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| AIDS and Cancer Specimen Resource (ACSR)         | Effective Date: August 2018 |
| Technical: Blood Products Body Fluids Collection | Version 2.0                 |
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## 1.0 PURPOSE

The purpose of this document is to establish the procedure to process and store blood, blood products, and urine for the AIDS and Cancer Specimen Resource (ACSR).

## 2.0 SCOPE

This standard operating procedure (SOP) describes how blood products and urine should be 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 AIDS Cancer Specimen Resource Regional Biorepositories and affiliates process and bank biospecimens under site specific approved Human Subjects Protocols. Biospecimens, Samples, Aliquots and Derivatives are entered into the ACSR database when consent for banking and research use have been verified by the Protocol PI or ACSR designee. Each RBR and affiliate site is responsible for Human Subjects compliance as per their institutional guidelines and their local approved Human Subjects Protocol. 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

ACSR SOP Tech009 Biospecimen Handling

ACSR SOP Tech010 Biospecimen Labeling

## 4.0 DEFINITIONS

| Term/Acronym       | Definition  |
|--------------------|---|
| ACSR               | AIDS and Cancer Specimen Resource   |
| Aliquot            | The sample has the original characteristics of the original or parent specimen but in smaller quantities (1 FFPE block vs unstained sections from the FFPE block)         |
| Biospecimen        | Human material such as urine, blood, tissue stored in a biorepository for use in laboratory research. For the ACSR this is considered the original or parent biospecimen. |
| Biospecimen vessel | A sterile container used to transport biospecimens such as: urine cup, draw tube, conical tube or capped vessel.  |

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| Derivative            | The original characteristics of the specimen are changed (FFPE vs DNA derived from FFPE).  |
| PBS                   | Phosphate buffered saline  |
| PPE                   | Personal Protective Equipment such as gloves, lab coat, face shield.   |
| RBR                   | Regional Biorepository   |
| Sample                | This is an aliquot, derivative or if the Parent Specimen received is stored as a whole specimen, it is referred to as a sample, as per ACSR database definition.   |
| SOP                   | Standard Operating Procedure. A set of written instructions that document a routine or repetitive activity followed by an organization.  |
| Specimen              | The same as Biospecimen. Human material such as urine, blood, tissue stored in a biorepository for use in laboratory research. For the ACSR this is considered the original or parent biospecimen/ specimen. |
| Transport Vessels     | A sterile container used to transport biospecimens such as: urine cup, draw tube, conical tube or capped vessel.   |
| Universal Precautions | This is an approach to infection control to treat all human blood and certain human body fluids as if they were known to be infectious for HIV, HBV and other bloodborne pathogens,                          |

## 5.0 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.

| ACSR RBR Personnel | Responsibility/Role  |
|--------------------|--|
| ACSR Staff Member  | Process biospecimen, label vials, perform data entry and record storage. |

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## 6.0 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

| Materials and Equipment   | Materials and Equipment (Site Specific or equivalent)   |
|---|---|
| Biospecimen/Processing form   |   |
| Cryo marking pen, pre-labeled container, or preprinted labels.  | Biospecimen labels may be hand written on the biospecimen container (Statmark #SMP-BK). Pre-printed labels or pre-labeled containers may be used. |
| Personal Protection Equipment (PPE)   | Gloves, gown/scrubs, lab coat, face shield, etc. as appropriate for the environment.  |
| Sterile specimen container for urine  | VWR#15704-085 or Fisher # 14-828-320  |
| Various cooling materials in appropriate containers. (wet ice, dry ice, liquid nitrogen and/or isopentane.) | Freezing processes vary at different sites. Each follows these guidelines to maintain high quality molecular integrity.                           |
| Appropriate storage containers  | Storage containers vary by site and should be appropriate for the type of biospecimen.  |
| Blood draw tubes  | Blood might be collected in tubes with EDTA/sodium heparin/ACD for whole blood or with coagulation factors for serum.                             |
| Swing bucket centrifuge with capped buckets   | Beckman Allegra X22   |
| Ice bucket or Styrofoam container   |   |
| 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, and Mg free   | VWR # 21909-612   |
| Sodium azide  | Macron Fine CHEMICALS Cat#1953  |

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| Scalpel blade               | VWR # 21909-612 |
| Needle/sharps disposal unit | VWR # 19001001  |
| -80 freezer                 |                 |

## 7.0 PROCEDURES

This procedure is intended to ensure that blood, blood products and urine 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 handling all biospecimens.

**7.1.2** Use PPE in accordance with the institution's guidelines.

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

### 7.2 Verification of Identification Information on Transport Vessels

As applicable, verify the accuracy of patient information (in keeping with privacy and ethical policies) and ensure that it corresponds with the label information on draw tubes or transport vessels. Ensure that all personnel are trained in the use of the ACSR database and local electronic information system(s).

### 7.3 General Considerations

**7.3.1** Prepare Biospecimen form and biospecimen vessel(s).

**7.3.2** Biospecimen form information may include: coded patient identifiers, date and time of collection, warm ischemia time, cassette/vial/tube identifiers, and the final location of the cassette/ vial /tube in the inventory.

**7.3.3** Treat all tissue as potentially infectious and use appropriate PPE.

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**7.3.4** If possible, minimize the time between collection and freezing.

**7.3.5** Keep the specimen on ice or refrigerate at 4°C 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 aliquoted in 1mL into 2ml cryovials.

**7.4.2** Annotate collection form and label storage 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 and record location.

**7.5** Blood processing, serum

**7.5.1** Blood collected for serum will be in a red top (clotting) tube.

**7.5.2** Centrifuge blood for 20 minutes @ 250-400xg at 4°C.

**7.5.3** Annotate collection form and label storage 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 processing 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).

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**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 Processing

**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 @250-400xg 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 @250-400xg for 1 minute.

**7.6.13** Pipette or aspirate off the remaining PBS.

**7.6.14** Snap freeze cells in liquid nitrogen. Label vials.

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**7.6.15** Transfer vials to -80°C freezer or liquid nitrogen storage as per RBR resources and record location.

**7.7** Record data

**7.7.1** Data should be recorded at the time of tissue acquisition or as soon as possible thereafter.

**7.7.2** Data may be documented electronically at the time of acquisition or on paper and then entered into a database at a later time.

**7.7.3** Paper documents (biospecimen forms) containing patient health information are stored in a locked room in a locked cabinet or scanned and saved electronically on a secure drive.

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

**7.7.5** Electronic data may be entered into the ACSR database or formatted in Excel and uploaded to ACSR database at regular intervals.

**8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES**

**8.1** NCI Best Practices for Biospecimen Resources

<http://biospecimens.cancer.gov/practices/default.asp>

**8.2** Declaration of Helsinki.

<http://www.wma.net/en/30publications/10policies/b3/index.html>

**8.3** Best Practices for Repositories IV. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). Feb 2018 <http://www.isber.org/?page=BPR>

**8.4** US National Biospecimen Network Blueprint

<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>

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**8.5** National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999.

<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/>

**8.9** Preece, Ann., H.T. (ASCP), 1972. A Manual for Histologic Technicians, 3<sup>rd</sup> ed., Little Brown and Company, Boston.

## 9.0 APPENDICES

Not applicable.

## 10.0 REVISION HISTORY

| SOP Number | Date revised | Author    | Summary of Revisions   |
|------------|--------------|-----------|--|
| Tech005    | 3-28-2018    | MS/TY/BGG | Replace sample with biospecimen, formatting and definitions. |
|            |              |           |  |
|            |              |           |  |
|            |              |           |  |