

Appendix H: Material Transfer Agreement

An example Material Transfer Agreement, as used by the University Of Southampton.

Draft, 11 September 2008

ACADEMIC – TO – ACADEMIC HUMAN TISSUE TRANSFER AGREEMENT

The University of Southampton (the “**Supplier**”), an academic institution whose principal address is at Highfield, Southampton, SO17 1BJ, has collected and/or developed the materials known as

Insert description of materials [.....]
(the “**Original Materials**”), which may include human cells or tissues or other “relevant material” as defined in the Act.

Insert name of scientist [.....]
(the “**Recipient**”), who is an employee of

Insert name and address of scientist's Institution [.....]
(the “**Institution**”), an academic institution, whose principal address is at [.....],

Insert quantity of materials wishes to acquire [.....] [vials] (the “**Quantity**”) of the Original Materials for academic research relating to:

Insert description of academic research for which materials will be used [.....]
[.....]
[.....]
[.....]
[.....]

(the “**Project**”), which will be carried out at the following laboratory located at the Institution:

Insert laboratory address and insert term for which materials may be provided [.....]
(the “**Location**”) for a period of [.....] year(s) (the “**Term**”) on the terms shown below on pages [2 – 6]. The Institution agrees to be bound by and to comply with those terms in consideration of the Supplier making the Materials available to the Recipient and will ensure that the Recipient and the Co-workers comply with the Institution’s obligations as if they were named as parties to this Agreement.

Agreed by the Parties by their authorised signatories:

For and on behalf of the University of
Southampton

Read and understood by the
Recipient

For and on behalf of [the
Institution]

Signed

Signed

Signed

Print name

Print name

Print name

Title

Title

Title

Date

Date

Date

1 Supply of the Materials

- 1.1 *Supply.* If the Supplier has sufficient Original Materials at its disposal and is otherwise able, the Supplier will make the Quantity of the Original Materials available to the Recipient without cost, but the Institution agrees to reimburse the Supplier for any reasonable shipping and related costs that may be incurred when procuring, preparing and sending the Materials to the Recipient. Delivery of the Materials to the Institution's facilities will be at the Institution's risk.
- 1.2 *Ethics approval.* The Institution acknowledges that the supply of the Original Materials to the Recipient is conditional upon the Institution obtaining approval for the use of the Materials in the Project from an appropriately constituted research ethics committee. The Institution will provide the Supplier with a copy of such approval prior to the Supplier making the Original Materials available to the Recipient. The Institution confirms that the potential benefits of the Project outweigh any potential risk to the Donor(s).
- 1.3 *Data Protection.* If the Materials include Personal Data, the Institution will ensure that its registration under the DPA is sufficient for its use of the Materials in the Project prior to the Supplier making the Materials available to the Recipient. In addition, the Institution agrees to comply with all other provisions of the DPA applicable to its use of the Materials and any data and/or other information derived from their use.
- 1.4 *Receipt.* The Institution will provide the Supplier with written confirmation of the safe receipt of the Materials promptly after their delivery to the Institution's facilities. The Institution will ensure that such confirmation includes details of when and where the Materials were received by the Recipient and by whom and under what conditions the Materials were transported to the Institution's facilities.
- 1.5 *Location.* The Institution will store and use the Materials only at the Location. The Institution confirms that such Location is suitable for the Project and is compliant with the Act and all other applicable laws, approvals, rules, codes of practice and regulations.
- 1.6 *Return of Materials.* As between the Parties, the Supplier will retain custodianship of the Materials at all times and the Institution agrees to return or, if requested by the Supplier, destroy all remaining Materials and Modifications immediately:
 - (a) on termination of this Agreement;
 - (b) if the Institution is in breach of any term of this Agreement; or
 - (c) at any other time on the reasonable request of the Supplier.
- 1.7 *Disposal.* Except as may be reasonably required by the Project, the Institution will not destroy any Materials without the prior written consent of the Supplier and, the Institution agrees to comply with any reasonable instruction given by the Supplier in relation to the destruction of the Materials. If the Materials are exhausted or destroyed, whether during the course of the Project, in accordance with Clause 1.6 or otherwise, the Institution will provide the Supplier with written confirmation of the same.

2 The Recipient's use of the Materials

- 2.1 *Use.* The Institution will use the Materials and any Modifications only for the Project and will not use the Materials or Modifications for any commercial purpose or commercially sponsored research even if those purposes are being pursued in the Recipient's laboratory. The Institution agrees not to use any third party funding or materials in the Project without notifying the Supplier and ensuring that the terms imposed by any third party are consistent with the terms of this Agreement.
- 2.2 *Security.* The Institution will:
 - (a) keep the Materials secure at the Location and protected against loss, damage and contamination;
 - (b) keep the Materials clearly labelled as the property of the Supplier at all times;

- (c) maintain complete and accurate written records to ensure that the Materials can be traced at all times and that details of all uses to which the Materials are put and any processes that are applied to them are documented;
- (d) provide the Supplier with copies of the records maintained by the Institution under Clause 2.2(c) upon the Supplier's request;
- (e) ensure that no one other than the Recipient and the Co-workers have access to the Materials and that the Recipient and the Co-workers are suitably qualified and trained to handle the Materials;
- (f) ensure that it has in place all necessary safety procedures and practices to handle the Materials and that the Recipient and the Co-workers will comply with all safety requirements applicable to the Materials necessary for their well-being and that of others;
- (g) ensure that all transportation, keeping, use and disposal of the Materials is in accordance with the appropriate containment level; and
- (h) ensure that, if the Materials were obtained with the consent of the Donor, all use of the Materials is within the scope of that consent.

2.3 *Donor(s).* The Institution will not contact the Donor(s) or their medical advisor(s) without the prior written consent of the Supplier, which may require additional approval from a research ethics committee. If the Materials are made available to the Recipient in an anonymised form, the Institution will not, and will not seek to, link, decode or otherwise identify the Donor(s).

2.4 *Standards.* The Institution will use the Materials in accordance with good laboratory practice, all due skill and care and with dignity, sensitivity and respect. The Institution will comply with all applicable laws, approvals, rules, codes of practice and regulations governing the transportation, keeping, use and disposal of the Materials.

2.5 *No human use.* The Institution will not use the Materials, Modifications or any other material derived or generated through their use, in humans or in animals, in clinical trials or for diagnostic purposes involving humans nor expose the same to any material to be administered to any human or animal.

2.6 *No transfer.* The Institution will not sell, gift, charge, pledge, transfer, or otherwise supply or disclose the Materials or Modifications to any third party.

2.7 *No licence.* Except as expressly provided by this Agreement, no licence or other right to any of the Supplier's property or intellectual property is granted or implied by this Agreement.

3 Confidentiality obligations

3.1 *Ownership.* Confidential Information belongs to the Supplier. During the Term of this Agreement and for five (5) years thereafter, the Institution will not disclose to any third party nor use any Confidential Information for any purpose except the Project.

3.2 *Exceptions.* The obligations set out in Clause 3.1 do not apply to any information that the Institution can show by written record that:

- (a) was known to the Institution before the information was imparted by the Supplier;
- (b) is or subsequently becomes publicly known through no fault, act or omission on the part of the Institution;
- (c) is received by the Institution without restriction on disclosure or use from a third party lawfully entitled to make the disclosure to the Institution without such restrictions;
- (d) is developed by any of the Institution's employees and/or students who have not had any direct or

indirect access to, or use or knowledge of, the information imparted by the Supplier; or

- (e) is required to be disclosed by the Institution to comply with the applicable laws or governmental regulations provided that the Institution, where possible, notifies the Supplier of such requirement prior to any such disclosure and limits the disclosure to the extent required by such law.

3.3 *Personal data.* Notwithstanding Clauses 3.1 and 3.2 above, if the Confidential Information contains any data that:

- (a) constitutes Personal Data; or
- (b) is otherwise protected either by law, an obligation of confidentiality owed to the Donor or otherwise;

the Institution agrees that it will not disclose any such data to any third party nor use the same for any purpose except the Project at any time and even after the Term of this Agreement.

4 Publication by the Recipient

4.1 *Acknowledgement.* The Institution will acknowledge the Supplier's contribution as the source of the Materials (and any other contribution that the Supplier may have made to the Project) in any Publication. The Institution will send the Supplier a copy of any proposed Publication, whether oral or written, prior to any Publication or submission for Publication, whichever is earlier. The Supplier's rights under this Clause 4 shall not affect the Institution's obligations under Clause 3.

4.2 *Publication.* The Institution agrees that it will not make any Publication that would disclose information that may allow the identity of the Donor to be deduced. The Institution acknowledges that data generated using the Materials may relate to the Donor, constitute Personal Data or otherwise be protected by law or an obligation of confidentiality owed to the Donor. The Institution agrees that it will not publish or disclose to any third party any such data.

4.3 *Data.* The Institution will make available, on the request of the Supplier, any data generated using the Materials, and the Supplier will be entitled to use all such data for academic research and educational purposes.

5 Arising intellectual property

5.1 *Notification.* If the Institution conceives, generates, or observes an Invention, then the Institution will promptly bring this to the attention of the Supplier on a confidential basis. The Institution agrees to obtain the consent of the Supplier, which will not be unreasonably withheld, prior to making any application to protect any Invention and prior to any commercialisation, transfer or grant of any rights to an Invention.

5.2 *Materials.* The Institution acknowledges that it may require a licence from the Supplier to use an Invention dependent on the Materials for purposes other than the performance of the Project and that the Supplier may be unable or unwilling to grant such a licence to its interest in the Materials.

5.3 *Supplier's share of revenue.* If any commercial revenues result from the Institution's use of any Invention or otherwise arise from the use of the Materials, the Supplier will be entitled to an equitable share of any such revenues that accrue to the Institution or any of its successors in title to any Invention.

5.4 *Supplier's right.* The Supplier will, at all times, retain the right to use all Inventions for academic research and educational purposes.

5.5 *Licence.* The Institution agrees that no Invention will restrict the Supplier's right to use, and to permit others to use, the Materials for any purpose.

6 No warranty or liability

- 6.1 *No warranty.* The Materials are experimental in nature, and the Supplier makes no representation and gives no warranty or undertaking in relation to them. As examples, but without limitation, the Supplier gives no warranty: (a) that it owns all necessary property, intellectual property, and other rights in the Materials and that their use will not infringe any rights owned by any third party; or (b) that the Materials are of merchantable or satisfactory quality or fit for any particular purpose, have been developed with reasonable care and skill or tested, for the presence of pathogens, infections, disease or otherwise, or are viable, safe, or non-toxic.
- 6.2 *No liability.* The Materials are made available by the Supplier free of charge as a service to the academic community and as such the Supplier and the Institution agree that the provisions of this Clause 6.2 are reasonable. The Supplier will have no liability to the Recipient, the Co-workers, the Institution, or any third party, whether in contract, tort, negligence, or otherwise, in relation to the supply of the Materials to the Recipient or their use or keeping by the Recipient or by any other person, or the consequences of their use, to the maximum extent permitted under applicable law. The Institution agrees that it will be wholly responsible for all claims and losses arising from such supply, use or keeping, including claims and losses arising from: (a) injury to the Institution's employees and third parties; (b) infringement of third-party intellectual property rights; and/or (c) the use of the Materials within or outside the scope of this Agreement.

7 General

- 7.1 *Definitions.* In this Agreement the following words have the following meanings:
- (a) **"Act"** means the Human Tissue Act 2004 as from time to time amended.
 - (b) **"Confidential Information"** means the Materials and all information, including technical, patient, clinical, medical, scientific or commercial information, that may be provided by the Supplier to the Institution that: (i) in respect of information provided in documentary or by way of a model or in other tangible form, at the time of provision is marked or otherwise designated to show that it is imparted in confidence; (ii) in respect of information that is imparted orally, any information that the Supplier or its representatives informed the Institution at the time of disclosure was imparted in confidence; and (iii) any copy or part of any of the foregoing.
 - (c) **"Co-workers"** mean employees and students of the Institution who are authorised co-workers under the direct and immediate supervision of the Recipient and who have contractual obligations to the Institution that enable the Institution to comply with its obligations under this Agreement.
 - (d) **"Derivative"** means any derivative of the Materials.
 - (e) **"Donor"** means the person from whose body the Materials have come or about whom the Materials relate.
 - (f) **"DPA"** means the Data Protection Act 1998 as from time to time amended.
 - (g) **"Invention"** means any discovery, improvement or, invention arising out of the Project that incorporates or relates to the Materials or their use.
 - (h) **"Materials"** mean the Original Materials and (i) all materials, documents, and information that the Supplier may provide to the Institution under or in connection with this Agreement; (ii) any Derivatives and Progeny created by the Institution from or as a result of the use of the Materials; (iii) any of the foregoing contained or incorporated in any Modification; and (iv) any copy or part of any of the foregoing.
 - (i) **"Modification"** means any substance created by the Institution that contains or incorporates the Materials.

- (j) **"Parties"** mean the Supplier and the Institution and **"Party"** means either one of them.
- (k) **"Personal Data"** means "personal data" or "sensitive personal data" as defined in the DPA.
- (l) **"Progeny"** means any unmodified descendent of the Materials.
- (m) **"Publication"** means any report, publication, presentation, poster or other disclosure that mentions or describes work carried out using the Materials or any Modification.

- 7.2 *Amendment.* This Agreement may only be amended in writing signed by duly authorised representatives of each Party.
- 7.3 *No waiver.* No failure or delay on the part of either Party to exercise any right or remedy under this Agreement will be construed or operate as a waiver thereof, nor will any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.
- 7.4 *Entire agreement.* This Agreement sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter. Each Party acknowledges that it does not rely on any representation, agreement, term, or condition which is not set out in this Agreement. Nothing in this Agreement limits or excludes either Party's liability for fraud.
- 7.5 *Survival.* The provisions of Clauses 1, 3, 4, 5, 6 and 7.5, will survive termination or expiry of this Agreement together with any other terms that by their nature or otherwise should reasonably survive termination or expiry of this Agreement.
- 7.6 *Third parties.* This Agreement does not create any right enforceable by any person who is not a party to it. Furthermore, no person except a Party to this Agreement has any right to prevent the amendment of this Agreement or its termination.
- 7.7 *Law and jurisdiction.* The validity, construction and performance of this Agreement will be governed by English law and will be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction in any court of competent jurisdiction.