University of Sussex

Work with Human Blood Products and other Human Tissue Specimens

University of Sussex Safety Procedure and Guidance
Code of Practice

Work with Human Blood Products and other Human Tissue Specimens

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Introduction

This document replaces all preceding documents. This update has been commissioned owing to the increased handling of human blood and tissue products taking place on the University of Sussex campus and the acquisition of Research Licences from the Human Tissue Authority (HTA).

- **Human Tissue Authority (HTA) Licences**

Two research licences are held by the University – Life Sciences and Brighton & Sussex Medical School (BSMS). The licence relates to the storage of human tissue and does **not** imply that tissue can be taken for research *without* obtaining Ethical approval. Relevant departments can store tissue, in accord with their own internal procedures, originally obtained through ethically approved projects where broad consent has been given. Tissue can originate internally from the University or from outside – please see departmental Standard Operating Procedures (SOP) for further details (Life Sci http://www.sussex.ac.uk/lifesci/internal/servicesandsupport/ethics/humantissue ; BSMS http://www.bsuh.nhs.uk/research/human-tissue-act).

- **Containment Level Criteria**

Biological laboratories are designed to set containment criteria for work with designated biological hazards. In the vast majority of cases human blood and other materials are classified as requiring containment level 2.
For further advice and guidance on containment level criteria refer to the following website:
http://www.hse.gov.uk/pubns/misc208.pdf
for a list of micro-organisms and under which containment level they are classed.
Biological agents: Managing the risks in laboratories and healthcare premises
http://www.hse.gov.uk/biosafety/index.htm for advice on laboratory standards and design.

Governance and Ethics

- **Sample Collection from Healthy Donors**

Ethical Considerations

Collection of blood samples or other tissue samples from healthy donors (this includes staff or students) counts as experimentation on human subjects and is regulated through the 'Human Tissue Act 2006. Approval for collection **must** always be sought from the local Research Ethics Committee **before** work begins.
Research Ethics Committees at The University of Sussex are:

- Sciences & Technology Cross-Schools Research Ethics Committee (C-REC).

- Social Sciences & Arts Cross-Schools Research Ethics Committee (C-REC).
- BSMS Research Governance & Ethics Committee (RGEC).
- Ethical Review Committee (ERC).

Information regarding the application process can be obtained from the Research Governance Officer.

You are not allowed to work with your own, or laboratory colleagues blood or tissue, as alterations to your genetic material may be introduced or occur. Your immune system may or recognise these changes as harmful and you may therefore be susceptible to disease. Colleagues should not be placed under pressure to give samples. All potential donors should be able to refuse to donate material, without having to give an explanation for a refusal. Any personal information obtained in connection with collection or use of a sample must be held in confidence.

Volunteers should be told before agreeing to donate

- how much material is to be taken
- the purpose for which the sample is to be used

Donor Information Sheets and Consent Forms must be included in the Ethics application and should be read and signed every time that blood is taken. Consent Forms are stored securely in the designated phlebotomy rooms and should be held for a minimum period of one year.

Donor Screening

Personnel must not be put under duress by research staff to give samples

Donors must be informed in writing of the use of the sample and must sign a consent form for each specific project.

In the case of blood donation a donor should use the national blood service life style self screening questionnaire http://www.blood.co.uk/pages/flash_questions.html

Donors have the right to refuse any request for samples and may not give more material than agreed limits.

Designated Sampling Areas

Blood may only be taken from volunteers in designated phlebotomy areas. These areas should not be in laboratories where substances hazardous to health are being used. The area designated should not be carpeted and must have washable flooring. The area ideally should be separate from other work areas , contain a hand wash sink with soap and hand-towels, a chair, or ideally couch (with plastic covering) and a table or other washable surface on which the volunteer may rest their arm during bloodletting. A telephone should be available to call for help in case of an emergency.

There should be a lockable cabinet containing the following items:

Sharps bin, Blood letting equipment, emergency eye-wash, water-free hand-washing gel, biocide for blood spills, hand-towels and gloves. Safe Sharps Practice and Emergency Procedures notices should be clearly visible.

- **Sample Collection from NHS Patients**

Collection of samples from NHS patients will take place either within a hospital setting where the standard procedures of the specific Trust will be followed or within designated clinical areas on the University of Sussex Campus (Clinical Imaging Sciences Centre, CISC). In the latter's case, the local rules developed within CISC will be followed.
In each case, a favourable ethical decision from an NHS Research Ethics Committee as well as approval from an NHS Trust R&D department is required prior to work commencing.
Once samples have been collected, they must be processed in designated Containment Level 2 laboratories; facilities are available at CIRU and the MRB (BSMS) and in various labs within Life Sciences.

- **Samples collected Elsewhere**

There are many considerations when receiving samples from elsewhere:

- how were the samples collected;
- has consent been obtained;
- is ethics in place for the current project?

As a minimum:

- A Material Transfer Agreement must be in place and approved by the University of Sussex legal team.
- The samples must be obtained with consent of the donor and a service level agreement stating such must be in place from the organisation sending the samples.

Legal Considerations

There are material and intellectual property rights associated with samples obtained for research which must be considered. When obtaining samples from another institute/individual/company, a Material Transfer Agreement must be in place and agreed by the University of Sussex's legal team. Instructions for these documents can be found here:
Life Sci http://www.sussex.ac.uk/lifesci/internal/servicesandsupport/ethics/humantissue ;
BSMS http://www.bsuh.nhs.uk/research/human-tissue-act

- **Sending Samples Elsewhere**

Human Tissue Act

As a minimum, the sender should ensure that the organisation receiving the samples should either hold an HTA licence for the storage and disposal of human tissue or should be in

possession of appropriate ethical approval to store the samples for project being undertaken.

Legal Considerations
See above.

Standard Procedures for Handling Samples

Working with human tissue products (blood, tumour tissue, urine, stool, plasma, serum) has inherent risks; tissue, whether screened or unscreened, can carry infectious agents and so will require careful handling. All researchers planning to work with human tissue must ensure

- that they are trained in all necessary procedures,
- that they are vaccinated against Hepatitis B (at the very least) and
- that they carry out a thorough risk assessment before they begin.
- that PPE (gloves, lab coat and eye protection) is worn

Guidance on vaccinations can be obtained through Occupational Health (http://www.sussex.ac.uk/humanresources/occupationalhealth).

- **Risk assessment**

Risk and CoSHH assessment forms are available from:
http://www.sussex.ac.uk/hso/healthandsafety/controlofsubstanceshazardoustohealthcosh/chemicalandlaboratorysafety
These forms must be completed prior to starting an experiment and must be submitted to your H&S co-ordinator (Life Sci - Graham Frost and Steve Pearce; BSMS – Natalie Chaplin). Guidance on completing these forms is available at
http://www.sussex.ac.uk/hso/healthandsafety/science-safety-procedures-and-guidance/sciencesafetyproceduresandguidance

The assessment should be specific for the procedures involved and take account of the nature and source of the samples to be handled. Of particular concern is the possible presence in the material of blood borne viruses (BBVs), most notably Hepatitis Virus strains and Human Immunodeficiency Virus (HIV). However, other pathogens may be present and it is important to take account of these. The key control measures when working with any blood and human tissues are maintaining good working practice standards and avoiding the use of sharps.

Once the assessment has been completed, the following must be implemented:

- Any specified control measure
- Staff must be trained and made aware of any emergency procedures

- A SOP must be completed to include specified control measures and emergency procedures
- Staff should be made aware of incident reporting arrangements
- The School should have review arrangements in place which should be specified in their local policies/guidance

- **Immunisation**

All human tissue products are deemed potentially infectious and as a consequence the risk assessment requires the researcher to be immunised against any relevant pathogens. Many blood products are infected with Hepatitis B and as a general precaution, all researchers working with human tissue should be vaccinated against Hep B as a minimum. If the products are known to contain other pathogens (eg *M. tuberculosis*), immunisation against the relevant pathogen (if possible) is required.
Occupational Health should be consulted before work with the human tissue begins.

All human tissue products must be evaluated prior to starting work as to their possible infectious content. If there is a high likelihood of a specific (eg a patient presenting with Hepatitis C) pathogen being present, the researcher MUST contact their Biological Safety Officer.

- **Transport of samples**

As all human tissue samples are deemed infectious and therefore pose a risk, they have specific transportation requirements. Transport refers to the movement of samples anywhere; from moving them across campus to across continents. Please refer to the Univeristy guidance on transport of dangerous goods found on the Health and Safety web page:
http://www.sussex.ac.uk/hso/healthandsafety/science-safety-procedures-and-guidance/sciencesafetyproceduresandguidance
However, general guidelines are:

- samples must always be secondarily contained in plastic watertight containers
- temperature controls must be used if required eg dry ice
- containers and individual samples must be labelled appropriately
- samples must never be placed in glass containers
- secure and appropriate transport companies must be used at all times

For guidance on category A and B samples refer to WHO guidance:
http://www.who.int/csr/resources/publications/biosafety/WHO_HSE_EPR_2008_10.pdf

- **Training**

Work with potentially infectious human products requires specialist techniques and equipment which in turn requires specific knowledge and training. All persons intending to use human tissue/products in their research will require training by their line manager or supervisor. Those whose tissue is stored under their School's HTA licence may require an additional induction and further training on the use of tissue tracking software. Please consult your respective Designated Individual, Person Designate or Human Tissue Manager for details.

- **Phlebotomy**

Blood may be donated by healthy volunteers to research projects which can be taken on campus. Donors will be required to sign consent forms which must be stored securely by the PI who is also required to keep a log of how much blood each donor has given – men can give a maximum of 500ml and women 250ml in any 6 month period.
Phlebotomy areas should be equipped with a phlebotomy chair, a hand wash basin and should be separated from laboratory and office areas. People taking blood should be formally trained – courses are available through BSMS (Clinical Skills Facilitator).

- **Handling in the laboratory**

All human tissue/product samples must be separately stored in watertight plastic containers and labelled appropriately (contents, date collected, name of researcher and a biohazard label). Labs must be equipped with spill kits for infectious material and workers should be aware of emergency procedures.

At work

- Always wear gloves and a lab coat and eye protection.
- Avoid the use of sharps, but if unavoidable, follow safe sharps practice; If possible, no sharps should be used when handling blood samples that have been collected elsewhere.
- Where possible, process samples in a Safety Cabinet.
- Only work in designated areas
- Samples -suspected to contain hazard group 3 blood-borne micro-organisms should be assessed as to whether containment level 3 conditions are required. (see HSE guidance)
- All other work with samples should be carried out in at Containment Level 2

- **Sending Samples Elsewhere**

This section is concerned with tissue samples that have been collected in the university and are being sent to other organisations for research or commercial purposes.

Risk Assessment

All blood, tissue or other body fluid samples collected and those sent to the University for Research Purposes should be handled using standard precautions, treated as a potential risk of blood borne pathogens, and be clearly labelled as one of the following:

Screened for known pathogens

Unscreened but low risk

Known to contain pathogens

Standard Procedures (section above) MUST be followed when handling any human sample.

- **Samples collected elsewhere**

There are many considerations when receiving samples from elsewhere:

- H&S – what infectious agents might the samples contain?
- Sample integrity – how were the samples transported; is there a record of storage conditions in place?

As a minimum

- the organisation sending the samples should follow the guidance outlined in the transport section of this document.
- A specific person should be identified to receive the sample at a pre arranged time and to ensure the sample is properly receipted, unpacked and stored.

- **Waste disposal of human material**

Sharps

All sharps should be disposed of directly into a purpose-made sharps bin. Do not re-sheath needles. Sharps bins must be kept as close to the work station as possible to reduce distance that sharps are carried before disposal. Sharps bins contaminated with CL1 or CL2 pathogens should be sealed with tape, placed in a bag and sent for incineration. Sharps used in a CL3 facility should be autoclaved in the CL3 suite before being sent for incineration.

Plastic

All plastic pipettes etc. contaminated with human blood/tissue should be soaked in Virkon (2 %) or similar disinfectant for 24 hours, drained and then autoclaved or sent for clinical incineration.

Paper

All paper-based waste should be placed into autoclave bags, autoclaved or sent for clinical incineration.

Emergency Procedures

- **Sharps Injury/Exposure**

Appropriate emergency procedures commensurate with the risk assessment should be in place when working with blood or tissue products.
The risk of infection varies according to the pathogen involved and the circumstances of the accident. An exposure is significant where:

- exposure is caused by a puncture wound, cut, scratch or by a splash into your eye, mouth or onto broken skin, or if an aerosol has been accidentally created contamination by inhalation exists
- the material involved is blood, serum, CSF, genital secretions or other body fluids (this includes urine & gut secretions but only if visibly blood-stained) or unfixed (fresh) tissue samples

The risk of disease transmission is increased if the injury is deep, or caused by a hollow needle especially if just used for venous or arterial puncture, or there is visible blood on the device.
A splash of blood etc. onto visibly intact skin is NOT considered a significant risk unless extensive or prolonged or is splashed into the eye.

Immediate Action Following Exposure incident
Encourage bleeding, but do not scrub the wound: this may increase tissue damage.
Wash any wound or contaminated skin with soap and clean water and cover with a sterile dressing.
If blood is splashed into the eye or mouth, stop & wash out immediately with tap water or saline
If cat 3 exposure occurs follow emergency procedures relevant to the pathogen

- **Spills**

Inside the safety cabinet
A spill inside a safety cabinet should be generously covered with paper towels and 10% Bleach or 1% Virkon sprayed onto the towels. They should be left for a minimum of 10min then wiped up with further towels and disposed of in autoclave bags. The whole area must be sprayed with 70% IMS and wiped down.
Outside the safety cabinet
If material is spilled outside the cabinet, the immediate area must be cleared of other researchers and the cordoned off. Spill kits are located in labs and should be used according to instructions. The person cleaning the spill must don PPE to include a mask.

- **Incident Reporting**

Report the incident to Occupational Health as a matter of urgency as soon as reasonably practical

They will require the following information:
Name: Time & Date of Injury
Details of Injury (including any possible blood contamination)

Report the incident your local Health & Safety Advisor and to the Health & Safety Office using the incident report form.

In the event of a potential exposure or sharp injury contact Occupational Health as a matter of urgency or if out of hours please go to Royal Sussex County Hospital Accident and Emergency Department.

Appendices

1. Phlebotomy Procedure

Purpose

To ensure that a systematic and safe approach is used when undertaking the procedure
All staff undertaking phlebotomy must have undergone theoretical and practical training, and have the knowledge and skills to perform the procedure competently and update their practice annually

Equipment

Vacutainer system
Correct sample bottles
Disposable kidney dish
Cotton wool balls
Tourniquet
Gloves (Non Latex)
Plasters/micropore tape
Sharps container
Yellow clinical waste bag
Plastic bag to put sample in
Appropriate laboratory form – if required
Infectious substances spillage kit
Alcohol hand gel

Procedure

- Gather all equipment together and ensure the sharps disposal bin is close to hand.

- Identify of the client and amount required must be confirmed
- Explain procedure and gain verbal and written consent
- Unless a fasting sample is required ascertain that the donor has had something to eat or drink during the day to minimise the risk of fainting
- The procedure is normally carried out with the client seated. Alternatively lying down may be preferred by the client, especially those who are prone to fainting
- Clean hands. The use of protective gloves is recommended for this procedure (DofH 2001). Although gloves cannot prevent percutaneous injury they may reduce the risks of acquiring a blood borne virus
- Prepare the vacutainer system
- Expose the site and apply a tourniquet to the upper arm and identify a vein in the ante-cubital fossa
- Insert the needle through the skin and then into the vein
- Hold the needle firmly in the vein with one hand and insert the appropriate blood tube into the barrel to collect the specimen. Remove the specimen tube gently whilst holding the needle firmly in place. Repeat this procedure until all the specimens required have been taken.
- Release the tourniquet. Place a dry cotton wool ball over the needle when withdrawing the needle. Place the vacutainer needle and holder (still connected) directly into the sharps bin.
- NEVER RESHEATH USED NEEDLES
- Ask the client to apply firm pressure with the finger/thumb to the cotton wool ball. Ask the client to keep their arm straight
- Ensure that all specimens are completely and accurately labelled and place in the appropriate bag with the completed laboratory form
- Inspect the puncture site and when you are satisfied that the puncture wound has stopped bleeding apply a plaster or cotton wool ball and micropore
- If pain, swelling or discomfort is experienced after procedure, instruct the donor to consult their GP
- Dispose of all soiled material into a yellow clinical waste bin
- Clean hands once procedure is completed

<u>Safe Sharps Practice</u>

Never re-sheath needles

Sharps containers should never be over-filled: discard when ¾ full*

Any inoculation accident from contaminated equipment should be reported as an accident & advice sought from Occupational Health as soon as possible.

Seal the container with biohazard tape and send for incineration. Consult your building Safety Advisor or Laboratory Manager about disposal of sharps containers.

2. Principles of Risk assessment

Key to the carrying out of risk assessments is the recognition that (a) risk assessments must be done **before starting** the work and (b) that making a proper risk assessment is an integral part of proper planning.

The starting point is an appreciation of the significant hazards related to the work. In the laboratory situation, major hazards may be related to the substances used (e.g., the chemicals, radioisotopes or the biological agents); or they may relate to key items of equipment (e.g., a centrifuge, or distillation equipment or a pressure vessel). In an office the hazards may relate to the equipment itself (e.g., electrical safety) or the way the work is done (e.g., lifting heavy items, or incorrect use of display screen equipment).

It is useful to define both Hazard and Risk:

- **Hazard is the potential to cause harm or damage**
- **Risk is the chance of that harm occurring**

An early stage of carrying out a risk assessment must be the consideration of who will actually do the work. You do have to consider the staff and take into account relevant factors that may affect safe working. This may relate to physical features such as size and strength; or pregnancy; or a member of staff possessing a particular disability, or conditions which may compromise their immune system. All these factors may affect the risk assessment, the overall objective being competent staff able to do the work in a safe manner.

Consideration of the basic facilities required for the work must be done at a very early stage. At the extreme, work may be proposed when there is simply no possibility of providing the proper facility. Examples may include work with a hazard group 3 organism when there is no prospect of providing a proper laboratory, or work with volatile toxic substances when total enclosure is not practicable and no fume cupboard is available. In these cases, work will not be possible.

All precautions or measures that are reasonably practicable to eliminate, minimise or control exposure to risk must be taken. The term ‘reasonably practicable’ incorporates consideration of cost (time, effort, money) against benefit, but there is an order, or ‘hierarchy’, which must be followed.

The first questions that must be asked for each significant hazard are:

Do I have to do the task at all?”, and “Do I have to use it and is there a biological agent which reduces or avoids the risk?”

If the decision is to proceed with the project and the need for further risk control measures has been identified, these must still be considered in a set order of priority. If, after

considering cost and benefit, it is reasonably practicable then engineering controls that provide physical containment such as microbiological safety cabinets should be used.
Work practices are the next level of control measure followed by the 'last resort' of Personal Protective Equipment (PPE). The definition of PPE would include laboratory coats or gowns, gloves, eye protection and airflow helmets or visors but not uniforms.
PPE, although it has its place, is limited in what it can achieve. Firstly, it only protects the wearer and no one else who is not also wearing PPE, secondly, the PPE may only have a limited life and needs to be continuously replaced or maintained, thirdly, training is an issue as wearers need to know how to don the equipment appropriately and the limit of its effectiveness to protect the wearer and finally PPE does not fit all as well as it should as everyone is a different shape.