Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: **HTA-8** **Version: 2.2**

Title: **Completing the HTA-8 Log Proforma**

Purpose: To describe the procedures and information required to log the provenance, use and disposal of relevant materials in accordance with the Human Tissue Act 2004.

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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	Change of HTA officer Change of updating procedure Addition of "Location" column to spreadsheet and SOP Clarification of "Room" and "Storage" columns in SOP	2.0
2.0	Details on column A/B updated Update Disposal (v2.1) Huxley officer corrections (2.2)	2.2

1. Introduction:

The Human Tissue Act requires that details of all relevant material are accurately recorded to allow traceability of relevant materials at all times from acquisition to disposal. This SOP clearly details the instructions for completing the Human Tissue Act Log proforma that must be submitted to the Human Tissue Officer (Dr Alan Harper or Dr Dan Tonge) when any new Human Tissue Act (2004) defined relevant material enters an ISTM premises whose activities are regulated under HTA Licence No. 12349.

2. Procedure:

N.B. This SOP should be read in conjunction with the accompanying Excel spreadsheet HTA-8 Log Proforma Template.

Informing HTA officer of changes in holdings of HTA relevant materials.

Upon receipt of relevant material to the licensed premises, the following information must be inserted into the HTA-8 Log Proforma (spreadsheet). A copy of this spreadsheet should be held locally and a copy should be emailed to either Dr Alan Harper (Guy Hilton Research Centre, a.g.s.harper@keele.ac.uk) or Dr Dan Tonge (Huxley Building, d.p.tonge@keele.ac.uk) The HTA-8 Log Proforma Template should be resaved with the users surname, HTA log followed by the date e.g. harper_HTA-8log_030910.

Users should send updates to the HTA officer when additional materials are acquired, or when previous materials are disposed of or removed from the building. Chief Investigators (CIs) will be emailed every 2 months requesting an update of their spreadsheets, or to provide a statement that there is no change in holdings since the previous update. A

response must be received from all CIs holding relevant material.

Spreadsheet

Tabs: CIs should update the spreadsheet tab name (in Excel) to indicate their surname, a short study identifier (if CI has multiple studies), and the date of log update e.g. TONGE_SkinMicrobiome_01.01.17.

Columns: All columns must be completed for each sample in accordance with the below guidance. If a column is not relevant, NA must be entered; do not leave blank cells. If you are uncertain what to include, please contact the local HTA Officer for guidance (a.g.s.harper@keele.ac.uk (GHRC) or d.p.tonge@keele.ac.uk (Huxley)).

- Column A. **Unique Sample ID**. Every sample stored should be identifiable by a unique sample ID. If multiple samples are taken from the same donor or cell source, these should be provided with distinct IDs such that each sample can be independently traced through the logbook. Each Unique Sample ID should occupy one row of the spreadsheet i.e. if you have 25 tissue sections, each section should occupy a separate row. ***The Unique Sample ID must correspond to that on the sample label to facilitate traceability.***
- Column B. **Source**. Where did the tissue come from? Was it obtained through UHNS, commercially, or from another hospital site?
- Column C. **Tissue type.** This column must indicate that it is a human tissue. What is the tissue type? Is it blood, skin, tendon, lung or a mixture of multiple types? ***This information should correspond to the information recorded on the sample label to facilitate traceability.***
- Column D. **Received**. When was the sample received into ISTM? This may not be the date of the procedure performed to obtain the tissue. ***This information should correspond to the date recorded on the sample label to facilitate traceability.***
- Column E. **CI of study**. Who is the Chief Investigator of the ethically-approved study. This is where the ultimate burden of responsibility lies and it must be this individual who is identified which may not necessarily be the person recording the

information. In the case of commercially obtained material, it should be the person responsible for the laboratory group who are performing the study. ***This information should correspond to the information recorded on the sample label to facilitate traceability.***

- Column F. **Room.** Which room are the Relevant Materials stored in? The room number or room name should be listed here. If you move a sample to a different room then you must update your spreadsheet to indicate this immediately.
- Column G. **Storage**. What are the conditions of storage of the material? Is it held at room temperature (if so where), 4^{o}C (which fridge), -20^{o}C (which freezer), -40^{o}C (which freezer), -80^{o}C (which freezer), liquid N_2 (which Dewar). The storage vessel utilised should bear an HTA identifier label carrying a numerical identifier as described in HTA-10, and this should be recorded here. If the container does not have an HTA identifier, please contact the HTA officer to get this location registered for storage audits. If you move a sample to a different storage vessel (e.g. from a liquid N_2 dewar to an incubator) then you must update your spreadsheet to indicate this immediately. If the sample was never stored and immediately used in experiments upon arrival, please indicate that here. If the sample has been used, disposed and/or transferred out of the building, the storage location must not be removed from the spreadsheet as this forms part of our auditing procedure. If a sample is transferred to another storage location, both the previous and current storage locations should be identified here.
- Column H: **Location**. The detail provided here must allow the sample to be found by the auditors in your absence. Please provide as much detail as possible here to allow effective tracking of your sample. For example, if placing in a freezer these must be sufficiently detailed to allow someone to locate the tissue in your absence (e.g. Drawer number, box colour, exact position in box etc). If you move a sample to a different location then you must update your spreadsheet to indicate this immediately, however details of the original storage location must be retained for auditing purposes.
- Column I. **Disposal/Transfer**. Four pieces of information should be listed here: i) The date of disposal/transfer, ii) The method of disposal or destination of transfer, iii) The reason for the disposal/transfer, and iv) The person responsible for

undertaking the disposal/transfer of the sample out of the building. This will be used to indicate the tissue sample can no longer be found in our buildings. If the sample remains in storage please indicate this with a "N/A".

- Column J. **Derivation of additional materials**. Have cell lines, DNA, RNA or protein samples been derived from the original material? If so, you must indicate: i) the number of each of these type of samples that were created originally, ii) how many remain currently in storage, iii) where these remaining samples are currently stored (room, location, conditions, as above) and iv) how are they labelled? All derived materials must be traceable for the purposes of internal or external audit. The user should state here the exact label applied to the derivative material to allow effective tracking and sample audit. ***N.B. Cell lines derived from tissue samples must also be logged in the Human Cell Log according to the outline provided in HTA-9.***
- Column K. **NRES Approval Number.** What is the approved NRES study number? If not applicable, the user should state whether this is due to Keele REC approval or samples are taken from a commercial source.
- Column L. **Approved Study Title**. Provide the study name which has been approved by either a NHS Research Ethics Committee or the Keele University Research Ethics Committee. If not applicable due to cells being obtained from a commercial source, please indicate that here.
- Column M **Validity.** When does the current study approval expire? If the study is extended this information should be added to the original declaration and sent electronically to the Human Tissue Officer. If not applicable due to cells being obtained from a commercial source, please indicate that here.
- Column N. **Consent**. Was informed consent given by the research participant who donated the sample? Consent is a central tenet of the Human Tissue Act and therefore if you are uncertain on this you must contact the HTA officer for further guidance.
- Column O. **Consent retained**. Does the study CI have a copy of the consent in a secure setting which is available for inspection at the time of audit? What is the location of the informed consent; building, room, location? If consent is not held, please state why here. For Commercially-obtained tissues, a statement must be

obtained from the suppliers that tissue was acquired in a manner consistent with HTA regulations, and this should be available to an auditing team.