Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-41 **Version: 1.0**

Title: **Writing Standard Operating Procedures (SOPs) for a human tissue project**

Purpose: This SOP describes the process of writing and reviewing SOPs for Human tissue projects

Written By: Alan Harper Date: 28.09.16

Approved By: Alan Harper Date: 28.09.16

Effective Date:28.09.16 Review Date: 28.09.16

SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	None	

1. Introduction:

Establishments licensed by the Human Tissue Authority (HTA) must be able to evidence compliance with the requirements of the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the HTA codes of practice. Current licensing standards for the HTA include a requirement for a standard operating procedure for all licensed activities.

A SOP describes the procedures required to complete a certain task. If adhered to a SOP provides uniformity of method between staff and becomes part of the organisations quality management system (QMS); it is also evidence of Good Laboratory, Clinical and Manufacturing Practice. Therefore, all human projects will be asked to email the human tissue officer a standard operating procedure prior to the onset of the project (a.g.s.harper@keele.ac.uk) alongside a risk assessment of these activities.

This SOP details the process of completing the associated HTA-41 proforma for writing a standard operating procedure for a human tissue project.

2. Procedure:

2.1 Authoring SOPs:

2.1.1 SOPs should be authored by persons(s) familiar with the task covered and reviewed by at least one other person before finalisation. All SOPs should have a cover sheet following the template of this SOP's cover sheet, the template is available in HTA-40 proforma. There should be a header with the SOP number and title and a footer with page number and page count. If the SOP is lengthy a contents section may be included after the title sheet.

2.1.2 In an Introduction section should include details about the project including a brief background to the project and aims and objectives of the project.

2.1.3 The Procedure section should be a step by step description of the actions to complete the procedure. This should include subsections on the ***Acquisition***,

transportation (if appropriate), ***storage***, ***use*** and ***disposal*** of the human tissue.

2.1.4 *Points to consider* are provided on the proforma for each subsection to help provide guidance on what areas could be commented in when writing a standard operating procedure. These questions are indicative of the sort of issues investigators should consider and are not exhaustive. Not all points to consider will require comment as some are not relevant to every project. These questions should be deleted from the final document.

2.1.5 The Procedure section should be clear and easy to follow. If specific training is required to perform the operation this should be clearly indicated. For a SOP covering a scientific method there should be a materials section detailing items required to complete the procedure and any safety aspects involved, followed by a step-by-step protocol.

2.1.6 If necessary include a Reference section listing other relevant SOPs, regulatory documents etc.

2.2 SOP number:

All SOPs will have an identification number with the format **HTA-PI Surname-Number** and will be saved with a file name **HTA-surname-Number**. Anyone authoring a new SOP should refer to the SOP index to determine the next available SOP number. During writing the file should be saved with the additional suffix **-draft** and will be saved in the DRAFT VERSION folder. Following authorisation the suffix draft can be removed and the file saved in the FINAL VERSION folder. The draft file(s) should be retained as archived material.

2.3 Version Control:

SOPs will have a version number in the format A.a, with A representing the finalised version of the document and a the draft version. When taking a document for revision assign a new minor version e.g. 1.1 and save each new revision accordingly. When finalised and approved the document can be assigned the next major version e.g. 2.0.

2.4 Approving SOPs:

SOPs should be sent to the human tissue officer (a.g.s.harper@keele.ac.uk) for approval before commencement of the project to ensure that appropriate procedures for receiving, handling and disposing of human tissues are in place.

2.5 Issuing SOPs:

All finalised SOPs should be provided to all members of the research team. A record will also be held by the Human Tissue Officer for audit purposes.

2.6 Reviewing SOPs:

Following approval all SOPs should receive an effective date, SOPs should be reviewed as required or one year after the effective date. Even if no changes are made the version number, effective date and date of review should be updated to reflect that the SOP has been reviewed. This should then be emailed to the Human Tissue officer for their records (a.g.s.harper@keele.ac.uk). Old versions of the SOP should be saved as archived material. If at the point of review it is decided that the SOP is no longer relevant it may be archived.