

# Report to the Meeting of the

**BOD 114/2018**

(Agenda item: 14)

# Oxford Health NHS Foundation Trust

# Board of Directors

**27 September 2018**

**Sponsorship of research studies**

**For: Discussion/Decision**

1. **Summary**

The NIHR Oxford Health Biomedical Research Centre proposes that Oxford Health NHS FT becomes Sponsor for BRC-adopted Clinical Trials of Investigational Medicinal Products.

1. **Role of Sponsor**

All clinical research projects require a sponsor and is a requirement under the Research Governance Framework and Clinical Trials Regulations. For Clinical Trials of Investigational Medicinal Products (CTIMPs), the European Commission Directive 2001/20/EC define the sponsor as:

*An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.*

Clinical Trials Regulations define legal responsibilities that the sponsor must arrange to carry out. These legal responsibilities should not be confused with liability for the harm of a subject. The NHS R&D Forum provided a comprehensive summary of the legal responsibilities that a sponsoring organization must ensure are in place when providing sponsorship for CTIMPs. (appendix)

Sponsorship of a CTIMP cannot be delegated although activates may be.

1. **Current Sponsorship Arrangements**

Oxford Health NHS FT (OHFT) currently undertakes the sponsorship of Non CTIMP research studies where the Principal Investigator (PI) has a substantive contract of employment with the Trust. The Trust hosts a number of CTIMPs including University and commercially sponsored studies. Sponsorship review is undertaken within the R&D Department by the Research Support Team

With the successful NIHR Oxford Health Biomedical Research Centre (BRC) initiated in April 2017 there has been an increase in the number of CTIMPs being undertaken within the Trust. These have usually been sponsored by the University of Oxford (UO) as part of the BRC partnership.

As part of the Oxford Health BRC the partnership hosts a clinical trials unit, which was been fully registered by the UKCRC until 2017. Renewal of the registration was not applied for due to high administration and cost burden, without – at the time - any formal need for this registration. Nonetheless, the core of the CTU is funded largely via the BRC including posts for trial managers, quality assurance, pharmacy support, statistical support and research assistants. In fact, the BRC-based CTU is now better resourced than it was when registered.

1. **Changes within the Sponsorship Arrangements within University of Oxford**

The University of Oxford has long acted as sponsor for clinical trials of an investigational medical product (CTIMP), supported by the NIHR and other funding bodies. However, on 5th June 2018, the Medical Sciences Division finance, research and general purposes committee stipulated that the University will no longer accept sponsorship of CTIMPS which are not fully managed by a UKCRC- accredited Oxford Clinical trials Unit (CTU). This decision was taken to guard against single inexperienced academics conducting CTIMPs. We should emphasise that the BRC’s position is entirely different from these *lone investigators* – we are probably the most experienced mental health CTU in the UK, having conducted landmark clinical trials including BALANCE and CEQUEL.

1. **Potential Consequences**

The timing of the decision – given the BRC’s recent decision about registration – is unfortunate because it jeopardises the BRC’s ability to conduct funded trials. As we need to start new funded CTIMPS this year, we need to sponsor funded CTIMPs. Failure to do so will have devastating reputational consequences for the BRC (and its host Trust). Further negative effects include:

* Failure of the BRC to fulfill its contracted obligations to deliver the aims and objectives set out in the application
* Cost pressures on the BRC funding due to duplication of resources
* Reduced leveraged funding across external funders – critical to success of BRC
* Failure to renew the BRC in the next NIHR competition.

1. **BRC and R&D Preferred Solution**

Following consultation with the University of Oxford Clinical Trials and Research Governance (CTRG) team and Oxford Health BRC Theme Leaders and Steering Committee, it appears that Sponsorship by OHFT might represent at least an interim solution for CTIMPs adopted by the BRC and supported by the BRC CTU infrastructure.

The only other real option would be to seek involvement of another Oxford University CTU, thereby potentially maintaining the possibility of University Sponsorship. While this may be a possible solution in the longer term, it would not work in the short term because it will take time to arrange. There are no CTUs with appropriate early phase experience in mental health.

**R&D therefore intends to provide OHFT sponsorship to BRC adopted studies for next 18 months** while other options are explored. Consideration will be given to re-establish the registration for our existing CTU or form arrangements with other Oxford CTUs.

In effect, apart from the formal change of sponsorship, there will be no material change in the way in which we run these CTIMPs. The BRC staff currently employed within the University Department and OHFT already have the expertise to undertake sponsorship reviews and to run CTIMPs using the Standard Operating Procedures established by the previously registered CTU which are consistent with those approved by the University CTRG.

We will establish a Trust process to provide a collective assessment and review of CTIMPs to provide a balanced multidisciplinary approach to sponsorship review.

We consider that there is minimal risk to the Trust. Insurance and indemnity is covered by NHS Resolution. The main practical implication is that there could be an MHRA inspection which requires a financial contribution to the inspection process – approximately £2655 per day. Inspections typically last two to five days and the costs will be fully borne by BRC/R&D.

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