**HTA-31: Risk Assessment for Human Tissue Projects:** To be completed with reference to the standard operating procedure “*HTA-31: Risk Assessment of human tissue projects*”

1. *Project Details*

|  |  |  |  |
| --- | --- | --- | --- |
| Project Title |  | Chief Investigator |  |
| Project start and end dates |  | **Human Tissue(s) used in study** |  |
| Human Tissue under consideration  |  | **Name of Assessor****Date of Assessment** |  |

1. *Identification of Risk*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Stage | Potential Risks Identified  | Control Measures *(include monitoring of effectiveness)* | Likelihood (L) | Severity (S) | Score (L\*S) |
| Acquisition | * Consent not or inappropriately obtained for tissue samples
* Failure to obtain proof of consent for tissue samples
* Lack of any required ethical/governance approvals for project
* Inappropriate storage, release or use of donor information
* Work continues after donor withdraws consent
* Loss of anonymity of donor sample

*\*Lack of material transfer agreement for tissues obtained externally (if applicable)* |  | **1-5****1-5****1-5****1-5****1-5****1-5****1-5** | **1-5****1-5****1-5****1-5****1-5****1-5****1-5** | **1-25****1-25****1-25****1-25****1-25****1-25****1-25** |
| Transportation*(If human tissue is not being transported as part of this project please delete this row)* | * Delay or loss in Transit
* Damage of tissue in Transit
* Packaging Failure
* Inappropriate condition of transportation used
* Loss of patient confidentiality
* Exposure of staff or public to biological or chemical hazards associated with the tissue sample.
* Loss of sample traceability to site of donation
 |  | **1-5****1-5****1-5****1-5****1-5****1-5****1-5** | **1-5****1-5****1-5****1-5****1-5****1-5****1-5** | **1-25****1-25****1-25****1-25****1-25****1-25****1-25** |
| Use | * Risk of infection from human tissue samples
* DNA/RNA analysed without explicit written consent from donor
* Samples used for other purposes not indicated on consent form
* Tissues handled/used inappropriately be research team
* Tissues handled by individual not part of the research team
* Procedure damages tissue sample
* Equipment malfunction
* Staff not properly protected by immunisation/PPE.
* Failure to document tissue use on storage logs
* Loss of data
 |  | **1-5****1-5****1-5****1-5****1-5****1-5****1-5****1-5****1-5****1-5** | **1-5****1-5****1-5****1-5****1-5****1-5****1-5****1-5****1-5****1-5** | **1-25****1-25****1-25****1-25****1-25****1-25****1-25****1-25****1-25****1-25** |
| Storage | * Incorrect storage conditions used
* Loss/loss of traceability of tissue
* Loss/loss of traceability of derived materials
* Loss of labelling of sample
* Breach of security/Theft of tissue
* Malfunction of storage equipment
 |  | **1-5****1-5****1-5****1-5****1-5****1-5** | **1-5****1-5****1-5****1-5****1-5** | **1-25****1-25****1-25****1-25****1-25** |
| Disposal | * Sample disposed of in error
* Unsafe, inappropriate or insecure disposal of tissues
* Disposal of sample not tracked or incorrectly recorded
* Failure to dispose of sample at end of project
 |  | **1-5****1-5****1-5****1-5** | **1-5****1-5****1-5****1-5** | **1-25****1-25****1-25****1-25** |

1. *Additional Control Measures Required*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Stage | Potential Risks Identified | Additional Control Measures *(include monitoring of effectiveness)* | NewLikelihood (NL) | NewSeverity (NS) | NewScore(NL\*NS) |
| Acquisition | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  | **1-5** | **1-5** | **1-25** |
| Transportation | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  | **1-5** | **1-5** | **1-25** |
| Use | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  | **1-5** | **1-5** | **1-25** |
| Storage | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  | **1-5** | **1-5** | **1-25** |
| Disposal | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  | **1-5** | **1-5** | **1-25** |

|  |  |
| --- | --- |
| **Date for review of risk assessment** |  |
| **Chief Investigator** | **Signed** | **Date** |
| **HTO/PD** | **Signed** | **Date** |

**Part 2: To be completed by chief Investigator before or on date of review listed in original risk assessment**

|  |  |  |  |
| --- | --- | --- | --- |
| Project Title |  | Chief Investigator |  |
| Project start and end dates |  | **Human Tissue(s) used in study** |  |
| Human Tissue under consideration  |  | **Name of Assessor****Date of Assessment** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Have there been any changes or additions to the procedures or control measures used?  | Yes / No | Have there been any new risks or changes to the level of risk identified? | Yes / No |
| If “Yes”, please provide details of changes here  |  |
| Summary of changes to original risk assessment  |  |

|  |  |  |
| --- | --- | --- |
| **Chief Investigator** | **Signed** | **Date** |
| **HTO/PD** | **Signed** | **Date** |