1.0 PURPOSE

The purpose of this document is to outline general procedures that can be used to ensure proper labeling for the AIDS and Cancer Specimen Resource (ACSR). Proper labeling prevents loss of biospecimens due to inadequate identifying information.

2.0 SCOPE

This standard operating procedure (SOP) describes how biospecimens should be labeled. This SOP applies to all personnel from the ACSR Regional Biospecimen Repositories (RBRs) and affiliates that are responsible for labeling specimens 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 Tech002 Solid Tissue Collection

ACSR SOP Tech003 Oral Biospecimen Processing and Storage

ACSR SOP Tech004 HPV Biospecimen Processing

ACSR SOP Tech005 Blood Products Body Fluids Collection

ACSR SOP Tech006 Live Tissue Collection

ACSR SOP Tech009 Biospecimen Handling

4.0 DEFINITIONS

This SOP applies to all personnel from ACSR RBRs and affiliates that are responsible for processing and storing biospecimens.

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 (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.
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.
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 the processing of biospecimens for storage.

ACSR RBR Personnel	**Responsibility/Role**
ACSR staff member	Transport and Process blood
Tumor bank Director, Manager, or Principal Investigator	Responsible for Operation and Quality Assurance at tumor bank

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 Form	
Cryo marking pen, pre-labeled container, or preprinted labels	
Personal protection equipment (PPE)	Gloves, gown/scrubs, lab coat, face shield, etc as appropriate for the environment
Laboratory gloves	VWR#82026-426 or Fisher #19-130-1597C
Appropriate Labels such as Cryogenic Thermal Transfer-Tags	Brady #PTL-76-490
Computerized Inventory system	
Label printer	Brady-Mark TLS PC Link #TLSPC
Label scanner	Brady 103522 #Cr1200

7.0 PROCEDURES

This procedure is intended to ensure that biospecimens are appropriately identified and tracked to eliminate the risks of biospecimen misidentification and loss.

7.1 SPECIAL SAFETY PRECAUTIONS

7.1.1 Comply with “Universal Precautions” when collecting and handling all biospecimens.

7.1.2 Use PPE (personal protective equipment) 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 Tubes

As applicable, verify the accuracy of coded 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 ACSR database and local electronic information system(s).

7.3 Labeling of Biospecimens

7.3.1 Label all level of receptacles containing human biospecimens or products, from the smallest unit (cryovial, histological slide, or filter) to the large storage units.

7.3.2 Make sure that each label used adheres tightly to the receptacle under all projected storage conditions. Do not use labels that will come off in liquid nitrogen or under specific conditions of heat or cold used for processing or storage.

7.3.3 Make sure the printing on the labels is resistant to all common laboratory solvents and water (e.g., use a cryomarker, cold-resistant label, waterproof/solvent-proof pen, thermal-transfer printer).

7.3.4 Test adherence of labels to containers as well as different types of marking ink under different storage conditions before implementing the labelling method for routine use.

7.3.5 Only include information on the label that is compliant with applicable privacy legislation. Do not include patient identifying information. Identifying information such as name, date of birth, health insurance number, etc. must not be on the label.

7.3.6 However, the information should be specific enough so that the encoded information (e.g., unique identifier or tracking number assigned by tumor biobank) can be associated with the biospecimen in the database.

7.3.7 If there is sufficient space on the label, additional information may be included. Only include static information. Caution: Inclusion of dynamic information will cause relabeling.

7.3.8 Consider labelling by computer and not by hand, as this will eliminate problems that arise due to variations in handwriting and misreading of labels.

7.3.9 If possible, use a bar coded labelling system in addition to labeling that includes human readable identification of contents.

7.4 Record data

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

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

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

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

7.4.5 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 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

8.5 US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

9.0 APPENDICES

Not applicable.

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
Tech010	3-28-2018	RH/TY/BGG	Biospecimen for sample, formatting and add definitions