

## INFORMATION SHEET

### Using and Taking Clinical Samples for Research

#### 1.0 Scope

The scope of this document includes the requirements for taking/ using blood or bodily fluids from healthy volunteers including consent, record keeping, training, vaccinations, personal protective equipment (PPE), and reporting incidents. It does not include the procedures for taking the samples or the research associated with it.

Anyone who is volunteering to donate blood should be made aware of the contents of this document.

#### 2.0 Introduction

This document outlines the requirements for taking/ using blood or bodily fluids from healthy volunteers for research at Swansea University (SU) to ensure compliance is met and standards maintained.

Human blood/ bodily fluids should be treated as potentially infectious and should be used as a minimum, at biological containment level 2. Following a risk assessment, a higher degree of containment maybe required. The main hazards include the transmission of communicable diseases such as Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

Blood/ bodily fluids can be donated by volunteers for research purposes providing they have given consent. They should not feel pressurised into giving blood/ bodily fluids and must always have the right to withdraw use of their sample at any time after it has been taken.

**Laboratory workers MUST NOT use their own blood/ body fluids as part of their research.**

#### 3.0 Requirements

##### 3.1 Approval

Before any work commences the PI must ensure all ethics approval and requirements of the Human Tissue Act (HTA) are approved and in place, and any relevant risk assessments have been approved by the University Biological Hazards and GMO Sub-Committee.

Please see the following for university processes and procedures:

- [Human Tissue Act - Swansea University](#)
- [Laboratory Safety - Swansea University](#)

### 3.2 Consent

Consent should be obtained before any sample is taken. The individual must not be pressured into giving any sample and should be made aware that consent can be withdrawn at any time. Any individual gaining consent should ensure the consent form/ study is approved by the Health Research Authority or the SU ethics committee and has to comply with their requirements, even if the sample is not stored and should follow the HTA SOP - Obtaining Informed Consent, which can be found on [HTA QMS Pages](#).

Any individuals gaining consent should have the following training that is available free from [NIHR Learn Website](#):

- Consent
- Good Clinical Practice

Blood should only be taken from healthy volunteers, donors will not be screened for infectious diseases, however donors are encouraged to check the advice on [Can I donate? - Welsh Blood Service \(welsh-blood.org.uk\)](#) and should be advised to only donate if they are eligible.

Potential donors who have a fear of needles or have had an adverse reaction in the past, such as fainting should be discouraged from donating and could provide a fingerpick for other studies where appropriate.

The individual donor should be informed of the following prior to any blood being taken:

- The volume of blood to be taken.
- What it will be used for, this may include a description of what you do such as methods and what the samples will not be used for e.g., genotyping.

Consent forms can be found at [HTA Forms and Templates - Swansea University](#)

### 4.0 Frequency

When taking blood, the blood taker should ensure the donor has not donated blood to the blood service in the last 6 months, and no more than 500ml of blood is be taken from a volunteer in a 6-month period.

### 5.0 Records

The PI is responsible for ensuring all records are stored securely for 10 years as per university guidance [Data Protection and GDPR - Swansea University](#).

The data recorded should include:

- Volume taken.
- Name of the person using the sample.
- Disposal.
- Storage, etc.

- [HTA Forms and Templates – Swansea University](#)

## 6.0 Taking blood

### 6.1 Training

Any persons taking blood should be trained and hold a certificate of competence. Training can be provided by external training providers.

Where blood is drawn i.e., less than 1ml and does not require venepuncture e.g., finger prick test, training provided locally.

Training records should be kept [HTA Forms and Templates - Swansea University](#).

### 6.2 Immunisation

Anyone taking or working on blood/ blood products should have a Hepatitis B vaccination, and a booster every 5 years.

It is the responsibility of the PI to ensure everyone is aware of the requirement to have a vaccination, and the responsibility of the individual taking or working with blood to organise their vaccination.

Please contact Occupation Health (OH) to arrange [occupational-health@swansea.ac.uk](mailto:occupational-health@swansea.ac.uk).

### 6.3 Designated space

The blood taking location should be:

- Away from microbiological, chemical, radiation work and where food and drink are prepared/ consumed.
- Large enough to accommodate the chair/ bed equipment, etc. and large enough to accommodate in the event of a donor fainting.
- Have hand washing facilities.
- Impervious work tops.
- Cleanable floor in the event of a spillage.

## 7.0 Emergency/ First Aid

When taking blood there should be a qualified first aider/medical practitioner present in the near vicinity to deal with the individual, this should be covered as part of the training.

Following an exposure to blood or other body fluids e.g., sharps injury, please follow the OH guidance below.

For skin exposures, the exposed site should be immediately cleansed by:

- Encouraging the wound to bleed by flushing with water (squeezing the wound to express blood is not recommended).
- The site should be washed with soap and water. Small wounds and punctures may also be cleansed with an antiseptic, for example an alcohol-based hand hygiene solution. Alcohol is viricidal to HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV). Other antiseptics, such as iodophors, chloroxlenol, and chlorhexidine also inactivate HIV.

In cases of mucosal exposure:

- The exposed mucous membranes should be flushed with a copious amount of water. Eyes should be irrigated with saline or water.

For further information please see [NHS guidance needlestick injury](#).

## 8.0 Transporting samples

Depending on where samples are taken, they may need to be transported. If blood is taken in the lab all samples should be placed in a rack prior to moving. If samples are taken in a separate location or transported from outside the building, the samples should be placed in an approved transport bag UN3373.

## 9.0 Spills

Spillages may occur due to breakages in the laboratory, during transportation or when taking the sample. In this instance the spillage should be cleaned up using the following procedure:

- Wearing a pair of non-sterile gloves.
- Use tongs or a pan and brush to pick up any container as soon as possible and place the containers in the red lidded anatomical waste bin.
- Using a disposable paper towel absorb as much of the spill as possible as dispose of into the red lidded anatomical waste bin.
- Wipe with water and detergent until visibly clean.
- Saturate the area with fresh virkon solution or use a biological spill kit.
- Disinfect and rinse off the tongs under running water and place to dry.
- Waste guidance - [wmqn24 Anatomical waste human animal non chemical and chemically preserved](#).

## 10.0 Reporting

If an individual has received a sharps injury that maybe contaminated with bodily fluids whether this is taking blood, working in the lab, or on clinical placement they should contact the OH department by emailing [occupational-health@swansea.ac.uk](mailto:occupational-health@swansea.ac.uk) who will then pass to a nurse who will contact them for details.

Any accidents/ near misses (including exposure to blood and bodily fluids) when taking blood/samples or in the work area should also be reported through the University Adverse Event system [Report it - Swansea University](#)

If a study is operating under HTA or intending to hold in future under HTA and a specimen was lost or persons were exposed to blood and body fluids the incident should be recorded on the [HTA 03 FORM Adverse Event Reporting Form](#).

## 11.0 Sharps

Advice and guidance on the safe use of sharps can be found in the [Sharps in Laboratories, Healthcare and Allied Practices Policy Arrangements](#).

All sharps should be disposed of in a yellow lidded clinical waste bin, when the bin is filled to the fill line it should be disposed of in line with University waste policy [wmgn26 infectious and chemically contaminated solid waste and sharps waste](#).

## 12.0 Personal Protective Equipment

PPE to be used includes:

- Lab coat.
- Clean disposable apron.
- Clean nonsterile nitrile gloves.
- Face covering.
- Where appropriate, eye/ face protection should also be used.

**If taking blood**, the PPE should be clean and separate to PPE used in the laboratory.

## 13.0 References

Human Tissue Authority [Find out what the HTA can do for you | Human Tissue Authority](#)

University guidance [Human Tissue Act - Swansea University](#)

WHO guidelines on drawing blood: best practices in phlebotomy. 2010

Welsh Blood Service [Welsh Blood Service \(welsh-blood.org.uk\)](#)