

Trust Board Paper

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| Board Meeting Date | 14th November 2023 |
| Title | Research and Development Annual Report 2022/2023 |
| | Item for Noting |
| Purpose | This report presents a summary of research and related activity for the year 2022/2023 |
| Format of the Report | The format of the report is not nationally prescribed |
| Business Area | Corporate (Medical Directorate) |
| Author | Kate Penhaligon, Head of Research and Development |
| Relevant Strategic Objectives | <p>Patient safety The report highlights the processes in place to ensure compliance to relevant frameworks and examples of hosted research projects aimed at addressing harm risk for our patients. Two studies are highlighted as examples of how research is being used to address patient safety in Self-Harm (the SafePIT study) and eating disorders (Panorexia).</p> <p>Patient experience and voice This report highlights the on-going programmes of work to ensure our patients' views are met in the design, conduct and output of the research process. An example of using coproduction with Kids charity is provided with a summary of information from the Patient Research Experience Survey (PRES) feedback and how carers have got involved in Research. Examples of hosted research projects are also noted.</p> <p>Health inequalities Research has been used as a tool within the Mental Health Act detentions project and for delivery aspects of the neurodiversity strategy, all projects aiming to reduce health inequalities across Berkshire. This report highlights some examples of home-grown and hosted research projects.</p> <p>Workforce The R&D department collaborate with several external partners who are research active. Our Research also supports several MSc placements, internships, apprentices, and studentships.</p> <p>Efficient use of resources Berkshire Research is predominantly funded by the National Institute for Health and Care Research (NIHR) to support delivery of Research. The core team also work to attract additional income based on research activity through industry (commercial research), grant funding opportunities, charitable funding, and education funding to sustain and grow capacity for research across the Trust.</p> |
| CQC Registration/Patient Care Impacts | Data and evidence is available to support key research questions arising from CQC inspections. |
| Resource Impacts | Research capacity is managing 1.8 whole time equivalent vacancies within the clinical research team |
| Legal Implications | <p>Operating according to the UK Policy Framework for Health and Social Care Research Compliance to statutory obligations:</p> <ul style="list-style-type: none"> • Medicines for Human Use (Clinical Trials) Regulations 2004 • Mental Capacity Act • Human Tissue Act 2004 • Section 111(7) of the Care Act 2014 • General Data Protection Regulation and Data Protection Act 2018 • International Conference on Harmonisation for Good Clinical Practice |
| Equalities and Diversity Implications | Equity of access to research studies has been a focus of the trust research strategy. This is well aligned with the trust strategy and values and also a national objective from the National Institute for Health and care Research (NIHR). |
| ACTION | The Board is asked to receive this report and note the content, progress made during the year, projected recruitment for 2023/2024. |

Executive Summary

This paper presents the Research and Development Governance and Performance report for 2022-2023. The Research portfolio at Berkshire Healthcare NHS Foundation Trust is predominantly hosted research projects of both observational and interventional research. The Trust sponsored 3 research projects across 3 services.

In March 2022, in readiness for the new financial year, the Department of Health and Social Care (DHSC) Chief scientific advisor issued a call to action to address the current clinical research delivery challenges in the NHS. The UK Clinical Research Recovery Resilience and Growth (RRG) programme, led by DHSC and NHSE to ensure restoration and delivery of a full portfolio of clinical research. The programmes aim was to recover the UK's capacity to deliver research by discontinuing poorly performing research, encouraging NHS sites to expedite commercial research, and introducing performance related payments to Trust's where more than 80% of commercial research is 'on-track'. Research sponsors were requested to take action to get studies that were not progressing back on track or, if this was not possible, close them to recruitment or close them completely.

The reset process was unable to recover commercial contract research at the same rate as non-commercial research and in May 2023, the DHSC instructed sites to 'expedite the setup and delivery of commercial contract studies' to clear the back log of commercial studies in setup and to achieve the globally competitive timelines. The DHSC recognise that the availability of both Research funded staff, including those supported through the National Institute for Health and Care Research, the Clinical Research Networks, and the wider NHS, is a major factor in the practicability of studies. Pressures on NHS R&D Departments remain high as they support large portfolios of studies and follow-up activities.

The findings and recommendations in the recent [O'Shaughnessy review](#) are welcomed as a national focus on how to improve performance for commercial trials. Commercial research within Community Mental Health and Physical Health remains low in numbers compared to acute-focused industry research. Berkshire Healthcare are working with NHSE on a demand signalling programme initiated in August 2023 which seeks to identify the gaps in mental health research and to identify the research priorities for funders and sponsors.

Our aim through this work has been to make delivery of our Research portfolio achievable and sustainable within the resource and capability we currently have across the Trust. Delivering on the Research and Development strategy, we continue to work to ensure a balanced research portfolio across the divisions. In the FY 2022/2023 year the Tissue Viability service hosted 2 commercial trials. This is a welcome addition of a research active service within our Community Physical Health division, given our research activity is predominantly within mental health.

In 2022/2023 we delivered **73** research projects; this compares to 94 research projects in 2021/2022. This includes **43** National Institute of Health Research (NIHR) Portfolio studies and **30** non-NIHR Portfolio studies. Most participants recruited to the NIHR Portfolio projects were recruited into non-commercial observational studies. We were ranked joint **16th** out of **48** similar Trusts (Mental Health and Community Trusts) for the number of national studies and were **22nd** out of **48** similar Trusts for the number of participants that we have recruited. We recruited **690** participants (**654** recruited into non-commercial trials and **36** into commercial trials) to Portfolio and non-portfolio studies.

The Research and Development strategy was approved by the board in October 2021. The strategy was aligned to the government's policy: The Future of UK Clinical Research Delivery. Owing to the national changes and changes to the way the NHS works and delivers its services, the Research and Development strategy will be refreshed accordingly to reflect the updates within the national strategies such as [Making Research Matter](#) (Chief Nursing Officer for England's strategic plan for Research), The Royal College of Physicians (making [Research everybody's business](#)) and the programmes of work that support Lord O'Shaughnessy's review of commercial clinical trials.

Dr Minoo Irani – Medical Director and Executive Lead for Research

Patient safety

Providing Safe Services

This report covers the period from 1 April 2022 to 31 March 2023 and examines data and activity in relation to the Clinical Research activity across the Trust, compliance to the UK Policy for Health and Social Care Research and how the Trust discharges its statutory duties and responsibilities applicable to Clinical Research.

Research and Development (R&D) is part of the Corporate Division of Berkshire Healthcare NHS Foundation Trust, reporting via the Medical Director, who is an Executive member of the Board. The Research and Development Committee is accountable to the Trust Board through the Clinical Effectiveness Group (CEG). It is chaired by the Head of Research and Development; it meets every 2 months and was quorate for 2022/2023. R&D is also represented as an invited member of the Quality & Performance Executive Group (QPEG).



Research governance refers to the framework to manage the research process from end to end. The Health Research Authority provides assurance to the NHS that study complies with required standards and criteria. They assess the governance, legal compliance and the ethics review and will issue approval once all other regulatory approvals, i.e. Research Ethics Committee Medicine Health Regulatory Agency, Confidentiality Advisory Group, are in place.



The Health Research Authority approval provides assurance to the NHS that study complies with required standards and criteria to free up NHS sites to concentrate on putting arrangements in place to deliver the study.



We have robust processes which are in line with the Health Research Authority guidance of assessing, arranging, and confirming capacity to deliver research. Assessment is captured within our quality management system and workflows are used to capture processes and evidence/information for in-depth reporting. We are responsible for assuring the framework is adhered to and the roles and responsibilities of individuals at the site, and any collaborating parties, are agreed and documented.

In 2022/23 the R&D department undertook a review of the governance processes to ensure compliance with the UK Policy Framework for Health and Social Care and to maximise efficiency.

The national HR Good Practice Resource Pack provides the expectations for the study and the pre-engagement checks that should and should not be undertaken. To ensure appropriate access for research purposes to our patients, staff and/or Trust premises, all researchers must have the relevant access, either a substantive/Honorary research contract (HRC) or be issued with a letter of access (LoA) accompanied by a complete Research Passport. The level of access is determined by the activity the Researcher is undertaking. In 2022/23 the department issued **30** LoAs and **1** HRCs to non-BHFT researchers. Local services have oversight and operational management for the individuals requesting the access.

All research falling under the remit of the Secretary of State for Health must have a formal Sponsor. This includes all research in health and social care that involve NHS patients, their tissue or information. The Trust sponsors home-grown research projects and hosts national projects and student research projects. No Trust sponsored applications were received in the financial year 2022/2023 however support was given to conceptual ideas which led to future sponsorship applications for FY 2023/2024. Three Trust sponsored studies were active in 2022/2023. We have governance processes in place that evidences our compliance to sponsorship activity. The Research & Development committee have oversight of all sponsored studies and are involved in assessing the risk for interventional clinical research projects prior to Trust sponsorship approval.

Reducing harm risk for our patients

We have two hosted research trials highlighted below to demonstrate how research can be used to reduce the potential for harm to patients in higher risk services and provide a positive experience to patients accessing our services.

Self Harm

SafePIT study: The Self-harm, Assessment, Formulation, Engagement Trial of Psychodynamic Interpersonal Therapy (SAFE-PIT). This study sponsored by the University of Leeds aims to find out whether a type of brief therapy, psychodynamic interpersonal therapy (PIT), helps people who attend an emergency department (ED) after an episode of self-harm (SH). With a focus on whether PIT helps people reduce future SH, ED attendance and improve their mental health and quality of life. This study also measure costs and potential cost-savings as this is important for the NHS. PIT therapy involves 4 weekly sessions and is intended for people who have 3 or fewer SH episodes.

Eating disorders

PANOREXIA – This study provides opportunities for our patients who have been suffering from a DSM-V diagnosis of anorexia nervosa for 3 years or more, and who have found other forms of treatment ineffective. Over a period of 6 weeks, participants who are deemed eligible at screening will partake in 8 study visits, including three psilocybin dosing sessions with varying doses. The maximum dose of psilocybin a participant will receive in a single session is 25 mg. Across these 8 visits, there will also be 2 MRI scans, 5 EEG recordings and a range of psychological measures (questionnaires and interviews). There will be a follow-up period of 12 months following the final study visit. This is a collaborative study with Oxford Health and Oxford Universities.

[For further examples please refer to studies captured under disease/condition area](#)

Patient experience and voice

Using patient experience and voice, we continue work to establish strong links with our local communities by gaining patient and carer feedback. Co-production and Co-design for research projects has been a national research focus since 2016 with the National Institute for Health and care Research mandating evidence of Patient Public Involvement in all funding applications.



Carers

Research active staff are members of the Carers Hub – Friends, Family and Carer network (Teams channel). Opportunities to participate in research projects or research design work and to understand what kind of support they would want are posted on this forum. In the FY 2022/2023, we opened the '**Continuing Compassion in Care (CCiC): Caring for someone living with dementia**' research project which is particularly focussed on self-compassion and how compassion for others starts with ourselves through an online support package. This study gathers the experiences of compassion, emotions, thinking styles and how carers feel about their relationships. We have continued to recruit to this study in FY 23/24.

We completed a study looking at the online support group use and wellbeing of carers of people with intellectual disability. This research aimed to explore the importance of carer networks and peer support as an adjunct to existing service support in health care. The Support Hope and Resources Online Network (SHaRON) was implemented within the learning disabilities services with a platform for relatives and paid carers and then a separate platform for people with an intellectual disability. The findings are being analysed.

Patient and staff experience

The Digital Health Tools in Psychosis study was hosted by the Early Intervention in Psychosis team. This survey was formed to understand what service users and staff think about using digital devices like a smartphone (e.g. Android phone or iPhone) or wearable device (e.g. Fitbit or smart watch) to help manage mental health. This study is looking to recruit 300 service users and 300 healthcare professionals (HCPs) nationally. Our site target is 20 and we have recruited 10 to date which is a mix of both service users and HCPs. It remains active and is open to recruitment until March 2024.

Patient experience

Improving Peer Online Forums (iPOF) trial. Berkshire Healthcare are the lead (and only) NHS site and hold the grant for this research study. As the host trust we are responsible for various outputs, the first one being an animation video <https://www.sharon.nhs.uk/research/> which looks at the opportunity and potential benefits of using a digital community to support well-being and positive mental health. This animation video which highlights the benefits of using an online forum like SHaRON was co-designed by the service-users and patients who use SHaRON and who are participating in the main research trial.

Staff voice

The open-door project was hosted by the perinatal mental health team. This project aims to develop recommendations for how services can increase and improve access to evidence-based psychological support perinatal parents. It is estimated that between 2-22% of parents in the perinatal period experience perinatal obsessive-compulsive disorder (POCD), with an increased amount experiencing sub-threshold symptoms. This project sought the professional's views of healthcare staff in answering these three Research questions:

1. What barriers, from a healthcare professional perspective, are a priority to focus on to increase access to psychological treatment for perinatal obsessive-compulsive disorder?
2. What are potential solutions to overcome the prioritised barriers, from a healthcare professional perspective?
3. How could solutions be implemented most effectively to improve access to psychological treatment for perinatal obsessive-compulsive disorder, including format, delivery and distribution?

Patient Research Experience Survey (PRES)

PRES is an annual nationally standardised survey used to collect participants' views and experiences of participating in NIHR supported research. In 2022/2023, Berkshire Healthcare received **19** returns from participants. Berkshire Healthcare utilise this feedback to improve our service provision.

In the financial year 2021/2022, a review of community and mental health Trusts within the South-East Central Network showed that Berkshire Healthcare is the only Trust which does not have an 'opt-out' approach to research. The Trust supported the move to an 'opt-out' approach which has significant advantages for both patients and researchers. Patients consider research to be important and that they want to be made aware of opportunities to participate in research. Research evidence has shown that an 'opt-out' approach to research recruitment could benefit both clinical research and patient care.

This is an organisational change and as such we are working with support and advice from Information Governance to engage with all clinical services to implement the changes. An action-plan is being utilised to ensure a smooth implementation and to populate a Data Protection Impact Assessment Form.

Health inequalities

The research team continue to support the Trust in their focus on health inequalities through planning and delivery of research studies

Learning and Disability team

We were successful in obtaining contingency funding to develop a Learning Disability Research Strategy which aims to ensure that research opportunities are provided to this patient population. This work is continuing in 2023/2024 in partnership with the learning disability service and the KIDS charity. Co-production is at the core of this work, the patient population are being consulted to ensure their voice is heard ensuring that we are inclusive in the outputs developed from this strategy. This work provides input and support to the neurodiversity strategy.

Mental Health Act Detention work

The core Research team have been integral in supporting the Trust with workstreams linked to health inequalities. In 2022/2023, we were successful in obtaining funding to support the Mental Health Act Detentions work and provided resource from the service to complete a literature review which has helped shaped the direction of this work in 2023/2024.

[Link to Highlighted study:](#)

[Why are black people overrepresented in Mental Health Act detention data](#)

Sensory App

The University of Reading collaborated with us to host this NHS England funded project. The project provided the healthcare community with an easily accessible open resource sensory App which was used to identify sensory reactivity differences in autistic adults, and provide specific recommendations for healthcare providers.

Workforce

Aligning with the Trusts strategy to make the Trust a great place to work for everyone **supporting our people** and **encouraging partnership working** is of paramount importance to the research that we deliver in Berkshire Healthcare.

We **collaborate with health and social care partners**, including Integrated Care Boards (ICBs); these partnerships allowed us to work with **23** universities, **6** NHS organisations and several commercial and small technology companies. This brought research opportunities to patients, staff, and carers aiming to **address Health Inequalities and provide better, more efficient care**. Through collaboration **our local communities** strengthen the opportunities and deliver research projects **that respond to local community needs**.

Our aim is to attract and retain research interested, skilled and experienced staff who feel that their skillsets are valued. That they are empowered to progress research interests and careers at Berkshire Healthcare. **Recruiting and retaining a consistent workforce continues to be one of the biggest challenges we face at Berkshire Healthcare.** In September 2022 the Trust hosted a recruitment and retention rapid improvement event backed by research. This has resulted in a programme of intended work supported by the R&D Team. This programme includes consistent competency sets across the workforce based on the four pillars of practice, one of which is research. These programmes have been initiated in 2023/2024.

Berkshire Healthcare enabled and empowered our most senior Clinical Research Practitioner to complete the new **Clinical Research Practitioner registration**. Given their wealth of experience and knowledge this work was completed. They were appointed as the Clinical Research Practitioner Engagement Lead for Thames Valley, South Midlands Clinical Research Network in February 2023.



Embedded

Berkshire Healthcare's research culture demonstrates **clear benefits for the development of staff skills**. It is our vision to ensure **all staff can articulate the role they play in research**. Clinical research increases staff engagement and retention by ensuring that innovations and advancements of clinical practice can be adopted into departmental practices, whilst also contributing to evidence-based practice and enabling skill and knowledge development for staff. The ambition is to support research development opportunities akin to the internship/clinical academic role, across several disciplines.

Evidence demonstrates that Trusts active in clinical research have better patient care outcomes. Delivering **innovative ways of working and care initiatives** aids the development of research skills and supports **development of staff** across the organisation ensuring that **we can build and sustain teams fit for the future**. Wherever possible externally research generated funds have enabled us to **invest in clinicians** based within clinical services. They support the **development and delivery of research** rather than this sitting within the core R&D team. This helps to provide embedded access to opportunities which are relevant to local populations and develops research knowledge and skills within the clinical services.

[Team Structure](#), [Plan on a Page](#) and [CQC Single Assessment Framework](#)

Efficient use of resources

The R&D department are predominantly funded by the National Institute for Health and Care Research (NIHR). The majority of this is Activity Based Funding (ABF) and is received via the Local Clinical Research Network (CRN) Thames Valley and South Midlands.

Funding is supplemented by NIHR Research Capability Funding (RCF), a small commercial and non-commercial stream of income and some trust finance. Funding is allocated annually; several team members hold short term contracts as funding is based on previous years' research activity.

[Income 2018-2023](#) and [Finance dashboard](#)

| Research External Income Sources | | | | | |
|-----------------------------------------------------------|----------------|----------------|----------------|----------------|----------------|
| Source | 2018/19 | 2019/20 | 2020/21 | 2021/22 | 2022/23 |
| Clinical Research Network Core Funding | 400,000 | 420,000 | 445,000 | 463,000 | 477,000 |
| Clinical Research Network Contingency Funding | 39,413 | 5,000 | 0 | 35,424 | 52,158 |
| Greenshoots Funding | 0 | 13,358 | 0 | 0 | 0 |
| Excess Treatment Costs Payments | 0 | 3,106 | 352 | 9,293 | 3,807 |
| Research Capability Funding | 20,000 | 20,000 | 52,960 | 48,054 | 29,073 |
| Commercial and non-commercial research Income | 10,453 | 2,414 | 3,457 | 35,123 | 46,964 |
| Other Funding | | | | | |
| Hosted NIHR Grant (IBER) | 5,258 | 150,353 | 63,279 | 26,555 | 0 |
| Non-commercial funding via a NIHR grant (STADIA) | 0 | 7,003 | 11,554 | 6,420 | 15,338 |
| Hosted NIHR Grant (ASCEND) | 0 | 2,755 | 151,125 | 117,133 | 0 |
| Doctoral Research Fellowship | 0 | 0 | 3,171 | 109,273 | 0 |
| Hosted NIHR Grant (iPOF Online Mental Health Communities) | 0 | 0 | 0 | 0 | 337,801 |
| MSK Physio Internship funding | 0 | 0 | 0 | 0 | 9,219 |
| Totals | 475,124 | 623,989 | 730,898 | 850,276 | 971,360 |

Ensuring we are a **financially sustainable organisation**, the aim is to have a minimum of three National Institute for Health and Care Research (NIHR) grant funded projects hosted by Berkshire Healthcare at any time. In 2022/23 we were successful in securing the National Institute for Health and Care Research Grant with the University of Lancaster for the delivery of the iPOF study "Realist evaluation of online mental health communities to improve policy and practice". We hosted a welcome grant award through the NIHR for a Doctoral Research Fellowship award. This award is to facilitate the educational award through the study "Developing a novel, co-produced, mental imagery intervention with people with mild to moderate intellectual disability". We continue to build and support collaborations with university partners to develop NIHR grant applications. 6 grant applications were submitted in the financial year of 2022/2023.

Research funded posts

| Funded Posts | | |
|----------------------------------------------------------|---------------------------------------------|----------------------------------------------|
| Service | Posts Funded | Funding Source |
| OPMH - Wokingham, Newbury, Reading, Slough and Bracknell | 0.2 wte funded in each (1 wte in total) | Clinical Research Network |
| Sexual Health | 0.21 wte funded (0.1 wte of consultant) | Clinical Research Network & Capacity Funding |
| Psychology Trauma | 0.2 wte funded | Oxford Health PTSD & BRC projects |
| Web Services SHaRON | 0.55 wte funded | Clinical Research Network/ iPOF project |
| Physiotherapy WAM MSK | Salary backfill for Internship £9.2k | ARC-OxTV and Oxford Brookes University |
| LD Psychology | 0.8 wte funded (maternity leave in 2022/23) | NIHR Fellowship |
| LD Management | 0.3 wte band 6 for 4 months funded | Clinical Research Network |
| Administration | 0.2 wte band 5 for 4 months funded | Clinical Research Network |
| Locality Management Childrens Services | 0.06 wte band 8C for 4 months funded | Clinical Research Network |

The focus for the next 6 months is to ensure that we are aligned with Trust priorities and maximise grant funding opportunities, increase the capacity and capability for industry (commercially sponsored research) and to continue to support Internship applications

Conclusion

Clinical research within the NHS has nationally reduced since 2020/2021 with Mental Health Research remaining low. Our participant recruitment for the financial year 2022/2023 is notably reduced. This reflects the national recruitment uptake and this trend has carried forward to 2023/2024. The recruitment pledge for 2023/2024 is 940. The government's current commitments to mental health are set out in the [NHS long term plan](#). This serves to provide the foundation for future clinical research.

We have proactively responded to the Demand Signalling programme which is a process used by NHS England to identify, prioritise, and articulate important health research priorities. It generates research questions in high-level priority areas for research funders and policy makers and involves practitioners, researchers, NHS England policy leads, charities and people with lived experience. Previous workshops determined seven priority topics as part of the demand signalling for mental health nursing research.

[Research Demand Signalling for Mental Health Nursing](#)

Our aim is to build the capacity and capability for Research across Berkshire Healthcare to support research projects developed to answer 7 priorities and to facilitate increased industry studies which will generate income to sustain and grow our research capability. Our Research strategy will be refreshed to reflect national strategies and a strategic implementation plan will be created to ensure delivery to the updated strategy.

Actions that support the recommendations in the recent O'Shaughnessy review will be carried through to the FY 2023/2024 and into FY 2024/2025 ensuring an increase of commercial/industry led research projects. These projects will provide opportunities to the population we serve and income to grow the capacity and capability for research.