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**Human Tissue Act 2004**  
**SOP – Material Transfer Agreements**

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<b>Version</b>	<b>Date</b>	<b>Reason for Change</b>
2.0	15/07/2015	Change header to reflect University wide license. Update DI details. Updates to Appdx B and D
3.0	17/07/2017	Change to reflect the update to DI

### 1.0 Purpose

The purpose of this standard operating procedure is to outline the procedures that govern the transfer of human tissue between University of Sussex and third parties, and vice versa. This includes the engagement of service providers for sample analysis.

### 2.0 Introduction

The removal, storage and use of human tissue is governed by the Human Tissue Act 2004 (the HT Act). Human tissue is defined by the HT Act as material that has come from a human body and consists of, or includes, human cells. It is referred to in the HT Act and below in this document as (“relevant material”).

The HT Act makes consent the fundamental principle underpinning the removal, storage and use of relevant material.

The Human Tissue Authority (HTA) regulates activities related to the HT Act and issues codes of practice and practical guidance for the storage and use of human tissue. It acts as the licensing authority and carries out inspections to ensure that licence conditions are met.

Sussex has three licences with the Human Tissue Authority. The licences and Designated Individual who has statutory responsibility for supervising the relevant licensed activity and who is therefore ultimately accountable to the HTA are as follows:

- HTA Research Licence: BSMS  
Designated Individual: Prof Kevin Davies
- HTA Anatomy Licence: BSMS  
Designated Individual: Dr Claire Smith
- HTA Research Licence: University of Sussex premises other than BSMS premises  
Designated Individual: Dr Georgios Giamas

The exchange of relevant material is important for facilitating research and enhancing research collaboration. A Material Transfer Agreement must be in place to cover the transfer of relevant material between establishments. The transfer must be made in accordance with the requirements of the HT Act and the HTA's Codes of Practice. Clearly laid out third party agreements ensure that all of the parties involved in a transfer of relevant material are clear about their rights and responsibilities in relation to that material and reduce the legal liability of a provider of relevant material for a recipient's use thereof.

### **3.0 Procedure**

If you propose sending relevant material (i.e. human tissue or cells) to a third party or you anticipate the receipt of such material from a third party this transfer must be governed by either an incoming or outgoing MTA. The exchange of research material between academic institutions is generally relatively straightforward. However, issues relating to confidentiality, publications, access to the results of research using the transferred material, intellectual property rights, and warranties and indemnities may need to be negotiated, in particular if a commercial organisation is involved in the research.

The MTA for Sussex's receipt of relevant material from a third party is generally provided by the provider of the material. Where an MTA is not provided, an incoming MTA can be obtained from the Contracts & IP Team.

The Contracts & IP Team will copy all correspondence received and sent to the applicable Designated Individual.

### **3.1 Contents of MTA**

The MTA sets out the terms and conditions governing the use, consent, storage, transfer, and disposal of relevant material and associated confidential data (which may be of human origin). As indicated above, it may also contain other terms and conditions, including as to intellectual property rights, access to the results of the research conducted with the relevant material and warranties and indemnities.

### **3.2 Outgoing material to another institution**

Outgoing material is relevant material transferring from Sussex to another Institution.

1. When an “in principal” agreement to transfer relevant material is made by the academics or clinicians involved, the first step is to ensure that any consent under which the material was obtained by Sussex permits the material to be transferred and used by other research groups.
2. A summary protocol/research outline and permitted use by the academic or clinician who will receive the relevant material should be agreed.
3. Sussex PI completes the “Instructions for sending Human Tissue to an Institution for Research Purposes” form” (see Appendix B) and sends this to the Contracts & IP Team via internal post or email. The email address is [contracts.instructions@sussex.ac.uk](mailto:contracts.instructions@sussex.ac.uk). Care must be taken to attach any documentation which is required by the form.
4. The request will be allocated to a member of the Contracts & IP Team who will review the MTA Request and (provided everything is in order) generate and send to the Sussex PI an Outgoing MTA Template in pdf form (see Appendix A). The Contracts & IP Team will contact you if they need further information.
5. Sussex PI forwards MTA template to the recipient institution, requesting that they either sign two copies and return one copy to the Contracts & IP Team, or summarise any questions or concerns they have regarding the MTA.
6. If any questions or concerns are raised by the recipient institution in relation to the content of the MTA, the Sussex PI must refer those questions or concerns to the Contracts & IP Team for their consideration and review. A member of the Contracts & IP Team will take this forward directly with the recipient institution and keep the Sussex PI copied in.
7. Once the MTA has been agreed it will be signed by authorised signatories for both institutions. (Note: the authorised signatory for Sussex must be one of the authorised signatories within Research & Enterprise. The MTA cannot be signed by the Sussex PI or their Head of School etc.)
8. The original copy of the signed MTA will be retained by the Contracts & IP Team. An electronic copy will be sent to the relevant Designated Individual and retained centrally for future reference.
9. Under no circumstances should any relevant material be transferred to the recipient institution before the MTA has been fully signed on behalf of both institutions and all necessary consents and approvals are in place.

### **3.3 Relevant material outgoing from Sussex to a Service Provider**

A service provider is an external commercial company that is providing a service such as sample analysis.

1. Where a need to use an external Service Provider for analysis of relevant material is identified, the applicable Sussex Procurement Regulations should be followed in the first instance.
2. When a Service Provider has been chosen, and is being used for the first time within a project, Sussex PI requests the following from the Service Provider: i) whether they have an HTA Licence and if so, the Licence Number and ii) their terms and conditions of Service. If it is found that the Service Provider does not have an HTA Licence, then this must be indicated in the instructions form and if the samples are to be handled within 5 days no licence is required
3. Once the required information in paragraph 2 above has been obtained from the Service Provider, Sussex PI completes the "Instructions for sending relevant material to a Service Provider" form (see Appendix C) and sends this to the Contracts & IP Team with the required attachments.
4. The request will be allocated to a member of the Contracts & IP Team, who will review all the necessary information and if there are any queries will work with the Sussex PI to determine the best contractual approach. The Contracts & IP Team member will contact the Service Provider and copy in the Sussex PI to reach a suitable conclusion. This may involve amending the Service Provider's terms and conditions, or Sussex's standard outgoing MTA template or an amended version thereof.
5. Once the contractual documents have been agreed they will be signed by authorised signatories for both institutions (note: the authorised signatory for Sussex must be one of the authorised signatories within Research & Enterprise. The MTA cannot be signed by the Sussex PI or their Head of School etc.)
6. The original copies of the signed contractual documents will be retained by the Contracts & IP Team, and an electronic copy to be sent to the relevant Designated Individual and retained centrally for future reference.
7. Under no circumstances should any relevant material be sent to the Service Provider before all of the necessary contractual documents have been signed by all the parties and all relevant consents and ethical approvals necessary are in place.

### **3.4 Incoming relevant material**

This is for receipt of material from other Institutions/Hospitals etc

- 1 Where a Sussex PI wishes to receive relevant material from a third party, they must contact the provider and obtain a copy of the provider's MTA for that purpose. If the provider does not have an MTA then one can be provided by the Contracts and IP team.
- 2 The Sussex PI must complete the Instructions for Incoming Human Tissue to Sussex for Research Purposes form (see Appendix D) and email both the form and the MTA to the Contracts & IP Team at [contracts.instructions@sussex.ac.uk](mailto:contracts.instructions@sussex.ac.uk).
- 3 The matter will be allocated to a member of the Contracts & IP Team, who will review the contents of the Provider's MTA and make any necessary changes. The

Contracts & IP Team member will liaise with the Provider to agree the terms of the MTA.

- 4 Once the MTA has been agreed it will be signed by authorised signatories for both institutions. (Note: the authorised signatory for Sussex must be one of the authorised signatories within Research & Enterprise. The MTA cannot be signed by the Sussex PI or their Head of School etc.)
- 5 The original copy of the signed MTA will be retained by the Contracts & IP Team, with an electronic copy to be sent to the relevant Designated Individual and retained centrally for future reference.
- 6 Under no circumstances will the Sussex PI take receipt of any relevant material until the MTA has been fully agreed and signed on behalf of each party and all necessary consents and approvals are in place.
- 7 Where material is procured from a clinician in circumstances where Sussex is unable to get a formal MTA signed by the clinician's institution, then the clinician must sign the Declaration of Compliance with the Human Tissue Act 2004 by Provider of Human Tissue Samples for Storage and Use by the University Of Sussex for Non-Commercial Research or Analysis Purposes (see Appendix E).