1.0 PURPOSE

The purpose of this document is to establish the procedure to bank oral biospecimens for the AIDS and Cancer Specimen Resource (ACSR).

2.0 SCOPE

This standard operating procedure (SOP) describes how oral rinse biospecimens should be processed, accessioned and stored. This SOP applies to all personnel from ACSR Regional Biospecimen Repositories (RBRs) and its affiliates that are responsible for processing oral rinse biospecimens. 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 (I 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.

DMSO	Dimethyl sulfoxide
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.
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 processing of oral biospecimens for storage.

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

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)**
Sterile 15 ml or 50 ml polypropylene centrifuge tubes	BD Flacon 350296 and BD Flacon 352070
2.0 ml cryotubes	Nalgene #5000-0020
1.0 ml cryotubes	Nalgene #5000-0012
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.
Centrifuge	Beckman Allegra X22
Microcentrifuge	
Pipets	VWR disposable pipet #414004-002
DMSO	Sigma #D2348
PBS, Ca/Mg-Free	VWR #45000-446
Laboratory gloves	VWR #82026-426 or Fisher #19-130-1597C
Sufficient appropriate labels for collection tubes	
Biospecimen/ Processing Worksheets	
Personal Protection Equipment (PPE)	Gloves, gown/scrubs, lab coat, face shield, etc. as appropriate for the environment.
-80 C Freezer	

7.0 PROCEDURES

This procedure is intended to ensure that oral samples are 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 biospecimen, disinfection of countertops and equipment used during testing, and disposal of biohazard waste into appropriate receptacles.

7.2 Verification of Identification Information on Biospecimen Vessel

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

7.3 Accessioning of Samples

Accession cell pellet and supernatant samples into ACSR inventory database system as per established procedure for the site-specific inventory system and affix appropriate labels on the vials.

7.4 Processing of Samples

7.4.2 If shipped frozen in conical tube, allow oral rinse biospecimen to thaw at room temperature or according to local SOP.

7.4.3 Centrifuge at 3400 rpm (4000 g) for 10 minutes.

7.4.4 Using an appropriate disposable transfer pipette, aspirate off the supernatant/saliva mouthwash layer into a maximum of four 2 ml cryovials.

7.4.5 Decant remaining supernatant into waste bucket, taking care not to dislodge the cell pellet. Label tube appropriately.

7.4.6 Place the 2 ml cryovials of supernatant in appropriate freezer storage units. For long-term storage, -80° C or colder is recommended.

7.4.7 Record the position and location of the tubes.

7.4.8 Resuspend the cell pellet in 2 ml of PBS, then vortex or pipet up and down.

7.4.9 Transfer cell pellet suspension in equal parts into two 1 ml cryovials. Label tubes appropriately.

7.4.10 Microcentrifuge the cryovials for approximately 1 minute, 250-400g.

7.4.11 Decant PBS into waste bucket, taking care not to dislodge the cell pellet.

7.4.12 Resuspend the cell pellet in 0.9 ml PBS and 0.1 ml of DMSO.

7.4.13 Place the 1 ml cryovials with the cell suspension in a control rate freezer container and place in a -80ºC freezer overnight.

7.4.14 After 8 hours, cryovials may be moved to a liquid nitrogen freezer for long term storage.

7.4.15 Record the position and location of the tubes.

7.5 Record data

7.5.1 Data should be recorded at the time of biospecimen acquisition or as soon as possible thereafter.

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

7.5.3 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.

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

7.5.5 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://biospecimnes.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

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 Canadian Tumour Repository Network Standard Operating Procedures http://www.ctrnet.ca/operating-procedures

8.7 Texas Cancer Research Biobank(http://txcrb.org/)

8.8 Preece, Ann., H.T. (ASCP, 1972. A Manual for Histologic Technicians, 3rd ed., Little Brown and Company, Boston

9.0 APPENDICES

Not Applicable.

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
Tech003	3-28-18	AL/TY/BGG	Replace sample with biospecimen, formatting and definitions.