Use of Human Material in Research

Paper F

1. CLS Procedures Governing the Use of Human Material (still to be finalised; click here for current draft)

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2. The Human Tissue Authority (HTA) and Human Tissue Act

The HTA is the regulatory body established under the Human Tissue Act 2004. There is separate legislation for Scotland – the Human Tissue (Scotland) Act 2006 – and the HTA performs certain tasks on behalf of the Scottish Executive. The HT (Scotland) Act is based on authorisation rather than consent, but these are both expressions of the same principle. Both Acts came into force in September 2006.

The HT Act (2004 & 2006) regulates removal, storage and use of human tissue.

Rather than human tissue, the Act uses the term Relevant Material. Relevant Material is defined by the Act as material other than gametes, which consists of or includes human cells. In the Act, references to relevant material from a human body **do not** include:
(a) embryos outside the human body, or
(b) hair and nail from the body of a living person.
Cell lines created outwith the human body are also excluded, but cell cultures that contain riginal cells from the human body, e.g. from a blood sample or biopsy, are classed as relevant material.

Certain activities now require a licence from the regulatory authority, e.g. storage of relevant material for use in research that does not have specific Research Ethics Committee (REC) approval.

The HT Act creates a new offence of DNA 'theft'. Having human tissue with the intention of its DNA being analysed, without the consent of the person from whom the tissue came, became unlawful from 1 September 2006. Note: the crime of DNA theft extends to human hair, nail and gametes.

See HTA Code of Practice for Research (code 9) for further details.

All personnel using human material in their research are strongly advised to read through COP 9 and the Key Points & FAQs on the HTA web site.

3. Other Useful Links

- National Research Ethics Service (NRES; formerly COREC) Guidance for Applicants
- Research Ethics Committee Meeting dates
- MRC Policy & Guidance on Use of Human Tissue
    - Human Tissue & Biological Samples for use in Research

4. Dundee University Policy & Guidance

- Ethics and Research Governance Policy
- Research on Human Participants (Code of Practice for)
- Non-Clinical Research Ethics Committee - Standard Operating Procedures (Taught Courses)

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CLS Procedures Governing the Use of Human Material

Note: the following procedures do not apply to cadavers/material derived from cadavers obtained for teaching purposes. Contact the Centre for Anatomy and Human Identfication for further information.

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1. Acronyms & Definitions

SLT: School of Learning and Teaching
CLS: College of Life Sciences
SNBTS: Scottish National Blood Transfusion Service
SOP: Standard Operating Procedure
TCMRE: Tayside Committee on Medical Research Ethics
LREC: Local Research Ethics Committee
RIS: Research and Innovation Services

Human Material: Referred to in the Human Tissue Act as 'relevant material' and defined as material that has come from a human body and consists of, or includes, human cells. Cell lines created outside the human body are excluded, as are hair and nail from living people*. Live gametes* and embryos outside the human body are also excluded.
**If the intention is to carry out DNA analysis, human hair, nail and gametes are included.*

Personal Data: All data/information about a person - electronic or hardcopy - that could be linked to them in any way. Note: it includes the results of tests or experiments carried out on human material.

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2. Ethical Approval

In many cases, work with human material on CLS premises must be approved by the TCMRE before it can legally proceed. The exceptions include work with human material obtained from an official Tissue Bank - each Tissue Bank will have its own application procedure that will deal with any ethical issues - and work with human material obtained from a collaborator that has been approved by the collaborator's LREC - see Section 8 for further infomation. The definition of human material, as given above, indicates that these procedures do not apply to work with cell lines. This is certainly true in the case of commercially available cell lines but some activities involving cell lines, e.g. deriving new cell lines from human material, will require ethical approval. If there is uncertainty about the requirement for ethical approval, the CLS H&S Information Officer will seek advice from TCMRE.

In the event that an application to TCMRE is required, there is a lengthy form to complete, several supporting documents to prepare and submission deadlines to adhere to. The CLS H&S Information Officer can provide further information and will assist with the application process.

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3. Informing RIS

Under the University's Ethics & Research Governance Policy, RIS must be notified of any work involving human material. Contact the CLS H&S Information Officer for further information.

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4. Ensuring Confidentiality & Data Protection

Samples of human material are often accompanied by personal data relating to the donor. This may take the form of official medical records, brief personal details and/or results of tests/experiments carried out on donated samples. Any data that can be linked to an identifiable individual, however derived, is subject to the Data Protection Act 1998. Breaches of this Act can result in prosecution of individual employees, their managers or the University and could result in a £5000 fine. If you are handling personal data you must adhere to the University's Data Protection Policy.

Key points relevant to the use of human material are identified below.

- All personal data must be anonymised as far as possible at the first opportunity.

- Published results must not allow for identification of an individual, family or group.
- Personal data must be securely stored so as to prevent unauthorised persons gaining access.
- Principal Investigators are responsible for ensuring confidentiality of personal data and deciding on who has access. Personal data should only be accessed by senior staff who have been fully briefed on their duty of confidentiality to the donor.
- Potential donors must be made fully aware of what personal data will be stored, who will have access to it, how it will be used and how confidentiality will be protected. Written consent must be given to these arrangements.
- Personal data cannot be disclosed to a third party without informed consent from the donor unless it has been anonymised prior to release.
- Personal data must not be transferred to a country outwith the European Economic Area unless it has equivalent data protection legislation or the data has been anonymised prior to release.
- The disclosure of test/experiment results to the donor must be addressed in the application for ethical approval.
- Gathering of additional personal data, not specified at the outset, will require separate ethical approval.

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5. Keeping Track of Samples

All samples of human material must be carefully catalogued and tracked. The person responsible must ensure records are kept that detail:

- date sample received/collected;
- secure storage location;
- specific use;
- final fate/disposal.

An example Consignment Register is available, but alternative formats can be used providing the required information is clearly recorded. If a purchase order has been raised in relation to obtaining the sample (e.g. when requesting a consignment for SNBTS) it would be permissible to record the required information in the CLS Electronic Order Book, as long as it can be easily retrieved for audit/inspection purposes.

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6. Handling Human Material Safely

Activities involving the use of human material, like any other work activity, must be risk assessed and

the assessment should be recorded in the CLS Risk Assessment Database. The risk assessment must clearly detail the control measures required to ensure the work is carried out safely. An example assessment – serial number 5 in the CLS RA Database – has been provided to simplify this task and the CLS H&S Information Officer will provide further assistance upon request. The finalised risk assessment must be read and signed by all personnel involved in the activity and the specified control measures must be implemented.

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7. Special Procedures for SNBTS Blood/Blood Products

There is no need to directly approach the TCMRE in this instance. A special SNBTS Application Form exists and this is automatically copied to TCMRE upon receipt by SNBTS. SNBTS also take care of donor information and consent. Therefore, section 1 does not apply and is replaced by the following procedure.

- Complete the official electronic Application Form then email it to the CLS H&S Information Officer in order to initiate the application process.
- Applicants are required to follow up the electronic application with a signed hardcopy. The CLS H&S Information Officer will arrange this.
- Use of SNBTS blood must be approved by TCMRE. Upon receipt of an application form, SNBTS will automatically issue a copy to this Committee.
- TCMRE/SNBTS will inform applicants of the success/failure of their application, via email, within two weeks of the initial submission.
- Successful applicants must adhere to the SNBTS SOP Governing the Supply of Blood Products for Research in Tayside.
- SNBTS charge a fee to cover their administration costs and therefore require a purchase order form to be presented upon collection of a consignment. When creating an order in the CLS Electronic Order Book please ensure the unique Reference Code (as issued by SNBTS upon approval of the application and beginning with CLS/) and the name of the person collecting the consignment is quoted on the order form.
- Applications must be renewed every two years. You will be contacted by SNBTS or the CLS H&S Information Officer when renewal is due.

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8. Managing Sample Collections

Each collection of samples of human material must have a Custodian who maintains and manages the collection. This will normally be the leader of the Research Group holding the collection. The

Custodian's duties are itemised below. They may be delegated to a subordinate, but the Group Leader holds ultimate responsibility.

- Facilitate optimum usage.
- Keep comprehensive records as detailed in section 4.
- Be satisfied that all uses have appropriate ethical approval.
- Ensure appropriate data protection measures are adhered to.
- Dispose of samples that are no longer useful, by the appropriate route.
- When necessary, seek consent for new use. Click here for additional guidance on this issue.

If a researcher wishes to move a sample collection to another institute, both the current and future host institute should agree in writing and, if appropriate, contributors to the collection should be notified. If a researcher moves on and the collection is retained by CLS, the Head of Division must appoint a new Custodian.

Users of sample collections must secure appropriate ethical approval for the specified use and ensure that the samples are not used for any other purpose. Surplus material should be returned to the Custodian or destroyed unless approval/consent has been given for retention or transfer to a third party.

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9. Receiving Material from Collaborators

When receiving human material from a collaborator, the Research Group Leader responsible for the arrangement must be satisfied that the collaborator has obtained appropriate ethical approval from their LREC and, if required, informed consent from the donor(s) of the human material. It is vital to have documented evidence confirming this, for example, in the form of a letter or email from the collaborator.

A separate application to the TCMRE will **not** be required providing, (1) the human material is used only for the purpose specified in the collaborator's approved application and (2) the approving LREC did not specifically request any sort of local ethical review. If, however, you intend to use the human material for a purpose other than that specified in the original application and/or the collaborator's LREC specifically requested local review, the work must be approved by the TCMRE. Contact the CLS H&S Information Officer for further advice.

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10. Applicability to SLT

The procedures described in this document apply to research and teaching. Approval has already been granted for the use of SNBTS blood in SLT practical classes and this will be renewed every two years. Teaching exercises involving other human material are unlikely to require TCMRE consideration but must be notified to the CLS Health & Safety Information Officer.

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