**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*

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| --- | --- | --- | --- |
| 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*

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| --- | --- | --- | --- | --- | --- |
| Stage | Potential Risks Identified | Additional Control Measures  *(include monitoring of effectiveness)* | New  Likelihood (NL) | New  Severity (NS) | New  Score  (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** |