Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-31 **Version: 1.0**

Title: **Assessing risk of human tissue projects**

Purpose: This SOP describes the process of assessing the risks of a forthcoming or ongoing research project failing to comply with the Human Tissue Act (2004) or the associated HTA codes of practices.

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Approved By:	Prof Nicholas R Forsyth	Date: 23.09.16

Effective Date: Review Date:

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. HTA licensing standards require all HTA-licensed premises to perform risk assessments of all activities involving human tissues regulated by the Human Tissue Act happening within these buildings.

All research projects using Relevant Materials as defined by the Human Tissue Act (see below) must submit a risk assessment considering potential areas in which the project could possibly fail to comply with the Human Tissue Act or associated HTA codes of practice. The principal aim of this process is to principally ensure that researchers have considered potential pitfalls of their procedures prior to the onset of research. These activities must be undertaken in addition to any additional governance requirements (e.g. a risk assessment of biological safety, acquisition of ethical approvals). This standard operating procedure will detail the procedure for completing the "*HTA-31: Risk Assessment for Human Tissue Projects*" form. Part 1 of this SOP should be used in conjunction with the HTA-31 form to perform the initial risk assessment of the human tissue project. Once completed these risk assessments must be submitted to the Human Tissue Officer (a.g.s.harper@keele.ac.uk). Part 2 should be utilised to perform the annual review of this assessment.

2. Completing the HTA-31 form

Part 1 – *Initial Risk Assessment*

2.1 *Project details.* Please fill in details regarding the project.

2.1.1 If exact start and end dates are unknown, please fill in the anticipated start and end dates.

2.1.2 If multiple human tissues are used in this study please detail in the box provided. The acquisition, transportation, storage, use and disposal of each tissue should be independently analysed on separate forms. The tissue under consideraition should be

highlighted in the box provided.

2.2 ***Identification of Risks.*** This section examines the whole process of human tissue use across the five main project stages: Acquisition, Transportation, Storage, Use and Disposal. Each of these stages of the research project should be considered individually. Whilst identifying and assessing risks please refer to the Keele Human Tissue Handling Manual as well as relevant HTA codes of practice (COP; see references below for weblinks) on Consent (COP1), Disposal (COP5), Import/Export (COP8), and Research (COP9).

2.2.1 If tissue is obtained internally, the transportation section may be removed from the risk assessment. Otherwise all sections must be completed.

2.2.2 For each section consider the potential risks associated with the human tissue in question. A list of generic risks has been listed for each section. It is expected each of these generic risks will be considered in all risk assessments. If a risk is not applicable, state this and indicate why this is the case.

2.2.3 Investigators should also consider specific areas of their protocols which could conceivably lead to harm or damage to the tissue sample or staff, students and visitors. These can be added to the lists and should be scored as for the generic risks identified above.

2.2.4 For each identified risk, consider the control measures you have currently built into your protocol. State these in the box provided, along with any monitoring procedures you will put in place to ensure the effectiveness of these control measures.

2.2.5 For each identified risk, consider the ***likelihood*** of this being the cause of an adverse event occurring during the timescale of the project. Score the likelihood using the following scale below

1: Highly Improbable (0-1% chance of occurrence)

2: Improbable (1-10% chance of occurrence)

3: Possible (10-33% chance of occurrence)

4: Likely (33-50% chance of occurrence)

5: Almost Certain (50-100% chance of occurrence)

2.2.6 For each identified risk, consider the ***severity*** of any adverse event that might be caused by this issue during the timescale of the project. Score the likely outcome using the following scale below;

1: No damage to individuals, institutional reputation or human tissue samples.

2: Minor harm to individuals or institutional reputation, or minor damage to tissue (all tissues still usable for studies).

3: Moderate harm to individuals or institutional reputation, or moderate damage to tissues (some tissues lost from study).

4: Major harm to individuals or institutional reputation (e.g. activity breaking HTA code of practices), or major damage to tissues (most tissues lost from study).

5: Life-threatening harm to individuals, University or researchers subject to legal consequences under Human Tissue Act, or complete loss of tissue.

2.2.7 Using your scores for ***Likelihood*** and ***Severity***, calculate a risk score for each component by multiplying the scores for these components together (Risk = Likelihood x severity). Enter the score in the box provided.

2.3 ***Additional Control Measures Required*** After a risk score is assigned then these need to be analysed

2.3.1 Assess the risk score (RS) of each individual risk identified in section 2, using the following table below:

RS = **1-4**: ***Low Risk*** – *No additional control measures are required*

RS = **5-12**: ***Medium Risk*** – *Additional control measures* ***should be considered****. These should be introduced as far as is practical.*

RS = **13-25**: ***High Risk*** – *Additional control measures* ***must*** *be introduced.*

2.3.2 Any component that is considered to be **Medium** or **High** risk must be subject to

additional consideration. These risks should be entered into the correct section of the table in part 3.

2.3.3 For all items, consider additional control measures which could be utilised to mitigate risk should be identified and entered into the appropriate box. For **High** risk items, these must be used. For **Medium** risk items, these should be used where practical. If a control measure is considered to be impractical to implement, then the control measure should be placed in parenthesis alongside a brief statement of why the control measure was deemed impractical.

2.3.4 After control measures have been reviewed. The ***Likelihood***, ***Severity***, and ***Risk*** scores should be reassessed based on the newly adopted control measures (and ignoring anything rejected as impractical), and updated scores entered into these boxes. If any item remains **High** risk then this should be subject to another round of review. If after this, the risk is still deemed in the High category, then the chief investigator should discuss this with the Human Tissue Officer (a.g.s.harper@keele.ac.uk) for further advice.

2.3.5 Once completed, the date for review should be set as for the one year after the date of completion of the initial risk assessment. The chief investigator should sign and send a paper (Dr Alan Harper, Guy Hilton Research Centre) or electronic copy (a.g.s.harper@keele.ac.uk) to the Human Tissue Officer for final approval. The Human Tissue Officer will assign the risk assessment a unique identification number which will be used to log all projects.

Part 2 - *Annual review of risk assessment*

2.4.1 The chief investigator will be sent an email reminder one month before the date for the annual review of the risk assessment and its associated standard operating procedure. The Chief investigator, or delegated member of the research team, must then complete section 2 of the form on or before the date of review stated in Part 1 of the risk assessment.

2.4.2 A separate Part 2 form should be completed for each individual type of human

tissue used in a given project.

2.4.3 Project details should be entered into the box provided. Start and end dates should reflect those stated on the relevant ethical approval under which the human tissue sample is stored.

2.4.4 The assessor should investigate each item of the risk assessment in turn and consider whether:

- there have been any changes to the original experimental procedures?
- there been any additional experimental procedures which have been introduced since the initial standard operating procedure was written?

2.4.5 If the answer to these is ***No*** this should be indicated on the form. If any of these questions is ***Yes*** then the change in procedure should be indicated on the form, and details should be provided in the box below. These changes could lead to addition of new risk items in section 2 and/or changes in the level of likelihood or severity of the risk. These should be updated on the original assessment, showing changes in **red**. The risk assessment procedure should then be followed through for each altered component of the original assessment as stated above. The overall changes to the reviewed risk assessment should also be outlined in the box provided in Part 2 of the form.

Amendments to the procedure should also be updated on the relevant standard operating procedure submitted prior to the onset of the project (with updated version number and changes indicated in **red** and summarised on Document history section at top). This document should also be updated and returned to the Human Tissue Officer.

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2.4.6 The assessor should investigate each item of the risk assessment in turn and consider whether:

- the research team has observed any additional risks to their human tissue that were not considered in the original analysis?
- the perceived ***likelihood*** or ***severity*** of the risk altered based upon the experiences of the research team in the last year?

2.4.7 If the answer to these is ***No*** this should be indicated on the form. If any of these questions is ***Yes*** for any of the identified risks should be indicated on the form, and details should be provided in the box below. These changes could lead to addition of new risk items in section 2 and/or changes in the level of likelihood or severity of the risk. These should be updated on the original assessment, showing changes in **red**. The risk assessment procedure should then be followed through for each altered component of the original assessment as stated above. The overall changes to the reviewed risk assessment should also be outlined in the box provided in Part 2 of the form.

2.4.8 Once completed, the assessor should give the reviewed risk assessment to their chief investigator to check, approve and sign. This document should then be returned to the Human Tissue Officer for final approval.

3. References:

HTA Codes of Practice: https://www.hta.gov.uk/guidance-professionals/codes-practice

Keele Human Tissue Handling Manual