected online survey data from 4450 school pupils in 2019 to inform our understanding of mental health needs in Oxfordshire, have secured external support from Public Health at Oxfordshire County Council to rerun and develop the survey in 2020 and 2021, and are already working with 3 other local authorities to align with their pupil surveys and make the similar data from 4 counties accessible for analysis on a platform.

We are currently using machine learning to further validate blood biomarkers that identify dementia prior to the onset of symptoms. The biomarker has already been successful in 2 independent datasets. Current plans are to test the biomarker in samples collected during past clinical trials, to assess the efficacy of the biomarker as a predictor of treatment response. There are also plans for the biomarker to be incorporated in at least one future clinical trial, as a measure of the biological response to drug treatment, working with clinicians in order to align the work with patient outcomes.

Other key achievements involve close collaboration with the Trust digital strategy board, strengthening the link between state-of-the-art research and patient care. This collaboration has led to development of the trust's policy for inviting patients to participate in research, and better trust alignment for the theme's flagship

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projects. The theme has also recruited a new clinical academic – Dr Dan Joyce - who is currently applying for funding and gathering support within the Trust to develop his ideas for improving patient care, using clinician- and patient-facing apps to structure and visualise clinical data in a meaningful way.

### **4.1.11 PATIENT AND PUBLIC INVOLVEMENT, ENGAGEMENT AND PARTICIPATION**

This report shares progress in delivering the OH BRC PPIE Strategy, highlighting activities related to diversity and inclusion, public involvement in governance, and capturing and reporting on impact.

#### Objective 1: Support

- Projects funded by the 2019/20 PPI Small Grants Programme have reported on the difference PPI made to their study (full details in this report). PPI has influenced across the design of studies including:
  - How studies are advertised
  - Information include in Participant Information Sheets and provided to study participants
  - The design of study questionnaires and tasks
  - New outcome measures
- We launched a series of PPI Research Meetings (November 2019), co-developed with PPI contributors and research staff, to facilitate PPI involvement in research development. Positive feedback has been received from PPI contributors, and researchers have recorded how PPI has influenced their project. E.g. ‘I was able to gain insight into public perception surrounding depression, dementia and pharmacological interventions. This has changed the idea of my future work.’
- Feedback from our experience survey with PPI contributors (December 2019) will inform our PPI training and approach, e.g. offering more remote methods for people to get involved.

#### Objective 2: Training

- We delivered 8 workshops for PPI contributors to support understanding and confidence in the research process, partnering with the Oxford BRC and ARC Oxford and Thames Valley, and in coproduction with a PPI contributor from each organisation. Further information is included in the evaluation report.
- We delivered 2 workshops for PPI contributors and staff on ‘Recording and impact’ (September 2019) and ‘Working with the seldom heard’ (November 2019), in partnership with the Oxford AHSN, Oxford BRC, CRN Thames Valley & South Midlands, and ARC Oxford & Thames Valley.
- We held a PPI workshop for research staff, co-delivered with 6 PPI contributors, and in partnership with RDS South Central, Oxford BRC and ARC Oxford & Thames Valley. The focus was how to work with patients and the public, it was attended by 45 researchers (December 2019).

#### Objective 3: Outreach & Diversity

The PPI theme worked with the Oxford Asian Cultural Centre to co-develop a research engagement event held on International Women’s Day (March 2020). Community participants fed back that it was a positive and safe environment to talk about mental health and try new activities. BRC researchers valued the engagement opportunity. E.g. the Older Adults theme reported it allowed them to tackle dementia myths and introduce dementia research with a new community. We are building on this to develop a wider community engagement plan.

- The NEUROSEC Young Person’s Advisory Group has recruited 23 new members from 12 schools in Oxfordshire (November 2019). Recruitment successfully focused on improving intersectional representation in the Group. We are exploring the development of a digital YPAG that deploys a strategic approach to increasing diversity and participation among under-represented and hard to reach groups.

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- OxDARE (Oxford Dementia Ageing Research) was jointly awarded the Department of Psychiatry's Award for Public Engagement 2019. Activities included:
  - Developing new PE activities e.g. 'wheel of fortune' to motivate discussion topics including dementia statistics, myth-busting and critical appraisal of 'cure' articles.
  - Continuation of Friends of OxDARE registry and quarterly newsletter to 600 members.

The PPI theme is developing an Equality Impact Assessment approach to integrate into future work.

Objective 4 relates to the NIHR Oxford cognitive health Clinical Research Facility, reported separately.

### Objective 5: Governance

- The OH BRC Steering Committee includes a Patient/Carer Representative.
- The PPIE Strategy is delivered in partnership with our Patients and Research Strategy Group (PAR). PAR has nine patient, carer and public members and six staff members. It is co-chaired by a patient/carers member and a staff member.
- In November 2019 we held a facilitated PAR Away Day, where the group reviewed progress towards the PPIE Strategy and identified next priorities, including governance, leadership of PAR, increasing diversity and evaluating impact.

### Objective 6: Research

- The patient/carers and staff co-chairs of the PAR Strategy Group were co-authors with PPI Theme researchers, in 'Co-Production: An Ethical Model for Mental Health Research' (American Journal of Bioethics, July 2019, Volume 19, Issue 8).
- NEUROSEC is developing a normative paper on inclusion and diversity in PPI that will aim to provide guidance to OH BRC researchers who want to conduct PPI in a meaningful and ethical way.
- NEUROSEC is developing two papers on the ethics of partnerships among university researchers, industry, and patients, in mental health research initiatives.

Between April 2019 and March 2020, the PPI Theme provided PPI support to 36 research projects and engaged around 40 patient and public involvement contributors. Examples of two PPI projects are below and further case studies can be found on our website.

#### Brain Health Centre (BHC) (Older Adults Theme)

- Over the last year the BHC PPI Advisory Group activities have included producing 2 questionnaires to collect pre- and post-appointment feedback from BHC patients, and participating in walk-through activities to provide feedback on length, structure and other practical aspects of the BHC clinic appointment.
- The group co-produced a poster about the role of PPI in the BHC, which was co-presented by a member at the Alzheimer's Society Annual Conference 2019.

At each Advisory Group meeting, a 'you said, we did' slide shares steps taken in response to feedback from the group.

#### Oxford Centre for Anxiety Disorders and Trauma (Precision Psychological Treatments Theme)

- A PPI panel made up of 7 bereaved adults supported the development of a study for a new therapist assisted digital intervention for Prolonged Grief Disorder (iCT-PG).
- The panel was involved in the design of the study and gave feedback on preliminary online modules. They co-wrote the plain English summary for the grant, determined the length of the intervention, commented on ethical considerations, and recommended safeguarding procedures.

5.2 Please highlight any significant challenges or barriers experienced, and identifying any areas where you would like further support or information

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- Challenges in delivering our PPIE strategy relate to the lack of guidance or standards around diversity and PPI; and also a lack of guidance around how to measure the impact of PPI. We would also highlight that, whilst being vitally important, building and sustaining relationships with new communities is time and resource intensive.

### **4.1.12 OHBRC EDUCATION and TRAINING programme**

We have now fully established the bespoke training courses that formed the core of the capacity development plans outlined in our application and which were highly commended by the panel. These are the Oxford Course in Experimental Medicine for Mental Health (OxCEMM) and the MSc Taught Course in Clinical and Therapeutic Neuroscience ([www.psych.ox.ac.uk/study/msc-taught-course-in-clinical-andtherapeutic-neuroscience](http://www.psych.ox.ac.uk/study/msc-taught-course-in-clinical-andtherapeutic-neuroscience)). We have been successful in establishing both of these: OxCEMM ran for the second time in January 2020, and the first intake of the MSc will complete their course in September 2020.

- OxCEMM is a short course designed to provide attendees with the practical information they need to design, conduct and analyse experimental medicine studies. Our aim was to attract attendees with diverse backgrounds, and from across the UK. We were successful in achieving both of these aims:  
  
our attendees (39 to date) came from a range of backgrounds, including psychiatrists, nurses, pharmacists, other allied health professionals and basic scientists, and from across England (including other parts of the NIHR infrastructure). Given its success, we plan to repeat OxCEMM essentially unchanged, albeit likely in 2022, given Covid-related constraints on face-to-face courses (see 6.2).
- MSc Taught Course in Clinical and Therapeutic Neuroscience. The MSc is a one-year, full-time taught MSc is delivered by pre-clinical and clinical research teams based in the Department of Psychiatry, in Oxford University centres within the neuroscience community, and in the NIHR Oxford Health BRC and NIHR Oxford Cognitive Health Clinical Research Facility.

Our areas of focus for the coming year are (1) to provide ongoing support for our former OxCEMM attendees, identified as an area of importance during our mid-term review, and (2) to develop a new training course for PPI contributors to provide specific information about research in the area of mental health. Further information about both of these is provided in 6.2.

OH BRC's contribution to increasing clinical academic capacity in nursing/AHP is further strengthened by our support of Oxford Brookes University's Oxford Institute for Nursing Midwifery and Allied Health Research OxINMAHR; <https://www.brookes.ac.uk/oxinmahr/> the only research institute in the UK dedicated to the full remit of healthcare professions, through research and education programmes for nurses, midwives, AHPs and paramedics, biomedical scientists and social workers.

A key priority is to increase Academy members. Numbers have grown year on year, since our BRC's inception. Despite the relatively small numbers, most of our outgoing trainees continue in research, and several have been successful in securing prestigious follow-on-funding

#### **Effect of COVID 19 on programmes:**

The Covid-19 pandemic has significantly affected our training plans. However, we are taking robust steps to mitigate the impact of these. Furthermore, we aim to capitalise on the increased ubiquity of online delivery to increase the reach of our training activities further than is possible face-to-face. Some examples of this are as follows:

1. We had to cancel a single event (a conference focused on the therapeutic use of ketamine) that was scheduled for the beginning of April. However, most of our events are now being delivered online. As well as a lively programme of seminars and workshops, we are running a writing retreat for nurses, in September 2020, and are planning a new training initiative for PPI contributors, currently under development with our PAR group. Since networking and face to face learning is a key component of OxCEMM (see below), we will substitute next year's OxCEMM event for a career

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development event targeting previous OxCEMM attendees. We are developing this with previous attendees to ensure it meets their current needs, although it is likely to focus on grant writing, which they have highlighted as an area of unmet need.

2. Clearly, the research of our NIHR Academy members has been significantly disrupted by the closure of research buildings etc. during lockdown, although the resumption of research activities has been prioritised during reopening. However, we have taken steps to allow our Academy members to continue to make progress during lockdown. For example, during the closure of laboratories, our BRC DPhil student undertaking bench research (Mr Syed Husain) moved onto a bioinformatics project that complements his laboratory work. This has not only allowed him to continue with his research during lockdown but has also enhanced his development by providing training in coding and data analysis that will be of significant benefit to him in the longer term. Crucially, we have worked with our university partners to ensure that, for those studying for formal qualifications, Covid-related disruptions are documented and are considered during assessment.

### Examples of impact of the Education and Training programme

1. OxCEMM was, once again, highly rated by all participants and the feedback was exemplary – all attendees said that they would recommend the course to a colleague. There was particular praise for the

‘hands-on’ nature of the course, for the level of engagement from senior experts, and the level of involvement and engagement from our PPI contributors.

A selection of quotes from participants were as follows: “Inspiring speakers”; “Opportunity to meet others from broad range of research backgrounds”; “Varied content delivered with great expertise - great learning experience” “Inspired to persevere with research work” “Great networking opportunity”

We believe that the success of OxCEMM came from the fact that it was designed explicitly to address an identified need – the lack of cross-disciplinary, practical training in experimental medicine research in the area of mental health. This model of developing new courses and training opportunities in response to need identified by consultation with relevant parties continues to form the basis of our approach to capacity development going forwards.

2. One of our NIHR Academy members (Dr Kirsten Smith) was awarded a prestigious MRC Clinician Scientist award following preparatory support from BRC funds.

Our training and capacity development plans are explicitly collaborative and outward-looking in approach.

OxCEMM was advertised to, and attended by, participants from other parts of the NIHR infrastructure (including several of the other BRCs with an interest in mental health). We aim to continue this model of collaboration in our future activities.

We continue to devote a significant amount of time to liaising with our local (and national) partners to determine how best to pool our resources for mutual benefit. As specific examples, we have partnered with our sister BRC (NIHR Oxford University Hospitals BRC) to offer Senior Fellowships, which provide resources and leadership training for promising researchers. Furthermore, our writing retreat for nurses has been codeveloped, and co-funded by our Clinical Research Facility.

Sharing best practice.

We continue to use a consultative and collaborative model, pioneered in the development of OxCEMM, to identify gaps in training provision and develop new programmes to address these. As an example, as the result of interest in OxCEMM from PPI contributors, we are now developing a bespoke version of OxCEMM for this group, in close consultation with our PAR group

### **4.1.13 LINKS WITH INDUSTRY**

Our overarching strategy is work closely with the life sciences industry to maximise opportunities for

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delivering health benefits and wealth creation. We have continued to build productive relationships across the Oxford ecosystem including Oxford Academic Health Partners (newly accredited AHSC) and Oxford

Academic Health Science Network which support early stage companies locally and promote growth. OAHP has the UK's leading rate and portfolio of spin out companies (~20/year).

We have built a strong strategic relationship with Johnson and Johnson/Janssen focused on experimental medicine and big data. This includes a postdoctoral programme and formal relationships with key leaders - e.g. Lovestone, VP; Disease Area Stronghold lead Neurodegeneration at Janssen retains a part-time substantive post in the Dept of Psychiatry and Manji, Global Head, Science for Minds at Johnson & Johnson is an honorary member of the Dept.

NIHR OH BRC span-out Cristal Health in May 2019, providing a sustainable pathway for the NIHR and MRCfunded UK-CRIS programme. UK-CRIS manages secure access to one of the World's largest repositories of deidentified patient data in mental health and dementia. Cristal Health will facilitate early-stage drug discovery, reduce clinical trial costs, and underpin Phase IV evaluation and pharmacovigilance. UK-CRIS supports NHS Trusts in participation in the global trials market and supports academic research by developing tools to support text-mining to create real knowledge from distributed and heterogeneous data.

Following our mid-term review in October 2019, we launched a refresh of our industry engagement strategy building on our strong relationship with the Business Development Unit of Oxford University Medical Sciences Division. This will help us to align incentives:

- The Commercial Incentive for Industry
- The Research Incentive for the University
- The Service Improvement incentive for Oxford Health (OH)

Older Adult Theme:

New Therapeutics in Alzheimer's Disease (NTAD). This focused biomarker study is funded by Dementias Platform UK and Alzheimer's Research UK in collaboration with industry partners (Lilly, Astra Zeneca & J&J Innovation).

The European Innovative Medicine Initiative supports the European Prevention of Alzheimer's Dementia (EPAD) Longitudinal Cohort Study with funding from a consortium from 39 private and public organisations. BRC adopted Older Adult theme. The EPAD, MICAD, DPUK and DFP projects all have several existing SMEs and large industry collaborators.

In addition, in the last 12 months DPUK has formed new industry collaborations with a non -UK based Pharmaceutical SME Life Molecular Imaging (part of UK-based Alliance Medical Group).

The AIP study involves industry collaboration with Alliance Medical UK, a large UK-based company.

RADAR-AD has several industry collaborators including: Altoida (US-based SME), the Medicines Evaluation Board (large Netherlands-based company), Janssen (large Belgium-based company), Lilly (large US-based company), Lygature (Netherlands based not-for-profit), Novartis (large Switzerland-based company), Software AG (large Germany-Based company), Takeda (large Japanese-based company), The Hyve (Netherlands-based SME).

The BEAR project includes confidential industry collaborators.

The Neuroimmunology Consortium (NIMA), a partnership between academia and industry (GSK, Janssen, Lundbeck) will deliver 2 studies. NIMA has successfully transitioned from part I to part II with funding from Pharma partners, matched with £5m from the Wellcome Trust. NIMA-Alzheimer's Disease part II will be led from Oxford as the sponsor site and will conduct a study of a neuro-inflammation compound in prodromal AD (Microglial CSF1R in AD (MICAD), see section 4 for further details) and a proof of concept study A randomised, placebo-controlled, double-blind trial of the antidepressant efficacy of a novel CNS-penetrant P2X7 receptor

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antagonist, JNJ-54175446, in people with major depressive disorder, an incomplete response to monoaminergic antidepressant drugs, and a biomarker profile predictive of active P2X7 signalling (ATP). Both studies are in set up and are due to open on the CRF in 2020. ATP follows on from the BIOMarkers in Depression (BIODEP) study, conducted on the CRF.

Investigator led (Dr Ivan Koychev) academic/industry (Novo Nordisk) – collaboration for an experimental RCT Brain Health through Action on Insulin Resistance is in set up, the CRF will deliver study activity and provide coordination. This experimental RCT will investigate the effect of Semaglutide vs placebo in APOE4 enriched diabetics, using Tau PET as the main outcome

Collaboration between SME P1Vital and Syndesi with the Experimental Medicine theme of BRC is progressing with a study in the early stages of protocol development will be delivered on the CRF

### **Experimental Medicine Theme**

This Theme is one of several that has strong links with Johnson and Johnson (see above) including an MRC-Johnson & Johnson funded experimental medicine study characterising the effects of the fast-acting antidepressant ketamine on human emotional processing, to develop experimental medicine models for future treatment discovery.

The effects of PF-04995274 on emotional processing in treatment-resistant, medicated depressed patients and the effects of PF-04995274 on emotional processing in un-medicated depressed patients. These studies look at a novel 5HT4 partial agonist in depression and treatment resistant depression. Pfizer provides the drug for this project through the asset sharing scheme and invests their time and experience. A further MRC-Industry collaboration (with J&J) will look at the effect of ketamine in an experimental medicine framework in healthy volunteers and then treatment resistant depressed patients is in set up and will be undertaken on the CRF

Completed phase 2 of our UCB-alliance funding developing novel experimental medicine markers for cognitive impairment in Parkinson's Disease (Harmer/Murphy)

#### **4.1.14 LINKS WITH OTHER NIHR INFRASTRUCTURE**

Oxford NIHR Oxford Health BRC works particularly closely with the NIHR Oxford cognitive health CRF which is now hosted by Oxford Health. The majority of CRF-delivered studies being supported by and adopted under one of the BRC's main themes (e.g. Restart and Restand studies, PREVENT, EPAD, SCOTIA, etc.).

The BRC and CRF partnership also collaborates closely with the wider OHFT R&D and recruitment for most CRF studies is supported by the Local Clinical Research Network (e.g. BI with CACT, Esketamine study, PAX-D, etc.

An example of strengthened collaboration between the BRC, CRF and other infrastructures is the Brain

Health Centre (BHC) which is a joint enterprise between the BRC and the Oxford Cognitive Health Clinical Research Facility. The Older Adults & Dementia and Cognitive Neuroscience and Neuroimaging themes of the BRC are particularly involved but the plan is to extend the BHC across the full BRC. Also links to NIHR DTRC and OUH BRC (consultation with Neurological disorders and Imaging themes).

The BRC's BHC integrates with the CRF, with staff supporting research activity and guiding clinical standards

The BRC has been centrally involved in the development of the NOCRI MH translational research collaboration (MH-TRC) – with our Director Prof John Geddes taking over as Chair of the MH-TRC from September 2020. We also work closely with the Dementia TRC for example via the CRF which provides clinical research study/trial support for NIHR TRC-D/TRC-MH activities. The TRC-D/TRD-MH facilitate multi-site investigations, encouraging collaborative BRC linking activity to DPUK.

MP also attends monthly Research Management Group meetings which include representation from Trust clinical directorates, OHFT BRC, CRF, CLAHRC, MIC, CRN, OUH, UO, OBU, AHSN and OAHP.

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The RMG provides a forum to discuss scientific opportunities across Oxford and provides assurance to the Trust that its host organisation responsibilities are met. The BRC finance manager (BW) was part of the UKRD and NHS R&D Finance group established to outline the potential impact of COVID-19 on UK research capacity. He is also the deputy chair of the OH Applied Research Collaborative (ARC) Management group.

Prof Geddes and the Head of R&D are members of the ARC Strategic Management Board

### **4.1.15 PROGRESS OF BRC-FUNDED RESEARCH THROUGH THE TRANSLATIONAL PIPELINE**

#### Precision Psychological Therapies

The Virtual Reality programme led by NIHR Research Professor Daniel Freeman is a key example of BRC supported research that has created a spin—out company (OxfordVR <https://ovrhealth.com> ) as well as a major study GAMECHANGE <https://gamechangevr.com/team/> funded by NHS National Institute for Health Research (NIHR) invention for innovation (i4i) programme (Project II-C7-0117-20001). See <https://bmjopen.bmj.com/content/bmjopen/9/8/e031606.full.pdf>

#### **True Colours:**

True Colours provides a key example of how a BRC project has progressed through the translational pathway. The True Colours remote symptom monitoring system has seen further development efforts for both research and clinical service contexts.

True Colours has become a standard outcome assessment tool in several NIHR funded trials including:

- the Lithium versus Quetiapine in Depression (LQD) Randomised placebo-controlled trial of Pramipexole addition to mood stabilisers for treatment resistant bipolar depression (PAX-BD)
- PAX-D: Randomised placebo-controlled trial evaluating the efficacy and mechanism of pramipexole as add-on treatment for people with treatment resistant depression NIHR EME 16/127/17 PHOSP-COVID

Following prior work to determine the status, the potential sustainability of True Colours and the formation of a new governing group, including members of the Department of Psychiatry at the University of Oxford, members of Oxford Health NHS Foundation Trust and Oxford University Hospitals an assessment of its potential and needs has been completed and disseminated and a data catalogue and future logging system that outlines detailed information on all existing and prospective research and clinical services instances of the tool

A partnership agreement and governance structure for True Colours been developed between the University of Oxford and Oxford Health and is currently pending signatures

Engagement from Oxford Health has resulted in resources to support a 3rd party Software Development company (Avco) to support the child and adolescent instance of True Colours as one of the primary digital patient reported outcome measures platform within the Oxford Health NHS Foundation Trust.

A new protocol has been completed and submitted as part of an ethics application to IRAS to formally create: 1) a digital consenting procedure for patient True Colours users and 2) a new True Colours research database that will provide a platform for research into the real-world feasibility and acceptability of the True Colours system and digital phenotyping studies, and for patient recruitment into future research studies.

- 2 manuscripts are in preparation to submit resulting from the protocol described above: 1) a research database protocol paper; and 2) a characterization of patient’s symptom monitoring for over a decade.
- Two new clinical trial instances of True Colours were developed. One study has opened, the other is in preparation.

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- True Colours IBD at OUH added a new program for Crohns disease and has spent the year developing a signature-based algorithm for identifying patients most at risk of their condition progressing.
- Multiple fixes and updates were delivered to the Oxford Health CAMHS team True Colours instance.

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

#### **4.2.1 Background**

CRF provides a flexible and integrated neuroscience resource that facilitates the efficient and timely conduct of experimental neuroscience research including high intensity early phase experimental medicine research and early phase clinical trials. The CRF's aim is to be fully aligned with the strategy of OH-BRC and that of OHFT to enable, encourage and facilitate high intensity research working with principal investigators and commercial partners both established and new to achieve this aim.

The primary objective of the CRF is to deliver novel therapies tailored to individual patient needs by breaking down disciplinary boundaries, capitalising 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 and strengthen our collaboration
- **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. This strengthened alliance will lead to increased research opportunities for OHFT patients, as well as cementing the research culture in clinical practice.
- **Long-term objective:** To deliver an efficient translational pipeline fuelled 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. We aim to do so by exploiting existing, identifying, and developing new research opportunities

#### **Renewal**

The NIHR CRF funding competition will launch on **23 June 2021**, with a submission deadline for applications of the **29 September 2021**.

Application outcomes are to be announced mid-January 2022 and the awards will start September 2022

One area being looked into for the renewal is the potential expansion of the CRF and research in general across the Trust through the use of the community services estate. Discussion have taken place recently with the Managing Director of Primary and Community Care Services and members of the Community Services teams

#### **4.2.2 Outputs**

Between Mar 2020 and Mar 2021, 27 studies were undertaken on the CRF.

The NIHR funded 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.

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**4.2.3 Open Studies (as at March 2021)**

Study	Full name	Funding	Disease area	BRC	Phase
EPAD	European Prevention of Alzheimer’s Dementia (EPAD) Longitudinal Cohort Study (LCS)	IMI Joint Undertaking	Alzheimer’s Dementia	Yes	Experimental medicine
PREVENT	PREvention of dementia by ENvironmental intervention and Therapy	Alzheimer’s Society	Alzheimer’s Dementia	Yes	Experimental medicine
Restart	The effects of PF-04995274 on emotional processing in treatment-resistant, medicated, depressed patients	Medical Research Council	Treatment Resistant Depression	Yes	Experimental medicine
Restand	The effects of PF-04995274 on emotional processing in un-medicated depressed patients	Medical Research Council	Depression	Yes	Experimental medicine
PAX-D	A trial evaluating the efficacy and mechanism of pramipexole as add-on treatment for people with treatment resistant depression	NIHR EME	Treatment resistant depression	Yes	Experimental medicine
Esketamine 3008	An Open-label Long-term Extension Safety Study of Intranasal Esketamine in	Janssen	Treatment resistant depression	No	Phase 3
LQD	A trial comparing the clinical and cost effectiveness of lithium and quetiapine augmentation in treatment resistant depression	NIHR Health Technology Assessment (HTA)	Treatment resistant depression	No	Phase 4
Alkermes	A trial to Evaluate the Effect of ALKS 3831 Compared to Olanzapine on Body Weight in Young Adults with Schizophrenia, Schizophreniform, or Bipolar I Disorder Who are Early in Their Illness	Alkermes	Schizophrenia Schizophreniform & Biipolar	No	Phase 3
BI-Cact	A trial to examine the efficacy and safety of BI 425809 with adjunctive Computerized Cognitive Training treatment period in patients with schizophrenia	Boehringer Ingelheim	Schizophrenia	No	Experimental medicine
SINAPPS2	A trial of intravenous immunoglobulins and rituximab in patients with antibody-associated psychosis. Recruiting takes place in OUH, but intravenous immunoglobulin/placebo infusions are delivered at the CRF	Medical Research Council	Treatment resistant psychosis	Yes	Trial
NTAD	New therapeutics in Alzheimer’s disease: MEG biomarker platform development	DPUK and ARUK	Alzheimer’s Disease/MCI	Yes	Observational
DFP	Deep and Frequent Phenotyping; Combinatorial Biomarkers for Dementia Experimental Medicine	MRC and NIHR	Dementia	Yes	Experimental medicine
PAX-BD	A trial of pramipexole in addition to mood stabilisers for patients with treatment resistant bipolar depression	NIHR Health Technology Assessment	Treatment resistant bipolar depression	Yes	Experimental medicine
APFEMA	Analysing patients’ facial expressions to improve mood assessments for people with bipolar disorder or treatment resistant depression	Medical Research Council	Mood Disorders	Yes	Observational
SPEAR	A study of participant’s experience of Alzheimer’s disease – sub-study of EPAD	IMI Joint Undertaking	Alzheimer’s Disease	No	Observational
The ENCRYPT study	Study aiming to identify the initial brain dysfunction in AD by investigating the entorhinal cortex and hippocampus for participants in the PREVENT study	Alzheimer’s Society	Alzheimer’s Disease	Yes	Observational
DPUK	Assessing models of AD risk and progression in Existing Cohorts using Tau PET imaging in combination with prospective follow-up	Medical Research Council	Alzheimer’s Disease	Yes	Observational

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CIAS	A trial to Evaluate the Safety and Efficacy of BIIB104 in Subjects with Cognitive Impairment Associated with Schizophrenia	Biogen Idec	Schizophrenia	No	Phase 2
MICAD	A study to characterise the biomarker effects of the CSF-1 receptor antagonist JNJ-40346527 in participants with mild cognitive impairment	Wellcome and Janssen	Alzheimer's Disease	Yes	Experimental medicine
C9orf72 Cohort Study	A study to characterise motor system dysfunction in established disease, and in gene carriers prior to disease onset by application of multimodal techniques (biofluids, neuroimaging, and neurophysiology).	NIHR/BRC	Motor Neurone Disease	Yes	Observational
C-MORE	A study assessing the effects of Coronavirus Disease (COVID-19) on multiple organ systems and impact on quality of life, functional capacity and mental health	BRC	Covid-19	Yes	Observational

#### 4.2.4 Studies in Set-up

Study	Full name	Funding	Disease area	BRC	Phase
ATP	A trial of the efficacy of a novel CNS-penetrant P2X7 receptor antagonist, in people with major depressive disorder	Wellcome Trust and Janssen	Treatment resistant depression	Tbc	Experimental medicine
SDI-118 phase 1b participants in remission from depression	A trial to evaluate CNS safety and tolerability of compound SDI-118 in participants in remission from depression	Syndesi Therapeutics SA	Depression	Yes	Phase 1b
RADAR-AD	A study to evaluate the performance of remote measurements technologies compared to standard clinical measure of function in mild to moderate AD	European Commission	Alzheimer's Disease		Basic science with human participants

#### 4.2.5 Other activity

During this time period, in response to the Covid-19 pandemic, the CRF also facilitated and delivered its first vaccine studies.

Study	Full name	Funding	Disease area	BRC	Phase
A Phase I/II trial of a candidate COVID-19 vaccine (COV001)	A trial to determine efficacy, safety and immunogenicity of the candidate Coronavirus Disease (COVID-19) vaccine ChAdOx1 nCoV-19 in UK healthy adult volunteers	BRC/UK Research and Innovation	Covid-19	Yes	Phase ½
Investigating a Vaccine Against COVID-19 (COV002)	A trial to determine the efficacy, safety and immunogenicity of the candidate Coronavirus Disease (COVID-19) vaccine ChAdOx1 nCoV-19	BRC / AstraZeneca	Covid-19	Yes	Phase 2/3
NOVAVAX trial	A trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1 Adjuvant in Adult Participants 18-84 Years of Age		Covid-19	No	Phase 3

The CRF hosts two sleep studies which take place overnight and at weekends.

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In collaboration with the Biomedical Research Centre and Oxford Health NHS FT, the CRF has also delivered the 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 part of the **BHC**, 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.

### **4.2.6 Buckinghamshire**

It has also run the following research studies at the Whiteleaf centre in Aylesbury which provides greater opportunities for staff and patients in Buckinghamshire to get involved in research.

<b>Study</b>	<b>Full name</b>	<b>Funding</b>	<b>Disease area</b>	<b>BRC</b>	<b>Phase</b>
Mission AD	A 24-Month Study to Evaluate the Efficacy and Safety of E2609 in Subjects with Early Alzheimer's Disease	Eisai Ltd	Alzheimer's dementia	No	Phase 3
Alkermes	A trial to Evaluate the Effect of ALKS 3831 Compared to Olanzapine on Body Weight in Young Adults with Schizophrenia, Schizophreniform, or Bipolar I Disorder Who are Early in Their Illness	Alkermes	Schizophrenia, Schizophreniform and Bipolar	No	Phase 3
BI-Cact	A trial to examine the efficacy and safety of BI 425809 with adjunctive Computerized Cognitive Training treatment period in patients with schizophrenia	Boehringer Ingelheim	Schizophrenia	No	Experimental medicine / Phase 2

### **4.2.7 Occupancy**

The last year (Apr20-Mar21) occupancy at the Warneford averaged at 71%. In response to the Covid-19 pandemic, the CRF extended its capacity to 7 days / week with extended working hours (7am to 9pm) to allow for both UPH vaccine trials and cognitive health studies to run.

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

### **4.2.8 CRF strategy**

The current award of £3.7m (Apr17–Mar22) included funding to develop CRF activity at OUH but an appropriate location has not been identified, therefore we have adapted to the development of translational neuroscience within Oxford by decreasing focus on CRF activity at the John Radcliffe hospital and developing capability for cognitive health research at the Warneford site (and Whiteleaf).

The CRF will continue to support early phase experimental medicine in cognitive health and it is also expanding its skillset to support trials investigating multimorbidity. During the pandemic we have increased CRF capacity by opening seven days a week, 13 hours a day to facilitate delivery of both RESTART NIHR studies but also an Urgent Public Health Covid-19 vaccine trial (Novavax). We are Lead Site for the Novavax trial with resource input from various other infrastructures in the region (OVG, CRN, etc.) which enabled us to develop tight collaborations and new ways of working. Our workforce and facilities have been used at capacity (and over) during this period to allow for both vaccine and non-vaccine (primarily OH-BRC adopted) to be delivered. This work has been delivered in the context of a high number of strict Infection Prevention Control processes and protocols to mitigate against COVID transmission and protect staff and participants due to the high volume of people going through the CRF (over 100 on some days). Both senior management and frontline staff responded quickly and flexibly to the needs of current research. CRF senior management staff have kept in close contact with clinical services (OHFT) and remain integrated in its response to the second COVID wave. We have also increased our capability for virtual visits and staff meetings and have adapted our sites to mitigate against risk

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of COVID transmission. During January and February 2021, the CRF has also accommodated one of the first OHFT hubs for delivery of deployed vaccines to OHFT staff.

Prof Andrea Cipriani is now CRF Director alongside his position of Associate Director of R&D. He provides oversight to CRF activity, together with Dr Mary-Jane Attenburrow, appointed CRF Deputy Director alongside her role of CRF Clinical Lead. Claudia Hurducas (CHu) has been appointed CRF Manager and R&D Research Delivery Manager and she line-manages the CRF staff. Dr Catherine Henshall is the Lead Nurse for Research and Head of Research Delivery, providing clinical supervision and nursing support to CRF nurses, and line-manages CHu. This management group, together with Bill Wells, Head of R&D, meets weekly to ensure strengthened communication between R&D and CRF, operational oversight of CRF activity and staff, and timely processing of new studies.

The CRF and R&D have reviewed existing protocols and procedures relating to study set-up and governance and developed a streamlined approach which prevents delays in processing requests for Expressions of Interest (EOI) and opening of new studies. CHu centralises, records, and processes all mental health related requests for EOIs to avoid duplication. Studies are then discussed by the wider CRF senior management group and, if deemed feasible, sent to the R&D Research Set-up Support team for processing. Key infrastructure stakeholders (CRF, BRC, Pharmacy, Finance, etc.) meet on a monthly basis to discuss and approve new studies (Pipeline meeting). This process has ensured significantly reduced times for study set-up CRF contracting

### **4.2.9 CRF contracting**

At the time of the first application the CRF contract was between the NIHR and Oxford University Hospitals (OUH) with Oxford Health managing the award. Following agreement between OUH and OH approval was sought and agreed from the NIHR to move the contact from OUH to OH in April 2020.

### **4.2.10 Staffing**

Val Paulley, Senior Administrator at the Clinical Research Facility received the NIHR Clinical Research Network Thames Valley and South Midlands award for Outstanding Member of Support Staff

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

Applied Research Collaborations (ARCs) were established to provide support for applied health and care research that responds to the needs of local populations and health and care systems. Particularly focusing on the challenges of an aging society, multiple long-term conditions and the increasing demands placed on the system. The 15 ARCs consist of local partnerships between NHS providers, universities, charities, local authorities, Academic Health Science Networks (AHSNs) and other organisations which drive implementation to increase the rate at which research findings are put into practice.

### **4.3.1 The key objectives for the ARC OxTV are to:**

- Improve patient outcomes across the Oxford AHSN region
- Lead evidence-based implementation locally, regionally, and nationally
- Provide high-quality evidence of clinical and cost-effectiveness
- Develop new services addressing key NHS and public health priorities
- Improve regional and national capacity to conduct, high-quality world-class health and social care research

The ARC OxTV was funded for 5 years to the value of £9.1 million and commenced in October 2019. The designation of the ARC was conditional with a one-year break clause in the contract. The areas identified in the conditions of funding to be addressed included public health, social care, public involvement, and mental health. The ARC has built on the legacy of the Oxford CLAHRC and has been efficiently established bringing in new themes and expertise. The COVID-19 pandemic dramatically impacted everyone, but the ARC has

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been responsive and the staff have adapted well to new ways of working which has mitigated any risks this would otherwise have posed. The review will happen in April 2021 with a decision being made by July 2021.

The ARC organisational structure and key staff can be found here. The ARC Strategy Board, chaired by Dr Nick Broughton, Chief Executive of the host NHS Trust and Theme Leads, public health and social care ARC member organisations' representatives oversee programme strategies. The ARC Management Group reports into the Strategy Board and is responsible for overseeing the day to day operations of the ARC. It includes ARC Managers, functional leads and supporting staff. The Management Group has recently evolved into a wider Executive Group, chaired by Prof Richard Hobbs, and attended by Theme Leads as well as core staff. This change was the result of feedback from some Theme Leads that they felt somewhat dislocated from the management team since their input had moved to the Strategy Board at the request of the previous Oxford Health Trust CEO.

The core team has expanded to include an Implementation Manager [Sarah Brown 1.0 FTE] and Public Health and Social Care Lead [Dr Bethan McDonald 1.0 FTE initially now 0.4] in addition to the PPI Manager [Dr Claire Schwartz 1.0 FTE], Communications Manager [Gavin Hubbard 0.4 FTE], Training Lead [Dr Katherine Tucker 0.1 FTE] and Senior Manager [Dr Paula Wray 1.0 FTE]. The additional roles, specifically addressing the conditional elements to the award, have increased the focus on:

- public health with a key link to local public health departments and Public Health England which has led to the development of a strategy focusing on local and regional need, including an evolving capacity development programme
- implementation by providing a role that spans the ARC and the AHSN
- expanded role for PPI, focusing on community involvement.

Public involvement runs throughout the ARC with PPI Champions both public and staff in the themes and public members on the Strategy Board to ensure involvement is embedded in the ARC. Additionally, individual project level involvement is ongoing, and we are working collaboratively with the Trusts and other infrastructure organisations to build the reach out in to the population to provide greater relevance and potential impact of our work.

We have secured additional funding to lead the development of a new module for the European Patients' Academy on Therapeutic Innovation (EUPATI) programme on Medical Devices and have developed and started to deliver, with the BRCs, a programme of webinars which are being well received and will provide an ongoing resource. Topics are selected through discussion with PPI members and feedback from public audiences and have included Health Economics, Qualitative Research and How to Find and Read a Research Paper. The webinars are open to all members of the public but have also gained popularity with public health staff.

### **4.3.2 Research Themes**

The highlights from the research themes are presented below. All themes are supported by the Academic Health Science Network (AHSN) through our Implementation Manager to deliver ARC outputs into practice across the region. This relationship is reciprocal with the ARC supporting evaluations of the roll out of initiatives locally, regionally and nationally. Additional opportunities brought to the ARC by the AHSN include:

- RESTORE2 a physical deterioration and escalation tool for care/nursing homes, which is being rolled out nationally and was developed in the South East region, (further information below in Theme 4).
- Theme 6 are supporting the Oxford AHSN to develop a partnership for current and future applications for the NHSX AI Award Evaluations. The ARC can offer methodological and health economics expertise and be part of the wider AHSN team evaluating these new AI technologies. There is the possibility of the ARC supporting the evaluation of Brainomix – a collection of tools using AI algorithms which help guide treatment and transfer decisions for stroke patients.

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### **Theme 1: Disease Prevention through Health Behavioural Change (Theme Lead: Prof Susan Jebb)**

Testing novel implementation interventions at the population level to improve the health of the public and prevent disease and multiple long-term conditions through workstreams to:

Produce a step change in weight management in the community, adapting those to the groups at highest need.

Improve the nutritional quality of food purchases.

The Priorities for Obesity and Weight-related research (POWER): brought together, health care practitioners, local commissioners, and national policy maker, and the public, to identify the top 10 research priorities in obesity and weight related research, providing a vital guide for the future work of the theme and weight management research nationally.

Working with major UK supermarkets: Data sharing agreement with three major supermarkets which is facilitating development of the SwapShop app

Informing national policy around obesity: including:

- House of Common's Health & Social Care Committee - Childhood Obesity Follow-up 2019,
- The House of Lords Select Committee on Poverty, Health, and the Environment report: 'Hungry for change: fixing the failures in food'
- DEFRA's: National Food Strategy.
- Advisory committees and working groups including Public Health England.
- NICE obesity workshops

Television and radio broadcast:

- BBC Horizon – Calories and exercise),
- BBC Truth and Scare,
- BBC Radio Oxford –The dangers of advertising fueling childhood obesity.

Theme 1 have also produced resources for health professionals on supporting patients to reduce their saturated fat and salt based on research completed in the CLAHRC. These documents were also included in the CVD prevention during and after the Covid-19 pandemic (Guidance for integrated care systems) document. This was jointly produced between the Oxford AHSN, Richard McManus from the ARC, Getting It Right First Time programme and the Association of Directors of Public Health. The document highlights the importance of a community-wide system-level approach and the importance of patient self-monitoring and self- management of hypertension, the focus for theme 2.

### **Theme 2: Patient Self-Management (Theme Lead: Prof Richard McManus)**

Using extensive applied research in cardiovascular disease as an exemplar, this theme is developing and evaluating a series of new interventions in patient self-management and prevention of chronic disease.

Home blood pressure monitoring as prevention: Facilitating and planning the roll out of home blood pressure monitoring as a prevention strategy for cardiovascular disease with the global NCD (noncommunicable disease) Alliance.

Working with Oxford AHSN:

- To integrate patient self-monitoring/management as part of the national AHSN cardiovascular disease programme
- To rapidly implement self-monitoring applications, both for women with hypertension in pregnancy (especially during the COVID-19 crisis) and the general population.

Working with global industry partners:

- OMRON—a global medical device company, providing high quality healthcare devices and solutions for home use.

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- Sensyne Healthcare – a clinical artificial intelligence company that connect patients, clinicians, and researchers, to help healthcare professionals deliver better patient care.

### **Theme 3: Mental Health across the Life Course (Theme Lead: Prof Cathy Creswell)**

Linking with the Oxford Mental Health BRC this theme is enabling local and national mental health service providers to provide rapid, effective support for mental health problems through development and evaluation of psychological interventions and by establishing innovative and scalable clinical decision support tools.

School age children's mental health: 19,000 children from 230 schools across the Thames Valley region took part in survey on school's mental health, working with Oxfordshire County Council, East and West Berkshire CCGs and Buckinghamshire Council Public Health team. Additional questions examining the impact of the lockdown were added to inform services and schools as to how best to meet the mental wellbeing needs of school age children - addressing a key priority for local authority Public Health teams. The 2020 preliminary findings are available as a summary report, with more detailed analysis currently being completed. Alongside this study, the team also completed a project with 88 School Mental Health Workers (SMHW) to investigate their experiences of providing support during lockdown and their thoughts around what mental health provision is needed when schools return. The published report is available [here](#). The findings were shared with colleagues at NHSE who lead the Mental Health Support Teams programme, Head of Children, Young People and Families (East Berkshire CCG) and NHS Mental Health Regional Implementation Lead (South East)

Co-SPACE: COVID-19 -Supporting Parents, Adolescents and Children in Epidemics:

- Rapidly response study to tell us how families are coping during the COVID-19 pandemic, and what parents can do to help support their children's mental health.
- Study materials for this online longitudinal survey have been shared with international collaborators in more than 15 countries.
- Co-SPACE addresses the questions of most importance to, Public Health England, Public Health Scotland, Department for Education, and Department of Health and Social Care, amongst others.

Increasing access to psychological interventions: Co-CAT (Child Anxiety treatment in the context of Covid-19) study is comparing an online parent-led programme with therapist support to NHS child and adolescent mental health service/local authority treatment as usual. The trial is currently being run in 42 clinical teams across 20 NHS Trusts and with 245 clinicians across England. The online platform was developed through a co-design and usability approach with parents, children and therapists.

### **Theme 4: Community Health and Social Care Improvement (Theme Lead: Prof Ray Fitzpatrick)**

This theme brings together three research teams with expertise in population health, healthcare improvement and musculoskeletal conditions improvement and in the investigation and evaluation of long term conditions. Its overarching aims is to produce evidence to improve community health and social care.

Evaluation of Family Safeguarding: In response to an urgent local need to reduce the number of children in care, Oxfordshire County Council (OCC) identified the implementation of a new working model of family safeguarding. Working with OCC and partners from key safeguarding areas including Thames Valley Police, Oxford Health and Cherwell District Housing Services and the families themselves, the ARC have developed an ambitious, robust evaluation strategy.

Outcomes Focused Service Development: Evaluation of innovation in social care services: Evaluated the use of digital voice assistant technology to tackle loneliness in isolated older people with Oxfordshire County Council.

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Falls Prevention: This work package will evaluate ways to deliver effective strength and balance training and increase our understanding of what puts an older person at risk of mobility decline and falling. The Oxford, Pain, Activity and Lifestyle (OPAL) cohort study enrolled 5000 older adults to understand when older people are at risk of mobility decline and falling. The OPAL cohort is being used to study the impact of COVID-19 on older people's physical and mental health. Survey responses have been received from 70% of this group providing a wealth of data.

Social Prescribing: Theme 4 research leads are also working with Oxfordshire County Council, Oxfordshire CCG, Public Health England and third sector organisations, to progress work to develop an outcomes framework for evaluating social prescribing.

RESTORE2 (Recognise Early Soft Signs, Take Observations, Respond, Escalate) Evaluation. This is a physical deterioration and escalation tool for care/ nursing homes and the ARC is supporting the evaluation of its roll out and implementation. This work is also building partnerships with Buckinghamshire Health and Social Care Academy and aims to increase evaluative capacity for social care staff through partnership with New Bucks University.

### **Theme 5: Applied Digital Health (Theme Lead: Prof John Powell)**

A new theme for OxTV ARC working to complement the existing Big Data Institute. It is developing and evaluating tools to reduce the variation in healthcare performance by modelling predictive associations between multiple long-term conditions and outcomes to target interventions.

Improving prescribing: Building on the OpenPrescribing platform supported by the ARC, the informatics team rapidly engineered the OpenSAFELY 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. It is now successfully delivering analyses across more than 24 million patients' full pseudonymised primary care NHS records.

Vigilance for patient safety following surgery: Work in collaboration with the NICE Interventional Procedures Programme to maximise the impact of the findings. Working with local surgeons in orthopaedics and urology.

Rapid evidence reviews: Contributions to NICE rapid COVID-19 guidance and the Oxford COVID-19 Evidence service.

COVID-19 data platforms and surveillance: Rapid creation and expansion of a data platform for disease surveillance and trials (ORCHID), is making huge contributions to the COVID response. ORCHID is now supporting some of the main UPH national priority COVID-19 studies, such as the 1a UPH badged PRINCIPLE Platform Trial, RAPTOR diagnostics trial, and community COVID surveillance.

### **Theme 6: Novel Methods to Aid and Evaluate Implementation (Theme Lead: Prof Rafael Perera-Salazar)**

Our cross-cutting theme is providing access to expertise in health economics, medical statistics, computing science and qualitative methods across the ARC and supporting the AHSN and other partners.

Evidence synthesis of pragmatic step-wedge design studies – reviewing the current available evidence around the use of the step-wedge approach (pros and cons) and provide information to support the delivery and analysis of studies using these designs.

Expert statistical support: Providing statistical support to both ARC OxTV studies and partners.

Expert methodological support: Advising ARC OxTV researchers and partners on the best methodological approaches for their intended aims before a study is set up.

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### **4.3.3 NIHR Annual Review**

NIHR made a virtual site visit on the 6th of November 2020. While there was no official feedback, verbally they were happy with the progress made and we did get the following from Val Mann at Central Commissioning Facility 'We appreciated the updates and presentations in relation to progress against the conditions of award and enjoyed the discussion with the theme leads.

### **4.3.4 Staffing**

The staff team remains the same. We have secured part funding for the Public Health & Social Care lead role from Public Health England. The management team is committed to underwriting part of the staff costs where opportunities arise. The ARC will be recruiting a Deputy Director during the course of this year as part of our succession planning.

### **4.3.5 National Priorities and Responsiveness**

In addition to Prof Susan Jebb (theme 1 lead) being the national lead for the cross-ARC collaboration on Behavioral Science. The ARC OxTV previously bid to lead the National Priority on Person Centred, Integrated Care was unsuccessful however the ARC is currently supporting the following National Priority Areas.

- Health Inequalities
- Prevention
- Multimorbidity
- Child and Maternal Health
- Social Care
- Mental Health

£109,000 was awarded to Theme 4 from the Social Care Priority funding. There are currently funding applications in for at least three of the other areas and opportunities to collaborate on projects across them all.

£125,000 additional funding was provided for each ARC to support the work of the Beneficial Change Network and we are working closely with the AHSN to establish a work programme that links strongly with the ARCs and AHSNs in the South East as well as the whole ARC network. The aim of this funding is to provide NIHR ARCs with additional support and capacity to work in partnership with their local AHSN on activities to prioritise 'Beneficial Change' requests in each region to a manageable number, synthesising and sharing existing evidence, identifying potential evidence gaps and defining questions for further research and/or evaluation.

### **4.3.6 COVID – 19**

Initially, the ARC OxV supported the release of clinicians to help with the emergency response to a new public health crisis, we then supported key COVID-related studies in a strategic and sustainable manner, which we continue to do.

In addition to other COVID-related activities mentioned throughout this report the following lists some of the more 'behind the scenes' work of the ARC OxTV:

- The PRINCIPLE trial: one of the initial three government priority treatment trial:
  - ARC supported rapid development of a platform website, working closely with partners at funders, government and test sites on coordinating publicity and media.
  - ARC communications support was instrumental in the design and distribution of clinician and patient recruitment materials for the PRINCIPLE study; materials which continue to be used nationwide.
- CONDOR study: a national platform for COVID-19 diagnostic testing.
  - Rapid development of the platform website and

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- Coordination with partners and funders (including the CCF) on media and press releases.
- The Oxford RCGP Clinical Informatics Digital Hub (ORCHID):ARC funding along with its Digital Health theme worked in partnership with the Royal College of General Practitioners (RCGP), to support the rapid engineering of a new national primary care digital platform.  
This provides a secure, scalable, and resilient digital database which:
  - Supports the PRINICPLE trial
  - Supports RAPTOR C-19 (part of the CONDOR series of studies)
  - Supports RCGP community surveillance projects (including seasonal Flu and COVID-19),
  - Provides a clinical informatics hub.

### **4.3.7 Capacity Development**

The OxTV ARC plans to significantly enhance academic capacity for applied health research through its development and training opportunities for researchers, clinicians, public health and social care practitioners and allied health professionals. We are working closely with Oxford Institute of Nursing, Midwifery and Allied Health Research and hosted a joint workshop to understand the local needs for capacity development. The recommendations from this have led to a joint plan being developed and presented to the Oxford Academic Health Partners to progress locally. The event also led to the development of stronger relationships between the two organisations, including on projects such as the ARC supporting a James Lind Alliance (JLA) Priority Setting Partnership (PSP) on Research priorities for Community Nursing.

Initiated and planned capacity development initiatives include:

- Research Studentships (pre-doctoral) in each research theme
- Two-year development of a programme of resources for Public Health practitioners supported by Health Education England funding (£20,000)
- Health Education England Funded Internships and bridging grants for pre and post-doctoral allied health care professionals and other non-medical staff. (£40,000)
- Provision of supervision for MSc candidates who choose to do their dissertation on evaluation- or implementation- related research projects

### **4.3.8 Metrics summary**

- 37 Projects supported by the ARC
- Across six research themes, all working on national and local priority areas identified either by the NIHR or by direct engagement with local partners and other stakeholders.
- 8 New COVID Projects
- ARC OxTV responded rapidly to the changing circumstances and research needs brought about by the COVID-19 crises, working to identify key areas of important for applied health and care research during the initial pandemic and beyond.
- 2 National Priority COVID-19 Projects
- ARC OxTV was quick to support the national priority PRINCIPLE trial, providing vital infrastructure support to enable this study to get it off the ground and running in near record time. The ARC was also instrumental in supporting the initiation of CONDOR platform, providing communication and technical expertise.
- £1.51m – External funding received and leveraged in the first six months
- Across all six themes, from Research Councils, Charities and other sources.
- Postgraduate students (DPhil) started
- 116 Publications produced

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

### **4.4.1 Industry consultations**

We have continued our industry engagement work during the pandemic, although meetings have all been virtual and there has been a marked shift toward support and engagement with companies developing diagnostics for SARS-CoV-2.

The MIC is working with the administrators of the Longitude Prize (Nesta) to support prize applicants and the selection process for Prize winners in collaboration with the other IVD NIHR MICs (<https://longitudeprize.org/challenge>).

### **4.4.2 Selected Publications**

- McLellan J, Bankhead CR, Oke JL, Hobbs FDR, Taylor CJ, Perera R. Natriuretic peptide-guided treatment for heart failure: a systematic review and meta-analysis. *BMJ Evid Based Med.* 2020;25(1):33-7.
- Hayward G, Verbakel JY, Ismail FA, Edwards G, Wang K, Fleming S, et al. Non-contact infrared versus axillary and tympanic thermometers in children attending primary care: a mixed-methods study of accuracy and acceptability. *Br J Gen Pract.* 2020;70(693):e236-e44.
- Kamfose MM, Muriithi FG, Knight T, Lasserson D, Hayward G. Intravenous Ceftriaxone Versus Multiple Dosing Regimes of Intravenous Anti-Staphylococcal Antibiotics for Methicillin-Susceptible *Staphylococcus aureus* (MSSA): A Systematic Review. *Antibiotics (Basel, Switzerland).* 2020;9(2).
- Verbakel JY, Richardson C, Elias T, et al. Clinical Reliability of point-of-care tests to support community based acute ambulatory care. *Acute Med.* 2020;19(1):4-14.
- Ordóñez-Mena JM, Fanshawe TR, Butler CC, Mant D, Longhurst D, Muir P, et al. Relationship between microbiology of throat swab and clinical course among primary care patients with acute cough: a prospective cohort study. *Family practice.* 2020;37(3):332-9.
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### **4.4.3 Selected Events / Engagement**

- The Oxford MIC led a team from the CONDOR collaborative team that attended the COVID-19 Taskforce meeting of the British In-Vitro Diagnostics Association during which early learnings from the CONDOR SARS-CoV-2 diagnostics projects were presented and discussed.
- The Oxford MIC took part in a CONDOR PPIE event convened by the CONDOR PPIE Chair (York and Humber AHSN). Dr Philip Turner and colleagues from Leeds and Newcastle delivered a presentation to explain key diagnostic performance metrics to public representatives.
- The MIC has established a new PPIE group in collaboration with the Oxford University Hospitals Academic Centre for Urgent and Emergency Care, which will support the work of Professor Dan Lasserson.
- A large number of scientific meetings have been cancelled or transitioned to online only events.
- MIC researchers attended and presented at the MEMTAB (Methods for Evaluation of medical prediction Models, Tests and Biomarkers) meeting virtually on the 10th and 11th of December; the team had originally planned to attend the meeting in person in Leuven.

### **4.4.4 Recent funding / bids**

- The MIC supported a collaborative bid for NIHR i4i funding with colleagues from Population Health and Oxford Brain Diagnostics to quantify the potential impact of early detection of dementia (including Alzheimer's Disease). The project has been funded and will begin shortly.

### **4.4.5 Selected Projects**

- MIC staff have supported the development of MHRA target product profiles for SARS-CoV-2 diagnostic tests.
- Professor Gail Hayward led the development of the COVID-19 National Diagnostic Research and Evaluation Platform (CONDOR) protocol which received Urgent Public Health approval as Co-Chief Investigator with Professor Rick Body of Manchester DiTA. The collaborative was subsequently funded by the NIHR, British Lung Foundation and Asthma Research UK for £1.4m (<https://www.condor-platform.org/>).
- The platform is examining the analytical, clinical and usability of new diagnostic tests for SARS-CoV-2.
- Oxford is leading the Rapid Community Testing for COVID-19 (RAPTOR-C19) clinical evaluation of diagnostics in community clinical settings element of CONDOR which includes national testing centres (CI – Professor Richard Hobbs). The RAPTOR-C19 protocol has been registered in the ISRCTN registry (<https://www.isrctn.com/ISRCTN14226970?q=&filters=ageRange:Mixed&sort=&offset=7&totalResults=628&page=1&pageSize=10&searchType=basic-search>). Two SARS-CoV-2 point-of-care diagnostic tests are under evaluation in approx. 25 community sites across England with the support of the CRNs. Community sites include general practices and community hot hubs.
- The EU IMI-funded Value Dx project, led by Professor Chris Butler, is focusing on the identification of value indicators and barriers to the adoption of diagnostics, with the objective of reducing AMR in community-acquired acute respiratory tract infections (<https://value-dx.eu/>). The consortium has been working to adapt the project with respect to the novel coronavirus SARS-CoV-2. The Value-Dx (<https://www.imi.europa.eu/projects-results/project-factsheets/value-dx>) project PRUDENCE trial led by Professor Chris Butler is currently in set-up.
- Our EPSRC funded project to develop a non-invasive device for the collection of urine from paediatric patients has been continuing in the Department of Engineering but has been restricted to theoretical work given ongoing lab access restrictions and a pause due to staff maternity leave. The project will continue shortly.
- The CARMEN II (official name to be determined) project will begin in 2021. This project is funded by NHSE and will build on the CARdiovascular disease management in patients with severe MENTAL

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Illness pilot (see refs 12 and 13 above) which aimed to determine the impact of the introduction of point-of-care testing for HbA1c and lipids into mental health outreach services on the completion of health checks in this patient group. The pilot was limited to a small number of sites in Oxfordshire and Buckinghamshire. CARMEN II will introduce point-of-care testing into mental health outreach / early intervention services in the whole of the South East region, with the South West region used as a comparator.

- Our project to determine the effect of point-of-care CRP testing on antibiotic prescribing in out-of-hours primary care services is in the data analysis stage. This project will compare antibiotic prescribing in intervention (point-of-care CRP) and control sites (regionally and demographically similar sites).
- Our project concerning the sufficiency of point-of-care testing for diagnosis of malaria in at-risk children in paediatric ED is currently in the data collection phase. This retrospective study will use data collected from individuals who received both point-of-care and laboratory reference standard tests for malaria to estimate the diagnostic performance of the point-of-care tests used. This project is being led by our Acute Paediatrics clinical theme with support from the MIC methodology group, with data contributed to the project by a number of hospital trusts via the PERUKI (Paediatric Research in the UK and Ireland) network.
- The MIC has experienced disruption and delays with a number of projects:
- The EIT Health ADVANCE project for the evaluation of a novel diagnostic test for UTI in primary care has been closed as a result of the pandemic (EU funding cannot be carried over into 2021). The team has paused the study officially with ethics whilst we seek an alternative source of funding to complete the project.
- The NIHR-funded Asthma Breathing Record Study has been delayed by the pandemic.
- A number of potential projects have not been progressed at present due to concerns associated with the pandemic:
- The MIC has been contacted by two companies that have developed novel diagnostic tests for influenza. We had hoped to conduct a clinical evaluation of the test during the flu season 2020, however we have recommended that the companies delay the evaluation until the situation with COVID has reached a steadier state.

### **4.4.6 Staffing**

- Professor Dan Lasserson, MIC Clinical Theme Lead for Acute Adult Ambulatory Care has move from the University of Birmingham to the University of Warwick. A variation to contract has been granted by the NIHR and the Trust is working with the contracts team at Warwick to incorporate Warwick into the CA.
- The MIC has recruited a new statistician to support the work of Professor Perera's Methodology theme. Dr Lazaro Mwakesi joined the MIC from Imperial College London in January 2021.
- In collaboration with the team of Professor Lennox (Department of Psychiatry), the MIC has supported the process to recruit a new clinical researcher to support the implementation and evaluation of POCT to improve the physical health of patients with severe mental illness (MIC Long-Term Conditions theme).

## **5 Leadership and Management**

### **5.1 Board feedback**

Prof John Geddes (Director of R&D) and Bill Wells (Head of R&D) attended a board seminar in January 2021. The key outcomes were to.

- Adopt a revised the governance structure
- Keep the Board more informed about research

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- Support the Board in developing its strategic objective to “Become a leader in healthcare research and education”

### **5.2 Staffing & Estates**

#### **5.2.1 Staffing**

The key staff change over the past year were

- Claudia Hurducas appointed as Research Delivery Manager and CRF Manager
- Dr Cathy Henshall was appointed to the NIHR CRN Associate Director of Nursing (interim) in Sep 2020
- R&D have identified short-term funding to provide a Research Delivery Manager to support Community Services (non-mental health) research opportunities

#### **5.2.2 Estates**

Pre-Covid, R&D was looking to identify more admin space; however, we will now be reflecting on lessons learned over the last year and review the space required. This will also inform requirements for the Warneford redevelopment.

A group has been formed to identify opportunities to expand clinical research across other Trust locations. This will help to grow research and provide wider access to research for participants

### **5.3 Research Management Team (RMT)**

#### **5.3.1 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 study data via Studyline

#### **5.3.2 Set Up**

Despite the pandemic the research management team have continued to open studies

Year	Number of Studies
Opened 2018-2019	41
Opened 2019-2020	52
Opened 2020-2021	44
<i>Currently in Set-up</i>	25

#### **5.3.3 Study Management**

Once given approval to open by the Associate Director of R&D the RMT monitors all studies for amendments, to ensure data held is up to date and the number of participants reported for the Trust is accurate. In March 2020 the vast majority of studies were put on hold due to the pandemic. The RMT played a critical role in reviewing that studies were Covid safe before allowing them to reopen. This required the interpretation and implementation of the national RESTART guidelines.

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

	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Active	51	50	53	53	60	71	69	70	81	90	85
on hold	44	44	43	43	38	29	26	24	23	20	20
<b>Total open Studies</b>	<b>95</b>	<b>94</b>	<b>96</b>	<b>96</b>	<b>98</b>	<b>100</b>	<b>95</b>	<b>94</b>	<b>104</b>	<b>110</b>	<b>105</b>
% of active studies	54	53	55	55	61	71	73	74	78	82	81

### **Open studies according to type and status**

Type	Number of studies
Recruiting site	88
PIC	11
other non-recruiting	4
research database	2
<b>Grant total</b>	<b>105</b>

Status	Number of studies
Active	13
Awaiting first participant	27
Recruiting	37
Follow up	8
On hold	20
<b>Grant total</b>	<b>105</b>

#### **5.3.4 Contracts**

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

	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Confidentially Agreements	0	2	0	0	2	3	0	1	3	2
Research Contracts	0	0	0	0	1	1	1	1	1	1
PIC Agreements	0	4	0	0	0	0	1	1	0	2
Collaboration Agreements	0	0	1	0	0	0	0	0	2	0

#### **5.3.5 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 on a project to outline a revised process based on a nationally agreed framework.

### **5.4 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

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### **5.4.1 GDPR and information governance**

The Head of RI works closely with the Trust 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.

Discussions have taken place with NHSX and further conversations are planned with the HRA to clarify specific areas of concern.

Other Trusts seem to have a more relaxed attitude to GDPR in relation to research studies and do not undertake further risk analysis. This analysis is time consuming and does delay studies being opened but it is felt necessary until further clarification is available.

The Head of RI and Head of R&D recently provided details for the Trusts Business Assurance Framework (BAF) regarding the potential impact of the Opt-Out process on data management. This helped to explain that Opt-Out is not an additional risk in itself, it is the systems and processes in managing data that are critical.

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 of the issues regarding GDPR and study sponsorship. These issues will need to be addressed to support the expansion of research.

### **5.4.2 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

We currently have 55 active CRIS users.

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

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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
- Consultancy Work – OHFT have delivered a number of pieces of work commissioned Akrivia Health
- Training - OHFT already provides ad-hoc support to other Trusts.

### **5.4.3 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 place over the period April to June each year. The same team member provides activity data to support capacity planning with the CRF.

### **5.4.4 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

## **5.5 Finance & IP Management**

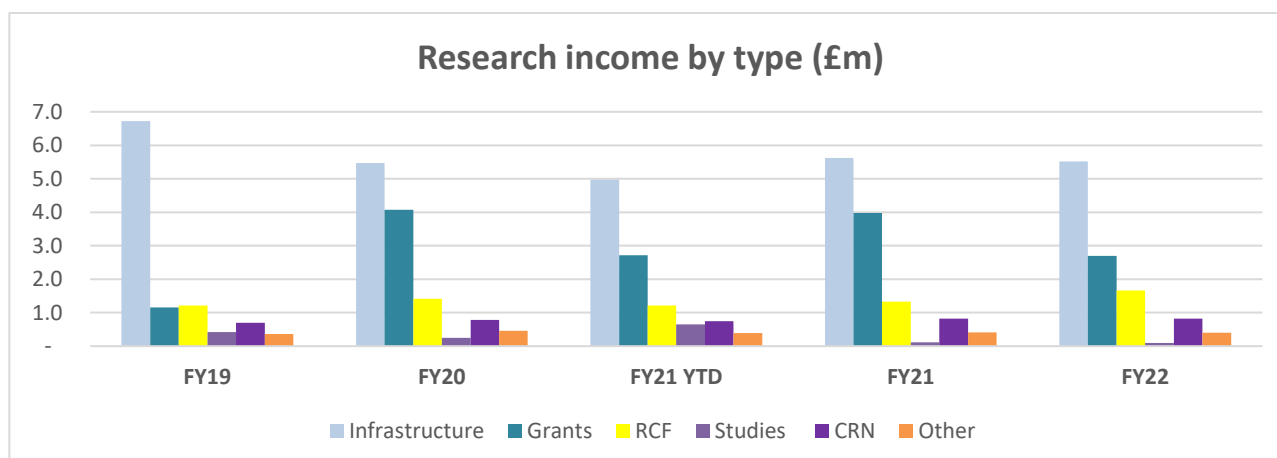
### **5.5.1 Finance**

#### **Research Income**

As shown in the table below, over the period FY19 to FY22 research income has and is expected to remain in the region of £10.5m to £12.5m per annum. Infrastructure income has remained fairly consistent at around £5.5m. the larger FY19 value includes a one-off £1m for CRIS. The fluctuations in grant funding reflects the differing payment profiles.

<b>Research Funding</b>	<b>FY19</b>	<b>FY20</b>	<b>FY21 YTD</b>	<b>FY21</b>	<b>FY22</b>
Infrastructure	6.7	5.5	5.0	5.6	5.5
Grants	1.2	4.1	2.7	4.0	2.7
RCF	1.2	1.4	1.2	1.3	1.7
Studies	0.4	0.3	0.7	0.1	0.1
CRN	0.7	0.8	0.7	0.8	0.8
Other	0.4	0.5	0.4	0.4	0.4
<b>Total</b>	<b>10.6</b>	<b>12.5</b>	<b>10.7</b>	<b>12.3</b>	<b>11.2</b>

*Note: FY21 YTD reflects 11 months to Feb 2021*



**Infrastructure income**

The table below details the infrastructure income

Infrastructure	FY19	FY20	FY21 YTD	FY21	FY22
BRC	3.8	2.9	2.6	2.8	2.8
CRF	0.7	0.7	0.7	0.7	0.8
CLAHRC \ ARC	2.0	1.7	1.5	1.8	1.7
MIC \ DEC	0.1	0.2	0.2	0.3	0.2
<b>TOTAL</b>	<b>6.7</b>	<b>5.5</b>	<b>5.0</b>	<b>5.6</b>	<b>5.5</b>

**FY20 Performance**

As at Month 11 performance was broadly in line with the Year to Date Budget of £275k however this may be improved by up to £0.5m depending on invoicing treatment for the Novavax vaccine study.

FY21 reported lower mental health related commercial income due to lack of activity replaced by vaccine related commercial income. This trend is expected to continue into the early part of FY22.

Commercial income is used to fund some Research staff and provides flexible funding for re-investment

**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 annual 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 (£1.40m) and Dept of Primary Care (£0.45m)

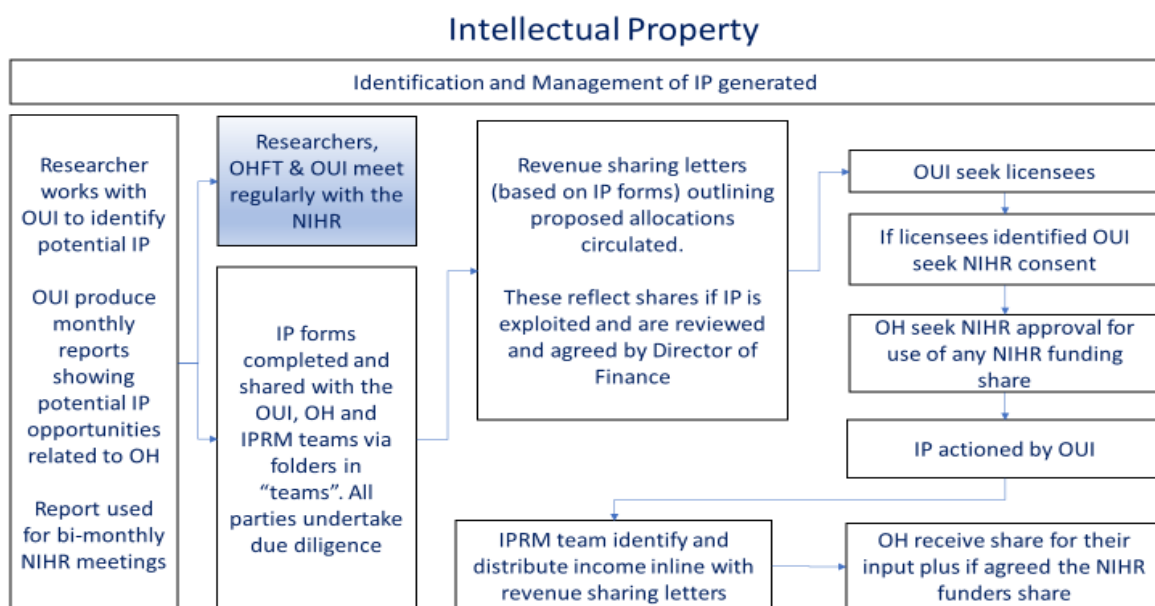
**Leadership**

The Head of R&D is a member of the UKRD finance group which represents 17 organisations across the UK and meets regularly with the R&D of Research Finance at OUH. These have provided valuable opportunities to share information.

**5.5.2 Intellectual Property (IP) Management**

OHFT is developing an IP Policy which is under the control of the Director of Finance.

The management process is shown below



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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

- **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 managed 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 developed and will be shared with the NIHR for approval.

## **6 Research Active Workforce**

### **6.1 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 leading the NIHR’s 70@70 Senior Nurse and Midwife Research Leader Programme and developing a robust evaluation protocol to identify the added value and impact of the programme 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 Public Health England to develop initiatives to embed research into clinical research 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 AHSP in late 2020. We are currently working with the two Oxford BRCs to finalize the strategy with plans to operationalize it in 2021. Stakeholders include the two Oxford BRC Training Leads, Chief Nurses at OUH and OHFT, the Director of OxINMAHR and the OSNM Director. The strategy aims to enable career pathway progression at pre-doctoral, doctoral, and post-doctoral levels.

Bi-annual Academic Writing Retreats for Nurses are co-funded by the OHFT and Oxford BRCs, CRF and OxINMAHR. The last retreat was in October 2020 and was successfully delivered online due to Covid-19. The online retreat evaluated very well and the next one is planned for Spring 2021.

Development of an online and face-to-face ‘Research Support Package’ for nurses and AHPs is underway 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 supported by spoke research modules including an introduction to research design and development, grant writing workshops, principal investigator essentials sessions and systematic review workshops. These spoke modules are utilizing a pan-Oxford approach, including input from the NIHR RDS and Oxford BRCs.

NIHR James Lind Alliance in Community Nursing: this ARC funded project involves undertaking a priority setting partnership in community nursing. The first survey sent out as part of this process is due to close in February 2021 and has been 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 has been

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established to guide the process. We anticipate project completion in late 2021. Findings will be used to identify the top 10 community nursing research priorities and we will work with colleagues at NHS England, the CRN, and NHS Engagement to ensure the research priorities are embedded within the national community nursing agenda.

A new Masters level MSc in Professional Practice has been approved and is due to launch 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.

## **7 Collaborations and Impact**

### **7.1 Oxford Academic Health Partners (OAHF)**

Professor Keith Channon (Director) has presented an overview of OAHF priorities to Executive Groups at each of Oxford's NHS Trusts and Universities following re-designation of the AHSC in 2020. He signalled closer involvement with the Oxford AHSN, training in research for nurses and allied health professionals, support for the Biomedical Research Centre renewals and planning for development of the Oxford campuses to deliver benefits for all Partners in his summary. Modern healthcare depends on innovation and training and relies on the wider disciplinary base for humanities, business, policy, and governance.

General discussion with leadership groups has confirmed the importance of operationalisation for strategies and streamlining regulatory oversight to sustain the competitiveness and prominence demonstrated during the pandemic.

Joint working is critical and shared principles will be established across OAHF. Improved data coherence will support research and deliver patient benefit in all settings including primary care. Streamlined data sharing and linkages will also have economic benefits for service provision.

Work is already underway to review in this area among combinations of teams. To augment this, a working group with representation from all Partners has been agreed and a preliminary meeting is scheduled for 16 March 2021. Clarification of governance arrangements and simplification will underpin objectives whilst ensuring individual organisations can meet their own specific requirements.

OAHF will provide support to ensure complementarity during the BRC renewal process and the OAHF Board is meeting every month until at least October 2021.

Oxford Health NHS FT has an active interest in including digital and culture change in research and innovation and recognised the utility of realistic problem-solving contributions, specifically to tackle multimorbidity in community settings and delivery of improvements in clinical pathways.

Other short-term goals relating to research include:

An integrated Oxford research office. OAHF will contribute to integration of this sort through the national AHSC network.

Facilitation and increased physical space for early-stage clinical research

### **7.2 OU \OUH Joint Research Office**

The OU \OUH Joint Research Office 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 OU and OUH leads on a regular basis and has had input into their objectives. This group has identified several areas of common interest, including

- Data sharing
- Opt-out

- Training
- Research Systems (Studyline & Sitaline)
- OAHP support for development of JROs (through AHSC network)
- Hosting JRO 'landing page'
- JRO accommodation
- Honorary Contracts for University staff

### **7.3 Oxford Academic Health Science Network (OAHSN)**

Oxford Academic Health Science Network (AHSN) maintains a significant focus of Mental Health within its programmes and we highlight below Mental Health work that is either hosted within Oxford Health NHS Foundation Trust (OHFT) or of relevance to the trust.

#### **7.3.1 The AHSN's Mental Health Programme**

The AHSN's mental health programme comprises National, Regional and Local Programmes. National programmes are selected by the AHSN network for national adoption and spread across the AHSN Network. We are collaborating with Kent, Surrey and Sussex and Wessex AHSNs on two Regional mental health programmes - we anticipate in the future there will be more Regional programmes as these collaborations have proved very productive. The remainder of our projects are locally (Thames Valley) initiated. All of these projects are described in this report.

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

The A&D Network (Oxford AHSN) is hosted by OHFT. Professor David Clark is Clinical Lead, Ineke Wolsey is the Network Manager and all IAPT (Improving Access to Psychological Therapies) services across Thames Valley and Milton Keynes are active members. The overarching objective of the network is to continuously improve patient outcomes and service delivery, working very closely with its active Patient Forum. Below an update on some of the most recently initiated projects which have had a strong focus on the following:

##### **Additional activity as a response to COVID**

The Network has led the development and production of training webinars and pocket guides for **Age UK volunteers/ befrienders and managers**. This was in response to an identified need for additional skills, with an increase in older adults suffering with anxiety/ depression as a result of increased social isolation. The focus is on supporting volunteers to feel more confident in having more complex and distressing conversations with their service users and for managers to feel more confident in supporting their volunteers and befrienders.

The A&D Network has supported national webinars on the **treatment of Long COVID/ Post COVID syndrome**, aimed at upskilling psychological therapists to treat Long COVID patients (either within an IAPT service or as part of the new Multi-Disciplinary Teams).

##### **Health Economics study now published**

"The employment and mental health impact of integrated Improving Access to Psychological Therapies services: Evidence on secondary health care utilization from a pragmatic trial in three English counties"

The above article is to be published shortly in the Journal of Health Services Research & Policy. This was an A&D Network led study and named authors include Professors Clark and Stuckler, Dr Veronica Toffolutti, our A&D Network IAPT service leads (including Jo Ryder and John Pimm from OH) and Ineke Wolsey.

##### **Relapse prevention/ staying well after patients have been discharged**

Many of our on-going projects such as the Paddle therapy support app and patient follow-up study as well as new Staying Well protocols and latent profile work were paused at the start of the first lock down March 2020 but have now been started up again. More information on Paddle can be found here: <https://www.paddleapp.org/>

##### **Improving Access to Psychological therapies for older adults**

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The activity as part of this network was re-focussed to respond to urgent COVID-related needs.

### **Psychological Perspectives in Education and Primary Care (PPEPCare)- CYP**

This A&D led initiative trains up experienced staff within CAMHS services to deliver training sessions to teachers and others with a focus on increasing confidence in detecting and managing CYP's distress and MH issues. Training was shifted online and some 25 staff have been trained up in the past 6 months to deliver modular sessions to teachers, GPs and other primary care staff and local authority staff.

### **Best practice network for Care homes health in-reach teams with respect to dementia**

This network has been in place since 2016 and supports the health teams (including OHFT's Care Home Support Service) that in-reach into care homes, helping care homes to provide better care to people living with dementia. In the normal course of events the network holds quarterly meetings for sharing of best practice and CPD for these teams. In spring 2020 at the start of the Covid pandemic, we held meetings every two to three weeks to support the in-reach teams with sharing best practice related to the very difficult situation evolving in care homes. As numbers of Covid cases reduced, the frequency of meetings was decreased, and we covered topics such as deterioration (RESTORE 2) and the Primary Care Network requirements for supporting care homes.

### **Integrated mental health care and policing teams**

This is a legacy AHSN national programme, in which police are integrated within a mental health team to work with high impact users of services, helping them towards safer and healthier lives. A version of this, based in part on a similar implementation in Hampshire, has been developed in Oxford and has been working very successfully with a cohort to reduce repeat crises and high levels of service use. The AHSN contributed to the initial cost of the police officer who is working proactively alongside care coordinators with mental health service users.

### **Sleepio**

Innovate UK has funded a collaborative partnership which has enabled free direct access to Sleepio, an evidence-based sleep improvement programme, for the 2.7 million adults living and working within 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 AHSN is working in partnership with Big Health to explore the best ways for people experiencing insomnia to access the online cognitive behavioural therapy-based digital therapeutic Sleepio. Since the launch of the project on World Mental Health Day (10 October 2018) over 11,500 people have engaged with Sleepio via the link [www.sleepio.com/nhs](http://www.sleepio.com/nhs) and a report and health economic evaluation (conducted by the Office for Health Economics) have been produced.

The learning from this Oxford AHSN project is now being extended as a SE Regional project across the South East of England to continue to explore how a digital therapeutic can be offered at scale and commissioned to benefit the population. A project established in North Hampshire involving 16 GP surgeries has enabled 518 individuals to commence the CBT element of Sleepio since it commenced in October 2020. Sleepio is also being offered to all NHS England staff as a package of support to aid wellbeing since March 2020 in response to coronavirus alongside Daylight, HeadSpace, and Unmind.

### **First episode and Rapid Early intervention for Eating Disorders (FREED)**

FREED is an innovative, evidence-based, specialist care package for 16 to 25 year olds with a first episode eating disorder of less than 3 years duration (and has been adopted as a national AHSN programme). FREED aims to overcome barriers to early treatment and recovery and provides highly co-ordinated early care, with a central focus on reducing the duration of an untreated disorder. It consists of a service model and a care package.

Two Eating Disorder services (Buckinghamshire and Berkshire) within the Oxford AHSN geography successfully applied for funding from NHSE/I to assist in the recruitment of a FREED Champion and are in the process of

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establishing the model (through training and seeking Champions) with a view to launching the services in April; though the impact of COVID-19 on referrals to Eating Disorders services has presented significant challenges.

A Network of Support has been established to ensure good practice is shared with similar services across the South East. Buckinghamshire are currently recruiting a FREED Champion to begin rolling out the service. Discussions with Oxfordshire's Eating Disorders Service about the feasibility of establishing the FREED model are taking place.

### **Focus ADHD – Introduction of Computerised Test into ADHD Assessment**

Focus ADHD is a national AHSN programme aimed at improving the ADHD assessment offer for school age children including reducing the time from referral to decision to diagnose / rule out ADHD, and reducing the number of outpatient appointments required. The core of the programme is implementation of a computerised test such as QbTest. As well as aiming to speed up assessment and reduce waiting times, within the East Midlands QbTest demonstrator site, there was found to be a cost saving of £3.37 for the NHS for every £1 spent. This test is already in place in Oxfordshire ADHD services and the Buckinghamshire service is now planning implementation.

### **S12 Solutions – supporting the process of Mental Health Act Assessments**

S12 Solutions is an app and website which enables S12 doctors to define their availability for undertaking Mental Health Act Assessments thus enabling Approved Mental Health Professionals (AMHPs) to build an assessment team using the most appropriate doctors available, and for the doctors to create and submit payment claim forms. This is one of the innovations within the SE Regional Collaborative Spread and Adoption initiative, and Oxford AHSN is currently working with Berkshire (West and East), Buckinghamshire and Oxfordshire CCGs to **look at the case for implementation**.

#### **7.3.3 Industry**

The Strategic and Industry Partnerships element of the AHSN supports the development of partnerships between academia, industry and the NHS across the development pathway for new products and services. In practice this covers new medicines, diagnostics, medtech and digital health innovations. This includes supporting new products and services which have potential to improve mental health services.

#### **7.3.4 Oxford AHSN and the NIHR Applied Research Collaboration (ARC) Oxford and Thames Valley**

An implementation manager is now in post jointly between the ARC Oxford and Thames Valley (hosted by OHFT) and Oxford AHSN. The aim of the post is to work across the ARC research programmes and AHSN Clinical Innovation Adoption team to optimise the development of research outputs that are ready for implementation in the regional health and social care system and more widely.

Additionally, Oxford Health is a member of the R&D group, represented by Bill Wells (Head of R&D), which discusses topics of common interest to Universities and NHS Trusts across the AHSN region.

### **7.4 Oxford Institute of Nursing, Midwifery and Allied Health Research (OxINMAHR)**

#### **7.4.1 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 researchers include 8 Professors, 9 senior researchers/fellows and over 45 other research academics who have a broad range of qualitative and quantitative methodological expertise. Many of our research projects are multi-disciplinary and address the complexities of modern healthcare. Our research expertise encompasses nursing, health research, physiotherapy, nutrition, exercise science, physiology, biology, movement science, midwifery, social care, occupational therapy and psychology.

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### **7.4.2 Our 2020 Annual Report has been published ([www.brookes.ac.uk/oxinmahr/](http://www.brookes.ac.uk/oxinmahr/))**

The highlights include:

- 15 major grant awards totalling £3.2 million (including grants from NIHR, UKRI, Health Education England and a number of national charities)
- 82 papers published in peer-reviewed high impact journals
- 13 Research Degrees awarded and 20 new Doctoral students recruited
- 50 Doctoral students on track to submit in the next three years
- 3 large national COVID-19 ESRC/UKRI awards totalling over £1.3 million

OxINMAHR comprises three Research Centres and four additional Research Groups.

RESEARCH CENTRE: Movement, Occupational and Rehabilitation Sciences (MOReS) Centre Director: Prof Helen Dawes [hdawes@brookes.ac.uk](mailto:hdawes@brookes.ac.uk)

The Clinical Exercise and Rehabilitation research group is led Dr J Collett, ([jcollett@brookes.ac.uk](mailto:jcollett@brookes.ac.uk)) and focuses on developing and evaluating exercise interventions and exercise response in health and disease. The 'OxSOCRATES' team (a trial of a prevention programme for children at risk of cardiovascular disease) have developed materials to deliver the intervention remotely online. Also in response to the pandemic, the CLEAR unit team rapidly produced a chair based exercise video with Oxford health NHS Trust. The content, informed by a recent PhD study, provides exercise for those with chronic conditions, the elderly self-isolating and for those recovering from infection. The video was made available on YouTube April 2020 (<https://www.youtube.com/watch?v=EJgZygWBKaE>). In addition, 'Stand Up for CP project' data collection has been completed and the main trial report is currently being written up for publication. The group has also been awarded funding from Great Ormond Street Hospital Children's Charity to develop a lifestyle weight management program for children with demyelinating conditions. International work includes Prof Helen Dawes leading the Definitions and Terminology work package of an initiative to develop a global consensus on Moving Exercise Research in Multiple Sclerosis Forward: The MoXFo initiative.

The Movement Science research group is led by Dr P Esser, ([pesser@brookes.ac.uk](mailto:pesser@brookes.ac.uk)). and focusses on measuring quality and quantity of movement in various national (MRC Insight46, SABRE, Whitehall II (Oxford)) and international cohorts (China, Jordan, Mexico, Japan) surrounding general ageing, Multiple Sclerosis, Parkinson's, Diabetes, and various other conditions. In addition, this group undertakes the continuous development of novel and bespoke outcome measurements, algorithms and data analysis programmes for both academic researchers (both nationally and internationally) as well as allied health professionals and commercial companies. Within the past 12 months, the group has been working on the validation and application of novel movement algorithms on a national and international level, has successfully secured commercial funding with SBRI, InnovateUK, and NIHR. The group have also supported 2 PhD students to completion (Nov/Dec '20), had 14 publications accepted within the past 12 months with a further 11 submitted at the time of writing.

The Clinical Applied Nutrition research group is led by Dr S Coe ([scoe@brookes.ac.uk](mailto:scoe@brookes.ac.uk)) and has continued to produce high quality research in the past year. Two PhD students within the group successfully completed their studies, and there have been numerous high-quality outputs resulting from the research in this theme and across themes. Research areas include paediatric and adult neurological and autoimmune conditions including Multiple Sclerosis, Cerebral Palsy (CP), Parkinson's and Juvenile Rheumatoid Arthritis, and lifestyle interventions including diet and exercise for improving the symptoms of the conditions. There are currently five ongoing projects within this theme, including three PhD projects, all which will produce high quality outputs and potentially for next stage funding and collaboration. The lead for this theme has joined the 'Children and Young people network' University initiated network as a steering member and as a member has joined the 'Healthy Ageing network', both of which have led to initial collaborative conversations across the University. She has also pursued collaborations internally between MOReS and OxBCNH, and also nationally

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and internationally, enabling multidisciplinary research around diet and lifestyle behaviours and health to commence and continue.

**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 Supportive Cancer Care and Long Term Conditions research group is led by Prof E Watson, [ewatson@brookes.ac.uk](mailto:ewatson@brookes.ac.uk)) and focusses on identifying unmet needs in people living with and beyond cancer or a long term condition and their carers/family members, and developing and testing supportive care interventions which address identified needs. The past year has seen the start of a six year NIHR PGfAR grant (Watson (Co-PI) and Brett (Co-I)) which aims to support women with breast cancer with adherence to adjuvant endocrine therapy (SWEET). A second NIHR programme grant which will trial a new, risk-stratified approach to follow-up for Head and Neck cancer (PET-NECK2)) has also commenced (Brett (Co-I), Watson (collaborator)). A new Blood Cancer UK-funded study being conducted in collaboration with Oxford University and Oxford University Hospitals NHS Foundation Trust to explore the Emotional and Psychological Needs of Patients with Blood Cancer (Watson (PI); Brett (Co-I); Henshall (Co-I) is also underway. The group also continues involvement with a number of significant national cancer trials including Mammo-50 (an HTA funded trial seeking to establish the optimal breast screening interval for women post-breast cancer diagnosis) and CLASP (an NIHR funded PGfAR study which is trialling internet based lifestyle and wellbeing support for cancer survivors in primary care). Kowlsowska has also been awarded her first grant as PI from the OHBRC focussed on incorporating the Diabetes Distress Scale into routine nursing diabetes care. – a feasibility and acceptability project. 16 papers have been published in peer reviewed journals by group members during 2020.

The Children and Families research group led by Prof J Appleton ([jappleton@brookes.ac.uk](mailto:jappleton@brookes.ac.uk)) and focuses on research around children, young people and family well-being, with particular expertise in child safeguarding. This research group has key research portfolios relating to reducing violence towards children (Eu ERICA); evaluation of the UK Adoption Support Fund (DfE funded); child and family health, health equity and provision of services for disadvantaged children. Many of these research projects are multidisciplinary in nature and include NHS and social care service organisations and social work researchers as well as health visitors and community nurses.

The Maternity and childbirth research group is led by Dr E Burns ([eburns@brookes.ac.uk](mailto:eburns@brookes.ac.uk)) and investigates factors aiming to optimise women's health and wellbeing during maternity, childbearing and beyond. Current projects include "estiMATE" (improving visual blood loss estimation during waterbirth) and an international collaboration examining intrapartum interventions, and maternal and neonatal outcomes following immersion in water during labour and waterbirth. A HHE funded study is exploring BAME applicants to midwifery programmes and the group is currently supervising three PhD projects and three MSc student studies.

**The Centre for Nutrition and Health Centre Director: Dr Jonathan Tammam; [jtammam@brookes.ac.uk](mailto:jtammam@brookes.ac.uk)**

The Centre for Nutrition and Health (CNH) experienced a period of rapid and significant change in 2020. In March, Isabel Butler took over as Centre Manager after Dr Mark Beggs completed his tenure as Interim Manager. We have developed a 5 year strategy in order to promote the long term stability of the Centre. Our commercial operations were naturally disturbed by the Covid situation, however, despite this we can report some significant positive outcomes. We were successful in being awarded HEIF grant in order to pursue our marketing and business development strategies and we have had major success in securing high-value contracts from international clients, in addition to the smaller scale contracts that keep our day-to-day activities afloat.

In addition, the commercial work has offered virtual volunteering sessions for nutrition students. We intend to build on this success by offering work experience opportunities to shadow Research Assistants, with the eventual aim offer internships for nutrition students.

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The Prevention Science Research Group is led by Prof D Foxcroft (david.foxcroft@brookes.ac.uk) and is an interdisciplinary research team dedicated to investigating the development and impact of prevention efforts for physical and psychological health and wellbeing. Linked to the Centre for Psychological Research and to OxINMAHR, we carry out high quality national and international research studies into the causes, consequences, and prevention of poor physical and mental health. The scope of the group spans the harms associated with substance misuse (e.g. alcohol, tobacco, illicit drugs), lifestyle behaviours (e.g. poor diet, lack of exercise), and poor mental health. Recent work has seen the completion of three large MRC and NIHR funded prevention trials looking at the effectiveness and cost-effectiveness of child and youth substance misuse prevention programmes with families and in schools. Ongoing work includes establishing a sports focus for the prevention of substance misuse in young people, with work in Goa, India, funded by the Global Challenges Research Fund (GCRF). We are also closely involved as part of the core research team in the Global Drug Survey (GDS), leading on alcohol, and have also expanded current work on the GDS to include Mental Health and Coping. Work on alcohol and sexual violence has been included in a parliamentary briefing. We are also taking forward research assessing alcohol consumption in midlife women and, working with AgeUK, a study looking at the functional significance for the elderly of town centre layouts and planning.

The Sport, Exercise and Physical Activity Research Group is led by Dr P Wright: (pwright@brookes.ac.uk) and is focussed on the understanding of effective methods for health promotion and rehabilitation, with a particular emphasis on the role of sport, exercise and physical activity in health promotion and rehabilitation. The group members investigate the use of exercise, and lifestyle interventions to improve physical health and psychological well-being in the general public and for patients suffering from various acute and chronic medical conditions. In 2020 Dr P Wright (CI) secured a substantial EU grant to fund the “FORTE” project. This project involves pooling leading expertise on a European and cross-Atlantic level with the aim to evaluate a personalised and standardised exercise intervention for children and adolescents undergoing anti-cancer treatment

The Centre for Psychological Research is represented at OxINMAHR by Dr E Davies (edavies@brookes.ac.uk). In July 2020 the psychology team, led by Professor Anna Barnett, received university approval for the new Centre for Psychological Research. Dr Mark Burgess and Dr Kate Wilmut are joint co-directors of this new research centre, supported by four assistant directors representing the research groups and wider interests within the team (Dr Emma Davies, Dr Nayeli Gonzalez-Gomez, Dr Sanjay Kumar & Dr Michael Pilling). Health-related research takes place across the four research groups in Psychology: Applied Social Psychology, Prevention Science (see above), Developmental Psychology, Cognition and Cognitive Neuroscience. There has been ongoing work on major projects funded by the John Templeton Foundation (Baimel), Ministry of Defence (Kumar) and Spread a Smile (Burgess and Morys-Carter). Two successful grants from the UKRI/ESRC response to Covid-19 scheme were awarded to Gonzalez-Gomez (£266,917), and Connolly (£385,000). Staff have had work published in a range of journals including International Journal of Drug Policy, Journal of Substance Abuse Treatment, Journal of Military, Veteran and Family Health and Psychology and Aging. They have also presented work at various conferences including the Indian Psychiatric Society Annual Meeting, European Society for Prevention Research Conference, UK Society for Behavioural Medicine Annual Scientific Meeting, British Sleep Society Scientific Meeting and British Association of Cognitive Neuroscience.

### **7.4.3 Our response to COVID-19**

Our researchers have been involved in a large number of COVID-related research studies and grant applications. This portfolio illustrates the breadth and depth of OxINMAHR research expertise and involves a wide range of internal and external multi-disciplinary collaborations.

At the time of writing, we have been successful of securing over £1.3 million for our COVID-related research and a number of these applications are still awaiting decisions.

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Project Title
The effects of social distancing policies on children’s language development sleep and executive functions. Awarded to: Dr N Gomez- Gozalez (PI)
Mindlamp App for COVID-19 mental health impact. Submitted (Led by Oxford Health NHS Foundation Trust)
Hearing the voice of student nurses working in the Covid-19 emergency: what works in education, regulation and professional leadership Awarded to : Dr M Malone (PI) and 7 Oxford Brookes CIs
The implications of team cohesion in task-organised Covid-19 NHS response teams for clinical performance and individual long term mental health. Awarded to: Prof V Connelly (PI), Prof P Carding (CI)
Getting children on bikes: what are the barriers to encouraging children to cycle post COVID-19? Submitted (Led by Oxford Brookes researchers)
Exploring remote consultation implemented since the outbreak of Covid-19 Awarded to Dr H Walthall PI (Oxford University Hospitals NHS Foundation Trust) Prof P Carding (CI)
Protecting children and young people vulnerable to harm and abuse during the Covid-19 recovery period – investigating NHS practices and pathways and new ways of working at the interface with children’s social care. Submitted (Led by Oxford Brookes researchers)
The experiences of BAME nurses during the COVID-19 pandemic in England. Submitted (Led by Oxford Brookes researchers)
ZEBRA: Safe and social workplace solutions. Submitted (Led by Oxford Brookes researchers)

### **7.5 Berkshire Healthcare**

OHFT have continued to maintain a productive relationship with Berkshire Healthcare over the last year. 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

This collaboration is endorsed by the Thames Valley Clinical Research Network with the potential to represent the Thames Valley in certain areas.

**Authors and Title:** Professor John Geddes, Director of R&D and the NIHR BRC  
Bill Wells, Head of R&D  
Dr Mark Hancock, Medical Director

**Lead Executive Director:** Dr Mark Hancock

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*
3. *This paper provides assurance and evidence against various Care Quality Commission Outcomes*