



SOP Name	Collection and Handling of Biological Materials
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1. SCOPE

This SOP applies to all applicable staff, researchers and research staff working in the VACCELERATE.

2. PURPOSE

The purpose of this procedure is to describe the safety guidelines for the collection and handling of biological materials: blood, urine and faeces.

3. POLICY

VACCELERATE works within the guidelines and regulations of the EU CT Directive 2001/20/EC, GCP Commission Directive 2005/28/EC, ICH/GCP and with all other local and international applicable regulatory requirements.

4. ROLES AND RESPONSIBILITIES

It is the responsibility of the research personnel carrying out this procedure to ensure that all steps are completed both competently and safely.

5. DEFINITIONS

None

6. RELATED DOCUMENTS

LAB001 Whole blood processing

LAB004 Processing urine

LAB005 Processing faeces

SPREP001 Venepuncture

SPREP002 Collection and handling of bio materials

SPREP003 Core lab sample receipt and storage

SPREP004 Courier packages

SPREP005 Sample handling

7. PROCEDURE

S 7.1

Equipment:

- Personal protective equipment: gloves
- Appropriate blood tubes and specimen containers

7.2. Collection of Biological Materials

- 7.2.1 Research personnel should wear gloves at all times during biological material collection.
- 7.2.2 Research personnel should use appropriate barrier protection such as gloves, gowns, masks and protective eyewear to prevent exposure to skin and mucous membranes when working with known infectious research participants.
- 7.2.3 Research personnel should ensure the correct disposal of sharp needles using the puncture-resistant incineration container.
- 7.2.4 Research personnel will take care to prevent needle stick injuries when using and disposing of needles. Local policy and procedures should be followed in the event of a needle stick injury.
- 7.2.5 Research personnel should ensure that the lids of the specimen containers are securely placed so that leakage does not occur during transport.
- 7.2.6 Using gloves, spillages should be covered with Milton or "Presept" granules, mopped up with paper towels and discarded into puncture-resistant incineration containers.

7.3 Handling of Biological Materials

- 7.3.1 Research personnel should be aware of the correct procedures for the handling of biological materials. All research personnel should receive the appropriate training when admitted to local research laboratory facilities.
- 7.3.2 All research personnel should receive the appropriate

immunisation as per local policy and procedures prior to working with potentially infectious materials. Regular control of immunisation status should be performed as per local policy and procedures.

7.3.3 All biological material collected should be treated as being potentially infectious for blood-borne diseases regardless of their own infectious status.

7.3.4 Universal precautions should be applied to all blood, body fluids and tissue specimen collections, regardless of their infectious status even when they do not contain visible blood.

7.3.5 Research personnel should use appropriate barrier protection, such as gloves, gowns, masks and protective eyewear to prevent exposure to skin and mucous membranes when working with biological materials.

7.3.6 After processing of research sample the original container should be disposed of in the waste bins provided, after the top has been resealed to prevent leakage.

7.3.7 Gloves should be changed after the handling of each biological material or when contaminated and should be disposed of correctly in the appropriate waste disposal bins provided.

7.3.8 Hands should be washed immediately after removing gloves, using a hand washing technique defined by local standardised procedures.

7.3.9 Specimens of biological materials (for example blood) should

be placed in a secure secondary container to prevent breakage and leakage during transport and transported in accordance with relevant regulations.

9. REVIEW AND REVISION

To be revised: May 2022

10. DOCUMENT HISTORY

Version Number	Effective Date:	Summary of changes from previous version:	Edited by: (name and role)
01	24-05-2021		