1.0 PURPOSE

The purpose of this document is to establish the procedure to collect, process and store blood, blood products, and urine for the AIDS and Cancer Specimen Resource (ACSR). Blood, blood products and urine samples are collected from patients with informed consent.

2.0 SCOPE

This standard operating procedure (SOP) describes how blood products and urine should be collected, processed and stored. This SOP applies to all personnel from ACSR Regional Biospecimen Repositories (RBRs) and affiliates that are responsible for processing blood, blood products and urine specifically for the ACSR. The SOP does not cover detailed safety procedures for handling biohazardous material and it is recommended that personnel follow institutional biosafety guidelines.

3.0 REFERENCE TO OTHER ACSR SOPS OR POLICIES

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all personnel from ACSR RBRs and affiliate sites that are responsible for obtaining blood, blood products and urine for storage.

<table>
<thead>
<tr>
<th>ACSR Personnel</th>
<th>Responsibility/Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Nurse or Research Technician</td>
<td>Obtain Patient Consent.</td>
</tr>
<tr>
<td>Clinic nurse or phlebotomist</td>
<td>Assists with blood and urine collection.</td>
</tr>
<tr>
<td>Research Technician/Technologist</td>
<td>Transport and process specimen, label vials, data entry and storage.</td>
</tr>
</tbody>
</table>
### 5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

<table>
<thead>
<tr>
<th>Materials and Equipment</th>
<th>Materials and Equipment (Site Specific)</th>
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</thead>
<tbody>
<tr>
<td>ACSR Collection Form</td>
<td>The ACSR Collection Form will include patient and specimen identifiers.</td>
</tr>
<tr>
<td>Cryo marking pen, pre-labeled container, or preprinted labels.</td>
<td>Specimen labels might be hand written on the specimen container. Pre-printed labels or pre-labeled containers might be used.</td>
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<tr>
<td>Personal Protection Equipment (PPE)</td>
<td>Gloves, gown/scrubs, lab coat, face shield, etc. as appropriate for the environment.</td>
</tr>
<tr>
<td>Sterile specimen container for urine</td>
<td>VWR# 15704-085 or Fisher #14-828-320</td>
</tr>
<tr>
<td>Various cooling materials in appropriate containers. (wet ice, dry ice, liquid nitrogen and/or isopentane.)</td>
<td>Freezing processes vary at different sites. Each follows these guidelines to maintain high quality molecular integrity.</td>
</tr>
<tr>
<td>Appropriate storage containers</td>
<td>Storage containers vary by site and should be appropriate for the type of specimen.</td>
</tr>
<tr>
<td>Blood collection vials</td>
<td>Blood might be collected in tubes with EDTA/ sodium heparin/ACD for whole blood or with coagulation factors for serum.</td>
</tr>
<tr>
<td>Laboratory gloves</td>
<td>VWR #82026-426 or Fisher #19-130-1597C</td>
</tr>
<tr>
<td>Swing bucket centrifuge with capped buckets</td>
<td>Beckman Allegra X22</td>
</tr>
<tr>
<td>Ice bucket or Styrofoam container</td>
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</tbody>
</table>

[http://acsr.ucsf.edu](http://acsr.ucsf.edu)
Various pipettors and tips as appropriate for the volume of fluid. | VWR pipets: 1ml #89130-892, 2ml #89130-894, 5ml #89130-896, 10ml #89130-898 or VWR disposable transfer pipet #414004-002
---|---
Cryovials and screw cap microfuge tubes. | Nalgene #5000-0020, Nalgene 5000-0012, Sarstedt # 72.730.005, Sarstedt# 72.694.005
Phosphate buffered saline (PBS) Ca, Mg free | VWR # 45000-446
Sodium azide | Macron Fine CHEMICALS Cat# 1953.
Scalpel blade | VWR # 21909-612
Needle/sharps disposal unit | VWR #19001001
-80 freezer

6.0 DEFINITIONS

See ACSR Glossary.

7.0 PROCEDURES

This procedure is intended to ensure that blood, blood products and urine obtained from consented participants are collected and processed in a safe and efficient manner while eliminating the risks of contamination and loss,

7.1 Special Safety Precautions

7.1.1 Comply with "Universal Precautions" when collecting and handling all specimens.

7.1.2 Use PPE (personal protective equipment) in accordance with collecting institution’s guidelines.

7.1.3 Standard best-practice working procedures include careful manipulation of the patient samples, disinfection of countertops and equipment used during testing, and disposal of biohazard waste into appropriate receptacles.

http://acsr.ucsf.edu
7.2 Verification of Identification Information on Collection Vessels
As applicable, verify the accuracy of patient information (in keeping with privacy and ethical policies) and ensure that it corresponds with the information on labels on collection tubes. Ensure that all personnel are trained in the use of the filing system.

7.3 Collection, General Considerations
7.3.1 Prepare Collection form and collection vessels.
7.3.2 Collection forms include: patient identifiers, date and time of collection, warm ischemia time, cassette/vial identifiers, and the final location of the cassette or vial in the inventory.
7.3.3 The time between collection and freezing should be less than 6 hours.
7.3.4 Keep the specimen on ice or refrigerated if not processed immediately.

7.4 Blood processing, whole blood
7.4.1 Whole blood collected in lavender top EDTA or green sodium heparin vials can be aliquotted in 2ml cryovials.
7.4.2 Annotate collection form and label collection vials with coded identifiers.
7.4.3 Remove the rubber/plastic stopper.
7.4.4 Using a 5ml pipette, transfer the blood from the collection tube to the cryovials (1-2 ml/vial).
7.4.5 Transfer vials to -80°C freezer.

7.5 Blood processing, serum
7.5.1 Blood collected for serum will be in a red top tube.
7.5.2 Centrifuge blood for 20 minutes @ 250-400xg at 4°C.
7.5.3 Annotate collection form and label collection vials with coded identifiers.
7.5.4 Check that the clot is tightly seated at the bottom of the tube.
7.5.5 Annotate the form if the serum is “pink”. This indicates that hydrolysis of the red blood cells has occurred and may affect downstream molecular analyses.
7.5.6 Using an extra-long pipette tip, transfer 1ml volumes of serum to 2ml cryovials.

7.5.7 Using gentle suction from the pipette tip, carefully transfer the clot to a sterile surface (tissue culture, petri dish).

7.5.8 Using a scalpel blade, cut the clot into manageable pieces and transfer them into 2ml cryovials.

7.5.9 If whole blood is collected in EDTA or sodium heparin tubes, skip steps 7.5.6 and 7.5.7.

7.6 Urine

7.6.1 Centrifuge urine for 20 minutes @ 250-400xg at 4°C.

7.6.2 Collect 5ml of cleared urine.

7.6.3 Aliquot into cryovials at 1ml volumes.

7.6.4 Add sodium azide to the urine to a final concentration of 5μM.

7.6.5 Keep on ice until ready to freeze.

7.6.6 Decant or aspirate the remaining fluid carefully. Do not disturb the cell pellet.

7.6.7 Re-suspend cells in 3-5ml PBS.

7.6.8 Transfer the cell suspension to 1-3 screw cap microfuge tubes depending on the size of the cell pellet.

7.6.9 Spin the cells in a 4°C microfuge for 1 minute.

7.6.10 Decant the supernatant.

7.6.11 Wash the cells twice in 1ml PBS.

7.6.12 Spin the cells in a 4°C microfuge for 1 minute.

7.6.13 Pipette or aspirate off the remaining PBS.

7.6.14 Snap freeze cells in liquid nitrogen.

7.6.15 Transfer vials to -80°C freezer.

7.7 Collection, Data record.

7.7.1 Data collection must be done at the time of tissue collection.

7.7.2 Data might be documented electronically at the time of collection or on paper and then entered into a database at a later time.
7.7.3 Paper documents (collection forms and consent forms) containing patient health information are stored in a locked room in a locked cabinet.

7.7.4 Electronic data is secured through institutional firewalls and is password protected.

7.7.5 Electronic data is formatted in excel and uploaded to the ACSR database at regular intervals.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 NCI Best Practices for Biospecimen Resources

8.2 Declaration of Helsinki.


8.4 US National Biospecimen Network Blueprint

http://bioethics.georgetown.edu/nbac/hbm.pdf

8.6 Blood Collection: Routine Venipuncture and Specimen Handling.
http://library.med.utah.edu/WebPath/TUTORIAL/PHLEB/PHLEB.html

8.7 Canadian Tumour Repository Network Standard Operating Procedures
http://www.ctrnet.ca/operating-procedures
8.8 Texas Cancer Research Biobank (http://txcrb.org/)


9.0 APPENDICES

10.0 REVISION HISTORY

<table>
<thead>
<tr>
<th>SOP Number</th>
<th>Date revised</th>
<th>Author</th>
<th>Summary of Revisions</th>
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