

Research and Development 2021/22

Annual Report

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This report serves to provide assurance to the board of compliance to the UK Policy Framework for Health and Social Care Research and applicable statutory obligations. It also serves to evidence our delivery of the Research and Development strategy

Executive Summary

Clinical Research activity is crucial to ensure the quality of care we provide and to discover new treatments and interventions. Our research activity and outcomes contribute to evidence-based practice by enabling skill development for staff.

Evidence demonstrates that hospitals that are active in clinical research have better patient care outcomes. Berkshire Healthcare is committed to clinical research and to providing research that is patient centred.

We are a research active organisation with an aim, for all patients to have access to research opportunities which are relevant to them.

The Covid-19 pandemic quickly brought into sharp focus the critical role of clinical research in helping to understand and combat disease. Throughout the pandemic, the Trust fully engaged in the national programme of Urgent Public Health (UPH) Covid-19 research. Trust staff, including executive board members, were inspired to lead and take part in National and urgent public health studies. As part of the national programme, this research provided hope and focus during the darker times and played a crucial role in furthering the understanding of Covid-19. This research led to the early identification and approval of treatments.

The Research portfolio at Berkshire Healthcare NHS Foundation Trust is a blend of hosted research projects and Trust sponsored research projects of both observational and interventional research.

In the financial year 2021/22 we delivered 94 research projects; this compares to 96 research projects in 2020/21. This includes 54 National Institute of Health Research (NIHR) Portfolio studies and 40 Non-NIHR Portfolio studies. The research projects also include a range of research from smaller scale student projects involving a subsection of our patients to national multi-centre clinical trials involving

several NHS sites. In addition, we supported other NHS Acute, Mental Health and Community Trusts and Primary Care colleagues in the region to deliver COVID-19 vaccine studies and three other Urgent Public Health COVID-19 studies. Most participants recruited to the NIHR Portfolio projects were recruited into non-commercial observational studies. We sponsored 6 research projects led by Clinicians from Berkshire Healthcare

In 2021/22 we were ranked joint 7th out of 48 similar Trusts (Mental Health and Community Trusts) for the number of national studies and were 8th out of 48 similar Trusts for the number of participants that we have recruited. We recruited 1723 participants (1608 recruited into non-commercial trials and 115 into commercial trials).

The Research and Development strategy was approved by the board in October 2021. The strategy is aligned to the government's policy: The Future of UK Clinical Research Delivery which is a UK vision to unleash the full potential of clinical research delivery to tackle health inequalities, bolster economic recovery and to improve the lives of people across the UK.

In Quarter 3 2021/2022 the Head of Research and Development was released from Berkshire Healthcare on secondment to the Berkshire Oxfordshire Buckinghamshire (BOB) ICB to deliver on the ageing-well programme. A secondee was appointed and released from The Royal Surrey NHS Foundation Trust (0.6 wte). The secondment opportunity has provided fruitful collaborations across the two Trusts. The collaboration between the two organisations has enriched the knowledge of the core clinical research delivery and governance team and has provided mentorship across several disciplines.

Dr Minoo Irani – Medical Director is Executive Lead for Research

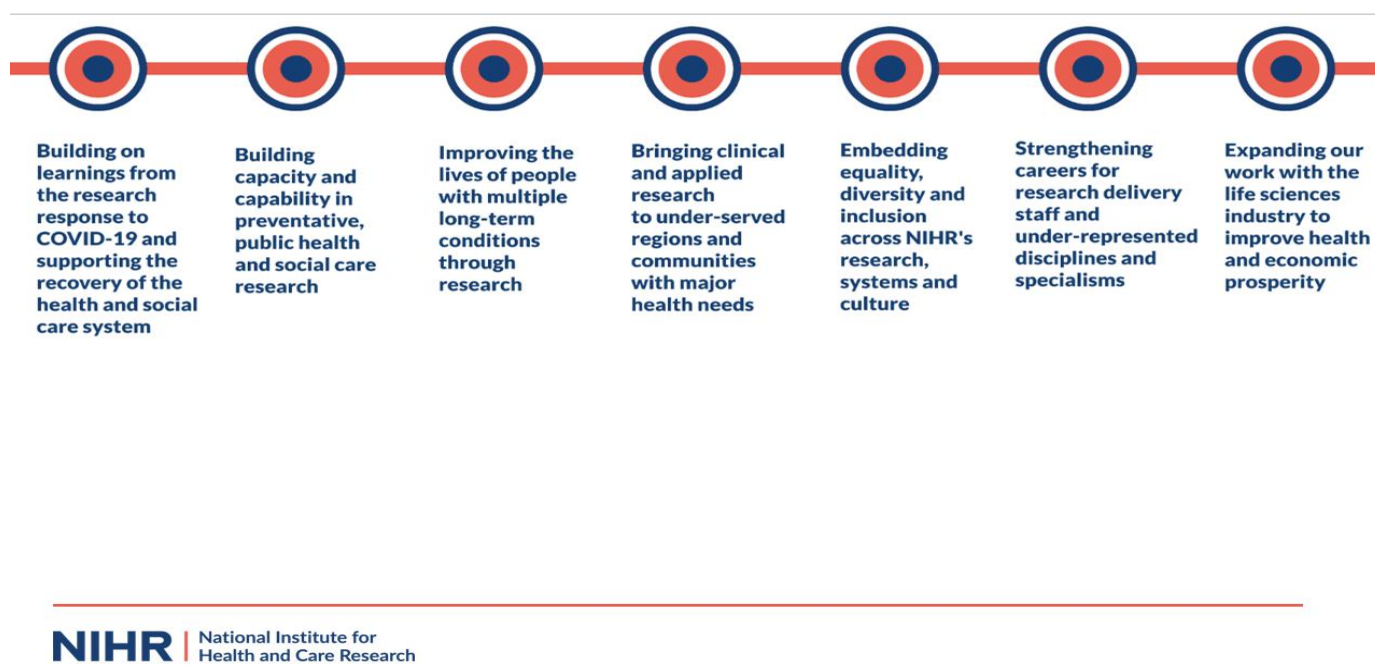
Future of UK Clinical Research Delivery – Setting the national scene

The National Institute for Health and Care Research NIHR leads the way in continued drive for improved clinical research delivery

The 3-year plan aligns with funding confirmed through the Government spending review for April 2022 to March 2025 and includes up to £150 million of additional funding from the NIHR and £25 million additional funding from RRG partners across the UK. This complements up to £200 million in England for the data for research and development programme, announced in March 2022.

The plan focuses on 5 themes shaped around the UK Government's bold vision for a more patient-centred, pro-innovation and digitally enabled clinical research environment, which builds on the successes and the lessons learnt in response to COVID-19. Our strategy is aligned to the Governments 7 actions, as shown below

2.1. Fig.1 Show the 7 actions to deliver the UK vision for research



Research Governance within Berkshire Healthcare

The Research and Development strategy is aligned to all the strategic priorities of the Trust relating to our patients, population, and people. The delivery on the True north goals; Patient experience, supporting our People, Harm Free Care and Money Matters are captured in the Research and Development 2021/2022 plan on a page.

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.

In addition to this annual report to the Trust Board, Research and Development activity, performance and compliance is provided via formal reports to the Clinical Effectiveness Group via the Research and Development committee. It is also represented as an invited member of the Quality & Performance Executive Group.

We have a robust research governance system to ensure compliance to the UK Policy for Health and Social Care Research and that any Research projects that we sponsor is designed, conducted, and delivered to the applicable standards and statutory obligations:

- 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

We continually improve and monitor this system to ensure it is fit for purpose. Assurances are provided to the Research & Development Committee and Clinical Effectiveness Group.

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 to free up NHS sites to concentrate on putting arrangements in place to deliver the study.

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.

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.

Within the core Research and Development team there are specialist roles who are responsible for Governance, Clinical Delivery, in-house/Sponsorship, review of contracts, Finance, and Management

In 2021/22 the R&D department undertook a review of all the existing Research policies, which were updated. An audit plan to review and update the Standard Operating Procedures (SOPS) to ensure compliance with the UK Policy Framework for Health and Social Care was put in place.

The following Standard Operating Procedures were reviewed in FY 2021/2022 and are in circulation

- Safeguard the participants of research projects
- Protect investigators/researchers by providing a robust and clear framework

- Monitor practice and performance
- Enhance the ethical and scientific quality of research
- Promote good practice and minimise risk

The R&D department began the development of a comprehensive audit programme at the end of 20/21, which continued in 2021/22 to ensure agreed procedures and policies are being followed as part of quality assurance.

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 2021/22 the department issued 21 LoAs and 4 HRCs to non-BHFT researchers. Local services have oversight and operational management for the individuals requesting the access.

The Trust sponsors home-grown Research projects and host national projects and student research projects. In the financial year 2021/2022 the Trust sponsored 6 studies

The Sponsor is an organisation that has overall responsibility of the research and

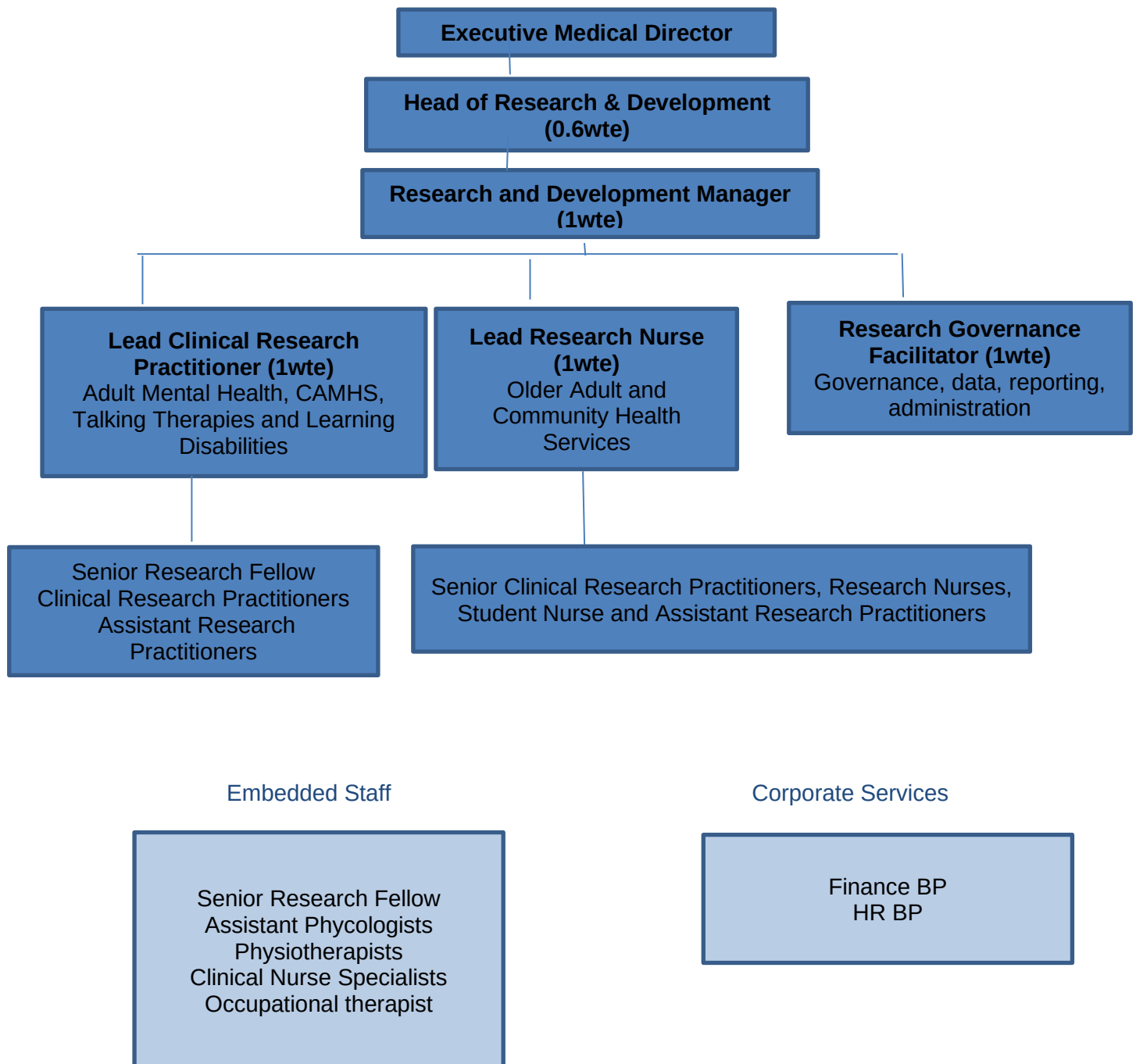
responsible for ensuring that the proposed research respects the dignity, rights, safety, and well-being of participants. The UK Policy Framework for Health and social Care Research requires that all research projects must have a Sponsor identified and declared prior to the commencement of the project.

The Sponsor takes on responsibility for initiation, management, and financing (or arranging the financing) of the research. We can delegate specific responsibilities to any other individual or organisation that is willing and able to accept them. All delegation of responsibilities to another party should be formally agreed and documented via a model Research Agreement. 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.

Student research: This is any research undertaken by a student (enrolled at University or College) for the purpose of an educational attainment. In all circumstances the University or College that is awarding the educational attainment should be approached to act as Sponsor for the research study.

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.

2.2. Fig.2 Show the structure of the core Research & Delivery team at the end of 2021/22



Collaboration

Aligning with the Trusts value of **working together to develop innovative solutions**, partnership working is of paramount importance to the research that we deliver in Berkshire Healthcare.

Ensuring that we **work in partnership with our health and social care partners**, the partnerships allowed us to work with 41 universities, 22 NHS organisations and several commercial and small technology companies. This brought research opportunities to patients, staff, and carers which aims to **address Health Inequalities to provide better and more efficient care**.

The relationship with these institutions was in their role as sponsor, employer of the Chief Investigator or base for the study team. Further strategic work to reinforce our existing collaborations and to collaborate with Research Design Support (RDS) South Central Charities, Local Council and Integrated Care Systems is underway. We are making good strides to ensure Research is integrated into the system.

The University of Reading remains a key partner with Berkshire Healthcare providing research projects aimed to improve the **health outcomes of our population**. We have collaborated with the University on the Oxford Health Biomedical Research Centre Dementia Theme to deliver Dementia Research

The University of Lancaster has collaborated with the Trust to deliver a National Institute for Health Research grant to deliver a project named “Realist evaluation of online mental health communities to improve policy and practice”, a collaboration born from the knowledge of the SHARON platform. This collaboration serves to evidence how we are a **leader in designing, adapting and embedding technology to improve patient care**.

In the financial year 2022/2023 additional collaborations with Bath University, Wilshire Health and Care and small technology start-up companies are creating opportunities to increase the leadership capacity for Research and Development at Berkshire Healthcare. It is acknowledged that the ambitious Research Strategy requires leadership investment to grow and sustain Clinical Research within the Trust. The early collaborations are providing funding to develop the capacity and capability and to sustain the expected growth. The Research & Development team provide expert advice to external organisations which has allowed fruitful collaborations on several grant applications and has created partnerships across the system.

As a Research active organisation, Berkshire Healthcare are members of the UK Research and Development (UKRD) which is a community of R&D Leaders, colleagues with responsibilities to Board for the R&D function in their organisation. The group is fed their expertise into key government departments to inform ministerial discussions. Our involvement in this group is via the Head of Research & Development. In addition, several staff members in the R&D department link into the NHS R&D Forum (RDF) which is a UK-wide community of practice and professional network for the health and care research management, support, and leadership workforce and the Head of Research and Development sits on the national steering group for the Health Research Authority, Central Portfolio Management System group and the UKRD Peer Development Groups. Membership to the national groups ensures Berkshire Healthcare maintains an up-to-date national perspective of Clinical Research within the NHS and can feed into the decision making of the UK Government with regards to Clinical Research within the NHS.

Prioritised and Embedded

Prioritised

The 2021 Research strategy pledged all research projects are assessed in terms of which priority area they link to as part of wider capacity and capability assessment.

In the financial year 2022/2023 a code has been allocated to indicate the priority link for studies e.g. Integrated Care System, Trust, and local service. The reporting requirements will evidence the delivery of this strategic aim and will form part of the Trusts Key Performance Indicators for Research.

In the financial year 2021/2022 the Research portfolio was weighted heavily towards mental health research. Community health and Children and Young People recruited notably less participants than the mental health teams. The delivery of the Research strategy and newly formed, and existing, collaborations has created space for Research that is aimed at priority themes. As we move into quarter 3 of this financial year, our newly formed collaborations with public health colleagues, small technology companies and charities has allowed for the development of new Research ideas to address the needs of our patient and population. This system approach evidences our strategic aim **to collaborate, support and learn from one another.**

The Research portfolio in the latter quarter of 2021/2022 demonstrated a shift change in direction as services such as the tissue viability service which is a new area of Research is hosting a study which confirms the ongoing safety and performance of Silver II Non-woven dressing in chronic and acute wounds.

Services across Berkshire Healthcare are collaborating with Researchers and **our local communities** to strengthen our community offer of Research opportunities and

deliver research projects **that respond to local community needs.**

We continue to work with colleagues across the region to increase capacity for Research within Integrated Care Boards (ICBs) and across the system.

Collaborations are being established with public health, local Clinical Research Networks, Universities, and partner organisations to build capacity for Clinical Research. The focus for the next 6 months is to ensure that we are aligned with our priorities and maximise grant funding opportunities

Embedded

It is a vision to ensure all our staff members in clinical services can articulate the role they play in research. Evidence demonstrates that hospitals that are active in clinical research have better patient care outcomes. Delivery on the **new ways of working and delivering care** initiative, research skills **support the learning of staff** across the organisation ensuring that **we can build and sustain teams fit for the future.**

Wherever possible external Research funds have enabled us to invest in a range of clinicians who are embedded within clinical services to support the development and delivery of research rather than within the core R&D team. This helps to provide local access to opportunities which are relevant to local populations.

In 21/22 clinicians were funded to undertake research in Older Adults, CAMHS, Talking Therapies, Sexual Health, Learning Disabilities, Perinatal, Cardiac, Tissue Viability Service, Urgent Care Services Respiratory and Diabetes Services. Some of these clinicians are located across the county of Berkshire from Thatcham in the West to Slough in the East, work in many settings- hospitals, Memory clinics, community bases, universities, and people's homes.

Equitable and Accessible

Equitable and Accessible

We continue to work hard to **establish strong links with our local communities** and gaining patient and carer feedback. We continued to engage with all physical health services who are not currently research active. **Patient and the public views are actively sought** throughout the research process and focus groups have been maintained, this financial year.

Whilst aiming to provide research opportunities to all as part of routine care we also maintain a Research Interest List (RIL) which clinicians can refer to/patients and carers can sign up to receive information about relevant research projects. The national 'Join Dementia Research (JDR)' database is also accessed to identify local research interested individuals.

As a research active Trust we are providing:

- **Patients** with the opportunity to receive assessments, treatments, therapies, and interventions that they would not otherwise have received as part of standard care.
- **Carers** with the opportunity to share their experiences and support their loved ones to participate in research.
- **Staff** with the opportunity to share their experiences, preferences, training needs and barriers re: the delivery of current services and interventions as research participants.
- **All research participants** (including the public for some studies) the chance to contribute to the evidence base to the NHS on topics that are important to them.

All this presents our organisation with the opportunity to receive funding to provide all the above opportunities and to support staff interested in research to lead or participate where relevant.

All NHS Research active organisations are required to take part in the national Participant Research Experience Survey (PRES). This is developed and led by the National Institute for Healthcare Research (NIHR) and supported locally by the NIHR Local Clinical Research Networks.

In 2021/2022, more than 9,000 participants volunteered for Research within Berkshire of which 1,723 participants (NIHR portfolio reported only) volunteered in 38 studies at Berkshire Healthcare.

The National patient Research survey found of 1,728 participants in Berkshire, Buckinghamshire, Milton Keynes and Oxfordshire, a total 93.2% of respondents said they would consider taking part in research again

The survey, conducted in the 12 months from April 2021, found:

- 71.1% said they had been kept updated about the research
- 78.6% said they knew how they would receive the results of the research
- 98.3% said they knew how to contact someone from the research team if they had any questions or concerns
- 92.5% said researchers valued their taking part in the research
- 93.6% said research staff always treated them with courtesy and respect

Patient and service user engagement is key to providing equitable research. Researchers are actively engaging service users on a range of topics. Towards the end of financial year 2021/22, our Research teams collaborated with Oxford Health and Oxford Biomedical Research Centre in

developing skills to encourage Researchers to actively involve communities in the development of their Research. Working with the team to facilitate Patient & Public Involvement Workshops. Updated resources have been utilised to review the Trusts Research Strategy for Patient Public Involvement and Engagement. Collaborations with the Applied Research Collaboration are offering opportunities in the financial year of 2022/23 as we join forces with Oxford Health in exploring the feasibility of creating Community Engagement Systems for People from Ethnic Minority Communities to Improve Access to Mental Health Care.

To provide an example, The SHARON team are working with users of their platform to understand what is important to an online peer forum. In addition to this, the group are also keen to understand the factors influencing use of online communities by ethnic minority groups and how they compare to the use of white British, and what factors influence this. The Garden Clinic is hosting a trial which engages the young men of Slough in the promotion of behaviour change in condom promotion, an intervention for young men which is aimed to improve attitudes towards condoms and promote use. The project also collects relevant health economic data which will provide additional data on how to engage a diverse population on sensitive topics or interventions.

Collaboration with Public Health Colleagues has presented the opportunity of exploring Research focusing on Berkshire Healthcare patients, specifically hoarders, and the impact on their health. Our teams are working to engage the community in the design on the study which is being led from the University of Reading.

Ensuring we reach as many patients and service users as possible we have explored how other sites are delivering their Research.

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. Research evidence has shown that an 'opt-out' approach to research recruitment could benefit both clinical research and patient care. Currently we have an 'opt-in' approach, where clinicians communicate opportunities to patients. Having an 'opt-out' approach 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. An 'opt-out' approach is optimal for ensuring NHS patients are made aware of these opportunities and are empowered to decide to what extent they wish to participate, it also helps make healthcare research more inclusive and representative, enabling access to information about research to currently marginalised groups. We are working with Information Governance to populate a Data Protection Impact Assessment Form. As this is an organisational change, there will be an action plan to consider and stakeholders to engage.

Using real world data to improve patient outcomes, we will be working to join the 17 NHS Mental Health Trusts in England who use the CRIS (Clinical Records Interactive Search) solution which is a tool which allow us to see when there are patterns and trends emerging in mental health, service and treatments allowing us to carry out research, assess the effectiveness of our treatments and identify ways we can improve our services.

Refer to Appendix A which demonstrates the split of Research in the divisions and the total Recruitment for financial year 2021/2022.

Supported, Visible and Impactful

Our vision is to ensure staff members who want to develop or deliver research have the guidance, training, support, and time to do so and that funding opportunities are regularly communicated.

The collaboration with the Learning and Development team will **enhance the exposure of opportunities for staff to explore** their path in Research both as a development opportunity and as an understanding of their role in Research.

Ensuring we explore **new ways of working** and that we are **building teams fit for the future**, the communication team is working with Research and Development colleagues to develop a communication plan that will **provide the reach to those staff members and services within Berkshire Healthcare** who cannot access Nexus and emails easily. The plan will ensure they are aware of how to find out about current research opportunities in their area **to provide greater deployment opportunities and support the learning of new skills across our organisation.**

Key members of the Berkshire Healthcare executive team participated in the EmHEP COVID-19 study in July 2021. The study was funded by the Health Foundation Programme looking into the quality and efficiency of mental healthcare provision in the time of COVID-19. The results were published this quarter and demonstrated that the pandemic emerged as a significant catalyst for major service innovations in mental health, opening new pathways of care in areas that over many years had made only incremental progress. Mental Health trusts demonstrated a high degree of flexibility and resilience by quickly adapting and transforming service delivery. In particular, the rapid deployment of digital technology and the shift to remote provision played a vital role in connecting providers with service users and allowed healthcare professionals and teams to remain connected within and across services, organisations and care systems.

Recruits, Values & Retains

Our aim is to attract and keep research interested, skilled and experienced staff because they feel that their skillsets are valued and that they are able to progress their research interests and careers at Berkshire Healthcare. **Recruiting and retaining a skilled workforce continues to be one of the biggest challenges we face at Berkshire Healthcare.** The Research culture at Berkshire Healthcare demonstrates **clear benefits for the development of staff skills.** Clinical Research increases staff engagement and retention by ensuring external clinical innovations and advancements of clinical practice can be implemented into departmental practices, whilst also contributing to evidence-based practice by enabling skill and knowledge development for staff.

Ensuring that **we support our people and provide a great place to work**, staff are encouraged to apply for Research opportunities and internships. In quarter 4 2021/2022 we successfully supported a MSK Clinical Physiotherapy Specialist in an application to the Applied Research Collaboration to create space and time for Research. The candidate was provided a joint offer from Oxford Brookes and the National Institute for Health and care Research. The internship has increased the capacity for Research within the physical health setting. This role carves out time for the team to focus on providing harm-free care by implementing Research studies such as the Darfibs study; Dance to reduce fall frequency and improve balance and strength. This is a preventative study which improves the physical health of our patients, reducing falls and related human costs (£2.3 billion a year). The ambition is to support Research development opportunities akin to the internship/clinical academic role, across several disciplines.

Income Generating

The Research and Development department are predominantly funded by the National Institute for Healthcare 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. This is then supplemented by NIHR Research Capability Funding (RCF), a small commercial income and some trust finance. Funding is allocated annually, and several team members hold short term contracts as funding is based on previous years' research activity.

Delivering on the true north objective of being a **financially sustainable organisation**, we aim to have a minimum of three National Institute for Health and Care Research grant funded projects hosted by Berkshire Healthcare at any one time. In 2021/2022 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 continued to host the Research for Patients Benefit grant for the ASCEND trial "Evaluating an early social communication intervention for young children with Down syndrome: a feasibility study" and for the IBER study: A feasibility randomised controlled trial of Imagery Based Emotion Regulation for the treatment of anxiety in bipolar disorder. In the financial year 2022/2023 we have submitted 7 grant applications with colleagues in University of Reading, Oxford Health Partners, Queens University in Belfast and 3 small technology companies.

The NHS is required to recover, from industry, all costs over and above the standard NHS Treatment Cost and the funding arrangements for non-commercial NHS research must fund the attributed costs to; research costs, NHS treatment costs and NHS support costs. Berkshire Healthcare receive income for the commercial clinical research we deliver. This income compensates us for the costs associated with delivering the research, as well as an allowance which is intended to enable investment in research capacity and capability longer term, this enables us to undertake more clinical research. Work is on-going with the Finance team to establish processes and create a commercial research income distribution policy that is aligned to the UK Research Finance guidance to ensure income flows through to where the activity is taking place.

Our income has increased year-on-year as Research activity, capacity and capability increases. Refer to Appendix B for the Research Income brought in over the last 4 years.

Innovative

Collaboration with the Head of Innovations and the Bright Ideas steering group continued to consider the Research aspects of new innovative ideas and solutions. **Collaboration with digital technology companies** has resulted in 4 innovation grants being submitted to date. An application to Veterans' Health Innovation Fund (Defence and Security Accelerator) was a result from a collaboration with Dr Deborah Lee and Virtual Health Labs. This interdisciplinary project regarding the development of an immersive virtual reality solution seeking to augment treatment for veterans and other people experiencing PTSD. This is important work with potential to improve the outcomes for veterans with PTSD. The proposal was to develop, test and evaluate an immersive virtual reality application which can be used as a treatment to possibly help to make psychological treatment for PTSD both more effective and more accessible.

Evidence Based

In 2021/2022 processes were implemented to enhance the knowledge to our staff members that they can have access to the latest evidence for their clinical area/speciality in which they work.

The current and previous annual reports have evidenced the steadily increasing level of research activity which takes place at Berkshire Healthcare NHS Foundation Trust with staff, patients, carers, and the public acting as research participants. We are continuing to develop strong links with National Institute for Health and social care Research evidence, the library team and clinical effectiveness services to better support this agenda.

Evidence show **clinical research is beneficial to people and patients**, with breakthroughs enabling earlier diagnosis, more effective treatments, prevention of ill health, better outcomes, and faster returns to everyday life. This has been particularly visible during the COVID-19 pandemic with real time changes occurring as the result of research findings. This has been seen with vaccine studies and epidemiological studies that have informed government decisions regarding policy.

Some evidence has suggested that people who take part in research have better health outcomes no matter what treatment they receive. This is known as the 'trial effect'. Even if the research you take part in is unsuccessful, many people feel they receive better care while the trial is running. Further research evidence that Trusts who support NIHR portfolio research studies have improved mortality rates.

To this end, we have provided further analysis to help us to better understand the benefits and impacts of the research that BHFT patients, carers and staff have participated in and supported in recent years. A summary can be found below and further details and links to findings from studies that we have participated in will be available on our website.

2.3. Highlights from studies we hosted 2021/2022:

- 215 participants took part in the Virus Watch Study, which aimed to identify how Covid spreads, and how to stop it. The results guided government policy during the pandemic.
- UK-REACH study looked at the disparity in Covid risk among ethnic minority workers to inform the development of risk reduction and to try to improve the long-term health outcomes of healthcare workers.
- 1,360 participants took part in psychological impact of Covid a large-scale online questionnaire investigating the psychological impact of Covid, the resultant restrictions, and the impact on behaviours and changes in mental wellbeing.
- The Behavioural Activation in Social Isolation (BASIL+) study investigated if it's possible to prevent depression and loneliness in older adults with two or more long-term physical conditions, who are social isolated due to the pandemic.
- By undertaking a comprehensive analysis of the needs of agile workers in the NHS, and the leadership behaviours required to meet these, researchers will be able understand how to support leaders as they adjust to the demands being placed on them to respond to and direct an agile workforce, whilst also attending to broader organisational goals and missives.
- Children and young people were able to access the 'Getting Help' services as part of the research study to examine their current sleep, diet, and physical activity behaviours, as well as their associations with mood.

Conclusion

Clinical research has become a subject of significant public interest especially during the Covid pandemic. The profile of Research and Development at Berkshire Healthcare Foundation Trust is now highly visible, especially in terms of embedding a culture of research, making collaborative working stronger across the region and contributing to important high quality global clinical trials.

The R&D Department aims to ensure that these achievements are sustained, improved further and research is embedded as part of everyday clinical practice across the Trust. Building on the research successes and lessons learned during the Covid pandemic, we can create an environment conducive to high quality research and develop even closer links with new and existing commercial and academic partners.

The UK clinical research delivery system is facing unprecedented challenges to support the delivery of research, following the COVID-19 pandemic. The ongoing impact of the pandemic on elective backlog, workforce pressures, as well as the need to complete existing COVID-19 research, has led to delays in the completion of studies. This has resulted in a substantial reduction in the number of studies able to recruit effectively and close on time.

The capacity of the NHS to support research delivery remains under continued pressure from workload and workforce issues, as well as the need to reduce the elective backlog. Limited capacity and resource mean that some studies have struggled in the current environment and have little chance of meeting their research endpoints and objectives. For others, the reduced resource and capacity means that study delivery within acceptable timescales is threatened. It is essential that the research system focuses on the studies that can be delivered with the capacity and resource available, whilst recognising there are some studies (e.g., in rare diseases) for which recruitment is expected to be less regular. The Department of Health and Social Care and colleagues in the devolved administrations, are working with partners across the UK's research system to identify measures to strengthen the UK's research base and life sciences sector, in a programme on clinical research Recovery, Resilience and Growth (RRG).

We expect the participant recruitment for the financial year 2022/2023 to be reduced, compared to previous years, given the change in our research portfolio. This reflects the national recruitment uptake. We expect that collaboration with our partners and Thames Valley and South Midlands Clinical Research Network will identify Research projects with a high recruitment number. It should be noted that the complexity of the interventional research we host has increased in the 2022/2023 financial year. Although it is anticipated that the recruitment for 2022/2023 may be lesser than previous financial years, our current approach of aiming to have a balanced research portfolio is in line with our research strategy

This report serves to evidence the Trust's commitment to Research. Research is included in the CQC well led inspection framework with a focus on how well an NHS Trust supports research activity at three levels, Research equity, facilitation and awareness. We will continue to build on the priorities within our Research strategy, focusing on access to Research and enhancing our collaborations. The Research culture at Berkshire healthcare demonstrates clear benefits for the development of staff skills, we have been successful in creating pockets of capacity within our clinical services with increasing internships, Research time within job plans and collaboration with the University of Reading will enhance MSc Opportunities and further embed Research into Clinical Practice. Clinical Research increases staff engagement and retention by ensuring external clinical innovations and advancements of clinical practice can be implemented into departmental practices.

At the Thames Valley and South Midlands Clinical Research Awards this September, Berkshire healthcare Research Delivery team won the All-round High performing team award, we were joint winners with the Primary care Research Nurse team from Oxford University Hospital Trust. Our Allied Health Professionals in Physio won the Research rising star award and Deputy Chief Pharmacist was highly commended in the Outstanding Allied Health Professional category.

As we move into a system-wide approach to delivering health and care Research, we are excited to partner with Oxford Health NHS Foundation Trust, the University of Oxford and other NHS and higher education partners on a National Institute for Health and Care Research (NIHR) Biomedical Research Centre for research into mental and brain health which is hosted by Oxford Health. Our contribution to the project will involve working in partnership with the Universities of Reading, Birmingham, Liverpool and Oxford Brookes on the research theme of 'Mental Health in Development'. The research aims to develop targeted, effective, and accessible mental health interventions that meet the needs of diverse children and young people.

Appendix A- Summary of all studies in Berkshire Healthcare NHS Foundation Trust FY2021/2022 by Condition/Topic area

Study	Status	Recruitment (as per central portfolio management system)
COVID		
PRINCIPLE	Now closed	0
BASIL+	Now closed	58
EMHeP COVID	Now closed	14
Psychological Impact of COVID	Now closed	349
Total		421
Older Adult Mental Health		
BDR3 Version 1.0	In follow up	N/A
NIDUS Family	Open	18
PRIDE APP	Now in follow up	5
PALLUP	Now closed	1
Total		24
Adult Mental Health		
BEAMS-ID	N/A	1
EMER	Now closed	105
EMHeP 3	Now closed	2
GameChange	Now closed	2
Genetic Links to Anxiety and Depression	Open	22
Getting Physically Active	Open	7
Hearing Nasty Voices	Now closed	7
MBCT	PIC	N/A
MolGen	Paused	1
NCISH	Open	46
Parents with Psychosis	Now closed	8
Partners 3	Open	5

PIPS	Open	714
PPiP2	Open	13
PREFER	Now closed	9
Safer Online Lives	PIC	N/A
Silvercloud Activation Study	Open	39
Silvercloud DLM	Open	55
Sleepwell	Now in follow up	7
SPRINT	Now closed	0
THRIVE	Now closed	2
Understanding Experiences of Feeling Exceptional	Open	23
Using Digital Tech	Open	14
Watch Study	Now closed	45
Total		1,127
Children and Young People		
ASCEND	Now closed	4
CO ASSIST	Now closed	1
CO-CAT	Open	19
MAPS	Now closed	0
OPTYC	Now closed	0
PANDA	Now closed	13
STADIA	Now in follow up	57
PTSD in Young People staff survey	Now closed	9
Total		103
Community Health		
Startright	In follow up	N/A
ADDRESS 2	Open	4
NEFERTITI	Now closed	21
AHP Perceptions of Research	Now closed	19
Use of locum doctors	Open	2
The Multicath Trial	PIC	0
Usability and efficacy of rainbow trays	N/A	2
Total		48
Overall total		1,723

Appendix B – Research and Development Finance 2018-2022

FY 2018-2022

R&D External Income Sources				
Source	2018/19	2019/20	2020/21	2021/22
CRN Core Funding	400,000	420,000	445,000	463,000
CRN Contingency Funding	39,413	5,000	0	35,424
Greenshoots Funding		13,358		0
ETC Payments	0	3,106	352	9,293
RCF Funding	20,000	20,000	52,960	48,054
Commercial Income	10,453	2,414	3,457	35,123
Other Funding				
IBER	5,258	150,353	63,279	26,555
STADIA		7,003	11,554	6,420
ASCEND		2,755	151,125	117,133
O Hewitt Doctoral Research Fellowship			3,171	109,273
Totals	475,124	623,989	730,898	850,276

The R&D Department has delivered improved Research productivity over the last 4 years resulting in a steady increase of Research income from several sources.