**Leeds Human Tissue Act Governance Framework for the Transfer of Human Tissues**

**Document A - Tissue Transfer Agreement involving human tissues for the scheduled purpose of research when the requirements of the Human Tissue Act, 2004 apply.**

**Agreement for the transfer of tissues between the SUPPLIER, RECIPIENT and SPONSOR (if applicable) for the purposes of research when the tissues are relevant to the Human Tissue Act 2004 and in the absence of exemptions (please refer to explanatory notes A, appended).**

|  |
| --- |
| **RECIPIENT ORGANISATION:** |
|  |
| **RECIPIENT’S DESIGNATED INDIVIDUAL:** |
|  |
| **RECIPIENT’S PERSON DESIGNATED:** |
|  |
| **RECIPIENT’S LOCAL INVESTIGATOR:** |
|  |
| **RECIPIENT’S PREMISES (list all that apply):** |
|  |
| **SUPPLIER ORGANISATION:** |
|  |
| **SUPPLIER’S DESIGNATED INDIVIDUAL:** |
|  |
| **SUPPLIER’S PERSON DESIGNATED:** |
|  |
| **SUPPLIER’S LOCAL INVESTIGATOR:** |
|  |
| **SPONSOR (if applicable):** |
|  |
| **sTUDY TITLE:** |
|  |
| **STUDY PROTOCOL (REF):** |
|  |
| **ETHICAL OPINION:** |
|  Conferred by: |
|  Reference: |
| **MATERIALS:** |
|  |
| **FORM(S) OF MATERIALS SUPPLY:** |
|  |

1. The relevant Protocol and Ethical opinion is attached to this Agreement. If there is any proposed change to the PROTOCOL or ETHICAL OPINION that would have an impact upon the use, storage or otherwise of the MATERIALS, the RECIPIENT’S PERSON DESIGNATED must obtain the written consent of the SUPPLIER’S PERSON DESIGNATED to such proposed changes. All agreed changes to the PROTOCOL or ETHICAL OPINION are to be attached by both parties to their copies of this Agreement.
2. The RECIPIENT agrees to only use the MATERIALS for the PURPOSES described in the Protocol and given a favourable Ethical opinion. The MATERIALS are only to be used and stored on the RECIPIENT’S PREMISES, as listed above. Any transfers between the different premises of the RECIPIENT ORGANISATION must be recorded to comply with the requirement to track all samples relevant to the Act.
3. The SUPPLIER confirms that the MATERIALS have been obtained and may be passed on for use by the RECIPIENT in accordance with the requirements of the Human Tissue Act 2004 (the “Act”). The SUPPLIER confirms the necessary informed consents of donors/donor’s representatives have been given or that an exemption applies under the Act not requiring such consents. Where consents are not required this must also be permitted under the ETHICAL OPINION.
4. The SUPPLIER’S and RECIPIENT’S PERSONS DESIGNATED must agree who shall take responsibility for organising the transport of the MATERIALS and on which date(s). This must be by a courier with suitable skill and experience to safely transport the MATERIALS in accordance with all applicable laws. The FORM(S) OF MATERIALS SUPPLY will determine the facilities required for transport. A list of the samples in each shipment will be forwarded by the SUPPLIER’S LOCAL INVESTIGATOR to the RECIPIENT’S LOCAL INVESTIGATOR, who shall provide to the SUPPLIER’S LOCAL INVESTIGATOR written confirmation of the safe receipt of the MATERIALS promptly after their delivery.
5. The RECIPIENT will bear the cost of carriage and any necessary insurance. Any further financial arrangements, for instance the operation of a cost recovery model by the SUPPLIER, shall be detailed in an appendix to this agreement.
6. The RECIPIENT agrees to use, store and otherwise access the MATERIALS only in full compliance with the Act. If the RECIPIENT is at anytime unsure about a proposed activity, they should immediately contact the SUPPLIER’S PERSON DESIGNATED. The RECIPIENT agrees to ensure that all persons involved in access or use of the MATERIALS shall be made aware of, and bound by, the terms of this Agreement.
7. Where any clinical data are supplied alongside the MATERIALS, the RECIPIENT agrees to use such clinical data solely for the PURPOSES described in the Protocol and given a favourable Ethical opinion and at all times to store, handle, use, and return or dispose of such clinical data in accordance with all applicable data protection laws, including the Data Protection Act, 2018. In particular, the RECIPIENT agrees not to make any attempt to re-identify individual donors of the MATERIALS nor to combine any supplied clinical data with other data sets.
8. The RECIPIENT agrees not to transfer or distribute any part of the MATERIALS or any extracts, replications, summaries or derivatives thereof to any third party without the prior approval of the SUPPLIER’S PERSON DESIGNATED, the SPONSOR and any relevant ethics committee. The RECIPIENT will provide assurance that any such transfer or distribution is within the scope of the relevant consents. Any such transfer or distribution will be subject to a separate tissue transfer agreement. Only the collaborators named in the protocol are covered by this agreement.
9. MATERIALS cannot be used for any purpose that is commercial or therapeutic. Sponsored academic or clinical research is not for these purposes deemed to be commercial.
10. The MATERIALS are supplied without warranty as to their properties, merchantable quality or fitness for any particular purposes and without any other warranty whatsoever, expressed or implied.
11. The RECIPIENT confirms that the LOCAL INVESTIGATOR is suitably qualified and will be responsible for the proper and safe handling, storage, use and return or disposal of the MATERIALS in accordance with the Act and as defined in the establishment’s standard operating procedures.
12. No rights of ownership in the MATERIALS or any clinical data supplied with the MATERIALS are granted to the RECIPIENT under this Agreement. The SUPPLIER makes no claims of ownership in respect of any results, analyses, modifications (except to the extent containing or incorporating the MATERIALS), or other outputs generated by the RECIPIENT in carrying out the PURPOSE. The RECIPIENT may publish the results it generates in carrying out the PURPOSE. Such publications will acknowledge the SUPPLIER as the source of the MATERIAL, and the RECIPIENT will provide a copy of any publications to the SUPPLIER.
13. During the conduct of the STUDY, there may be findings of potential clinical significance for the donor. The RECIPIENT’S LOCAL INVESTIGATOR undertakes to inform the SUPPLIER’S PERSON DESIGNATED, who will follow the SUPPLIER’S procedures for dealing with this event.
14. As soon as the STUDY has been completed by the RECIPIENT, the RECIPIENT’s LOCAL INVESTIGATOR shall inform the SUPPLIER. Used MATERIALS may be retained under the terms of this Agreement only for audit and verification purposes relating to the STUDY.
15. Subject to agreement with the SUPPLIER, all unused MATERIALS that are relevant to the Human Tissue Act will be either disposed of, or returned to the SUPPLIER, to be stored under the responsibility of the SUPPLIER’S PERSON DESIGNATED in accordance with SUPPLIER’S Human Tissue Act governance framework.
16. Subject to the SUPPLIER meeting its commitments under this Agreement, the RECIPIENT agrees to hold harmless the SUPPLIER from any and all claims, suits and liabilities arising from any use by the RECIPIENT of the MATERIALS.
17. This Agreement may be terminated by a party upon written notice if the other party shall be in material breach of its commitments and not remedied such commitments following thirty days’ written notice of the breach upon termination. Upon request the RECIPIENT shall on termination securely and confidentially either dispose or return the MATERIALS as directed by the SUPPLIER’S PERSON DESIGNATED.
18. MATERIALS shall be returned to the SUPPLIER or securely and confidentially destroyed where required for ethical reasons by the relevant ethics committee or if the donor withdraws consent.
19. This Agreement represents the entire understanding of the parties relating to the use of the MATERIALS and supersedes and overrides all other understandings. Variations require the written consent of both parties nominated representatives.
20. All communications between the parties relating to the substance of this Agreement shall take place through the RECIPIENT’S PERSON DESIGNATED and the SUPPLIER’S PERSON DESIGNATED.
21. This Agreement shall be interpreted in accordance with English Law and be subject to the jurisdiction of the English Courts.
22. No third party may rely upon the provisions of this Agreement.

|  |  |
| --- | --- |
| Authorised by SUPPLIER’S LOCAL INVESTIGATOR: | Authorised by the RECIPIENT’S LOCAL INVESTIGATOR |
| Designation: | Designation: |
| Signature: | Signature: |
| Name:  | Name:  |
| Date: | Date: |

|  |  |
| --- | --- |
| Authorised by the SUPPLIER’S PERSON DESIGNATED  | Authorised by the RECIPIENT’S PERSON DESIGNATED  |
| Designation: | Designation: |
| Signature: | Signature: |
| Name:  | Name:  |
| Date: | Date: |

|  |  |
| --- | --- |
| Signed for and on behalf of the SUPPLIER | Signed for and on behalf of the RECIPIENT |
| Signature: | Signature: |
| Name:  | Name:  |
| Designation: | Designation: |
| Date: | Date: |

|  |
| --- |
| Signed for and on behalf of the SPONSOR (if applicable) |
| Signature: |
| Name:  |
| Date: |

**Leeds Human Tissue Act Governance Framework: Transfer of Human Tissues**

**Explanatory notes A, to be used in conjunction with document A - Tissue Transfer Agreement involving human tissues for the scheduled purpose of research when the requirements of the Human Tissue Act, 2004, apply.**

**Please also refer to the HTA governance framework Standard Operating Procedure, LRTB M07 Transfer of Tissues between Organisations**

This tissue transfer agreement covers the transfer of human tissues that are relevant to the Human Tissue Act, 2004 from an establishment licenced by the Human Tissue Authority (the Supplier Organisation) to another licenced establishment (the Recipient Organisation). Tissues are relevant if they contain human cells, for example whole blood or unprocessed urine.

To check whether the tissues are relevant to the Act or not, please go to:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm>

**However**, relevant material may be subject to **exemptions** to the requirements of the Act, either because:

A) An NHS Research Ethics Committee (REC) has granted project/study-specific approval for the use of the tissue based on the study protocol;

 OR

B) An NHS Research Ethics Committee (REC) has granted a Research Tissue Bank (RTB) the permission to confer project-specific approval for the research after review of the study protocol by the RTB Governing Board.

These exemptions apply for the duration of the period of project/study-specific approval. A separate Tissue Transfer Agreement is available for Research Tissue Banks transferring tissues under project/study-specific approval (see Document B).

**The Parties:**

The Recipient: the organisation receiving the Tissues.

The Recipient's Designated Individual: The Designated Individual (DI) is identified in the Human Tissue Act 2004 governance framework as the person under whose supervision the collection and storage of tissues for research are carried out. Each licenced establishment must have a named DI to comply with the requirements of the Act. The DI is directly responsible for ensuring the proper conduct of the activities carried out under the licence under Section 18 of the HT Act by developing the governance framework, policies, procedures and systems that, if followed correctly by researchers, will ensure that their activities are compliant with the Act.

The Recipient's Person Designated: The Person Designated (PD) is a named individual who assists the DI in the governance of the activities authorised by the licence on a specific site or within a specific research group. The PD who oversees the activities of the Local Investigator must be identified here. The PD is appointed by, and therefore has the confidence of, the DI. Therefore the PD will act on behalf of the DI wherever appropriate.

As the tissues are relevant to the Act, it will be the PD, rather than the Local Investigator, who will be responsible for certain undertakings (see clauses 1, 4, 6, 8, 15, 17 and 20).

The Recipient’s Local Investigator: this would normally be the Principal Investigator responsible for conducting the research project according to the study protocol.

The Recipient’s Premises: This will be the site(s) where the research will be conducted or the samples are stored. The Local Investigator may collaborate with others and delegate certain elements of the research to another laboratory within the same organisation, in accordance with the agreed Protocol.

The Supplier: the organisation supplying the Tissues.

The Supplier’s Designated Individual: Please see the description of the Recipient’s Designated Individual.

The Supplier’s Person Designated: Please see the description of the Recipient’s Person Designated

The Supplier’s Local Investigator: this will depend on the circumstances of the tissue transfer.

* If the exchange of tissues is in the context of collaborative research, it may be the lead researcher who is collaborating with the Recipient’s local investigator;
* If the tissues are supplied by an organisation with no collaborative links to the Recipient’s Local Investigator, this would normally be the person responsible for documenting the Supplier’s consent and release processes.

The Sponsor: This role is defined by the Health Research Authority. In the context of a clinical trial in particular. The Sponsor must agree to the transfer of Tissues.

Study Title: This is the title of the study as submitted to the ethical approval process.

Study protocol: This is the information supplied to the committee approving the use of tissues.

Ethical opinion: In the context of relevant material that is not covered by the exemption described above, this opinion is generally conferred by an organisation’s (e.g. a University’s) local ethical committee.

Materials: These are the types of tissues to be transferred, for instance blood, skin samples etc. All types must be listed here.

Form of material supply: The tissues may be transferred either fresh, frozen, or may be fixed in the form of paraffin blocks.

The Signatories: Each organisation will have recognised individuals authorised to sign on their behalf, usually through the relevant Research and Innovation unit.

The numbering below is by reference to the clauses within the Tissue Transfer Agreement (the ‘Agreement’)

1. The Supplier is prepared to supply the Material based upon the Study Protocol submitted for ethical approval. Any changes to the Study Protocol could fundamentally alter the views of the Supplier. By way of example, the Supplier may have given donors the opportunity to opt out of certain types of research, for instance animal studies. Any amendment to the Study Protocol must therefore be submitted to the Supplier’s Person Designated to check whether the proposed change still falls within the limits of the donor’s consent.

2. The purpose of use for Material must be defined and maintained within specified parameters. The Materials must be tracked, hence the need to retain the Materials under the overall responsibility of the Recipient’s Local Investigator on defined premises listed under “Recipient’s premises”. This is important for at least two reasons:

 - an individual donor may withdraw consent for the use of their samples when the study is still ongoing. Their samples must be located without delay and the appropriate steps taken.

 - at the end of the study period, there may be unused material and if they are relevant to the Act, appropriate steps must be taken for their disposal or return to the supplier depending on the supplier’s decision.

3. The Recipient and the Sponsor will want reassurance that the Supplier has obtained any necessary informed consent/appropriate ethical approval.

4. The Supplier and Recipient are committing to deliver/receive the Materials on a specified date or dates, in an agreed format and by a transport company with the appropriate equipment, skills and processes. The Materials must be appropriately packaged and transported to maintain them under optimal conditions and this will depend on the Form(s) of Material Supply listed in the table on page 1. They must be catalogued and stored promptly on receipt. All HT Authority standards concerning the transfer of tissues must be respected, including keeping complete records of all agreements and transfers.

 A ‘Tissue Sample Sheet’ will detail in particular the form(s) of tissues supplied (eg frozen or paraffin embedded), the number of samples and their individual, unique identifier. No donor identifiable data will be included. This sheet may accompany the tissues or be sent securely by electronic means, depending on local preference.

5. The costs of transport are borne by the Recipient. RTBs may operate under a cost recovery or other financial framework to ensure the long-term viability of the bank. Details of any such arrangements will be included in a separate appendix.

6. The tissues remain relevant to the Act and must be managed and stored in licenced premises following the Recipient’s local policies and procedures set out by the Recipient’s PD under the guidance of the Recipient’s DI. Furthermore, adherence to the boundaries of consent and ethical approval is not just an issue for the individual signing the Agreement, but all those who may be involved with the Materials. It is therefore important that the Recipient ensures that those coming into contact with the Materials are aware of the terms of this Agreement.

7. All relevant data protection laws apply to the clinical data supplied with the Material. The Material is supplied using codes that render it anonymous to the Recipient. The Recipient must not seek to identify any of the donors. As a reminder, any transfer of person identifiable data must be the subject of a separate data sharing agreement between the Supplier and the Recipient.

8. The Supplier is agreeing to pass the Materials to the Recipient based upon the understanding that the Recipient is assessed as an appropriate organisation to receive the Materials. The Recipient may, however, name collaborators in the Study Protocol in their application. The Supplier must retain control over who else may receive the Materials and be able to impose conditions if it agrees to the further transfer of the Materials to third parties. Third parties would be required to sign up to another Tissue Transfer Agreement.

9. The Supplier only wants for the Materials to be used on a research-related basis and not directly sold for profit. This does not preclude collaborations with, or supply to, industries involved in healthcare research.

10. Although the Supplier makes every best effort to collect and store the Material under optimal conditions, the Supplier has little or no control over the pre-collection conditions (eg surgical or other procedure) and generally would not/could not seek to improve to meet a general standard. The Materials are provided on a ‘as is’ basis.

11. It is important to identify that the Local Investigator is ‘the person on the ground’ who is deemed day-to-day to have responsibility for ensuring that the Materials are used responsibly in accordance with the Agreement. The Local Investigator must ensure that accurate tracking of the location of the tissues is in place to allow the return of any unused materials if requested by the supplier, for instance if the donor withdraws consent or at the end of the period of ethical approval. The Local Investigator must abide by the Recipient’s HTA governance framework.

12. The only right granted to the Recipient under the TTA is a permission to use the materials in the specified research. The Supplier does not own the outputs of the research, giving the Recipient flexibility to arrange ownership of outputs in accordance with its conditions of funding, requirements of collaborators or other considerations.

13. During the conduct of the Study, there may be findings that could be significant for the health of the donors or their families. Examples include the discovery of infectious agents or genetic abnormalities. The exact procedure to deal with such a circumstance will depend on the terms of the donor’s consent but may include informing the donor’s clinical team of the finding so that it can be investigated in a clinically accredited laboratory.

14. The Materials are only to be used for their specified activity (see points 1 and 2) and cannot be used for another study unless a new project has been approved by the Supplier following appropriate ethical review. This would require a new Tissue Transfer Agreement. The Recipient can only retain the derivatives they have produced from the Material, for instance stained slides, for audit and evidence of the results if required.

15. If at the end of study, the unused materials are relevant under the Act (see the links to the Human Tissue Authority in the opening section), the Supplier’s Person Designated must be informed to agree either to return the Material to the Supplier or dispose of the Material. For instance, disposal may be the most appropriate option if only a small amount of tissue remains, insufficient to be useful for future projects.

16. This is an exclusion of liability arising from the use of the Materials. The Supplier is providing the Materials “as is” in good faith, and may have little or no experience of testing Materials for any difficulties associated with the Material.

17. The Supplier has to retain the right in particular to require Recipient to conform to the obligations with the Agreement. The Supplier has to have the opportunity to challenge the Recipient’s use and where it breaches the terms of this Agreement, require ultimately the Recipient to cease using the Materials and return/dispose of such Materials as directed by the Supplier.

18. Ethics committees need to retain the right to control use of the Materials where they are not happy with the Recipient’s handling of the Materials.

19. This clause makes it clear that this is the entire understanding of the parties relating to the Materials.

20. This clarifies that communication should take place between Persons Designated to avoid confusion.

21. This clause in particular deals with transactions where one of the Parties may be based outside England. The Agreement’s construction was on the assumption that English Law would apply.

22. This makes it clear that only those parties signing the Agreement can rely upon its contents.