How NHSBT’s R&D Office takes a “joined up” approach to approving research Sponsorship

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Summary
The NHS Blood and Transplant (NHSBT) R&D Office has a dual function of R&D and Sponsor Office. The Office regularly receives requests for Sponsorship from researchers affiliated with NHSBT. Sponsorship decisions are made by the Clinical Directorate Senior Management Team (CDSMT) with input from the R&D Office.

NHSBT is an organisation that provides a myriad of complex services to the wider NHS and beyond. Each arm of the organisation prides itself in its LEAN approach; therefore it is essential that operational considerations are addressed at a research study outset.

The R&D Office has recently revised its Sponsorship approval process. This ‘joined-up’ approach to Sponsorship, one which addresses operational considerations such as deliverability, in addition to other Sponsor considerations, has resulted in significantly improved outcomes for all involved. Engagement with all stakeholders and mapping key operational pathways was essential in making this revision a success.

Who are the key stakeholders in the Sponsorship process?

Chief Investigator (CI) and team: having a process that is clear and practical is key. Timelines are attributed to the Sponsorship process so that the CI can know when to expect an outcome.

Clinical Trials Unit (CTU): when NHSBT’s CTU is involved, the R&D Office process ensures that the CTU has the capacity to take on more studies.

Operations: where it is proposed that an NHSBT resource will be used in the research, operational sign off is required to confirm that there is a capability to provide this resource. This can range from blood products, tissue material, data or staff.

Research Strategy Groups (RSG): taking advice from their operational colleagues, the relevant RSG gives final approval on whether that element of the research is deliverable.

NHSBT R&D Office: as a Sponsor, the R&D Office performs due diligence to ensure that it is appropriate for it to Sponsor the research, and that the research is of the highest quality.

NHSBT Donors: considerations are made to ensure that any research that NHSBT undertakes does not negatively impact donors.

What is the role of the R&D Office?
The R&D Office makes a recommendation to the CDSMT as to whether or not a study should be Sponsored. Before informing CDSMT of a proposal, the R&D Office helps applicants to obtain approval and support from an operational perspective, ensuring that the R&D Office can make the most informed recommendation to CDSMT.

The R&D Office acts as a conduit between the research team and the associated NHSBT research theme. Each research theme that NHSBT supports has a strategy group associated with it, that ensures the research study is in line with NHSBT’s strategic research aims. The R&D Office also links applicants with the Information Governance and Clinical Audit, Risk and Effectiveness (CARE) committees where necessary.

The R&D Office also offers advice on study design, practicalities, funding, safety, risk and deliverability.

Conclusion
The R&D Office acts as a facilitator for Sponsorship checks and guides researchers throughout the process. Work is underway to ensure that NHSBT researchers are aware of the necessary pathways before they initiate the Sponsorship review process. Close links have been forged with the Operational and CARE personnel to ensure that queries are addressed in a timely manner.

Since introducing these additional steps to the Sponsorship review process, CDSMT has been able to make fully informed Sponsorship decisions, allowing the R&D Office to Sponsor the highest quality, deliverable research. Since the new approach has been taken, on average it takes 30% less time to complete the Sponsorship assessment process and issue a Sponsorship letter.

Documents required to apply for NHSBT R&D for Sponsorship