Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-39 **Version: 1.0**

Title: **Management of Records for HTA-regulated projects**

Purpose: To provide a procedure for the creation, amendment, retention and creation of records generated in the course of research projects using human tissues.

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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	None	

1. Introduction:

The Research quality management system used by Keele University to ensure compliance with the Human Tissue Act necessitates the generation of a number of documents relating to the acquisition, storage, use and disposal of human tissue.

During a research project involving the use of human tissue, the following types of documents may be created and are subject to the procedures outlined below:

- Risk Assessments relating to individual project and premises
- Standard Operating Procedures
- Donor consent form and questionnaires
- Ethical and research governance approvals
- Human Tissue Storage logs
- Material Transfer Agreements
- Human Tissue transportation and delivery records
- Records of research data, laboratory records and associated metadata
- Records of equipment maintenance, calibration and servicing
- Reports of audits of storage conditions, sample records, consent and disposal
- Records of adverse events and complaints
- Records of Staff training and health and safety assessments

To ensure we meet the standards required for HTA-licensed buildings, there must be a clear policy in place to ensure appropriate management of each of these documents. This document provides the procedures that must be followed with regards to the creation, amendment, retention and disposal of these records.

In addition to the guidelines detailed below, all research teams must also ensure that their projects are compliant with all Keele University record management policies prior to commencement of any research project using human tissues. This includes policies relating to *data protection, freedom of information, confidential records*, *record retention* and *Whistleblowing* (see ***References*** below for links).

2. Procedure:

2.1 *Record Creation*

2.1.1 Records should be created using the relevant template document and associated standard operating procedure document for each type of record. HTA related templates can be found on the research governance website

2.1.2 If no template is available, additional records should be created in a standardised manner for each research project. As a minimum these should include the project title, the name of the chief investigator, the type of document and the version number and date.

2.1.3 Information that could allow the identification of the donor should only be included in an uncoded format on donor consent forms or questionnaires. Appending any donor details should be avoided on all other documentation. The types of information that should not be appended are specified in the Keele University Policy on ***Confidential Records***. If necessary, research records should only include information regarding the donor by use of a sample identification number.

2.1.4 Electronic files should be named in a manner that allows their easy identification by the entire research team as well as external auditors. For example “Document Title_Project code/name_PI surname_version date_version number” would provide a systematic approach to record naming.

2.1.5 Paper records should be completed using pen only, in a legible manner. Pencil must not be used as this could allow untraceable amendment to the document.

2.1.6 To ensure information is easy to find, avoid duplication of records as far as possible.

2.2 Record Amendment

2.2.1 If amendment of an electronic document is required then a separate file should be created with an updated version number and date associated with it to identify the progression of the file. This should be stored alongside the original document and a

summary document outlining the changed made to each new version to ensure amendments to the document can be traced.

2.2.2 If amendment of a paper document is required then this should be made by putting a single line through the text to be changed and initialled to ensure auditing of the changes made. Tipp-ex or other correction fluids should not be used, nor should text be scribbled out to become illegible.

2.3 *Record storage during the project*

2.3.1 A project file containing all project records must be securely stored in the HTA-licensed premises in which the research is conducted. The only exceptions to this would relate to records of donor-related information held by external research partners supplying tissue under the auspices of a material transfer agreement. Written assurances of the storage of these research documents should be obtained and securely stored by the chief investigator.

2.3.2 Confidential information relating to the personal information of donors or staff must be stored according to the regulations in Keele University's ***Data Protection*** and ***Confidential Records*** policy documents (see references for links).

2.3.3 Paper records should be stored securely in a locked filing cabinet only accessible to members of the research team. If paper records are removed from secure storage, they should not be left unattended in the absence of a member of the research team.

2.3.4 Electronic records must be stored on password-protected computers connected to the Keele computer network. Electronic files related to human tissue projects should be stored securely on Keele network drives rather than the hard disk to ensure the document can be recovered in the event of a computer malfunction.

2.3.5 Paper and electronic records should be filed in a systematic manner which should facilitate their identification both by the research team as well as external auditors.

2.4 *Access to Records*

2.4.1 Due to the need to protect donor confidentiality, access of research records should be controlled by the chief investigator, and should be limited to those members of their research team directly involved in conducting the research project.

2.4.2 The chief investigator of a project is responsible for supervising and monitoring the correct handling of records by the research team during the day-to-day running of the project. However, records may also need to be scrutinised as part of audits of human tissue research projects carried out internally by the Designated Individual and Human Tissue Officer, as well as externally by the Human Tissue Authority. The chief investigator should allow access to research records at the requests of these individuals. Those concerned about disclosure of patient identifiable information should refer to the HTA guidance on disclosure of patient identifiable information (see references below)

2.4.3 As detailed under Keele University's ***Data Protection*** policy, donors and staff are entitled to access any personal information held about them. If a research team is approached about providing access to a donor or staff members personal data, they should refer the enquiry to the University research governance officer (n.leighton@keele.ac.uk) for assistance.

2.5 Record retention following project

2.5.1 Records relating to a specific human tissue ***sample*** should be retained for until its use or disposal. If data arising from the use of this tissue is to be published then records should be held beyond the use of the tissue to ensure that this can be made available for audit of this research data. The chief investigator should use the University ***Records retention policy*** and ***Records retention schedule*** (see references below for links) for exact details on how long each record must be held available for audit.

2.5.2 Records relating to a human tissue research ***project*** should be retained for audit beyond the end of the completion of the project. The duration of retention depends on the type of tissue and also the funder of the research. The chief investigator should use the University ***Records retention policy*** and ***Records retention schedule*** (see references

below for links) for exact details on how long each record must be held available for audit.

2.6 *Record Disposal*

After the requisite retention period for records, they should be disposed of securely. For paper records this must occur by shredding and/or use of confidential waste disposal routes. For electronic records, the data files should be securely removed by the IT services helpdesk, as files disposed of via the recycling bin can be relatively easily restored. Further advice is available on the IT website. If computers that have held confidential records need to be disposed of these will be disposed of in line with the university policy on ***electronic records.*** Investigators should contact the residential Operations, CFM, who will pass the computer to Keele's accredited PC disposal agent after IT services has cleansed the computer.

3. References:

HTA guidance on disclosure of patient identifiable information
https://www.hta.gov.uk/policies/disclosing-patient-identifiable-information-hta

Keele University data protection policy
https://www.keele.ac.uk/policyzone/viewbyowner/planningandacademicadministration/name,70905,en.php

Keele University Freedom of information policy
http://www.keele.ac.uk/policyzone/viewbyowner/planningandacademicadministration/name,70907,en.php

Keele University Confidential records policy
http://www.keele.ac.uk/policyzone/viewbyowner/planningandacademicadministration/name,70852,en.php

Keele University record retention policy
http://www.keele.ac.uk/policyzone/viewbyowner/planningandacademicadministration/name,83019,en.php

Keele University records retention schedule
http://www.keele.ac.uk/policyzone/viewbyowner/planningandacademicadministration/name,153716,en.php

Keele University electronic records policy
http://www.keele.ac.uk/media/keeleuniversity/paa/qa/recordsmanagement/Records%20Management%20Guidance-Electronic.pdf