Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: **HTA-12** **Version: 2.1**

Title: Auditing relevant materials held under the ISTM license

Purpose: To describe the procedures and process of performing an audit of human samples stored within ISTM. This process aims to ensure that materials stored under NRES approval remain within a valid open project or have approval for subsequent storage, that records of disposal are accurate, and that records of storage are accurate.

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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	Change of HTA officer	2.0
2.0	Auditor selection to reflect local and external HTA officers. Addition of 2.2.1.2 Sample Labelling	2.1

1. Introduction: Under the ISTM HTA Licence No.12349 we are required to exemplify the traceability of materials defined as relevant by the Human Tissue Authority as the body responsible for the enforcement of the Human Tissue Act (2004) and internally by the Human Tissue Committee. To meet this requirement, we perform a quarterly audit of stored materials recorded in accordance with HTA-8 or HTA-9. This includes human tissues for use in NRES-approved projects, human tissues stored for use in subsequent NRES-approved projects, cells of human origin (embryonic stem cells, mesenchymal stem cells, tissue-specific stem cells, primary cells extracted from tissues, cancer-derived cell lines, immortalised cell lines, etc). The aim of the sample audit is to check the factual accuracy of the records supplied by users; for instance, the location of storage, the actual disposal of samples, the validity of NRES approval, the existence of consent forms. Audits will alternate between focussing on samples stored in the Guy Hilton Research Centre (GHRC) and the Huxley building. These sample audits will be organised by the local HTA officer - either Dr Harper (GHRC) or Dr Tonge (Huxley) as laid out by the SOP below. In some instances, the sample audit will be performed by two individuals other than the local HTA officer.

2. Procedure: The procedures for performing the sample audit are outlined below. These procedures should be read in conjunction with HTA-12 ISTM HTA Sample Audit Template.

2.1. Preamble. Two auditors will meet in advance of the sample audit and determine which samples will be traced on that day. The inspection team will consist in a three-audit cycle of:

1) Local HTA officer of building and external HTA officer

2) Local HTA officer and a randomly-selected individual who has declared materials in an

HTA-8 or HTA-9 logbook

3) External HTA officer and a randomly-selected individual who has declared materials in an HTA-8 or HTA-9 logbook.

Samples logged by either HTA officer may be selected at any time, but the other auditor should lead in the auditing of these samples.

2.1.2. Sample Selection. All samples will be randomly selected unless a recorded cause for concern has been received. Samples will be chosen by using a random number generator to select a Chief Investigator (CI) from a list of all of the CIs numbered in alphabetical order of surname. Once a CI is selected, if they have multiple human tissue projects ongoing then a random number generator will be used to select a project at random, followed by a second number selected to identify the row number of the sample to be audited. If a CI has a single human tissue on project ongoing then a single random number will be used to identify the row number of the sample to be audited from their logbook.

If possible, two samples will be selected from both HTA-8 and two samples from HTA-9. In the event that there is only one PI who has an HTA-8 or HTA-9 spreadsheet logged at the time of audit, then the auditors may choose to pick more than two samples from the other type of logbook.

From the four samples selected, at least one of these samples should have been declared as having been disposed of. This sample is intended to define the accuracy of disposal records. In the other instances the intention is to define the accuracy of sample storage records, the fidelity of the existing NRES approval, and the existence of a recorded informed consent (an underlying principle of the Human Tissue Act).

Once samples are chosen the Information regarding each of the sample should be taken from the logbook and recorded in the “pre-meet” section of the HTA-12 HTA sample audit spreadsheet. The information recorded here will then be checked on during the audit. The Information regarding the CI, the logbook location (tab name and row number), and the unique sample identifier should also be duplicated in the yellow coloured cells of the “audit” section of the HTA-12 spreadsheet. Once this task has been completed the auditors should also examine the logbook to ensure that it is being used in a standardised manner across all recorded samples. If this is found to be the case then “Accurate” should

be recorded in the relevant “logbook usage” cell of the pre-audit section of the HTA-12 spreadsheet. If this is not found to be the case, constructive feedback on how to improve the use of the logbook should be recorded here to be relayed to the CI in their post-audit feedback.

Once completed this template should then be saved as “HTA-12 Sample Audit audit team date of inspection”, for instance “HTA-12 Sample Audit Forsyth El Haj 18.03.10”. A copy of this spreadsheet should be provided to both auditors, and printed on the day of the audit to be used to record findings.

2.1.3. Inspection Notification. Prior to the actual inspection, the CI responsible for any selected materials will be notified of the intention to inspect materials that they are solely responsible for. The CI will be requested to identify a time when they will accommodate an inspection of consent forms in order to confirm the existence of informed consent for the stored sample. This inspection should be within one week of the sample inspection. A failure to comply with this will result in repeated non-random inspections on a weekly basis where three subsequent failures will be interpreted as a failure to meet the obligations of a CI storing materials under HTA Licence 12349. In this instance the CI will be required to evidence all requested information in 1 calendar week and a failure to comply will result in all CI samples being removed from buildings under the governance of HTA Licence 12349.

2.2. Audit. The process of audit is performed by the two selected auditors and without assistance from any others. Additional information provided by the CI or members of their group following the notification of audit will be ignored until after the completion of the inspection.

2.2.1. Areas of declaration in HTA-8 to be inspected. From the original sample declaration according to HTA-8 as well as visual inspection of the samples there are seven sub-headings which should undergo inspection on the day of the audit. These are; Room and Storage, Sample Labelling, Disposal/Transfer, Derived Materials, Ethical Approval, Validity and Consent.

2.2.1.1. Room and Storage. In the completion of HTA-8 the individual logging the sample is asked to declare the room in which the sample is stored, the

condition of storage and the HTA-10 defined storage container. This information should be attempted to be confirmed during the audit. If the information is correct then “Accurate” should be recorded in the relevant “Room and Storage” cell of the audit section of the HTA-12 spreadsheet. If the information is ambiguous, incomplete or incorrect, then these shortfalls should be detailed here to allow constructive feedback to be relayed to the CI in their post-audit feedback. In the event of an inaccurate entry all samples declared by the CI in question will be subjected to a focussed audit based on the principles outlined in this SOP but without the random aspect. This focussed audit will be performed by the local and external HTA officers.

2.2.1.2. Sample labelling. Labels will be checked to ensure they fufill the requirements laid out in the Human Tissue Handling manual (p45), as well as the HTA-2 (subsection 2.13-2.16) and HTA-3 (2.6-2.9) SOPs. This will include ensuring that printed labels are securely attached, legible and containing the information detailed in the specified SOPs. . The inspection team will then enter “Accurate” (when the disposed sample is not at its previous declared location) or “Inaccurate” (when the sample recorded as disposed is found at its previous declared location) into the relevant “Disposal/Transfer” cell of the audit section of the HTA-12 spreadsheet In the event of an inaccurate entry all samples declared by the CI in question will be subjected to a focussed audit based on the principles outlined in this SOP but without the random aspect. This focussed audit will be performed by the local and external HTA officers.

2.2.1.3. Disposal/Transfer. To maintain the accuracy of the sample logs the CI is responsible for ensuring that an accurate record of when samples are either disposed of or transferred out of the building. The inspection team will determine the accuracy of any such declaration by attempting to locate such a sample in its previously declared location. The inspection team will then enter “Accurate” (when the disposed sample is not at its previous declared location) or “Inaccurate” (when the sample recorded as disposed is found at its previous declared location) into the relevant “Disposal/Transfer” cell of the audit section of the HTA-12 spreadsheet In the event of an inaccurate entry all samples declared by the CI in question will be subjected to a focussed audit based on the principles outlined in this SOP but without the random aspect. This focussed audit will be performed by the local and external HTA officers.

2.2.1.4. Derivation of additional materials. To maintain the accuracy of the

sample logs the CI is responsible for ensuring that an accurate record of when samples have additional materials derived (cells lines, DNA, RNA or protein samples) from them and where those samples are stored. The inspection team will determine the accuracy of any such declaration by attempting to locate such a sample in its location declared according to HTA-8. The inspection team will then enter “Accurate (when the derivative materials are found at the declared location) or “Inaccurate” (when the derivative materials are not found at the declared location) into the relevant cell of HTA-12 spreadsheet. In the event of an inaccurate entry, as much information regarding the shortfall should be recorded to allow clear, constructive feedback to be provided to the CI. In addition, all samples declared by the CI in question will be subjected to a focussed audit based on the principles outlined in this SOP but without the random aspect. This focussed audit will be performed by the local and external HTA officers.

N.B. this may create overlap with HTA-9 declared materials but does not substitute for a HTA-9 based inspection.

2.2.1.5. Ethical Approval. Is the correct University or NHS research ethics committee study title and approval number held on file? The inspectors should confirm this with the CI and enter the confirmed NRES number into Column G Row 16 of the HTA-12 ISTM HTA Sample Audit Template which was saved according to the instructions outlined in HTA-12 Section 2.1.2.

2.2.1.6. Validity. Is the study still within the dates approved by the approving ethics committee or has the date expired? The inspectors should consult the previously entered date according to HTA-8 and check that it is still relevant. If the date is within three months of expiration the inspectors should contact the CI and request information clarifying plans beyond the expiration date. The date of study expiration should be entered into the relevant HTA-12 ISTM HTA Sample Audit Template which was saved according to the instructions outlined in HTA-12 Section 2.1.2.

2.2.1.8. Consent. The inspection team are required to visually confirm that informed consent for the sample declared in HTA-8 is retained by the CI and held in a secure location. Once visual confirmation has been made the word confirmed or non-confirmed should be entered into the relevant cell of the HTA-12 ISTM HTA Sample Audit Template which was saved according to the instructions outlined in HTA-12 Section 2.1.2. In the event of a non-confirmed entry the CI will be given a period of one calendar week to

locate the evidence of consent. If unable to do so the CI will be required to notify the local NRES committee of the transgression within two calendar weeks and to follow the advice given by the local NRES committee including the destruction of the sample and updating of the Sample Log according to the instructions provided in HTA-8.

If this is not possible as the ethics is held elsewhere (e.g. by collaborating group or commercial suppliers)

2.2.2. Areas of declaration in HTA-9 to be inspected. Cell samples recorded on an HTA-9 logbook will be subject to the same inspections for an HTA-8-logged sample as outlined above, as well as one additional check.

2.2.2.1. Derived from. In the instructions for completion of HTA-9 the CI is asked to declare what tissue the cells are derived from, if the tissue is from an NRES-approved study what its identifier is in the Human Tissue Log, and has it been marked as disposed (if appropriate for cell generation) according to the instruction outlined in HTA-8. The entry detailed in HTA-9 should be confirmed and entered into Column C Row 20 of the HTA-12 ISTM HTA Sample Audit Template which was saved according to the instructions outlined in HTA-12 Section 2.1.2.