Keele University

Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-43 **Version: 1.0**

Title: **Completing the Human Tissue Handling Logbook**

Purpose: To facilitate research groups in completing the HTA-43 Human Tissue Handling logbook

Written By: Alan Harper Date: 29.09.16

Approved By: Alan Harper Date: 29.09.16

Effective Date: 29.09.16 Review Date: 29.09.17

SOP History:

VERSION	**AMENDMENT**	**CURRENT VERSION**
1.0	None	

1. Introduction:

Establishments licensed by the Human Tissue Authority must be able to demonstrate that staff are provided ***competency training*** in the handling and use of human tissue (Checkpoint GQ3 – HTA licensing standards; see References). The HTA-43 form records the personal training and supervision needs for every staff or student performing a role in a human tissue research project. Once this assessment has been completed this form provides a basis for logging training and supervision of the staff such that both the Principal Investigator and the University can demonstrate that staff are competent to perform the tasks allocated to them.

2. Procedure:

Part 1 - Original Assessment of training needs

2.1.1 The Principal Investigator (PI) should perform the assessment in a meeting with the student or staff member undertaking a role in a human tissue project prior to them beginning their work on the project. Both the PI and Staff/student should have read the Project Standard Operating Procedure (HTA-41) and risk assessment (HTA-31) prior to the meeting.

2.1.2 The logbook form should be assigned a logbook I in the top right hand of the form. This should comprise of the PI's surname and the SOP number of this PI. For example, Dr Harper's 1st logbook would be assigned "Harper-1", and his fifth would be "Harper-5". This logbook ID should be included in the appropriate box of the Staff/Students entry of the Human Tissue Users database (HTA-42)

2.1.3 The details of the Staff/Student, PI and research project should be recorded in the *Project Details* section of the form. The date of the meeting should be recorded along with a review date within 3-12 months of the original assessment as determined necessary by the PI.

2.1.4 The PI should go through the SOP and list all the tasks that the staff/student will be undertaking on the project in the "*Tasks to be performed"* column of the relevant sections of the HTA-43 form.

2.1.5 The PI should discuss with the Staff/Student what training or supervision requirements they will require to undertake each component of the task. These should be recorded in *Training/Supervision required*. These can include attendance at internal or external training courses, or direct supervision by the PI or another designated researcher who is appropriately experience in the techniques to be used.

2.1.6 The number of hours of training required for the Staff/Student to be competent should be recorded in this box. This will vary significantly between tasks with some require a single demonstration to others requiring more comprehensive supervision. The number of hours recorded should be guided by both the ***degree of difficulty*** of the task to be performed and the ***Risk*** assigned to the task as part of the project risk assessment (HTA-31 form). Any task designated as either medium or high risk would be expected to have a minimum number of hours of documented supervision of 5 (medium) and 10 (high) hours respectively.

2.1.7 If the Staff/Student member has previous experience of any of the tasks then this should be recorded in *Training/Supervision required* and the *hours required* can be recorded as "0". If training has been previously recorded in a logbook from a previous Keele University study, this logbook ID should also be provided here.

2.1.8 A copy of this form should be held by the PI and emailed to the Staff/Student and the HTA officer (a.g.s.harper@keele.ac.uk).

2.1.9 A printed copy of this form should also be made and signed and dated by both PI and Staff/Student. This will form the logbook. As the Staff/Student receives training/supervision the dates of this should be recorded on the form. This should include a date in which training/supervision was provided. The number of hours of training/supervision should be indicated alongside the date in parenthesis (e.g. for 2 hours of training on the 29th September 2016, "*29/09/16 (2)*" would be recorded. For all dates a signature of the PI or another appropriate supervisor should be given. Any course attendance certificates should also be held as proof of attendance.

2.1.10 The logbook should be held securely when not in use, and a back-up made at appropriate intervals to ensure that information cannot be lost if misplaced or damaged when taken into the lab.

Part 2 – Review of Training Needs

2.2.1 At the date of review the PI and Staff/Student should meet again to complete Part 2 of this form

2.2.2 The PI and Staff/Student should examine the original training schedule and identify if all training/supervision required has been provided. If not all training has been provided, then this should be indicated on the form, and the deficit should be included in the *additional training needs* section of the form.

2.2.3 The PI and Staff/Student should also discuss if additional training requirements have arisen since the onset of the project. If this is the case, this should be described in the form and the additional needs included in the *additional training needs* section of the form.

2.2.4 Once all training has been received, the PI and student should sign and date the form. A duplicate or scan should be sent/emailed to the HTA officer (a.g.s.harper@keele.ac.uk), and the original held securely by the PI for their project records.

3. References:

HTA licensing standards (Checklist point GQ3)
https://www.hta.gov.uk/policies/research-sector-hta-standards