NBT Terms & Conditions of Sponsorship

Where North Bristol NHS Trust (NBT) agrees to act as Sponsor for any named project, the following terms and conditions apply. Sponsorship may be withdrawn at the Trust's discretion if any of these are breached:

1. The Chief Investigator, Principal Investigator(s) and all members of the research team shall comply with all regulations applicable to the research, including but not limited to the following, as from time to time amended:
    a) The UK Policy Framework for Health and Social Care 2017;
    b) The World Medical Association Declaration of Helsinki (2000);
    c) Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended);
    d) ICH Guidelines for Good Clinical Practice (E6 R2, Step 4, 2016);
    e) Human Tissue Act 2004;
    f) Mental Capacity Act 2005;
    g) Data Protection Act 1998 until 24th May 2018, and the General Data Protection Regulation from 25th May 2018;
    h) NBT's Research Policies and SOPs.

2. The project must be conducted in accordance with the *Delegation of Responsibilities* and any further delegations recorded in the *Delegation of Responsibilities Log* for the study.

3. The project must not commence at North Bristol NHS Trust or any other research site until:
    a) A favourable ethical opinion has been obtained from the relevant NHS Research Ethics Committee (REC) and the Health Research Authority (HRA);
    b) The NBT R&I office and the R&D offices of all other NHS organisations participating in the project provide confirmation in writing of their capability and capacity to undertaken the project, and all necessary site agreements are executed;
    c) Non-NBT employees having direct contact with patients and/or having a direct bearing on the quality of their care have honorary contracts in place;
    d) Arrangements are made for the recovery of associated costs or, if externally funded, financial arrangements are covered by a suitable agreement approved by the NBT R&I office;
    e) In the case of a clinical trial of an Investigational Medicinal Product (CTIMP) Clinical Trial Authorisation has been obtained from the MHRA;
    f) In the case of a clinical investigation of a Medical Device (ciMD) a Declaration of No Objection has been obtained from the MHRA;
    g) Such other regulatory approvals required for the research to proceed have been obtained.

4. All publications (including poster presentations and annual reports) must be submitted to the Sponsor for review and approval (in the case of CTIMPs or device studies) or acknowledgement (in the case of non-CTIMPs) before submitting for publication.