University of Sussex
Code of Practice for
Work With Human Blood products and other tissue specimens

Contents

Introduction

This document replaces all preceding documents. This update has been commissioned due to the increased handling of human blood and tissue products that has arisen on the University of Sussex campus since the opening of the Brighton & Sussex Medical School.

Principles of Risk Assessment

HAZARD & RISK

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, not a 'bolt-on' accessory.

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**

Who will do the work and where it is proposed they do it?
An early stage of carrying out a risk assessment must be the consideration of who will actually do the work. In most situations you will be looking at staff recruited because they are considered to be suited to the work. However in making a risk assessment 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. 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.

Risk evaluation
This is the process of estimating the likelihood of an event occurring, such as exposure to a micro-organism, plus identifying the likely consequence of exposure. This can be represented by a risk matrix which gives a final risk ranking which allows a prioritising of risk to take place. This ranking also allows for control measures to be introduced for the highest risks first of all as part of an overall process for reducing the exposure to risk.

Risk Ranking Example; Potential severity of harm x the likelihood of the event occurring

Hazard Factor: 1 = screened samples 3 = unscreened samples

Probability Factor Number of samples handled in 6 month period
1 = 1-10 1.25 = 11-40 1.5 = 41-80 2.0 = 81-120 3.0 = >120 samples

Risk Factor = Hazard x Probability

Risk factor > 6 is high Risk factor < 3 is low

Risk control
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 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 such as not resheafing used hypodermic needles 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 can have 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 limits 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.

CONTAINMENT LEVEL CRITERIA

Refer to HSE website for advice on containment level criteria:

http://www.hse.gov.uk/pubns/misc208.pdf for a list of micro-organisms and which containment level they are classed under.

Biological agents: Managing the risks
in laboratories and healthcare premises http://hse.gov.uk/biosafety/biologagents.pdf

STANDARD PROCEDURES

The following precautions should be made when handling any blood or tissue in the laboratory.

Prior to Starting Work

- Consult Occupational Health before you beginning work with human samples to check if any immunisations or other interventions are required.

At work

- Always wear gloves and a lab coat.
- Avoid the use of sharps, but if unavoidable, follow safe sharps practice (Appendix 4).
- Where possible, process samples in a Safety Cabinet.
- Only work in designated areas.

TRAINING

All persons working with blood and human tissue should be given appropriate training and be vaccinated against Hep B. Any worker or student on the University of Sussex campus who will handle blood and human tissue must contact Occupational Health in advance of beginning work.

Phlebotomy

Phlebotomy training can be arranged with the Clinical Skills Facilitator at the Brighton & Sussex Medical School. Non-medical school personnel may be charged for this training.

Laboratory Handling

Workers handling blood in the laboratory should be trained and a record should be kept of this training. Training should be designed specifically for each laboratory and should involve details on waste disposal, emergency procedures and safe use of equipment.

SENDING SAMPLES ELSEWHERE

Note: that there may be ethical and intellectual property rights issues associated with sending samples to other institutions and other countries.

Transport

Blood and tissue samples should never be stored in glass for transportation. Even when samples are being taken from one laboratory to another, or across campus, they must be sealed inside a waterproof box and labelled properly.
If samples need to be transported to other campuses or institutions they should be sealed inside a box, with appropriate packing to absorb any spillage, if vials/bottle leak. When transported by car the samples should be placed in the boot. Samples sent by courier or post should be clearly labelled. See WHO guidance:
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2cc.pdf

WASTE DISPOSAL

Sharps

All sharps should be disposed of directly into a purpose-made sharps bin. 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.

Disposable Consumables
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.

Contaminated Paper/Tissue/Sterets etc.
Dry waste should be autoclaved before disposal.

Emergency Procedures

The risk of infection varies according to the pathogen involved and the circumstances of the accident. If you do have an accident, do not assume that you are safe. 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.
- 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.

Immediate action following a potential 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 first aid treatment is required dial 3333

In the event of a potential exposure or sharp injury contact Occupational Health immediately on 7255.

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

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

Tissue/Blood of Human Origin

SAMPLE COLLECTION FROM STAFF AND STUDENTS

Risk Assessment

Even through the risk of transmission of blood-borne pathogens to workers is relatively low (see Principles of Risk Assessment), this risk may be further reduced by screening all potential volunteers.

Blood, tissue and other body fluids from all volunteers either screened or unscreened volunteers **must** be treated at a minimum of Containment Level 2.

Volunteer Screening

All departments requiring use of healthy blood donors should offer all new staff and students the option to join the University Blood Donor List (The most appropriate time for this will be during induction). Personnel must not be put under duress to give blood by research staff.

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

Anybody agreeing to become a donor should use the national blood service life style self screening questionnaire http://www.blood.co.uk/pages/flash_questions.html If you are able to donate blood then contact OccupationalHealth@sussex.ac.uk to be registered on the blood donation list and to obtain a blood donation card.

Researchers with current ethical approval for projects will be given the names of current donors and may approach these donors when they require blood samples.

Donors on the list have the right to refuse any request for blood and may not give more blood than agreed limits on their donor card. No member of staff or student may give blood on University Research premises if they do not hold a University of Sussex donor card.

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 a washable flooring. The area ideally should be separate from other work areas ,have 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 and hand-towels and gloves. A copy of the Checklist (Appendix 1), Safe Sharps Practice and Emergency Procedures (Appendix 2) should be clearly visible.

Ethical Considerations

Collection of blood samples from colleagues counts as experimentation on human subjects and is regulated through the '*Human Tissue Act'*. Approval for collection **must** always be sought from the local Research Ethics Committee **before** work begins.

Colleagues should not be placed under pressure to give samples. All potential donors should be able to refuse to give blood, 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 blood is to be taken
- what the sample is going to be used for.
- what tests for markers of disease, if any, are to be carried on the sample whilst it remains traceable back to the donor.

Consent forms should be signed every time that blood is taken and the consent forms kept in the phlebotomy room.

SAMPLE COLLECTION FROM THE PUBLIC

Risk Assessment
A separate risk assessment should be written for every cohort of volunteers recruited.

Volunteer Screening
Screening should take into account the demographics of the target donors and whether or not they will be excluded on the basis of a lifestyle questionnaire or any other screening method. All unscreened samples must be handled at a minimum of CL2.

Designated Sampling Areas
Blood taken from the general public may only be taken in a suitable clinical setting, such as the occupational health department at the University of Sussex and may only be taken by staff with clinical training.

Ethical Considerations

All studies requiring use of volunteers from the general public should have specific ethical approval. Approved consent forms and volunteer information leaflets must be produced for each research project.

Volunteers should be told before agreeing to donate

- how much blood is to be taken
- what the sample is going to be used for.
- what tests for markers of disease, if any, are to be carried on the sample whilst it remains traceable back to the donor.

SAMPLES COLLECTED ELSEWHERE

This section is concerned with blood samples that have been collected elsewhere and are being sent to the University of Sussex campus for research purposes.

Human Tissue Act

Use of all human tissues and blood samples is regulated by the human tissue act. All work with Human Tissue Samples must comply with the Act. Approval must be sort prior to work commencing from the appropriate Designated Individual (Genome Centre and BSMS) or Licence Holder. Approval will normally entail approval by a LREC or Licence obtained from the HTA.

Risk Assessment

Samples sent to the University for Research Purposes should be clearly labelled as one of the following:

- Screened for known pathogens
- Unscreened but low risk
- Known to contain pathogens

The Standard Precautions (appendix MUST be taken when handling any blood sample.

- Samples known to contain hazard group 3 blood-borne viruses should be assessed if containment level 3 conditions are required. (see HSE guidance)
- All other work with samples should be carried out in at Containment Level 2
- If possible, no sharps should be used when handling blood samples that have been taken elsewhere.

Biological agents: Managing the risks
in laboratories and healthcare premises http://hse.gov.uk/biosafety/biologagents.pdf

TISSUE/BLOOD OF ANIMAL ORIGIN

Risk Assessment

Risks to health from blood/tissue obtained from non-human (non-primate) animals will be very unlikely, but researchers must be aware of the risks to health not only from work involving the deliberate intention to use a biological agent, but also from any incidental risk of exposure from work with animals or from material obtained from animals. Consideration should be given to treating primate material as human material. For example, simian immuno-deficiency virus (SIV), an animal retrovirus, has infected laboratory workers but has caused no observable disease. SIV infected animals require animal Containment Level 3.

The first step in dealing with work involving materials obtained from animals is to identify any biological agent which may be present and assign it to a risk group as described on page 2. If the biological agent present or suspected to be present falls into risk Group 2, 3 or 4 precautions should be taken as detailed for handling of human blood/tissue.

Waste Disposal

All sharps should be incinerated. Although autoclaving is not strictly necessary for waste contaminated with animal blood/tissue it is good practice to send all such waste for autoclaving. Animal carcasses should be disposed of via the ancillary unit.

Appendix 1

Checklist to be completed EVERY time that blood is taken from a volunteer

YOU MUST TELL YOUR VOLUNTEER

- That donors must be registered with Occupational Health prior to donation
- How much blood you are going to take on this occasion
- The use that will be made of the sample
- You should not donate today if any of the following apply

  You are pregnant
  You feel unwell today

YOU MUST ASK YOUR VOLUNTEER

- Including the sample being taken today, have you given a total of more than 250 ml (women) or 500 ml of blood (men) to anyone in the last six months (this includes blood given for medical purposes).
- Are you currently taken antibiotics
- Have you eaten today

Appendix 2

Safe Sharps Practice and Emergency Procedures

Safe Sharps practice

- Use a Vacutainers™ collection equipment whenever feasible
- Wear gloves when taking blood
- Needles should never be recapped
- Never carry used sharps in your hand (including vacutainers, which should always be transported inside a box)
- Sharps disposal containers should be available at the point of use
- Used equipment should be discarded into a sharps disposal container immediately after use. Equipment should never be re-used
- Sharps containers should never be over-filled: discard when ¾ full*
- Needles & syringe should be discarded as a single unit
- Any inoculation accident from contaminated equipment should be reported as an accident & advice sought from the local OH Service 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.

Immediate action following a potential 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. Cover with a sterile dressing.
- If blood is splashed into the eye or mouth, stop & wash out immediately with tap water or saline.
- Fill in a University Incident Form
- REPORT TO OCCUPATIONAL HEALTH IMMEDIATELY.

A copy of this document should be placed in a prominent position in any area where workers may be exposed to human blood/tissue.

Appendix 3

Good Venesection Practice

Staff Donor Safety

- The collector must be trained and competent in taking blood samples, or supervised by an experienced colleague until competent.

- Only Registered Donors are allowed to give blood. The donor registration list is held by the Occupational Health Service.

Public Donor Safety

- The collector must be qualified in phlebotomy (i.e. be a registered clinician or nurse) and must be covered by medical indemnity.

- Volunteers must sign a consent form that has been approved by an ethics approval committee.

- Volunteers may need to provide medical information to ensure that they are suitable to become donors. This may or may not include a lifestyle questionnaire, depending on the demographics of the target group.

Common Procedures for Donor Safety

- It is preferable that samples are taken with the donor lying down on a suitable couch. However, if taking samples with the donor sitting ensure there is sufficient space immediately adjacent to lie the donor down should they faint.

- For samples of >50ml a physician, nurse or an appointed person or first aider available should be close by to assist with faints.

- For samples of >200ml a haemoglobin (Hb) estimation should be carried out prior to collection.
    - Samples should not be taken from men if Hb is lower than 13.0g/dl.
    - Samples should not be taken from women if Hb is lower than 12.0g/dl.

- Where blood is to be collected regularly from a donor, a record of donations & the total collected should be maintained.

- The total (including donations elsewhere) should not exceed 500ml in a 6 month period for men or 250ml in 6 months for women.

Appendix 4

User safety

All blood & serum samples must be treated as potentially infectious and safe sharps practice followed when taking or handling blood. Negative tests for known blood-borne viruses do not rule out the possibility of infectious agents being present in a sample.

If samples are taken from unscreened volunteers, extra vigilance should be taken to ensure that staff do not become infected. These precautions should be taken by the phlebotomist and by any personnel handling the samples in the laboratory.

It is good practice to avoid using one's own blood for any tissue culture. No-one should work with their own blood samples or those of colleagues working in the laboratory, if the intention is to transform lymphocytes as in the event of an accidental exposure, their immune system will not challenge the transformed cells.

Volunteers will be screened using a life style self assessment and will not be accepted on to the donor register if their life style poses a risk of infection of a blood-borne infection.