



AIDS and Cancer  
Specimen Resource

AIDS and Cancer Specimen Resource (ACSR)	Effective Date: August 2018
Standard Operating Procedure SOP	Version 1.0
ACSR SOP ID# Tech016 SOP of SOPs	Page 1 of 7
Approved by ACSR Executive Committee	July 2018

**1.0 PURPOSE**

To define the process for creating, revising, approving, maintaining, and retiring Standard Operating Procedures(s) (SOP) used in support of the AIDS and Cancer Specimen Resource (ACSR). All ACSR SOPs should use the format and sections as outlined in this SOP.

**2.0 SCOPE**

This procedure defines activities for SOPs created and revised by the Quality Working Group (QWG) and approved by the ACSR Executive Committee (EC).

**3.0 REFERENCE TO OTHER ACSR SOPS OR POLICIES**

ACSR Quality Management Plan

**4.0 DEFINITIONS**

Term/Acronym	Definition
Standard Operating Procedure (SOP)	A set of written instructions that document a routine or repetitive activity followed by an organization.
ACSR	AIDS Cancer Specimen Resource
QWG	ACSR Quality Working Group
EC	ACSR Executive Committee
Revision History	A brief summary in bullet form of changes made to a document during a revision cycle.
Form	A document with blank spaces for the insertion of details or information (may include figures, flowcharts, or diagrams).
Template	A guidance document with a preset format, used as a starting point for a particular application so that the format does not have to be recreated each time it is used.
Master List	List of active SOPs
Master Log	List of all versions of SOPs including retired SOPs.



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Approval Date	The date an SOP is approved by Executive Committee (EC).
Active SOP Folder	An electronic folder of active SOPs.
Retired SOP Folder	An electronic folder of retired SOPs.
Effective Date	The date of SOP implementation.
SOP Binder	A set of effective or retired SOP procedures and associated documents maintained in a binder(s).

## 5.0 ROLES AND RESPONSIBILITIES

This SOP applies to all personnel from ACSR RBRs and affiliate sites.

<b>Role</b>	<b>Responsibility</b>
Author	Creates and revises SOPs in accordance with this procedure.
Technical Reviewer	Reviews SOP for accuracy and content.
Operator	Follows the SOP as specified. Performs duties as assigned by this procedure. Ensures that SOPs and any associated documents are current, approved and effective prior to use.
Executive Committee	Approves SOP. Performs other duties as assigned by this procedure.



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Quality Working Group	<p>Provides draft SOP and associated document(s). Reviews SOP for accuracy, content, and compliance to industry and company regulations. Verifies adherence to processes outlined within this procedure. Routes SOPs for final approval. Notifies impacted areas when an SOP interval review is required. Notifies impacted areas when a new or revised SOP is implemented. Maintains the SOP Master Log sheet (version) and SOP Master List.</p> <p>Maintains and archives SOPs. Recommend retirement of SOPs.</p>
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## 6.0 MATERIALS, EQUIPMENT AND FORMS

NA

## 7.0 PROCEDURES

These procedures are intended to ensure that ACSR SOPs are produced, revised, and followed.

### 7.1 SOP Creation and Revision

- 7.1.1 The author will ensure that a new SOP number is requested from the QWG.
- 7.1.2 The author will create or revise a SOP using the approved ACSR template.
- 7.1.3 For the revision of existing documents, the author will request the current effective editable version of the SOP and associated documents from the QWG.
- 7.1.4 The author enters the following information into the header and/or footer of the SOP, as appropriate:
  - 7.1.4.1 ACSR logo



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**7.1.4.2** Effective date

**7.1.4.3** SOP title

**7.1.4.4** SOP version

**7.1.4.5** SOP number

**7.1.4.6** Page x of y

**7.1.4.7** Approval date

**7.1.5** The author shall create or revise an SOP that includes the following sections as appropriate:

1.0 Purpose

2.0 Scope

3.0 References to other SOPs

4.0 Definitions and Acronyms

5.0 Roles and Responsibilities

6.0 Materials, equipment, and forms

7.0 Procedures

8.0 References

9.0 Appendices: Forms and/or Templates

10.0 Revision History

**7.1.6** The author may not delete any of the required sections. Any section that is not applicable for a given SOP shall be documented as "Not applicable or N/A".

**7.1.7** Rows can be added or deleted from the tables as needed.

**7.1.8** Additional information can be added as an appendix.



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- 7.1.9** The author shall create or revise SOP form(s) and/or template(s) as deemed necessary,
- 7.1.9.1** The header must include a Form Title, Form number, Revision number, and Page number(s).
- 7.1.9.2** Creation of a new form and/or template to an SOP revision will require a new revision number to the entire SOP in order to incorporate the use of a new auxiliary document.
- 7.1.9.3** Form and/or template may not be revised independent of the SOP.
- 7.1.10** The author will indicate “New SOP” in the SOP Revision History section when creating new procedures.
- 7.1.11** Steps that do not directly impact processes do not need to be recorded in the revision history (i.e., format changes).
- 7.1.12** For SOP revisions, the electronic draft of the SOP and any associated forms are submitted by the author to the QWG with all changes tracked.
- 7.1.13** The QWG will submit the SOP draft electronically to the appropriate reviewer(s) of the impacted area(s) for their review of the draft. Review must be completed with all changes tracked.
- 7.1.14** The SOP draft will be routed by the QWG accordingly. When the SOP has completed routing with review(s), the QWG will then submit the SOP back to the author to reconcile any questions, comments and/or suggested revisions.
- 7.1.15** The SOP draft review process will continue until a final review is completed by the QWG.

**7.2 SOP Approval**

- 7.2.1** The QWG shall route an official copy of the document to the author, or designee, to obtain signatures.
- 7.2.2** Signatories will provide acknowledgement of review of the SOP and agreement that the information is complete, accurate and ready for approval by the ACSR EC by signing and dating the signature page.



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**7.2.3** The official copy of the SOP must be approved for use by the following:

**7.2.3.1** Author

**7.2.3.2** QWG

**7.2.3.3** ACSR EC

**7.3 SOP Review Interval**

**7.3.1** Each SOP will be reviewed annually by the QWG.

**7.3.2** A revision of an SOP or its associated forms and/or templates may occur at any time prior to the SOP review interval.

**7.3.3** The QWG will electronically email the current effective editable version of the SOP and associate document(s) and follow the procedure beginning from section 7.0.

**7.3.4** When SOPs are revised, changes and rationale will be recorded in the revision history at the end of the SOP.

**7.3.5** For a review interval that is listed on the SOP, but does not require changes, no revision number will be assigned.

**7.3.6** If no changes are made to the SOP during the periodic review interval, the revision history will indicate "No Changes."

**7.4 SOP Retirement**

**7.4.1** The QWG will provide written notification with rationale/justification to the ACSR EC for SOP retirement approval.

**7.4.2** After the ACSR EC approval of the SOP retirement, the QWG will:

**7.4.2.1.1** Notify impacted areas of retirement by electronic notification.

**7.4.2.1.2** Update the SOP Master Log and Master List.

**7.4.2.1.3** Remove the SOP from the Effective SOP Binder.



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**7.4.2.1.4** Add the retired SOP to the Retired SOP Binder with associated rationale.

**8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES**

**9.0 APPENDICES**

Not applicable.

**10.0 REVISION HISTORY**

SOP Number	Date revised	Author	Summary of Revisions