

**BOD 14/2022**

(Agenda item: 09)

**Report to the Meeting of the**

**Oxford Health NHS Foundation Trust**

**Board of Directors**

**March 2022**

**Research and Development Report**

**For information**

**Executive Summary**

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

The current CRF funding award comes to an end in August 2022 and in September 2021 the CRF team submitted a renewal application for a further five years. In February 2022 the NIHR informed Professor Cipriani (CRF Director) that its application was successful and just over £4m had been awarded. This reflects the work done by the CRF team over the last 10 years.

The CRF has and continues to be a key element of research infrastructure at Oxford Health, along with our key partner, the University of Oxford.

**Leadership**

During the last twelve months new appointments have been made to Trust R&D Director and Director of the MIC posts. The current overall leadership is now

* Oxford Health Biomedical Research Centre (BRC) Director, Prof John Geddes
* Trust R&D Director, Dr Vanessa Raymont, Associate Director Prof Andrea Cipriani
* Oxford Clinical Research Facility (CRF) Director Prof Andrea Cipriani, Co-Director Dr Cathy Henshall
* Oxford Applied Research Collaboration Oxford and Thames Valley (ARC) Director, Prof Richard Hobbs
* NIHR Community Healthcare MedTech and IVD Co-operative (MIC) Director, Professor Gail Hayward

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

The current BRC award will finish at the end of November 2022 and while the OHBRC continues to deliver against objectives agreed with the NIHR, the focus over the last six months has been on the application for renewed funding.

Under the leadership of Prof John Geddes stage 1 was submitted in May 2022 and in August 2022 the OHBRC was invited to submit to Stage 2 of the competition.

More detail is included in the paper for the private session of the March Board meeting

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

The ARC portfolio continues to expand bringing in more partners and funding opportunities. The ARC is hosting a Collaboration Event on the 24th of May 2022 in Oxford

**Consent to discuss participation in research**

*Count me in,* an ‘opt-out’ initiative for informing patients about research relevant to their care was launched within the Adult and Older Adult Mental Health services, in August 2021.

Preliminary findings are that in the first 5 months of the initiative 14,300 patients have become contactable through *Count Me In*. This is a significant increase from the number of patients contactable about research in the Trust through the “standard” opt-in utilised prior to August 2021 (only 2,013 patients).

**Oxford Joint Research Office (JRO)**

In December 2021 the Oxford Joint Research Office (JRO) was expanded with Oxford Health and Oxford Brookes University formally joining with the University of Oxford and Oxford University Hospitals

**NIHR Infrastructure Managers Group**

The Research Management Group has recently been revamped as an NIHR Infrastructure Managers Group. This provides the opportunity for the managers of the four OHFT NIHR awards, the Chief Operating Officer of the Oxford Academic Health Partnership, and the R&D Director to meet on a regular basis

**Governance Route/Approval Process**

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

**Statutory or Regulatory responsibilities**

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

**Recommendation**

The Board is asked to support these developments

**Author and Title:** Vanessa Raymont, Research and Development Director and Karl Marlowe, Chief Medical Officer

**Lead Executive Director: Karl Marlowe**

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

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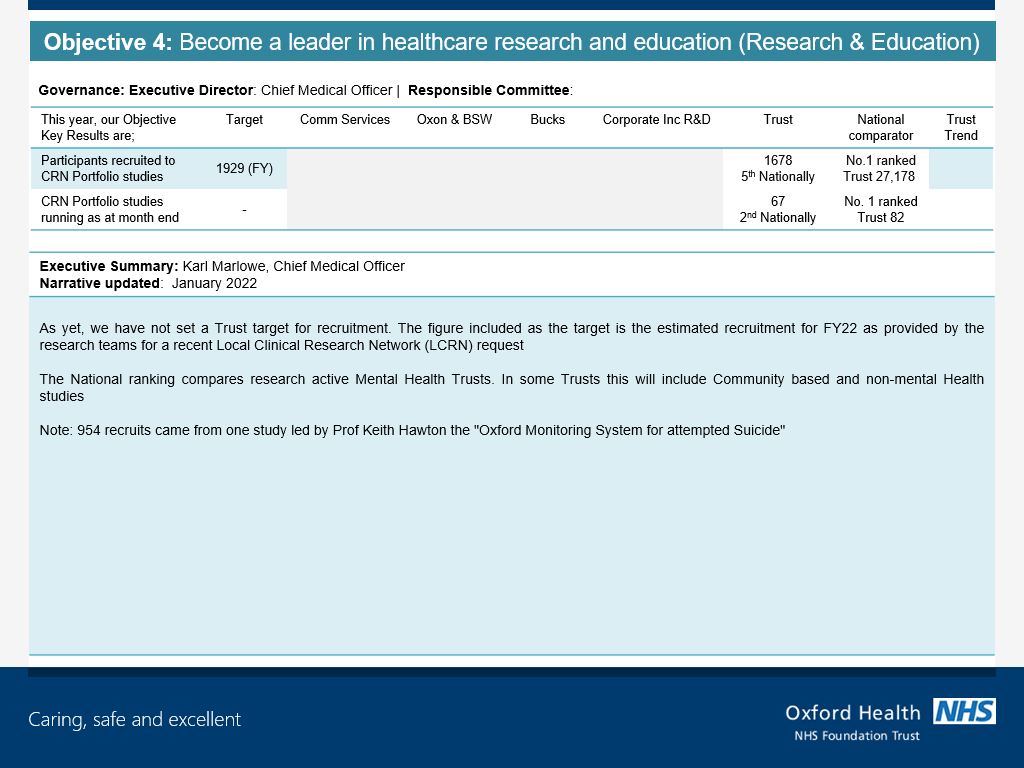
# Introduction

Participation in research produces direct benefits for patients and, more generally, improvements in the quality of care and is a right for patients under the NHS constitution. Organisations can also benefit financially from service innovation led by research, subsequent potential cost savings and income generation, and opportunities involving research to recruit and retain staff. Oxford Health NHS FT (OHFT) is a leading research-active mental health and community trust with strong strategic research links to both the University of Oxford and Oxford Brookes University. OHFT has strengthened and broadened its research portfolio and infrastructure greatly over the last few years. We are now within a period of further change and renewal, which presents an opportunity to increase OHFT’s research presence locally, regionally, nationally and beyond to ultimately deliver outstanding services for all our patients. We therefore plan to start setting strategic 5-year research goals for OHFT during the second quarter of 2022, which we will present at a OHFT research conference in June 2022.

## 2021- 2026 Trust Strategy

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

The Integrated Performance Report (IPR) currently includes two Objective Key Results (OKR) for research, the number CRN Portfolio studies running in the Trust and the number of participants recruited to CRN portfolio studies. The February report is shown below



## COVID-19

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

**Novavax**

In October 2020, OHFT successfully set up the urgent public health Novavax vaccine trial. Successful delivery of the trial 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 was 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 - exceeding our recruitment target. Following a major amendment, we went on to support a Novavax crossover trial design in which those participants who received the Novavax vaccine in the initial phase of the trial received placebo, and vice-versa. Almost half of the OHFT participants took part in the Novavax crossover trial, which was implemented at a national level in response to the number of participants being unblinded due to increasing opportunities to receive the deployed vaccines. In addition, OHFT is also one of only two NHS Trusts in the UK to be supporting the Novavax serology sub-study. Novavax follow up study visits ended in December 2021, with the study end date anticipated at the end of March 2022.

**PRINCIPLE**

This priority one urgent public health Covid-19 trial was successfully set up at OHFT and opened to recruitment in Jan 2021. It aims to evaluate treatments for Covid-19 that can be taken at home. To date, recruitment is primarily through the District Nursing teams in the community directorate, with support from R&D. Further to this, we have now engaged an Associate Principal Investigator (API) to support this study. A recent amendment involved an update to the inclusion criteria relating to age which has been widened to 18yrs and over (was 50yrs+ with co-morbidities). In response to this change, we approached the out of hours (OOH) GP service as a potential route to recruitment. Discussions with OOH team have been positive and we are exploring how to operationalise recruitment in this area, hoping that it may open further opportunities with this service. The central study team report that they expect to remain open to recruitment until Sep 2022. However, we await updates from them regarding the upcoming changes to the Government’s Covid-19 rules. To date, we have not recruited any participants to PRINCIPLE due to the clinical demand and OPEL4 level pressures on Community teams.

**Virus Watch**

OHFT successfully supported the Virus Watch study involving over 50,000 participants nationally. Virus watch aims to better understand local and community incidence and transmission of Covid-19 through regular questionnaires assessing incidence, symptom profile, severity, and transmission risk. OHFT supported an immunity subset of the Virus Watch study which involved obtaining blood samples to assess immune response to help establish whether Covid-19 infection led to protective immunity and antibodies. We rapidly set up and delivered various clinics through Oxfordshire and Buckinghamshire to help understand the local immune response to Covid-19. The study recruited 41 participants in total and closed in September 2021.

## Communications

Since September 2021 R&D communications have continued to support the ongoing renewal bids for both the Oxford Health BRC and the Oxford cognitive health CRF. In both cases this has included developing new and refreshed content for our online platforms including an interactive visual timeline of the BRC’s achievements to date and an accompanying social media campaign scheduled for the immediate run up to the BRC interview date in early April.

The [CRF section of the BRC website](https://oxfordhealthbrc.nihr.ac.uk/clinical-research-facility/) has been a particular focus for attention and, in collaboration with CRF colleagues, this has been fully updated with new content including a range of vibrant professional images commissioned for the purpose. A new section has been created on the website for the newly founded Experimental Medicine and Industry Partnership (EMIP) and we celebrated the Experimental Medicine AIMday which launched the EMIP with the online publication of [a collection of blogs from the event](https://online.flippingbook.com/view/481049496/).

The profile of R&D at Oxford Health was raised at the Trust’s annual general meeting where research was one of the key themes presented to our stakeholders. Using the Brain Health Centre as a case study we highlighted the mutual benefits to researchers, clinicians, and patients of the BHC’s innovative combined research and clinical model, [creating this short film to show the patient pathway through the centre and showcase its benefits](https://youtu.be/5tlkVVg8RSY).

The changes to research contact implemented by the trust in August 2021 have continued to be an important priority for comms activity. The ‘count me in’ project was launched with communications activity across a range of channels and this momentum has been maintained over the following months with regular posting on social media and in the OHFT staff bulletin. In early 2022 [a follow up news item on ‘count me in’](https://www.oxfordhealth.nhs.uk/news/227296/) was published on the trust website detailing preliminary data and early signs of the project’s success. Social media coverage of the story reached nearly 3.5k people with a strong engagement rate of up to 6.5%. ‘Count me in’ communications activity will continue throughout the duration of the pilot scheme with the hope of sharing case studies of patients and staff who have benefited from the project in the summer of 2022.

Internal research communications remain a key focus and the R&D pages in the staff bulletin continue to provide a prominent space for the promotion of research news, events and training. The growing number of news items and notices submitted for inclusion in the bulletin demonstrate the need for this dedicated platform. Over the course of the year we have used the bulletin, R&D intranet and other internal communications channels to successfully recruit participants for a range of studies including the [Resolution study](https://ohft365.sharepoint.com/sites/research/SitePages/Resolution-study--a-safe-space-for-nurses-to-enhance-resilience.aspx) into wellbeing and resilience among nurses at the Trust. Internal promotion of research will be further boosted in June when R&D will be the theme of the second Inspire Network event of the year.

Since September we have published 18 online news items covering topics including Long Covid, the Novavax vaccine trial and new PPI projects around diversity in research. We continue to collaborate closely with communications colleagues in the University of Oxford to release stories to national media. All our news stories are supported by posts on the BRC twitter account and across OHFT social media channels.

## Consent to discuss participation in research

**Background**

*Count me in,* an ‘opt-out’ initiative for informing patients about research relevant to their care was launched within Oxford Health NHS Foundation Trust Adult and Older Adult Mental Health services, in August 2021.

*Count Me In* is a 12-month implementation study, which aims to promote inclusivity for research, by enabling greater equity of information provision about research opportunities to patients across the trust. The change means that patients who have received care in associated services can expect to hear about research opportunities as part of their care unless they say that they do not wish to receive this information. This enables information about research to be provided to all patients, helping to ensure that such information can be accessed by groups who may otherwise be marginalised, or may not be approached when relying on clinician-led recruitment, or an ‘opt-in’ approach.

Clinical teams provide all patients with a leaflet or letter informing them of this approach at the outset of their treatment. This letter/leaflet provides simple information about how to opt out of research contact if anyone wishes to do so.

The change only relates to patients hearing about research opportunities. The decision to take part in research remains entirely voluntary.

Led by Research and Development, a core team was set up to plan, implement, evaluate, and manage the change throughout the course of the initiative. Having successfully launched the initiative in clinical services in August 2021, the impact of the change is currently being monitored, with a plan to complete a full evaluation and publication of the findings in Autumn/Winter 2022. Following completion of the evaluation, it is expected that this change in approach will be adopted in other areas of OHFT, such as the community directorate in 2022, as well as in other NHS Trusts nationally.

**Implementation period**

During the ongoing implementation and evaluation phase, the following actions are being taken by the core team:

* Data reporting: Monthly reporting is provided to the core team allowing for regular monitoring of the use of new Carenotes forms (created to document patient contact preferences and subsequent research contact) throughout the evaluation period. Monitoring has enabled the team to quickly respond to data quality and user issues as they arise.
* Documentation and guides: User guides and processes for staff are being regularly reviewed and updated to reflect feedback from those undertaking the processes described.
* Strategic group: Monthly updates and quarterly meetings are held with a strategic group for the initiative, to keep stakeholders up to date with news and to discuss any arising matters as a wider team. This group includes representatives from Information Governance, Patient and Public Involvement, the Trust Executive Team, service Medical Directors, the Communications Teams and Research & Development.
* Resources: An Intranet hub site has been established to support staff, explaining the change and providing links to relevant resources and documents relating to the change such as Standard Operating Procedures, guides, recorded information and training sessions, and FAQs ([here](https://ohft365.sharepoint.com/sites/research/SitePages/Changes-to-research-contact---everything-you-need-to-know-about-'opt-out'.aspx)).
* Communications: A comprehensive communication plan has been implemented by the OHFT Communications team. This plan aims to keep staff and patients informed about the change. The plan includes regular posts across the trust social media channels, news stories on the Oxford Health website, a patient facing leaflet (available in a variety of formats), posters displayed in clinic areas across the Trust, an information campaign within the Trust via the intranet and the weekly staff bulletin, and all staff emails to inform staff of the change and equip them with information they may need to answer questions from patients. A press releases was also made to local media to announce the launch of the initiative.
* Preliminary findings: An article describing the impact of the project to date and sharing some preliminary data (see details below) was published on the Trust website in January 2022. A letter was also published in the journal Evidenced Based Mental Health, sharing these preliminary findings.
* Feedback: Patient and staff feedback is being sought to understand the impact of the change. Links to an anonymous staff feedback survey have been provided to all staff on the intranet and in the weekly staff Bulletin. Every patient effected by the change is now provided with a link to an anonymous patient survey in the information leaflet/letter they will receive about the initiative.
* Contacting the team: Contact details for the team have been provided to all affected patients in the *Count me in* information leaflet/letter. Trust staff have also been encouraged to utilise these details to get in touch if they have questions or problems. This includes a dedicated email and telephone line for the *Count me in* team.

**Preliminary findings**

Early data has illustrated that in the first 5 months of the initiative 14,300 patients have become contactable through *Count Me In*. This is a significant increase from the number of patients contactable about research in the Trust through the “standard” opt-in utilised prior to August 2021 (only 2,013 patients).

Only 164 patients have opted out of research contactsince August 2021.

Of 283 patients who have been contacted directly, due to being potentially eligible to participate in research studies in the Trust, 57 patients (20%) consented to participate in a research study.

Inclusivity across age, gender, ethnicity, and diagnostic group is being monitored and early evidence signals positive changes in equity of research access. For instance, the *Count Me In* cohort now represents patients across 62 of the 70 diagnostic groups represented in the Trust’s caseload, in comparison to only 44 groups represented using the standard ‘opt-in’ approach.

## NIHR Local Clinical Research Network (LCRN) Thames Valley and South Midlands

**Update**

In February 2022 Trusts received a letter from Professor Lucy Chappell, Chief Executive of the National Institute for Health Research and Dr Louise Wood is Director of Science, Research and Evidence at the Department of Health and Social Care (DHSC) and Deputy CEO of the NIHR entitled “*URGENT ACTION TO ADDRESS THE CURRENT RESEARCH DELIVERY CHALLENGES IN THE NHS”.* An extract of the letter is included below

*Dear colleagues*

*We are writing to update you on continued efforts to support the delivery of research and our commitment to support a diverse and balanced portfolio of studies. We remain committed to delivering on the ambitions set out in Saving and Improving Lives: the future of UK clinical research delivery, and to supporting the recovery of UK clinical research delivery system needed to enable this. However, clinical research delivery is facing unprecedented challenges at present, and we believe there is now an urgent need and an opportunity to reset to build a stronger future.*

*We have consulted with stakeholders across the research system and the NHS and have heard consistently that we now need to take radical action to address the situation. We have therefore initiated work at pace to develop options for a revised approach.*

*It is likely that this will include closing some studies that are struggling in the current context. Subject to agreement from Ministers, we will share plans with partners and stakeholders in the first weeks of March 2022.*

*In developing options, we will consider the open portfolio, new studies coming into the system, supporting sites to make transparent and realistic assessments of capacity and capability, and potential implications of any changes on the future portfolio and UK ecosystem.*

*The aim of this work is to ensure that the research ecosystem can continue to flourish. We are committed to undertaking this essential work in a transparent and informed way so that together we are able to deliver on the potential of clinical research to tackle health inequalities, improve the lives of people across the UK and to boost economic recovery.*

This could have implications for OHFT, but we await further information

**CRN Contract renewal**

The CRN contact is due for renewal and we expect to get more detail on this in late Autumn.

**2022/23 Budgets**

The LCRN have recently agreed budgets for 2022/23 with all Trusts. The co-ordinating centre kept their allocations to LCRNs the same and the LCRN: Thames Valley and South Midlands have tried to keep funding at a similar level to last year plus a small inflationary element.

## Equality, Diversity, and Inclusion (EDI)

A group including the Research Delivery & CRF 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

* *The Listen, Share, Hold, Respond* (LiSHoRe) project: This is 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). The Research Delivery Manager is on the EDI advisory panel for this project and data is currently being collected for it.
* *Implementation of an Equality Monitoring Form*: developed an EMF based on the OHFT-endorsed EMF. This has now been implemented for a number of supported studies and made available to staff both online and in paper format to collect and analyse data to establish a baseline of participant composition. This will be used to help identify populations we could target in our diversity outreach. We will also compare this data to staff baseline demographics (where appropriate) to check for representativeness and potential patterns. This pilot is currently underway and has been recently implemented for all relevant / feasible studies within the three delivery teams. This process will be reviewed beginning of April 2022.
* *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)
* *Research Lab Lunch*: a session has been planned and will be delivered in March 2022 for all OHFT staff on PPI in research and how diversity can be supported with small, practical steps
* *CRF PPIEP Lead*: a new role for a PPIEP Lead for the Clinical Research Facility (1 day / week) has been developed, advertised, and appointed to in order to enhanced focus and develop a more robust EDI and PPI strategy for the new CRF award (2022-2027)
* *Reciprocal Mentoring Programme*: the Research Delivery Manager is now part of the OHFT Reciprocal Mentoring Programme led by the Head of Inclusion. Reciprocal Mentoring is a tool for supporting greater systemic change that actively reduces inequity. The expectation is that the mentoring pairs are not just committed partners during the mentoring sessions – they are actively engaged in challenging inequality and developing more inclusive cultures in their organisation when they are not mentoring.

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

## NIHR Oxford Health Biomedical Research Centre (BRC)

The NIHR Oxford Health Biomedical Research Centre (OHBRC) update is being presented to the March Board during the private session

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

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

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

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

In the past six months the CRF has extended its opening hours to accommodate the restart of funded activity previously paused due to Covid-19 and Urgent Public Health studies. This flexibility will remain during the pandemic recovery period to enable to development of overnight studies and encourage participant inclusivity. Currently, all studies paused during the pandemic for risk management have re-opened and new studies are being set up.

In collaboration with the Biomedical Research Centre and OHFT, the CRF has delivered Brain Health Centre clinics. This project aims to develop enhanced, standardised radiology reports, which compare an individual patient’s results to normative data from a large number of healthy brains (the ~40,000 UK Biobank participants). The enhanced reports used for patients attending the Brain Health Centre will provide clinicians with more clinically relevant measures of brain health that will facilitate accurate and earlier diagnosis of memory problems. This project is a joint enterprise between the BRC and the CRF.Through the BHC, this project is linked with the Older Adults & Dementia and Cognitive Neuroscience and Neuroimaging themes of the OH BRC as well as linking with NIHR D-TRC and OUH BRC.

The CRF has had a staff recruitment campaign due to high staff turnover and it used the opportunity to re-assess the skill mix and develop a strategy in line with its medium and long-term objectives. The CRF is now fully staffed as per latest skill-mix structure (with a few members of staff still undergoing induction or training).

**Renewal**

The current CRF funding comes to an end in August 2022 and in 2021 the NIHR lunched a funding competition for the period 2022-2027. The CRF Director collaborated with the CRF SMT, OHFT R&D, OHFT clinical services, OUH, OH-BRC, and Oxford University to develop the strategy for a renewed CRF with the application being submitted in September 2021. Input was sought from all relevant stakeholders.

We are delighted to share with you the great news that the NIHR Oxford Health CRF application was successful, and funding has been awarded for a further five years starting in September 2022. The Committee’s feedback included that the facilities were considered appropriate to deliver early translational and experimental medicine studies and there was access to suitably experienced research delivery staff. However, the committee highlighted that there did not appear to be any acute medical care on site, which has been an issue for setting up some early phase studies. We should therefore consider whether we need to liaise with OUH to set up a way of working with a crash team. The plans to undertake trials in the community were welcomed and the committee considered one strength of the CRF to be in its community-based partnership. We should bear this in mind as we expand our research further into the community.

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

### Summary update

This report provides an overview of activity at ARC OxTV for the last six months (Sept 2021-March 2022).

**Activity**

The ARC portfolio continues to expand bringing in more partners and funding opportunities (further detail within the report). NIHR accepted changes to our original objectives following last year’s annual reporting, to incorporate additional work taken on to tackle COVID and where access to community services and public health was restricted which meant projects had to be postponed or cancelled.

Projects are progressing well, and we are increasing the information on the website. Our focus on Public Health continues to develop with the following activities:

* Co-applicant supporting Oxfordshire County Council to develop the full funding application of the NIHR [Health Determinants Research Collaboration](https://www.nihr.ac.uk/documents/nihr-health-determinants-research-collaborations-hdrc-specification/28341) £5million funding.
* Children and Young People’s Mental Health – Association of Directors of Public Health Network meeting (January 2022). Mina Fazel presented the Oxwell Schools Survey work and there was a lot of interest across the South East region and several new collaborations have been initiated.
* Public Health Practitioner Development programme

1. The University introduction to Evidence Based Medicine is being tailored to be more inclusive of a public health audience. Health Education England see the potential value of the course and are looking to further fund its development.
2. We will be delivering a training session on communicating research evidence in a political environment.

The NIHR Finance and Activity report for 21/22 is being prepared for submission, at the end of May and again shows substantial progress for the ARC.

The ARC is hosting a Collaboration Event on the 24th of May 2022 in Oxford. The theme is Discover-Develop-Deploy to frame the position of the ARC in the pathway but also demonstrate our partners’ (Trusts, AHSN, local authorities) roles and how the combination is having tangible outcomes and impacts for both our local and national health and care systems. We hope the day will be a celebration of the achievements to date combined with a look forward to the opportunities ahead.

**New work and partnerships**

We have secured an additional £28,000 from the NIHR Centre for Engagement and Dissemination to work with local NIHR infrastructure and trust partner PPI leads to develop training for staff, public and researchers on how to prevent and mitigate difficult situations in PPI. The programme will be developed in partnership with research teams in Manchester and the East Midlands with an aim to roll out nationally towards the end of the year.

The AHSN/ ARC partnership were successful in applying for an additional £275,000 to deliver a project for the NHS Insights Prioritisation Programme <https://www.ahsnnetwork.com/rapid-insights-to-support-post-pandemic-priorities> . The project is looking at the use of virtual, hybrid and face-to-face clinics within the assessment of patients who’ve experienced a transient ischaemic attack (TIA). We are working with trusts across the South East region, which covers five different Integrated Stroke Delivery Networks (ISDNs).

PANORAMIC Trial being led by the Department of Primary Care is being supported by the ARC through communications support and we are capturing the inclusive approach led by Prof Mahendra Patel to provide a toolkit to support inclusion for others.

**Capacity Development**

The ARC continues to support our Senior Research Fellows, who are also supporting additional projects and developing their leadership in their areas of expertise. The internship programme is progressing well for both projects and we have secured a further £41,000 to run the programme again this year. We are working with Oxford Brookes University as they receive similar funding from Health Education England and both organisations have very different offers but the combination will reach out further into our health and care systems. The ARC is also supporting a recipient of an NIHR Development and Skills Enhancement Award in Mental Health.

Four new DPhils have started. Lucy Goddard, DPhil student attended the Academy Doctoral Training Camp and has written a [blog](https://www.arc-oxtv.nihr.ac.uk/blog/nihr-academy-training-camp-my-experience-from-a-brilliant-3-day-residential-training-camp) sharing her experiences.

A pilot workshop on Interrupted Time Series Analysis has been developed by members of ARC Theme 6 and will be delivered this month. The two day training introduces different methodologies, when they are suitable and will also include practical training for staff in the AHSN, Commissioning Support Units etc. on the use of R programme to ensure routine data is utilised as effectively as possible.

The ARC funded four places (two places for ARC and two for AHSN) on a Real-World Evaluation course hosted by University of Sheffield. Through funding received by the ARC to support work aligned with the NHS Beneficial Changes Network Programme, including capacity development.

Finally, the Masters in Digital Health has recruited its first cohort to start in the Autumn of 2022.

**Staffing**

We are pleased to announce that we appointed Professor Stavros Petrou as our Deputy Director to provide additional support and networks for the ARC and to support succession planning.

**Community Involvement**

The OxWell Schools project has actively involved young people in the development, delivery and dissemination of the project and its outputs. One suggestion was to utilize TikTok as a medium to disseminate outcomes, the first TikTok video can be seen [here](https://vm.tiktok.com/ZM8Qh7vvq/).

Monitoring of our public involvement activity overseen by the cross-ARC PPI Champions Meeting. DPhil and ARC researchers are bringing their project ideas to support development of the involvement activities and rationale for the projects.

Working with the BRC and the Department of Primary Care, the ARC has developed a PPI online web resource for our own researchers and those working in any aspect of health and social care research across the Medical Sciences Division. [Patient and public involvement (PPI) Researcher Guidance - NIHR Oxford Biomedical Research Centre](https://oxfordbrc.nihr.ac.uk/ppi/ppi-researcher-guidance/)

**Implementation, evaluation and AHSN collaboration**

Key activities during the last 6 months include:

* ARC contributed to the AHSN NHSE visit (December 2021). Shared how the research on blood pressure self-monitoring and self-management (Theme 2) supported the system work on cardiovascular disease (CVD).
* ARC/ AHSN Implementation Oversight meeting (October 2021). ARC projects are now RAG rated both for project progress and also progress with dissemination, implementation and impact. Red rated projects will be discussed at ARC Strategy Board to identify what support can be provided. Currently the AHSN are integrated with three themes (2, 5 and 6) and responsive to requests from the other three. This is due to either the current stage of the projects or the projects are not for AHSN implementation support. However, there may still be opportunities for the AHSN to offer guidance, alongside working with the ARC Implementation Manager.

**National Context**

**NIHR Update**

NIHR have released their updated [open access policy document](https://www.nihr.ac.uk/documents/nihr-open-access-policy/28999). NIHR has also published their first [NIHR Diversity Data Report](https://www.nihr.ac.uk/about-us/our-key-priorities/equality-diversity-and-inclusion/NIHR-Diversity-Data-Report-2021.pdf).

The National ARC/AHSN Winter meeting took place in January 2022. The meeting focused on deepening the collaboration between both organisations to increase impact within the health and care system. As part of the meeting, each partnership submitted a Collaboration Statement on how they currently work together and future plans. We have an incredibly strong partnership with our AHSN and work well across the whole of the South East region.

The ARC has applied for an additional £320,000 funding to increase capacity and capability in high quality dementia research. The application focuses on sharing innovations developed locally with the populations and areas where the need is greatest, through partnership with Oxford Health, the Brain Health Centre and Department of Neuroscience, we will hear the outcome of this application in May 2022.

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

### Summary update

**Twelve-month extension of the NIHR MIC**

* OHFT were advised by DHSC and NIHR of the offer of a 12-month costed extension to the current award in August 21, with a new end date of December 2023.
* The MIC management and theme leads developed new aims and objectives for completion of an amended business plan for the extension period, which was submitted in November 21.
* Extension business plan funding was approved by the DHSC and NIHR in December 21.

**CONDOR update**

* The MIC has continued its leadership (CI Prof Gail Hayward) of the NIHR-funded CONDOR programme (<https://www.condor-platform.org/>) for the evaluation of diagnostics for SARS-CoV-2 / COVID-19.
* The CONDOR collaborative group is seeking a further no-cost extension to the NIHR CONDOR funding to facilitate the completion of a further test evaluation, with an extension requested until 30/09/2022
* Efforts to extend the scope of CONDOR work to cover multiplex tests for respiratory viruses through a costed NIHR extension did not proceed, as the NIHR indicated a move away from the prioritization of new funding to reactive COVID-related research.
* The CONDOR consortium is preparing a programme grant application related to diagnostics and preparedness for future pandemics. It is anticipated that this application will be submitted for the NIHR July deadline.

**RAPTOR-C19 update**

* Work has continued on the RAPTOR-C19 element of the CONDOR programme (evaluation of diagnostics for SARS-CoV-2/COVID-19 in community settings - <https://www.condor-platform.org/condor_workstreams/raptor>).
* RAPTOR has completed the evaluation of the first two candidate point-of-care diagnostics for SARS-CoV-2, with a report manuscript currently in preparation. The results of the performance of one of these tests will be presented at the SW-SAPC conference w/c 07/03/22.
* The RAPTOR team has negotiated a contract with a further company for the supply of an additional diagnostic for inclusion in the study. This evaluation will proceed shortly pending approval of the no-cost extension to CONDOR by the NIHR.

**EMPOWER (Femtech) project**

* The MIC won external funding from the NIHR SPCR for a new project to identify clinical needs for women’s health across the life course (<https://www.community.healthcare.mic.nihr.ac.uk/research/femtech>), with work having continued at pace since the last report to the Board.
* The EMPOWER team has two live surveys for healthcare professionals and public/patients respectively to collect opinions on need for women’s healthcare technologies, to support priority setting within the project.
* EMPOWER focus groups will follow completion of survey data collection in May, for both healthcare professionals and public/patients.

**New grant applications**

* Submission of an application to NIHR HTA call 21/608 ‘What is the diagnostic accuracy of different pulse oximeters at oxygen saturation levels (SpO2) relevant to their use by patients at home and how does this vary in people with darker pigmentation and skin tones?’, in collaboration with colleagues in the Medical Sciences Division and the University of Birmingham.
* Submission of an application to the NIHR SPCR to support the development of a platform for the evaluation of novel diagnostics for urinary tract infection in general practice, in collaboration with the Universities of Southampton and Bristol, and Public Health Wales.

**Workshops and meetings**

* MIC Diagnostic Evidence Workshops will take place face to face at St Hugh’s College in June 2022. The MIC will begin to advertise tickets for the workshop during March. The workshops comprise 1. General introductory day, 2. Health Economics for Diagnostics day, 3. Statistical Methods for Diagnostic Medicine day. Students can choose to attend any or all days of the course.
* The NIHR MIC Methodology Group of all 11 MICs will reconvene in Oxford during the morning of the 7th July.
* The CONDOR consortium meeting will take place on the 7th and 8th of July at Trinity College Oxford, with speakers and attendees also invited from outside the consortium.

## Research Management Team (RMT)

### Set Up

Despite the pandemic, 47 studies have been opened this year to date (08 March 2022). 46 were opened in 2020-2021 and 52 in 2019-20.

This year studies have been turndown due to lack of capability and capacity (C&C) within OHFT which is new for us as a Trust. The complexity of studies coming though has contributed to this and we need to prepare ourselves as a Trust to ensure that we do not miss out on the opportunity to deliver high quality and innovative studies with massive impact for our community in suture.

The main barriers to research set up at present are:

* The increasing complexity of clinical trial protocols – these have impact not only on C&C issues but also due to the complexity of contractual and research informatics requirements.
* Shortage of capacity in the delivery teams (lack of trained staff ie qualified nurses or phlebotomy trained staff, etc).
* Lack of engagement from services required at Oxford University Hospital NHS FT (OUH) examples being scanning and lab services. This can be mitigated by prioritising overarching service level agreements between ourselves and OUH, which is something that we have been trying to put in place over the last twelve months

The Research Management Team itself is currently fully staffed and well positioned to support the set up of research in the Trust. The Research Management Team will leave the Trust at the end of April 2022, and the process for a replacement has already begun.

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

As at 08 March 2021 we have 87 **active (open) studies** and 12 on hold for a total of 99 open studies. This is very close to our pre-pandemic level.

Studies according to the site type:

|  |  |
| --- | --- |
| Site type | Number of studies |
| Recruiting site | 82 |
| PIC | 13 |
| other non-recruiting | 1 |
| research database | 3 |
| **Grand total** | **99** |

These numbers do not necessarily illustrate the complexity of the trials that we have in delivery.

### Contracts

To date, during 2021-22 76 contracts and legal agreement have been signed compared to 72 in total last year.

## 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, including ‘count me in’
* Managing the CRIS system
* Completion of the NIHR BRC and CRF annual return metrics
* Supporting the development of efficient systems and processes to support research management and delivery

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

OHFT RI team work closely with Akrivia Health, a company which spun-out of the BRC and provide the Trust with the CRIS system, as de-identified pseudonymised research platform. The Trust also has a seat on the Akrivia Board.

Akrivia continue to access the high level of expertise within the CRIS team at OHFT and work with them to identify areas of common interest. The CRIS platform continues to undergo user acceptance testing (UAT). This system has now been in a UAT phase with ongoing issues since April 2021. The RI team continue to work closely with Akrivia Health (the developers of the pseudonymised research data platform, to resolve the ongoing system issues. Once resolved users will then be regranted access.

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

## Research Pharmacy

The pharmacy team is a key element of research within OHFT. It currently has 18 trials open for dispensing, a mixture of commercial and non-commercial trials, and 8 in set up. They continue to meet regularly and all QMS criteria are up to date.

They are the central pharmacy for a multi-site trial sponsored by University of Oxford, currently running only in Oxford but very soon due to open at other nationwide sites where IMP will be posted to participants.

They are increasingly opening trials where the day to day running involves the use of new technologies and software. These trials are both challenging and exciting for the team as they learn and adapt to new and future work practices.

The expansion of the team recently has been a great asset as workload has increased. In common with all other research teams, pharmacy is experiencing the pinch point of current open trials extending the trial end dates competing with new trials in set up ready to open. The pharmacy team was able to add to their number as well as expand the skills of current team members to give greater capacity.

At the time of writing there has been no problematic impact of the Brexit regulations which came into full UK regulation as of January 2022. Some sponsors asked pharmacy to accept more stock prior to the deadline and for others we have processed amendments on how their medication will be certified or imported into the UK. These issues have all been managed by the pharmacy team so that no negative outcome or delay has been experienced by participants.

## Financial Performance

**2021-22 Performance**

The current year has been distorted by two notable streams of income, our Research Capability Funding (RCF) allocation and commercial income from the Novavax vaccine study. Due to this R&D are currently estimating a contribution to the Trust of £611k and a favourable budget variance of £929k for the year ending March 2022.

We will be meeting with the finance department to try and find ways in which this surplus can be used for research and to mitigate potential cost pressure during 2022-23

**2022-23 Forecast**

The next financial year will see a £1m reduction in RCF, non-recurrence of the Novavax surplus (circ. £600k) and potential cost pressures within the CRF. This will reduce our flexibility and limit our response to new opportunities. We will also be in transition from the current CRF to a new award starting in September and hopefully from the existing BRC to a new expanded BRC.

## Research Active Workforce

**NIHR 70@70**

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

Other initiatives linked to the 70@70 programme include:

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

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

Bi-annual Academic Writing Retreats for Nurses are co-funded by the OHFT and Oxford BRCs, CRF and OxINMAHR. The last retreat was in January 2022 and was successfully delivered online due to Covid-19. The online retreat evaluated very well and the next one is planned for October 2022. Monthly ‘lunch lab’ clinical research educational sessions for staff are also well established.

An online ‘Research Support Package’ for clinical staff has been launched and is available to all OHFT staff via the Trust’s L&D portal. The two main online modules focus on aspects relating to research design and research delivery from a Trust perspective.

NIHR James Lind Alliance in Community Nursing: this ARC funded project involved undertaking a priority setting partnership in community nursing to identify the top 10 evidence uncertainties in this area. The two surveys sent out as part of this process were shared with community nurses, patients and carers at a national level. A national steering group, with representation from Chief nurses, community nurses, patients and carers across England was established to guide the process. A final workshop in mid-September resulted in the identification of the top 10 evidence uncertainties in community nursing <https://www.jla.nihr.ac.uk/priority-setting-partnerships/community-nursing/>

with project completion shortly afterwards. The process enabled national collaborations with colleagues at NHS England, the CRN, and NHS Engagement to ensure the research priorities are embedded within the national community nursing agenda. In addition, the NIHR ARC TVSM has committed to hosting a workshop in late Spring 2022 to identify which of the evidence uncertainties can be supported and prioritised through the ARC.

A new Masters level MSc in Professional Practice was launched in 2021. Dr Henshall led the Advanced Research Design module and the module team was made up of experienced research and teaching colleagues across the R&D team. The MSc Programme will be available for all clinicians across the Trust to access through either the Mental Healthcare or Physical Healthcare workstreams. The module ran from October to December 2021 and the next intake is planned for October 2022.

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

We have also created secondment opportunities for nurses and allied health professionals working in clinical settings to allow them to spend up to 12 months working within the R&D department. Additionally, we are supporting student nurses to undertake their clinical and management placements on the CRF and across the R&D department. Similarly, we are supporting an NMAHP colleague to take on Associate PI responsibilities on the PRINCIPLE trial, as part of the NIHR Associate PI scheme.

## Collaborations

### Oxford Academic Health Partners (OAHP)

OAHP facilitates and supports major programme renewal submissions to NIHR. CRF was completed and, following stage 2 submission in October 2021, work to ensure coherence and distinctiveness for both BRCs continued. In Jan 2022 OAHP initiated a series of cross organisational discussions with **NIHR infrastructure leaders**, starting with Oxford and Thames Valley Applied Research Collaboration (ARC).

**Integrated Care Systems** (ICS), still at an early stage of development following changes in the Health and Care Bill that will be implemented later this year, remain a priority. OAHP works closely with Oxford AHSN, whose streamlined approach will benefit from effective relationships with Frimley and BLMK as well as BOB-ICS.

OAHP will contribute as required in efforts to determine the research and innovation needs of ICSs. Detailed surveys and discussion with the ICS teams will be held annually. Three OAHP Board members, including the OHFT Chief Executive, sit on the BOB-ICS executive Senior Leaders’ Group. The Director of Strategy at BOB-ICS has moved on recently, active engagement with his successor is underway.

OAHP contributes on behalf of the Partnership to an important **project on clinical data flow** comprising parallel working groups on Governance, Intellectual Property-Value and Infrastructure. OAHP facilitated Oxford Health’s involvement, collated material for a successful bid to NHSx (Nov 2021) for funding to develop a Trusted Research Environment (TRE) for Thames Valley and Surrey led by OUH NHS Foundation Trust.

Following the government Spending Review, OAHP is considering the aims and requirements to deliver to the Life Sciences Vision. The following missions align with OHFT’s strategy:

* Improving translational capabilities in neurodegeneration and dementia
* Increasing the understanding of mental health conditions, including work to redefine diseases and develop translational tools to address them

In addition, OAHP **maintains a watching brief** on relevant local developments such as the Oxford-Cambridge Arc, cluster groups at the Harwell campus and works with other AHSCs nationally, contributing to roundtable discussions and developing their focus on Health Inequalities.

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

### Background

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

* Movement, Occupational and Rehabilitation Sciences (MOReS) Interim Centre Director: Dr Patrick Esser: [pesser@brookes.ac.uk](mailto:pesser@brookes.ac.uk)
* Nursing, Midwifery, Health and Social Care Research Centre Co-Director: Prof Eila Watson: [ewatson@brookes.ac.uk](mailto:ewatson@brookes.ac.uk)
* The Centre for Nutrition and Health Centre Director: Dr Jonathan Tammam: [jtammam@brookes.ac.uk](mailto:jtammam@brookes.ac.uk)

**Recent Staff Appointments**

* Deputy Director of OxINMAHR (*Prof Eila Watson*)
* OxINMAHR Research Governance Manager (*Mr Boki Savelyich*)
* OxINMAHR Research Fellow (Health statistics) to be announced

**Vacancies and Opportunities**

* Prof Helen Dawes has left OBU. *Seeking to appoint x2 joint clinical academic AHP professorial appointments*
* Prof Jane Appleton is retiring in 2022. *Seeking to appoint x 2 joint clinical academic nursing professorial appointments*

**External Advisory Board Appointments**

* Prof Tracy Howe: *Director of the Cochrane-Campbell Global Ageing Partnership, Co-chair of Cochrane’s Governing Board*
* Prof Danny Kelly: *RCN Chair of Nursing Research Cardiff University*
* Prof Debra Bick: *Professor of Clinical Trials in Maternal Health, and Deputy Pro Dean for Research at Warwick Medical School.*

**OH BRC**

Named OxINMAHR senior researchers in 2 OU BRC themes

* Professor David Foxcroft (Prevention: population and individual approaches)
* Professor Jane Appleton (Mental Health and Development)

**Grant activity**

|  |  |  |
| --- | --- | --- |
|  | **2020** | **2021** |
| Bids submitted (n) | 100 | 76 |
| Bids awarded (n) | 13 | 26 |
| Bids awarded (£) | £2,917,834 | £3,631,854 |

**Doctoral Training Programme**

* **9** OxINMAHR Doctor of Philosophy Degrees conferred in 2021
* **46** current OxINMAHR PhD candidates
* **2** new PhD Scholarships funded for 2022
  + *Development of Rehabilitation Interventions for acute Spinal Cord Injury (Dr Mark Williams)*
  + *Digital self-management platform for personalised supportive cancer care (Dr Peter Wright)*

**Other relevant activities**

* OxAHP award: Internship for OxINMAHR and Institute of Public Care
* NIHR Clinical Masters programme bid (OBU Led): awaiting decision
* HEE OxINMAHR Internships: 2 awarded in 2021 and 2 to be advertised for 2022 intake.

### Oxford Joint Research Office (JRO)

The following is an extract from an internal briefing shared with JRO members in December

A JRO, bringing together staff from clinical research support teams at the University of Oxford (OU) and Oxford University Hospitals NHS Foundation Trust (OUH), was established formally in 2011. Its purpose is to promote and to facilitate the conduct of clinical research involving its partner organisations, to improve patient and public health locally, nationally and internationally. The JRO has set out to achieve this by improving communication and streamlining processes through sharing knowledge and expertise between OU and OUH.

The JRO has always had a close working relationship with OH and OBU, but this has now entered a significant new phase with both organisations joining as formal partners in an expanded JRO. This development will bring together the teams responsible for supporting clinical research across both NHS Foundation Trusts and both Universities in Oxford, as part of an initiative supported at the highest level in each organisation and by the Board of the Oxford Academic Health Partners, chaired by Professor Sir John Bell.

A further wider briefing note is being developed by the OUH communications manager

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1. *A risk assessment has been undertaken around the legal issues that this paper presents and there are no issues that need to be referred to the Trust Solicitors.*
2. *This paper (including all appendices) has been assessed against the Freedom of Information Act and the following applies:*

* *THIS PAPER MAY BE PUBLISHED UNDER FOI*

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