**4. Risk Assessment Form**

**Part 1: Risk Assessment Form for Research Tissue Banks, Groups or Studies operating under the Leeds HTA research licence**

1. ***Details***

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| --- | --- | --- | --- |
| RTB, group or study title |  | Type(s) of Tissue |  |
| Person Designated |  | **Principal investigator**  |  |
| Name of Assessor |  | **Date of Assessment** |  |

1. ***Identification of Risk and Scoring Guidelines***

|  |  |
| --- | --- |
| **Likelihood of Risk with Controls (L)** | **Severity of Impact (S)** |
| **1** | Highly improbable (0-1% chance) | **1** | No distress to individuals or damage to samples or institutional reputation |
| **2** | Improbable (2-10% chance) | **2** | Minor distress to individuals or minor damage to samples (all tissues usable) or institutional reputation |
| **3** | Possible (11-33% chance) | **3** | Moderate distress to individuals or moderate damage to samples (some tissues lost) or institutional reputation |
| **4** | Likely (34-50%) | **4** | Major distress to individuals or major damage to samples (most tissues lost) or institutional reputation |
| **5** | Almost certain (51-100%) | **5** | Severe distress to individuals or complete loss of samples or severe damage to institutional reputation |

| **Stage** | **Item** | **Potential risk** | **Consequences if risks realised** | **Control measures in place (including monitoring of effectiveness)** | **Likelihood (L 1-5)** | **Severity** **(S 1-5)** | **Risk score****(L\*S) (1-25)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **A Consent** | A1 | Incomplete consent details | Consent is not valid until all details are complete. If the missing details cannot be completed (e.g. by returning to the donor), samples could not be used for intended research failing to meet the expectations of the donor |  |  |  |  |
| A2 | Samples acquired without consent | Major breach of the Human Tissue (HT) Act with potential legal consequences (loss of licence) for LTHT and University. Distress to donors and families. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
| A3 | Completed consent form lost | Samples could not be used for research and risk of patient identifiable data being revealed, breaching the Data Protection Act (DPA), 2018 |  |  |  |  |
| A4 | Consent obtained using the wrong documentation, e.g. an old version of the forms | Consent may not be valid with loss of samples for intended research purposes, failing the expectations of the donor.  |  |  |  |  |
| A5 | Donor anonymisation compromised and identity known to researchers | Breach of the DPA, 2018 leading to potential legal penalties. Donor distress. Reputational damage to staff involved and LTHT/UoL  |  |  |  |  |
| A6 | Samples supplied to the RTB by external organisations are being stored without consent | Samples could be stored and released for research without any consent, in breach of the HT Act.  |  |  |  |  |
|  | A7 | Work continues after donor withdraws consent | Major breach of the Human Tissue Act with potential legal consequences (loss of licence) for LTHT and University. Distress to donors and families. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
|  |
| **B Sample collection and processing** | B1 | Samples mixed up |  Loss of traceability of samples involved therefore unable to retain them for research thereby failing to meet donors’ expectations  |  |  |  |  |
| B2 | Sample contaminated | Unable to be sure whether contamination would affect results. Unable to retain samples for research thereby failing to meet donors’ expectations |  |  |  |  |
| B3 | Samples contain pathogens | Serious impact on staff if infected depending on nature of pathogen |  |  |  |  |
| B4 | Failure of equipment, e.g. centrifuge, results in loss of sample | Loss of samples for intended research purposes failing donor expectations leading to donor distress. Reputational damage to LTHT/UoL |  |  |  |  |
|  |
| **C Sample use** | C1 | Patients consented but samples released to researchers without the required ethical /governance approvals for project to exempt them from the requirements of the HT Act eg NHS REC project specific approval or approval granted by an NHS REC approved Research Tissue Bank (RTB)  | Breach of the HT Act if samples stored in unlicensed premises. |  |  |  |  |
| C2 | Samples used for purposes the donor has not consented to  | Major breach of the Human Tissue Act with potential legal consequences (loss of licence) for LTHT and University. Distress to donors and families. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
| C3 | Samples used for research not covered by the patient information sheet and/or consent form | Major breach of the Human Tissue Act with potential legal consequences (loss of licence) for LTHT and University. Distress to donors and families. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
| C4 | Inappropriate release of identifiable patient information with the samples | Breach of the DPA, 2018 leading to potential legal penalties. Donor distress. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
| C5 | Tissue handled inappropriately by research team/procedure damages tissue sample | Loss of samples for intended research purposes and as intended by the donor. Donor distress. Reputational damage to LTHT/UoL |  |  |  |  |
| C6 | Failure to document tissue use on storage logs | Breach of the traceability standard with potential legal consequences |  |  |  |  |
|  |
| **D Sample storage** | D1 | Incorrect storage conditions used | Loss of samples for intended research purposes and as intended by the donor. Donor distress. Reputational damage to LTHT/UoL |  |  |  |  |
| D2 | Loss of tissue integrity due to critical failure of a piece of storage equipment | Loss of samples for intended research purposes and as intended by the donor. Donor distress. Reputational damage to LTHT/UoL |  |  |  |  |
| D3 | Samples stolen or accessed and used accidentally by other researchers | Loss of samples for intended research purposes and as intended by the donor. Donor distress. Reputational damage to LTHT/UoL |  |  |  |  |
| D4 | Major incident (eg fire / flood) affects storage facility | Major loss of samples for intended research purposes and as intended by the donor. Donor distress. Reputational damage to LTHT/UoL  |  |  |  |  |
| D5 | Loss of labelling of sample | Loss of samples for intended research purposes and as intended by the donor. Donor distress. Reputational damage to LTHT/UoL |  |  |  |  |
|  |
| **E Sample transport** | E1 | Sample fails to arrive in the lab | The sample would be unavailable for research and not used as donor intended |  |  |  |  |
| E2 | Loss of patient confidentiality during transport | Breach of the Data Protection Act leading to potential legal penalties. Donor distress. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
| E3 | Inappropriate condition of transportation used/ Samples are damaged, e.g. thawed, during transportation with a courier | Samples are lost for research purposes |  |  |  |  |
| E4 | Packaging failure/ Sample leakage during transit | Potential risk of exposure to pathogens. Loss of sample for research |  |  |  |  |
|  |
| **F Sample traceability** | F1 | Sample cannot be located | Breach of the Human Tissue Act with potential legal consequences for LTHT and University. Distress to donors and families. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
| F2 | Sample identifiers are lost or wrong so no linkage with the consent and clinical data is possible | Breach of the Human Tissue Act with potential legal consequences for LTHT and University. Distress to donors and families. Reputational damage to staff involved and LTHT/UoL |  |  |  |  |
|  |
| **E Sample disposal** | E1 | Samples disposed of through incorrect route | Potential risk of accidental exposure to pathogens |  |  |  |  |
| E2 | Accidental disposal of the wrong samples | Waste of donated sample and not used as donor intended and may be rare sample |  |  |  |  |
| E3 | Samples incorrectly recorded as destroyed | Samples unavailable for research studies as unaware they are still stored. (Risk that incorrect samples have been disposed of instead with the same consequences as for “accidental disposal”). |  |  |  |  |
| E4 | Disposal of sample not tracked or incorrectly recorded | Samples would wrongly appear to be available for research from the records |  |  |  |  |

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| --- | --- | --- |
| **Risk Score (L\*S)** | **Assessment of Risk** | **Action Required** |
| 1-4 | Low | No additional control measures are required |
| 5-12 | Medium | Additional control measures should be considered and introduced as far as practical. The reasons for the decision not to introduce them must be explained. |
| 13-25 | High | Additional control measures must be introduced. |

1. ***Additional Control Measures Required***

| Stage | Potential Risks Identified | Additional Control Measures *(include monitoring of effectiveness)* | NewLikelihood (NL 1-5) | NewSeverity (NS 1-5) | NewScore(NL\*NS) |
| --- | --- | --- | --- | --- | --- |
| Consent | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample collection and processing | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample use | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample storage | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample transport | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample traceability | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample disposal | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Person responsible for initiating next review** |  | **Date of next review:** |  |
| **Assessor** | **Signed** | **Date** |
| **Chief Investigator** | **Signed** | **Date** |
| **Person Designated** | **Signed** | **Date** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| RTB, group or study title |  | Type(s) of Tissue |  |
| Person Designated |  | **Principal investigator (study**) |  |
| 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 |

I**f “Yes”, please provide details of changes below, expanding the table to include all items that have changed.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Stage** | **Item** | **Potential risk** | **Consequences if risks realised** | **Control measures in place (including monitoring of effectiveness)** | **Likelihood (L 1-5)** | **Severity** **(S 1-5)** | **Risk score****(L\*S) (1-25)** |
|  |  |  |  |  |  |  |  |
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**Additional Control Measures Required**

| Stage | Potential Risks Identified | Additional Control Measures *(include monitoring of effectiveness)* | NewLikelihood (NL 1-5) | NewSeverity (NS 1-5) | NewScore(NL\*NS) |
| --- | --- | --- | --- | --- | --- |
| Consent | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample collection and processing | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample use | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample storage | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample transport | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample traceability | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |
| Sample disposal | *Insert Medium or High Risk items from section 2 here. If None please state this here* |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Person responsible for initiating next review:** |  | **Date of next review:** |  |
| **Chief Investigator** | **Signed** | **Date** |
| **Person Designated** | **Signed** | **Date** |