NBT Terms & Conditions of Sponsorship

Where North Bristol NHS Trust (NBT) agrees to act as Sponsor for a research project, the following terms and conditions apply. NBT reserves the right to withdraw Sponsorship at any time if these conditions are breached or if Sponsor oversight cannot be assured;

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 (2025);
    b) The World Medical Association Declaration of Helsinki (2024);
    c) Medicines for Human Use (Clinical Trials) Regulations 2025 (as amended);
    d) ICH Guidelines for Good Clinical Practice (E6 R3, Step 4, 2025);
    e) Human Tissue Act 2004;
    f) Mental Capacity Act 2005;
    g) UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018;
    h) NBT's Research Policies, and SOPs and contractual obligations

2. The project must be conducted in accordance with the Delegation of Responsibilities and all further delegations recorded in the Delegation of Responsibilities Log. Delegations must be documented prior to undertaking any delegated task

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 approval received from the Health Research Authority (HRA);
    b) The NBT R&D 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 undertake the project, and all necessary site agreements are executed;
    c) All non-NBT staff requiring access to patients or data hold appropriate honorary contracts, Letters of Access or research passports, in line with HRA guidance.
    d) Financial arrangements are in place and fully executed, including confirmation of cost recovery or externally funded arrangements approved by the NBT R&D office
    e) For CTIMPs, a valid Clinical Trial Authorisation (CTA) has been granted by the MHRA
    f) For Medical Device investigations, a MHRA Declaration of No Objection has been obtained

g) Any other regulatory approvals required for the study (e.g., CAG support, ARSAC approvals, HTA licences) have been obtained

h) All relevant contracts including but not limited to the head contract, have been executed.

i) A data sharing agreement, where needed, has been executed; no data should be shared without this in place.

j) A Material Transfer Agreement, where needed, has been executed; no material should be shared without this in place.

k) A CI declaration has been signed by the chief investigator;

l) Sponsor Greenlight has been issued by NBT confirming that recruitment may commence

4. All primary publications and abstracts arising from the project must be submitted to the Sponsor for review prior to submission.
   • For CTIMPs and medical device studies: Sponsor approval is required.
   • For non-CTIMP studies: Sponsor acknowledgement is required.

   The End of Study Report must be submitted to the Sponsor prior to submission to the HRA and/or MHRA, and no later than 12 months following the end of study declaration.

   Primary publications should be published in alignment with funding agreements and within a reasonable timeframe.