

Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-42

Version: 1.0

Title: Completing the Human Tissue Users Spreadsheet

Purpose: To facilitate research groups in completing the HTA-42 Human Tissue Users Spreadsheet

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Date: 29.09.16

Approved By: Alan Harper

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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	None	

1. Introduction:

The misuse of human tissue can present risks to Staff, Students and the General Public. Establishments licensed by the Human Tissue Authority must therefore be able to demonstrate that staff are appropriately qualified and trained in the use of human tissue, and protected by the relevant health and safety precautions (Checkpoint GQ3 – HTA licensing standards; see References). The HTA-42 spreadsheet forms a record by which the Principal Investigator can ensure that all staff and students are appropriately monitored during their work on a human tissue research project. This spreadsheet will also be compiled into a University-wide database, such that those overseeing the management of research are also able to ensure there is appropriate training and monitoring of staff undertaking human tissue research.

2. Procedure:

2.1 When instigating a human tissue research project, the Principal Investigator (PI) should either compile a new HTA-42 spreadsheet entry or update a pre-existing entry for all Keele University Student or Staff members who will be undertaking a role in the **acquisition, transportation, storage, use** or **disposal** of human tissue. The PI should also complete an entry for themselves regardless of whether they play a direct hands-on role in the project.

2.2 Each staff member should be assigned a separate tab of the spreadsheet. The Tab label should be updated to indicate the **Surname** of the PI/Staff member/Student and the **date of completion**. Changes can be made by right clicking on the tab and selecting “Rename”.

2.3 The template spreadsheet comes with 5 identical tabs, if additional staff/student members of the team need to be included these should be made by duplicating the tab. This can be done by Right clicking on one of the pre-existing tabs, and selecting “Move or copy...” from the pop-up menu. On the screen, check the box “Create a copy” and then select “<move to end>” from the list. Click OK and a duplicate of the tab should be made.

2.4 Details of Staff/Student/PI

All sections of the form should be completed using the following guidance

2.4.1 Name – Provide Name of PI/Staff member Student

2.4.2 Job Title – Provide Job title or Course title

2.4.3 Qualifications – Provide details of qualifications at degree level or above. Also include any professional memberships or fellowships. If a student is studying for a first degree indicate that here.

2.4.4 Research Passport – If the PI/Staff/Student has applied for or received a research passport, please provide details here. If not applicable, please state that here.

2.4.5 Occupational Health - It is the expectation that anyone handling primary human tissues should be provided with hepatitis B vaccinations and any other relevant occupational health screenings. Dates of vaccination and when a booster would be required should be provided here.

2.5 Basic Training

Details of when basic training has been attended should be recorded in these boxes. If training has not been attended this should be indicated here. All courses except the departmental induction, should be subject to refresher training based on departmental policy. Good Clinical Practice Training should be refreshed every two years, and Human Tissue Act training should be refreshed every three years. For further information about the training courses please contact the human tissue officer (a.g.s.harper@keele.ac.uk).

2.6 Project Specific Information

This section contains information regarding the projects that students and members of staff are working on. Projects not involving the use of Relevant materials as defined by the Human Tissue Act, should not be included here. The spreadsheet makes provision for staff involvement in up to 3 projects, if additional columns are required these can be added by the PI. Please complete the boxes for each study contributed to using the following guidance:

2.6.1 Title of Research Project – Please provide the Keele University Research Ethics Committee (REC) or NHS REC approved title for the project here. Include any Approvals reference numbers where possible. If no ethics approvals gained due to the use of commercially-obtained primary cells, state project title and then place (unapproved)

afterwards (e.g. “Research Project Title (unapproved)”)

2.6.2 *Relevant Materials Used* – State the Relevant human tissue(s) being used in the project here.

2.6.3 *Principal Investigator* – State the name of the Principal Investigator of the project here.

2.6.4 *Start and end dates of project* – Please include the start and end dates approved by Keele or NHS REC here. If an unapproved study using commercially-obtained primary cells, please indicate the likely start and end dates of the project here.

2.6.5 *Human Tissue Handling Logbook ID* – All staff members taking part in human research projects should have a competency training assessment with their PI. This is recorded on the HTA-43 form. The ID for this assessment should be recorded in this box.

2.6.6 *Internal Project specific training (Planned and completed)* – A list of Keele University training courses which the Staff member/Student/PI has attended or plans to attend should be listed here. If already attended, attendance dates should be indicated in parenthesis after course title. Evidence of attendance should be retained by Staff member/Student.

2.6.7 *External Project specific training (Planned and completed)* - A list of external training courses which the Staff member/Student/PI has attended or plans to attend should be listed here. If already attended, attendance dates should be indicated in parenthesis after course title. Evidence of attendance should be retained by Staff member/Student.

2.7 Once a tab for the PI and **all** staff members and students involved with the project have been completed, save the spreadsheet as “HTA-42 – PI surname – one word project identifier-date” (e.g. “HTA42-Harper-pericellular-290916”). The PI should email the compiled spreadsheet to the Human Tissue Officer (a.g.s.harper@keele.ac.uk). Please do not send individual entries in isolation.

3. References:

HTA licensing standards (Checklist point GQ3)

<https://www.hta.gov.uk/policies/research-sector-hta-standards>