

**University of Oxford
Research Services**

**HTA LICENCE
12217**



**UNIVERSITY OF
OXFORD**

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DOCUMENT TITLE: HTGT011 GUIDANCE ON REGISTRATION OF SAMPLES UNDER AN HTA LICENCE AT THE UNIVERSITY OF OXFORD

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1. PURPOSE

- 1.1** The University must provide assurance that all samples of human origin that require it are stored on premises licensed by the Human Tissue Authority (HTA) and are identified, catalogued and within the governance arrangements for the appropriate HTA Licence.
- 1.2** The purpose of this guidance document is to assist research staff in determining whether samples require storage under an HTA Licence, and to define the procedure for registering sample collections under an HTA Licence.

2. LICENSING REQUIREMENTS OF THE HUMAN TISSUE ACT

- 2.1** The Human Tissue Act (2004) regulates the storage of material of human origin for “scheduled purposes”. Scheduled purposes include research, anatomical examination, public display, transplantation; for samples collected from deceased donors, scheduled purposes also include clinical audit, education and training relating to human health, performance assessment, public health monitoring, and quality assurance. Please note that samples which are not currently being used in research, but are stored for possible future use in research are considered stored for the purpose of research in the context of the Act.
- 2.2** This document is focused on storage of samples for the purpose of research; staff storing samples of human origin for a scheduled purpose that is not research should contact the Human Tissue Governance group within Research Services’ Research Governance, Ethics and Assurance team (RGEA) at hta_help@admin.ox.ac.uk for advice.
- 2.3** Samples stored for a scheduled purpose and falling under the scope of the Act (called relevant material) must be stored under an HTA Licence unless they are covered by an exemption. Relevant material is defined as material, other than gametes, which consists of or includes human cells. Note that this does generally include cell deposits and tissue sections on slides, but not lysed cells, or samples which have been processed to remove cellular components. Cell cultures composed of cells which have divided outside the human body are not considered relevant material.
- 2.4** The series of questions below is designed to help you determine whether your samples require storage under an HTA Licence. If you do not know the answer to one of the questions, please contact hta_help@admin.ox.ac.uk for advice.

- a) **Are the samples stored for a scheduled purpose as defined in 2.1 above?**
- If the answer is no, the samples do not require storage under an HTA Licence (no further questions required).
 - If the answer is yes, please proceed to the next question.
- b) **Are the samples relevant material under the Human Tissue Act as defined in 2.3 above?**
- If the answer is no, the samples do not require storage under an HTA Licence (no further questions required).
 - If the answer is yes, please proceed to the next question.
- c) **Is ethical approval from an NHS Research Ethics Committee (REC) in place for the samples?**
- If the answer is yes and the sample collection has received ethical approval as a Research Tissue Bank, **storage under an HTA licence is required** – see section 3 for the process to follow. Research Tissue Banks (RTBs) must operate under an HTA licence even when ethical approval from a recognised REC is in place; guidance about RTBs is provided by the Health Research Authority: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/>
 - If the answer is yes, the sample collection is not a Research Tissue Bank, the ethically approved Protocol covers the work done on the samples (rather than past work, even if it is related) and no end of study notification has been submitted for this study, the samples do not require storage under an HTA Licence (no further questions required). Please note that this exemption expires when ethical approval is no longer in place.
 - If the answer is yes but the end of study notification has been submitted to the REC or the proposed end of study date has passed, please contact HTG Group at hta_help@admin.ox.ac.uk to discuss whether samples will require storage under an HTA licence.
 - If the answer is no, there is no current ethical approval in place covering these samples (for example because they are not currently being used in research), or there is ethical approval in place from a REC that is not an NHS REC (e.g. University REC, REC from outside the UK), please proceed to the next question.
- d) **Are the samples stored for less than 7 days before they are transferred to another institution, disposed of or processed to render acellular?**
- If the answer is yes and research data are derived from the samples on premises outside the University of Oxford / Oxford hospitals, or from acellular sample derivatives, or the samples are stored only pending disposal: storage under HTA licence is not required (no further questions required).
 - If the answer is yes, but research data are derived from cellular samples before they are transferred elsewhere, disposed of or processed to render acellular: **storage under an HTA Licence is required** – see section 3 for the process to follow.

- If the answer is no, the samples are stored for more than 7 days: **storage under an HTA Licence is required** – see section 3 for the process to follow.

2.5 Please note that samples collected prior to 1st September 2006 ('existing holdings') **are** subject to licensing requirements, although they are not subject to the consent requirements of the HT Act. All other HTA standards including Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards apply to existing holdings. Thus, if your answers to the questions above indicate that the samples must be stored under an HTA Licence, please contact HTG Group at hta_help@admin.ox.ac.uk for assistance regardless of when the samples were collected.

3. REGISTERING SAMPLES UNDER AN HTA LICENCE IN OXFORD

3.1 If the samples require storage under an HTA licence, they must be stored on premises which are licensed by the HTA; please contact the appropriate licence staff to assist you. In Oxford, licensed premises which may host samples stored under an HTA licence for research are:

- a) **For the Richard Doll Building (CTSU), Old Road Campus** – HTA Licence 12168 (Research licence), contact Chloe Bird (chloe.bird@ndph.ox.ac.uk).
- b) **For the Sherrington Building (DPAG)** – HTA Licence 12178 (Anatomy licence), contact HTG Group (hta_help@admin.ox.ac.uk).
- c) **For the Weatherall Institute of Molecular Medicine (WIMM)** - HTA Licence 12433 (Research Licence), contact HTG Group (hta_help@admin.ox.ac.uk).
- d) **For the Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM)** – HTA Licence 12326 (Research Licence), contact HTG Group (hta_help@admin.ox.ac.uk).
- e) **For all buildings in the John Radcliffe Hospital including the Main JR Hospital, the West Wing and Children's Hospital, the Eye Hospital, the Academic Centre, the Women's Centre, and excluding the WIMM-** HTA Licence 12217 (Research Licence), contact HTG Group (hta_help@admin.ox.ac.uk).
- f) **For all buildings in the Churchill Hospital including the main wards, the John Warin Ward and Vaccine Centre, the Cancer and Haematology Centre** – HTA Licence 12217 (Research Licence), contact HTG Group (hta_help@admin.ox.ac.uk).
- g) **For Old Road Campus buildings including ORCRB ('green building'), the Kennedy Institute, the NDM Research Building, the Henry Wellcome Building, the Big Data Institute, but excluding the Richard Doll Building and the BioEscalator** - HTA Licence 12217 (Research Licence), contact HTG Group (hta_help@admin.ox.ac.uk).
- h) **For the Nuffield Orthopaedic Centre including the Botnar Research Centre** - HTA Licence 12217 (Research Licence), contact HTG Group (hta_help@admin.ox.ac.uk).
- i) **For the Pharmacology Building (Mansfield Road), the Peter Medawar Building for Pathogen Research (South Parks Road) and the Dorothy**

Crowfoot Hodgkin Building (South Parks Road) - Satellites- HTA Licence
12217 (Research Licence), contact HTG Group (hta_help@admin.ox.ac.uk).

- 3.2** If your samples require storage under an HTA Licence but are not stored in any of the premises listed above or if you have any questions about licensed premises, please contact hta_help@admin.ox.ac.uk for assistance.
- 3.3** Other facilities such as the [UK Biocentre](#) which has facilities in Milton Keynes and Oxford (Osney Meads) offer storage solutions for samples requiring HTA licensing – contact information@ukbiocentre.com for more information.
- 3.4** For samples requiring registration as established above, registration must take place prior to any sample of relevant material being stored on licensed premises. In cases where samples are already stored on licensed premises in breach of the licensing requirements of the HT Act, please contact hta_help@admin.ox.ac.uk.
- 3.5** Please note that acceptance of samples under an HTA licence is at the discretion of the Designated Individual for the licence; it is each Principal Investigator's responsibility to comply with the decisions and directions of the relevant Designated Individual with regards to HTA licensing.

4. HTA LICENSING AND ETHICAL APPROVAL

- 4.1** Please note that the HTA licenses the storage of human tissue samples and not the use of human tissue samples in research. Research teams must ensure that any research conducted on samples, whether or not they are stored under an HTA licence, undergoes appropriate ethical review. Guidance on ethical review is available on the University's research support website <https://researchsupport.admin.ox.ac.uk/governance/ethics>.