	Title: Assessing risk of human tissue Projects.	Author: P. Lympany	Date: 11/Oct/2019
	No: SOP_R17	New Author: P. Madhou	Date: 1/Sept/2024
	Version: 3		Review Date March 2026

SOP_R17: ASSESSING RISKS OF HUMAN TISSUE PROJECTS

Disclaimer

When using this document, please ensure that the version you are using is the most up to date either by checking on the City St George's /PORTAL/HTA website for any new versions or contact the HTA coordinator to confirm the current version.

Out of date documents must not be relied upon and should be destroyed.

3	Aug 2024	City merge, review and formatting	PM	HTLRG
2	Sept 2023	New DI, updated contacts & formatting	AS	HTLRG
1	April 2020	Updated	AS/PL	HTLRG
0	October 2019	Issued for comment	PL	HTLRG

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Purpose/Background

1.1 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 codes of practice.

1.2 All SOPs used in connection with licences issued by the Human Tissue Authority must, where appropriate, be read and used in conjunction with associated City St George's Policies and Procedures.

1.3 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.

1.4 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).

1.5 This standard operating procedure will detail the procedure for completing the "HTA: Risk Assessment for Human Tissue Projects" form. This SOP should be used in conjunction with the Form R17 to perform the initial risk assessment of the human tissue project.

2 Scope

2.1 All research projects using Relevant Materials as defined by the Human Tissue Act 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.

2.2 The principal aim of this process is to 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).

2.3 This process applies to the following licence: HTA 12335 Storage of relevant material which has come from a human body for a scheduled purpose.

3 Responsibilities

3.1 The overall responsibility for ensuring that the required SOP is created and adhered to, rests with the Governance Manager acting on behalf of the Licence Holder, hereafter referred to as "the Licence Holder".

3.2 Responsibility for creation, approval, review and revision of SOPs and for ensuring that the processes defined in this SOP are properly carried out rests with the Governance Manager in the Joint Research Service of St George's.

3.3 Responsibility for timely review and final approval of SOPs lies with the Human Tissue Licence Review Group (HTLRG).

4 Procedure for completion of Form R17

Part 1–***Initial Risk Assessment***

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

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

4.1.2 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 consideration should be highlighted in the box provided.

4.2 ***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 projects should be considered individually.

4.2.1 If tissue is obtained internally (within City St George's University), the transportation section may be removed from the risk assessment.

4.2.2 If the tissue samples are obtained from the St George's Hospital Trust, then the risk assessment between the two sites (St. George's & Trust) must be addressed and all sections of the transportation must be completed

4.2.3 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.

4.2.4 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.

4.2.5 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.

4.2.6 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)

4.2.7 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.

4.2.8 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.

4.3 ***Additional Control Measures Required***

After a risk score is assigned then these need to be analysed

4.3.1 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.*

4.3.2 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.

4.3.3 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.

4.3.4 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 DI (pmadhou@sgul.ac.uk) or PD (asameja@sgul.ac.uk) for further advice.

4.3.5 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 principal investigator/tissue custodian should sign and keep a copy with other HTA paperwork.

Part 2-***Annual review of risk assessment***

4.4.1 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.

4.4.2 A separate form should be completed for each individual type of human tissue used in a given project.

4.4.3 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.

4.4.4 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?

4.4.5 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).

4.4.6 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?

4.4.7 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.

4.4.8 Once completed, the assessor should give the reviewed risk assessment to their Principal Investigator to check, approve and sign.

4.5 SOPs will be approved for a period of up to 12 months by the Licence Holder.

4.6 Within a period of 12 months following initial approval of a SOP, it shall be reviewed and approved by the HTLRG (with appropriate revision where necessary).

4.7 SOPs will generally be approved for a maximum period of 2 years. Towards the end of that time, they must be put to a meeting of the HTLRG for review.

4.8 When approved (in initial or in final form), SOPs shall be circulated to all those responsible for its implementation. The Governance Manager shall be responsible for ensuring that training in the implementation of each SOP is carried out, and that those who are so trained certify completion of training by signing the master copy of the SOP.

4.9 Master copies of SOPs shall be kept by the Governance Manager in paper and electronic formats. Responsible Persons (RPs) nominated to be responsible for each tissue collection (see SOP HTA – 3), shall retain a copy of all SOPs relating to HTA Licence 12335, and shall confirm that they have read each SOP by signing the master copy held by the Governance Manager.

4.10 All members of staff carrying out work on a tissue collection covered by HTA Licence 12335 shall retain a copy of all the SOPs relating to it and shall confirm that they have read each SOP by signing the master copy held by the Governance Manager.

4.11 The Governance Manager, Designated Individual or Persons Designate will be responsible for providing copies of SOPs to those requiring them.

5 Related documents

5.1 HTA Licence 12335 Storage of relevant material which has come for a scheduled purpose

5.2 https://www.hta.gov.uk/guidance-professionals/codes-practice

6 Amendment of SOPs

If, in the course of applying this document, the user identifies a modification which will improve this document, please bring the suggested changes to the attention of the Person Designated (PD) so that amendments can be reviewed and implemented.

7. Contacts DIs and PDs

Research Licence	DI	Dr Priya Madhou	Ext 1603	pmadhou@sgul.ac.uk
	PD	Mr Ash Sameja	Ext 2428	asameja@sgul.ac.uk
	PD	Ms Lara Painter	Ext 3077	lpainter@sgul.ac.uk
Anatomy Licence	DI	Miss Georga Longhurst	Ex 5208	glonghur@sgul.ac.uk
	PD	Mr Paul Carter	Ext 5228	pcarter@sgul.ac.uk
	PD	PATHOLOGY MUSEUM Dr Carol Shiels	Ext 0729	cshiels@sgul.ac.uk

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