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

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1. **INTRODUCTION**

**Scope**
This document replaces all preceding documents. It applies to all staff and students undertaking work with human or animal blood products and other tissues.

Although applicable to all work with human blood products and other material the University recognises that certain professional areas e.g. Surrey CRC, Clinical Investigation Unit and the Robens Centre for Occupational Health and Safety operate to their own standard operating procedures which as a minimum meet the requirements of this document.

**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 which containment level they are classed under.

And to 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

2. **SAMPLE COLLECTION**

**Ethical considerations**
Collection of blood samples from colleagues (staff or students) 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.

Donor Information Sheets (Appendix 1) must be read by donors and Consent Forms (Appendix 2) should be signed every time that blood is taken. Consent Forms are kept in the designated phlebotomy rooms and should be held for a minimum period of one year.

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.

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Risk Assessment

The risk of transmission of blood-borne pathogens to workers is relatively low. However blood, tissue and other body fluids from all volunteers must be treated at a minimum of Containment Level 2.

Some studies may require blood which is free of (or specifically contains) blood borne pathogens. In these cases specific consent will be obtained at the point of sample collection for the blood to be screened.

Volunteer screening

All staff and students should be given the opportunity to join the University Blood Donor List. The most appropriate time for this will be during induction. However periodic ‘recruitment’ of healthy blood donors may take place at any time. Personnel must not be put under duress to give blood by research staff.

The blood donor list will be kept by the FHMS Blood Donor Co-ordinator. To register and be included on the blood donation list donors should approach the FHMS Blood Donation Co-ordinator or his deputy who will require only that basic contact information is recorded and consent that this information may be shared with researchers. The FHMS Blood Donor Co-ordinator is Dr Noel Wardell (06 AW 01 ext. 9722 j.wardell@surrey.ac.uk). His deputy is Dr Shelagh Hampton (20 AY 02 ext. 9732 s.hampton@surrey.ac.uk).

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

Potential donors are advised to consult the national blood service lifestyle self-screening questionnaire at http://www.blood.co.uk/pages/flash_questions.html prior to volunteering to donate. This will guide the potential donor through a self-assessment process to ascertain their personal risk factors relating to blood borne pathogens.

Donors on the list have the right to refuse any request for blood and may not give more blood than agreed limits (see below) 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 Surrey donor card.

Collection process

Donor Record Cards – all people listed on the University Blood Donor List will be issued with a Donor Record Card. Blood can not be taken from a donor unless this card is produced.

The card will record all donations given including time, date and volume. Limits are placed on the maximum total (including donations elsewhere) volume of blood it is permissible to donate these are:
- 500ml in a 6 month period for men and
- 250ml in 6 months for women

For samples of >200ml a haemoglobin (Hb) estimation should be carried out prior to collection. This can be requested via the Robens Centre if required
- 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.

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This should be recorded on the Donor Record Card prior to donation.

Donor Information Sheet – prior to each donation the donor is required to read the Donor Information Sheet (Appendix 1). This will give information about the maximum amounts of blood they are able to donate in a specified period of time, lifestyle activities which may increase the risk of blood borne virus transmission and circumstances where donation should be avoided.

Consent – Consent will need to be obtained from every donor prior to every donation. A sample consent form is included in Appendix 2 and contains the minimum amount of information required. Researchers may use this as a start point for developing enhanced consent where the donor is required to consent for specific testing.

Donors will need to confirm that they have read the Donor Information Sheet.

Consent forms will be kept by the requesting researcher.

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. A list of designated areas is given below:

CIU Clinical area.

There should be a cabinet containing the following items:

Sharps bin, phlebotomy equipment, emergency eye-wash, water-free hand-washing gel and hand-towels and gloves. Donor Information Sheets (Appendix 1), Consent forms (Appendix 2), Phlebotomy Procedure (Appendix 3) and Immediate Action Following Exposure (Appendix 4)

It is preferable that small samples are taken with the donor sitting down. However, if taking samples with the donor sitting ensure there is sufficient space immediately adjacent to lie the donor down should they faint. For larger samples greater than 220ml a couch is preferable.

Where samples greater than 50ml are to be taken consideration should be given to the proximity of assistance in the event of a faint.

Phlebotomists – Staff taking blood should be competent in the procedure. A course in phlebotomy should be undertaken. Supervised practice is then required to consolidate the clinical skills learnt and local assessment of practice required to attain competence. Written records must be kept of training, supervised practice and competence assessment. These may be requested by a donor at any time.

All staff taking blood must inform Occupational Health, health risk assessment undertaken and appropriate vaccination offered.

Phlebotomists must follow the Phlebotomy Procedure in Appendix 3.

Insurance will be required to cover this activity as it is considered an invasive procedure.
Special considerations when taking blood from members of the public - a separate risk assessment should be written for every cohort of volunteers recruited.

Consideration should be given to the use of clinicians (doctors or nurses) in collecting samples from donors.

Volunteers must sign a consent form that has been approved by the FHMS Faculty Ethical Committee and will cover as a minimum the items in Appendix 2.

Public donors 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.

Screening of samples 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.

3. USE OF SAMPLES

All blood, tissue or other body fluid samples obtained for the purposes of research, should be used only for the research outlined in consent form which the volunteer is aware of and has signed.

Risk assessment:
This should be carried out prior to commencement of work regarding the handling of blood, tissue or other body fluid samples. Staff and non supervised research students handling blood, tissue or other body fluid samples should be assessed by occupational health and offered appropriate immunisations. Supervised students should received an appropriate briefing on working with human blood and the necessary precautions to take prior to starting work with human blood and other tissues.

Controls
Standard Operational Precautions
Prior to commencement of work:
- Risk Assessment of the activity to be undertaken prior to commencement of work (see risk assessment)
- Training; all persons working with blood and human tissue should be given appropriate training and a record should be kept of this training. Training should be specifically designed, relevant, involve details of waste disposal, emergency procedures and safe use of equipment.
- Ensure staff have undergone Occupational Health assessment
- The Robens Centre for Occupational Health provide services for the University and are contactable on 01483 686690.

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.

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

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

• Samples known to contain hazard group 3 blood-borne micro-organisms 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 collected elsewhere

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

Training
All people working with blood and human tissue should be given appropriate training. 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.

Waste Disposal
All sharps should be incinerated.

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.

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 EBU.

Emergency Procedures
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.

Appendix 4 outlines the immediate action required following accidental exposure.

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Special considerations regarding animal samples - Risks to health from blood/tissue obtained from non-human (non-primate) animals are 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.

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. They should also consult other relevant bodies such as DEFRA to check if any specific guidance applies to working with animal pathogens.

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.
4. Samples obtained or to be transported elsewhere

This section is concerned with blood samples that have been collected in the university and/or collected elsewhere and are being sent to the University of Surrey for research purposes.

Human Tissue Act
Use of all human tissues and blood samples is regulated by the Human Tissue Act 2004. All work with Human Tissue Samples must comply with the Act. Approval must be sort prior to work commencing from the appropriate Designated Individual. Approval will normally entail approval by a LREC or Licence obtained from the Human Tissue Authority (HTA).

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 viruses, and be clearly labelled as one of the following:

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

The Standard Precautions (section 3) MUST be taken when handling any blood sample.

Samples collected elsewhere
If at all possible samples should be obtained and used on University premises to avoid the additional hazards associated with transport. If this is not possible communication channels should be established with the organisation sending the sample to ensure a risk assessment is done.

As a minimum the organisation sending the samples should follow the guidance outlined below. 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.

Transport of samples elsewhere
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 below.

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

Transport of Dangerous goods in Private vehicles

Transport of Samples containing Category A infectious agents by private vehicle / public transport is not permitted.

Transport of Samples containing Category B infectious agents by private vehicle / public transport.

If substances are packed in accordance with packing instruction P650 they are not subject to any other requirements of ADR.

*University driving policy requires persons using private vehicle for work purposes must be insured for business purposes, consult with Faculty H&S advisor.*

Guidance/ good practice suggests the package must be,
- Concealed from public view – either by placing in the boot or concealing in an anonymous package such as a shopping bag.
- Must not be left unattended at any time
- Employee must carry University ID at all times

Should the packaged become lost, the person responsible must make every attempt to trace it whereabouts as soon as possible. This may involve contacting the relevant operator (Transport for London, British Rail)

Lost package should be reported to the Health & Safety Department as a dangerous occurrence.
Appendix 1 - Donor Information Sheet

This donor information sheet is to be read by all donors prior to EVERY occasion that blood is taken. Donors are asked to consider the questions posed carefully and decide for themselves if it is appropriate to continue with the donation.

Donors are required to sign to say they have read this sheet as part of the consent process.

The donation of blood for research or teaching is voluntary, and individuals volunteering should not be placed under any pressure to donate. You do not have to agree to give a blood sample nor explain if you choose not to. Refusal will have no effect on your employment or on your status or marks if you are a student. You will be given an explanation of what your blood will be used for before it is taken. Any personal information provided by you in connection with the donation will be held in confidence.

Prior to donating blood you should complete the national blood service lifestyle screening questionnaire to ascertain whether you should donate blood. http://www.blood.co.uk/pages/flash_questions.html

The questions below are intended to prompt you to deciding whether you should give blood today. If you answer YES to any of the questions you should not give blood.

- Are you unwell at the moment?
- Do you know you are, or think you may be, infected with HIV (the AIDS virus) Hepatitis B or Hepatitis C?
- Have you had a sexual partner who is infected with Hepatitis B, Hepatitis C, or HIV?
- Have you given blood in the last month (if more than 100ml is requested)?
- Are you pregnant, think you may be, or are woman with a baby less than 9 months old?
- Are you taking any prescribed medicine, tablets or other treatments (except HRT for the menopause, the pill or other birth control)?
- Are you anaemic or receiving treatment for anaemia or iron deficiency?
- Have you jaundice or hepatitis?
- Have you had acupuncture, ear, face or body pierced, had a tattoo or any cosmetic treatment that involved piercing your skin in the last 12 months?
- Are you a man who has ever had oral or anal sex with a man, with or without a condom?
- Have you ever been given money or drugs for sex?
- Have you ever injected yourself or been injected with illegal or non-prescribed drugs including body-building drugs or cosmetics (even if it was only once or a long time ago)?
- In the last 12 months have you had a sexual partner who has been given money or drugs for sex or injected drugs?
- In the last 12 months have you ever had a sexual partner who may ever have had sex in parts of the world where AIDS/HIV is very common (this includes most countries in Africa)?
- In the last 7 days have you seen a doctor, dentist, or any other healthcare professional or are you on the waiting list to see one?
- Have you received medical treatment outside the UK in the last 12 months?
- Have you had any hospital investigation, tests or operation in the past 12 months?

If you have any query or concern about your suitability to donate blood please ring Occupational Health who can discuss the situation and assist you in making your decision.

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### Appendix 2 - Staff / Student Volunteer Donor Consent Form

**Donor details:**

<table>
<thead>
<tr>
<th>Surname</th>
<th>First Name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth</td>
<td>Sex</td>
</tr>
</tbody>
</table>

**I have read the donor information sheet:** YES/NO

**I agree to provide a blood sample for use by:**

**I have been informed of the following:**

<table>
<thead>
<tr>
<th>The quantity of blood to be taken</th>
<th>(specify amount)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The frequency of blood donations – if repeat donations are required</td>
<td>(specify frequency)</td>
</tr>
<tr>
<td>The use that will be made of the sample</td>
<td>(specify use)</td>
</tr>
<tr>
<td>Any tests for disease, or markers of disease, which will be undertaken while the sample can be identified as originating from me</td>
<td>(specify which, if any)</td>
</tr>
</tbody>
</table>

**I agree to the sample being stored for possible further uses in future:** YES/NO

(For regular donors) I understand I should not give blood if I develop one of the conditions listed in the Donor information sheet YES/NO

**Donor signature:**

<table>
<thead>
<tr>
<th>Date:</th>
</tr>
</thead>
</table>

**Signature of person taking blood:**

<table>
<thead>
<tr>
<th>Date:</th>
</tr>
</thead>
</table>

Name and contact details of person taking blood
Appendix 3 - 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
- Spillage kit
- Alcohol hand gel

Procedure
- Gather all equipment together and particularly 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 (DoH 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
• Dispose of all soiled material into a yellow clinical waste bin
• Clean hands once procedure completed

Safe Sharps Practice

• 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. Also see the emergency procedures outlined in Appendix 4

• Seal the container with biohazard tape and send for incineration. Consult your building Safety Advisor or Laboratory Manager about disposal of sharps containers.
Appendix 4 - 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

**If first aid treatment is required dial 3333**

- 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 on 01483 686690 or if out of hours please go to Royal Surrey County Hospital Accident and Emergency Department.

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