

AIDS and Cancer Specimen Resource (ACSR)	Effective Date: 06/15/2015
Technical: Oral Specimen Processing and Storage	Version 1.0
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1.0 PURPOSE

The purpose of this document is to establish the procedure to collect oral specimens for the AIDS and Cancer Specimen Resource (ACSR). Oral specimen samples are collected from patients with informed consent.

2.0 SCOPE

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

ACSR Personnel	Responsibility/Role
Research Coordinator or Equivalent	Obtain Patient Consent
Clinician	Collect expectorated oral rinse material from patient
ACSR Staff Member	Transport and Process oral specimen

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.

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Materials and Equipment	Materials and Equipment (Site Specific)
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
Centrifuge – capped rotor cups	Beckman Allegra X22
Microfuge	
Pipettors	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	Brady PTL-76-490
Specimen Collection/Processing Worksheets	ACSR Specimen Collection Form.
Personal Protection Equipment (PPE)	Gloves, gown/scrubs, lab coat, face shield, etc. as appropriate for the environment.
-80 C freezer	

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6.0 DEFINITIONS

See ACSR Glossary.

7.0 PROCEDURES

This procedure is intended to ensure that oral samples 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.

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 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

7.4.1 If shipped frozen in conical tube, allow oral rinse specimen to thaw.

7.4.2 Centrifuge at 3400 rpm for 10 minutes.

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- 7.4.3 Using an appropriate disposable transfer pipette, aspirate the supernatant/saliva mouthwash layer into a maximum of four 2 ml cryovials.
- 7.4.4 Decant remaining supernatant into waste bucket, taking care not to dislodge the cell pellet.
- 7.4.5 Place the 2 ml cryovials of supernatant in appropriate freezer storage units. For long-term storage, -80°C or colder is recommended.
- 7.4.6 Record position and location of the tubes.
- 7.4.7 Re-suspend cell pellet in 2 ml of PBS, then vortex or pipet up and down.
- 7.4.8 Transfer cell pellet suspension in equal parts into two 1 ml cryovials.
- 7.4.9 Microfuge for approximately 1 minute.
- 7.4.10 Decant PBS into waste bucket, taking care not to dislodge the cell pellet.
- 7.4.11 Re-suspend cell pellet in 0.9 ml PBS and 0.1 ml of DMSO.
- 7.4.12 Place the 1 ml cryovials of cells in a control rate freezer container and place in a -80°C freezer overnight.
- 7.4.13 After 8 hours, cryovials may be moved to a liquid nitrogen freezer for long term storage.
- 7.4.14 Record position and location of the tubes.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- 8.1 NCI Best Practices for Biospecimen Resources
<http://biospecimens.cancer.gov/bestpractices/2011-NCIbestpractices.pdf>
- 8.2 Best Practices for Repositories: Collection, Storage, and Retrieval of Biological Materials for Research, International Society for Biological and Environmental Repositories (ISBER).
http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/ISBER_Best_Practices_3rd_Edi.pdf

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9.0 APPENDICES

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions