HUMAN TISSUE OVERSIGHT COMMITTEE (HTOC)

TERMS OF REFERENCE

Remit

The Human Tissue Oversight Committee (HTOC) is responsible for overseeing all activities surrounding the use of human tissue at the University of Birmingham (UoB), with recognition that the majority of the relevant activity takes place within the College of Medical and Dental Sciences (MDS) and College of Life and Environmental Sciences (LES).

The Terms of Reference, including the membership of the HTOC shall be reviewed every three years. The next review will be September 2026.

Constitution and Membership

Chair

The HTOC will be chaired by a UoB senior academic who will usually have Designated Individuals (DI) or licence holder experience and detailed knowledge in the conduct of human tissue activities.

The Chair is to be appointed by the Pro-Vice-Chancellor for Research (PVC) in their role as Licence Holder Representative, in liaison with the Head of the College of MDS. The Chair is appointed for a 3-year term, renewable for up to another 2 terms with agreement by the Head of the relevant College and input from the Pro-Vice Chancellor for Research.

Membership

Current Members are defined in *Appendix 1 – Membership List*. Additional attendees, or expert input, may be identified/invited on an *ad hoc* basis at the discretion of the Chair depending on the content of the meeting. The PVC will receive the minutes from all Committee meetings and attend at least one meeting per year. The LES Deputy Director of Operations (R&KT) will receive meeting minutes and attend on an *ad hoc basis* as required according to need.

Secretariat

The MDS Research Office Administration Team will provide secretarial support to ensure effective administration of the HTOC.

Quorate

The HTOC is quorate with the following members in attendance:

- the Chair (or a delegate selected from the current HTOC membership)
- at least two named DIs on the HTA licences held by the UoB (or a suitable delegate)
- a member of the Research Ethics, Governance & Integrity Team (REGI) (or a suitable delegate)
- a member of the Clinical Research Compliance Team (CRCT) (or a suitable delegate).

Any other member of the Committee may send a suitable delegate should they be unable to attend a meeting.

Whenever issues are discussed that may cause a conflict of interest, or an appearance of conflict of interest, the Chair or delegate, as agreed by members present, will assume responsibility for the relevant section of the meeting.

Where required to deliver the remit of the HTOC, formal working groups will be established to deliver specific activities, as agreed by HTOC members.

Function of the Committee

The HTOC provides support for quality assurance and risk management processes in relation to activity carried out under the HTA licences held by the UoB (currently, as of September 2023, HTA research licence (Dental School) 12313, HTA research licence (Medical School) 12358, HTA anatomy licence 12236 and HTA human application licence 22672).

The HTOC also provides support and oversight for the MHRA MIA(IMP) Licence 21762 relating to the MMF, and the Human Fertilisation and Embryology licence (under the HFE Act) and receive their updates on a yearly basis. The Qualified Person (QP) named on the UK MIA(IMP) licence and the Licence Holder of the Human Fertilisation and Embryology licence are responsible for their own quality assurance and risk management processes of the related activities under their licenses and may seek support and advice from the HTOC.

The HTOC reviews compliance with the HTA standards of HTA licences so that the DIs and named Persons Designated can be supported to fulfil their responsibilities, and meet the conditions associated with licensed activities.

The UoB quality management system for clinical research is managed by the CRCT. The Committee will provide guidance to investigators on UoB processes and procedures that ensure adherence to the relevant regulatory requirements for the conduct of studies that involve the use of human tissue or need to be conducted in line with Good Clinical Practice (GCP) / Good Manufacturing Practice (GMP).

In extreme cases or persistent non-compliance, with support from the Heads of Colleges, Institutes and Schools, the HTOC has the power to order destruction of human tissue, incorporation of tissue under HTA licence, and to terminate activity relating to the analysis of clinical trial samples within laboratories. The Committee is empowered to collect information in order to ensure that human tissues have been correctly managed and that laboratory GCP/ GMP standards have been achieved (where appropriate), and to refer information to the Licence Holder Representative, Heads of Colleges, Institutes and Schools for further action.

The Committee supports the development and delivery of a comprehensive training programme for staff and students that work with human tissue. This training programme will ensure staff & students at the UoB are made aware of, and need for them to comply with, the statutory and regulatory requirements as well as UoB guidance.

HTOC will receive and review internal / external audit and other compliance reports (e.g. Sponsor Support Visit reports), or summaries thereof, and will support the inspection by regulatory bodies to ensure that any actions arising out of audits / inspections are implemented and completed in an appropriate and timely manner.

Meeting Frequency

The HTOC will meet quarterly at least and on an *ad hoc* basis as required according to need.

Reporting Lines

The Chair of HTOC is a member of and reports to the University Research Governance Ethics & Integrity Committee (RGEIC). The Chair is also a member of the College R&KT Executive Committee. Where relevant there will be appropriate reporting to other UoB College Boards.

In the interest of complete transparency of processes, the HTOC meeting minutes will be made available to the MDS R&KT Executive Committee, University RGEIC and the UoB Head of Internal Audit.

See also **Figure 1 - The current UoB Research Governance Framework**.

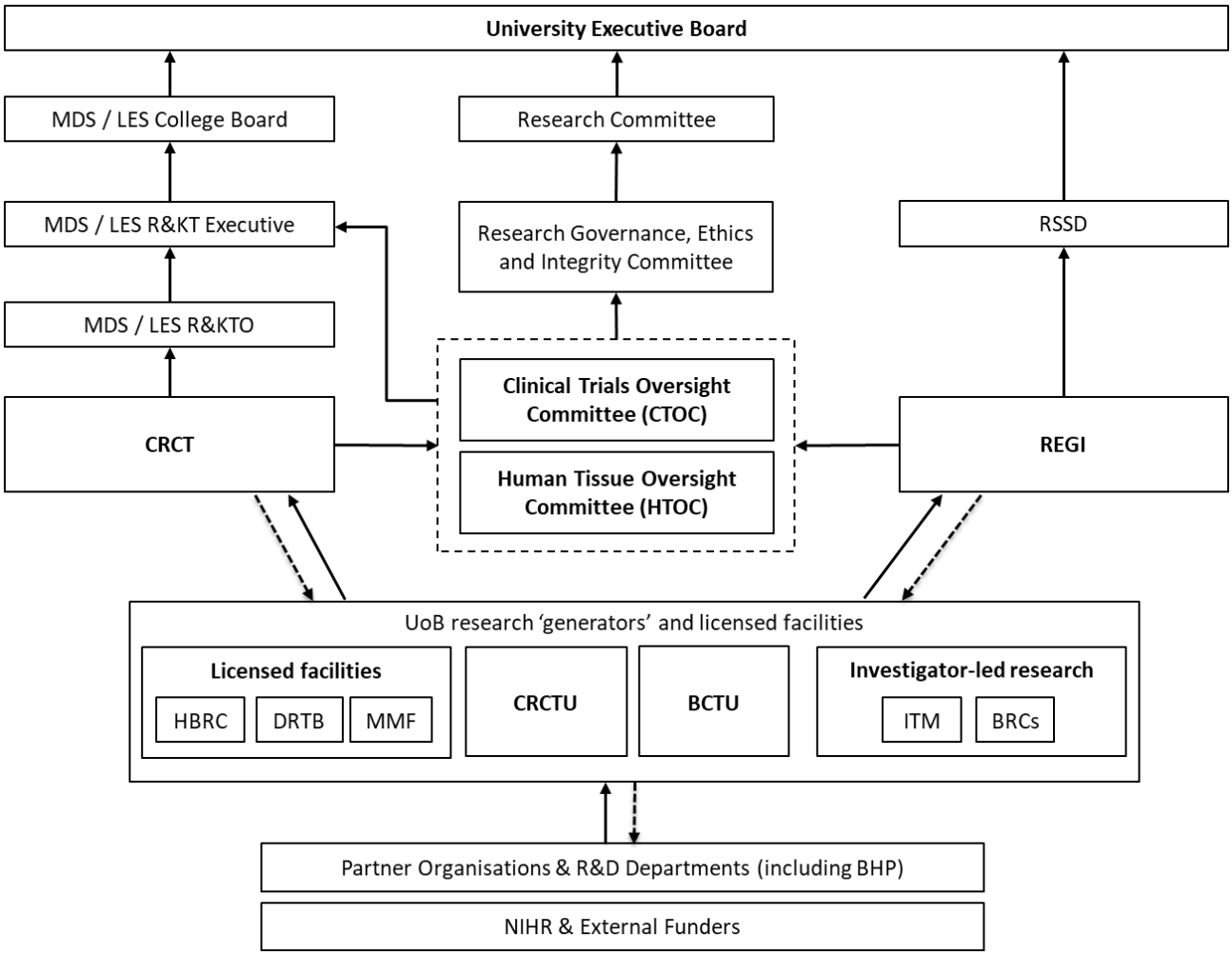

Figure 1. UoB Research Governance Framework. Solid line denotes reporting pathway and dotted line denotes compliance review pathways. Abbreviations: BCTU, Birmingham Clinical Trials Unit; BRC, Biomedical Research Centre; CRCT, Clinical Research Compliance Team; CRTCU, Cancer Research UK Clinical Trials Unit; DRTB, Dental Research Tissue Bank; HBRC, Human Biomaterials Resource Centre; ITM, Institute of Translational Medicine; LES, College of Life and Environmental Sciences; MDS, College of Medical and Dental Sciences; MMF, Medicines Manufacturing Facility; NIHR, National Institute for Health Research; R&D, Research and Development; REGI, Research Ethics, Governance & Integrity Team; RSSD, Research Strategy & Services Division; UoB, University of Birmingham.