

Providing Safe Services – Compliance to Research Governance FY 2023/24

Summary

This report covers the period from 1 April 2023 to 31 March 2024 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 Central Services in 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 three of the five meetings in 2023/2024. No decisions were made in meetings that were not quorate. The December committee meeting was cancelled due to member availability. R&D is also represented as an invited member of the Quality & Performance Executive Group (QPEG).

UK Policy for Health and Social Care Framework

Research is delivered across all divisions within the Trust. Research relevant policies and Standard Operating Procedures (SOPs) are continuously reviewed to ensure compliance with UK Policy Framework for Health and Social Care Research. Representatives from within the Research Governance team attend the Policy Scrutiny Group as a core member. Their role is to ensure that Research Governance and applicable statutory obligations are incorporated into Trust Policies and guidance where applicable. There are five Trust policies specific to Research:

1. ORG026 Research Governance
2. ORG027 Intellectual Property Policy for Research
3. ORG064 Honorary Research Contract, Letters of Access/Assurance
4. ORG074 Research Related Adverse Event Reporting
5. ORG078 Research Fraud & Misconduct

In the year 2023/24 all 5 policies were reviewed in Q4 of 2023/24 and updated inline with national guidance. These policies were ratified in Q1 of FY 2024/25, the details of which will be reported in the annual report for 2024/25.

Research related Standard Operating Procedures (SOPs) are continuously reviewed to ensure compliance with national guidance and operational changes both at local, service, regional and national levels. SOPs are used by staff across the Trust and access to these is important, currently access to SOPs is restricted and facilitated by the Research Governance team, this is

not a supportive mechanism. Through using the Trust Quality Improvement tools an Improvement idea has been proposed for FY 2024/25 to publish the SOPs on the Research and Development web page and Nexus page for all services to refer to. Expected timeline for this Q2 of FY 2024/25.

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 2023/24 the department issued access to 34 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. In 2023/24, Berkshire Healthcare received 5 applications for sponsorship from 5 services areas (Speech and Language Therapy, Veterans Complex Treatment, Eating Disorders, Learning Disabilities and Children and Young People) and two of these were collaborative projects with the University of Reading. 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.
