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| TITLE: | MMU Human Tissue Act (HTA) Guidelines For Blood Sampling Via Venepuncture & Cannulation Standard Operating procedure (SOP) |
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| **SOP Author**  Your signature verifies that to the best of your knowledge this document is accurate and complies with Manchester Metropolitan University (MMU) and all department policies and procedures and any applicable regulatory standards and requirements.  **Author:** Jason Ashworth  **Date:**  \_\_\_11/07/2024\_\_\_\_\_\_\_\_\_\_  **Job Title:**  Principal Lecturer |
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| **SOP Subject Matter Expert (SME) Reviewer**  Your signature/approval verifies that you have reviewed this document and to the best of your knowledge it is accurate and complies with all with MMU and all department policies and procedures and any applicable regulatory standards and requirements.  **Reviewer:** Garry Pheasey **Date:**  23/10/2024  **Job Title:** Person Designated |
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| **SOP Approver**  Your signature/approval approves this document for use; that you consider the activities identified within are accurate and sufficient for successful execution by trained operators and the document complies with MMU and all departmental policies and procedures and any applicable regulatory standards and requirements.  **Approved by:** \_Hans Degens\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** \_23/10/2024\_\_\_\_\_\_\_\_\_\_\_  **Job Title:**  \_Designated Individual\_\_\_\_\_\_\_\_ **Signature:** |

# Introduction/SCOPE

Background

The University has introduced a quality management system for the governance of the acquisition, storage, and use of human tissue.

This system will ensure that all work is carried out to the highest standard and that the University complies with the licensing obligations of the Human Tissue Act (HTA, 2004).

This SOP forms part of a suite of SOPs (MMUHTA\_001 – MMUHTA\_019) that support implementation of the quality management system and should be used as directed in [Manchester Metropolitan University’s HTA Code of Practice](https://www.mmu.ac.uk/sites/default/files/2023-06/MMU%20HTA%20Code%20of%20Practice_V1.2_0.pdf).

## Purpose

This SOP aims to set out a standard template for Blood Sampling Via Venepuncture & Cannulation that falls under the Human Tissue Act (2004).

## Scope

All Manchester Metropolitan University staff participating in work/projects involving relevant material

# definitions and abbreviations

SOP - Standard Operating Procedure

HTA - Human Tissue Act

Human Tissue - Any, and all, constituent part/s of the human body containing cells

PI - Principal Investigator

DI - Designated Individual

PD - Person Designated

# Responsibilities

It is the responsibility of all Manchester Metropolitan University personnel taking blood samples to follow this procedure.

# references and ASSOCiaTED DOCUMENTS

[HTA Codes of Practice of Standards](https://www.hta.gov.uk/guidance-professionals/codes-practice)

# Safety Requirements

Please refer to MMU HTA risk assessment: RA 002 Receiving and storing of Specimens. [RA\_002 Receiving and Storing of Specimens V1.2.docx](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.mmu.ac.uk%2Fsites%2Fdefault%2Ffiles%2F2023-06%2FRA_002%2520Receiving%2520and%2520Storing%2520of%2520Specimens%2520V1.2.docx&wdOrigin=BROWSELINK)

# Procedure

General

Any student or member of staff taking blood samples must have successfully completed a phlebotomy course and adhere to the procedures described here. Lab coats and disposable gloves must be worn when taking blood samples and when handling body fluids or materials which may have been in contact with any bodily fluids.Wherever blood sampling is taking place, appropriate information on first aiders should be clearly displayed. Members of staff participating in blood sampling procedures are encouraged to obtain a first aid qualification.

Screening Process

Before taking blood, informed consent must be obtained and several screening questions (shown below) must be answered by the patient/participant. Before giving consent patients/participants should be informed of any discomfort that may arise from the blood sampling procedure and be given the opportunity to ask questions. If participating in a research study, volunteers should complete an additional medical screening questionnaire before undertaking any experimental trials/activities.

Please Inform the Phlebotomist if you have/had any of the Following:

1. Any current evidence of haematoma/inflammation.

2. Current infection.

3. Any device in situ.

4. Vascular grafts or fistulae.

5. If you have a history of mastectomy, or planned mastectomy in the future.

6. Cardiovascular event (stroke)

7. If you have fainted in the past when phlebotomy has been performed.

8. If you suffer from anxiety attacks in relation to needles or blood.

9. If you have been diagnosed with any blood borne illnesses such as hepatitis, or HIV.

10. Please talk to your phlebotomists about any concerns you may have i.e. if you prefer to lie down or if from previous experience you feel you know which veins are usually reliable.

Following completion of consent forms and the screening procedure, the phlebotomist will undertake the blood sampling procedure, ensuring bleeding stops and the participant feels sufficiently well enough before leaving the premises.

Hand Washing

Hand washing is recognised as the single most effective method of controlling infection. There are two populations of microbes present on the hands. These are transient micro-organisms (temporary microbes superficially present on the skin surface) and resident micro-organisms (established microbes that populate the skin). Good practice in hand washing consists of prior removal of jewellery, nail polish and artificial fingernails; the use of running water, a liquid/foam antibacterial wash (to remove resident microbes) and thorough drying of skin with disposable paper towels. Cuts, abrasions and other skin lesions must be covered with an occlusive waterproof dressing. Examples of antiseptic solutions are: chlorhexidine, iodophors and triclosan.

Blood Sampling

Venepuncture and intravenous cannulation are to be carried out only by staff that have provided evidence of their ability to perform the technique.

* Never Re-Sheath Needles
* Never Re-Use Needles or Cannulae
* Always Wear Gloves When Handling Blood Samples

Finger prick sampling may be carried out by other laboratory users after instruction from supervisors. However, an experienced individual should be present. Always wear gloves. Never re-use finger prick lancets (e.g. Autoclix) and NEVER pipette by mouth.

If containers or surfaces become externally contaminated, clean these with sterilising agents (e.g. alcohol wipes or Milton’s reagent). Do not answer the telephone with gloves on because blood droplets from the outside of the gloves could become deposited on the phone.

Handling of Blood

Viral Hepatitis. A cautionary note:

Whole blood, serum, plasma, and other blood products can be infectious, and transmission of the infectious agent from these materials can lead to serious diseases such as hepatitis B (serum hepatitis), a serious disease of viral origin that can lead to permanent liver damage and death. Thus, a high standard of personal hygiene and care is essential when handling such specimens.

There are two main types of hepatitis caused by viral infection. Viral type A hepatitis is responsible for the occasional outbreaks of ineffective hepatitis, and it is thought that infection is transmitted by the oral-faecal route. However, viral type B hepatitis is typically transmitted from blood to blood and is of major concern when taking blood samples. For example, receiving an injection from a contaminated needle, accidentically pricking oneself with a needle used to withdraw blood from an infected subject, or allowing even a small scratch to become contaminated with infected blood.

The incidence of the carrier state of hepatitis B is low in the general population. Although the virus is rare in the general population, precautions must be taken to prevent unintended spread of the virus by observing a simple code of practice based on elementary principles of hygiene wherever human blood is taken from subjects. Similar precautions apply with respect to other blood-borne viruses (BBV) such as human immunodeficiency virus (HIV). Medical screening questionnaires completed prior to participation should include the likelihood of hepatitis or HIV infection.

Code of Practice for Obtaining Blood Samples

The procedure outlined below should always be followed with the greatest care to minimise the risk of infection:

1. Ascertain whether the subject has ever suffered from hepatitis or if they are known to be a hepatitis carrier (the same applies for HIV and other blood borne diseases). If so, it would be wise to exclude the individual from the study to limit the risk of infection of the experimenter, unless the aim of the investigation is to study patients suffering from these disorders.
2. Set out a tray in an organised fashion. It should include a vacutainer/lancet (Autoclix), sterile swab, paper tissues, cotton wool, gauze, plaster, disposals box (biohazard) and yellow biohazard bags.
3. Wash hands with soap (see hand washing procedures).
4. Label the tubes clearly.
5. Put on protective gloves.
6. Swab the site and dispose of the swab into a blood disposables bag.
7. Obtain the sample.
8. Dispose of the vacutainer/lancet/needle/syringe etc into a sharps box. The district health authority will arrange suitable disposal.
9. Swab off excess blood using light pressure and dispose of the swab into a disposables box once the bleeding has stopped.
10. Put a cotton pad onto the site of entry and tape onto the arm.
11. Any spillage and equipment concerned with drawing blood should be cleaned/washed with 2% Hycolin Concentrate and then with 5 mg/l Chlorhexidene made up in 70% spirit or another suitable disinfectant.
12. The gloves should be disposed of in a biohazard bag.
13. Following blood collection, it is good practice to again wash and dry your hands.
14. As a matter of good practice, all surfaces that may have encountered any biological fluid, including blood, should be washed with a suitable disinfectant.

Sharps Injury

To reduce the risk of exposure to blood-borne viruses (BBV), sharps must be disposed of correctly according to local health and safety policy, and the safe handling and disposal of sharps should be part of an overall strategy of clinical waste disposal. A sharps injury could result in the transmission of a range of infections shown below (risk shown in brackets):

* Localised skin infection
* Septicaemia
* Malaria and syphilis
* Hepatitis B (1:3)
* Hepatitis C (1:30)
* HIV (1:300)

If you obtain a sharps injury it is very important that you act quickly and seek medical advice from a trained healthcare professional. Post Exposure Prophylaxis (PEP) will involve:

* an assessment of the risk of exposure
* a programme of treatment
* counselling and support.

There is currently no PEP available for Hepatitis C. For HIV, some anti-retroviral choices are available. Medication/risk assessment should be taken at the earliest possible opportunity as delay in receiving prophylaxis (if required) could affect the outcome. It is recommended that following a sharps injury:

* Bleeding from the wound is encouraged but do not suck the wound site.
* Wash the area thoroughly with warm running water and soap.
* Cover with water-proof dressing.

The incident form should also be completed (see SOP MMUHTA\_002; [MMUHTA\_002 Adverse Event Reporting V1.3.docx](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.mmu.ac.uk%2Fsites%2Fdefault%2Ffiles%2F2023-06%2FMMUHTA_002%2520Adverse%2520Event%2520Reporting%2520V1.3.docx&wdOrigin=BROWSELINK)).

There is a vaccine available to give active immunity to hepatitis B. It is recommended that individuals taking blood should be vaccinated. Information on this can usually be obtained from a general practitioner or occupational health.

Handling and Storage of Human Blood Samples

Handling, storage and collection of human blood samples must comply with the Human Tissue Act, 2004 (https://www.legislation.gov.uk/ukpga/2004/30/contents). The Human Tissue Act 2004 regulatory aim is: “to create an effective regulatory framework for the removal, retention, use and disposal of human tissue and organs in which the public and professionals have confidence”. The following procedures should be adhered to when handling and storing blood samples:

* Each blood sample must receive a unique identification number (ID) that anonymously identifies it as belonging to a particular ethics-approved study.
* Blood samples must be kept in sealed and anonymously labelled containers that bear no sensitive patient details/data.
* Blood samples must be handled, transported, and stored strictly according to Health and Safety Regulations and Local Ethics Approval.
* An inventory and tracking system must be implemented to record information relating to the physical location, usage, and disposal of each blood sample.
* Blood samples that are no longer required, or when consent is withdrawn, must be sent for appropriate disposal (See Clinical Waste Collection and Disposal).

Clinical Waste Collection and Disposal

It is the user’s responsibility to dispose of used sharps as soon as possible after the use. The used sharps should be disposed safely:

* Dispose syringes and needles as a single unit.
* Always dispose used sharps into properly constructed containers/bins that meet requirements of BS 7320: 1990 Specification for sharps containers. Clinical waste disposal containers are available for purchase from several companies (i.e. Stericycle, UK).
* Always carry a sharps container/ bin by the handle and away from the body.
* Label or tag disposed sharps containers/bins with the name of the institution and date.
* Sharps container/bins must be sealed/locked and taped before collection for disposal.
* Sharps containers must be securely stored until collected by the local clinical waste contractor: Stericyle SRCL Ltd, Knostrop Treatment Works, Knowsthorpe Lane, Leeds, LS9 0PJ.

# Summary of ChaNGES

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| **Version** | **Date** | **Summary of Changes** | **Author** | **Training Requirements \*1,2,3** |
| 1.0 | 14th June 2021 | New document | Jason Ashworth | 1 |
| 1.1 | 25th November 2022 | A new SOP was added to the suite therefore writing changed to state ‘SOPs (MMU-HTA001 – MMU-HTA016)’ rather than SOPs (MMU-HTA001 – MMU-HTA015) |  | 3 |
| 1.2 | 30th January 2023 | Changed writing to state ‘SOPs (MMU-HTA001 – MMU-HTA018)’ rather than SOPs (MMU-HTA001 – MMU-HTA016) |  | 3 |
| 1.3 | 3rd March 2023 | Author & Reviewer fields added to title table + changed writing to state ‘SOPS (MMU-HTA001 – MMU-HTA019)’ rather than SOPs (MMU-HTA001 – MMU-HTA018) + minor grammatical & formatting changes |  | 3 |
| 1.4 | 23-10-2024 | Updated the SOP format  Made document accessible to meet ‘[The Public Sector Bodies (Websites and Mobile Applications No. 2) Accessibility Regulations 2018](http://www.legislation.gov.uk/uksi/2018/952/contents/made)’ law | Sarika Ellul  Gemma Hughes  Jason Ashworth  Emma Columbine | 3 |

\*Training Requirements:

1 – new document or revised document that requires full training

2 – revised document that requires limited training

3 – revised document that requires no additional training