1.0 PURPOSE

The purpose of this document is to establish the procedure to monitor and assess the quality of the Organizational Components (Office of the Chairs, Executive Committee, Hub for Integrated Informatics and Research Support and Working Groups) in the AIDS and Cancer Specimen Resource (ACSR).

2.0 SCOPE

This standard operating procedure (SOP) describes the minimum assessment required to evaluate the quality of the Organizational Components by utilization of the Self Audit Checklist.

3.0 REFERENCE TO OTHER ACSR SOPS OR POLICIES

ACSR SOP Tech014 Quality Assurance

4.0 DEFINITIONS

Term/Acronym	Definition
ACSR	AIDS and Cancer Specimen Resource
ACSR Management	ACSR staff designated by their official job title and descriptions as a Principal Investigator, Manager or Director.
Assessment	The gathering of information on the condition of a process or activity for evaluation of such.
Competence	An individual's demonstration of knowledge of key concepts, ability to apply knowledge and skills, or adequately perform a task.
Conformity	Fulfillment of a requirement, or compliance with a set standard.
Corrective action	Action to eliminate the cause of a detected nonconformity or other undesirable situation; **NOTE 1:** There can be more than one cause for a nonconformity; **NOTE 2:** Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.
Deviation	A change from what is usual or expected. Deviations can apply to any documented policy, process or procedure as well as behavior.
Document	Information and its supporting medium; **NOTE:** This may be paper-based or electronic. Examples include Standard Operating Procedures and Pathology Reports.

Error	A deviation from truth, accuracy, or correctness; a mistake.
EC	Executive Committee
Failure	In the broadest sense, a case when the system does not meet user or customer expectations; **NOTE:** This includes the inability to perform its intended functions satisfactorily or within specified performance limits.
Form	A paper or electronic document on which information or results are captured; **NOTE:** Once completed, a form becomes a record.
HIIRS	Hub for Integrated Informatics and Research Support
Objective	Planning element that delineates in detail how to accomplish a specific goal at the process level.
OC	Office of the Chairs
Policy	A documented statement of overall intentions and directions defined by those in the organization and endorsed by management.
PI	Principal Investigator
Procedure	Specified way to carry out an activity of a process. A procedure is a set of instructions that describes the stepwise actions taken to complete activities identified in processes.
Process	Set of interrelated or interacting activities that transform input into outputs.
Quality System Essentials	Management foundation of interrelated processes that support the laboratory's path of workflow for quality management.
RBR	Regional Biorepository
Record	Document stating results achieved or providing evidence of activities performed. Some examples include freezer logs, incident reports, the master equipment file, etc.
SOP	Standard Operating Procedure. A set of written instructions that document a routine or repetitive activity followed by an organization.
Validation	Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled; **NOTE:** Examples include validation of the process to use a new diagnostic tool, such as an automated laboratory test system or information system; or evidence-based medicine.
WG	Working Group

5.0 ROLES AND RESPONSIBILITIES

This SOP applies to all the Organizational Units of the ACSR.

ACSR Personnel	Responsibility/Role
Office of the Chairs, Executive Committee, Hub for Integrated Informatics and Research Support, and Working Groups	Performs Self-Audit
Quality Working Group	Receipt of report of findings and summarize findings and report to EC.

6.0 MATERIALS, EQUIPMENT AND FORMS

Self-audit forms.

7.0 PROCEDURES

These procedures are intended to ensure that the ACSR Organizational Units are performing their designated tasks.

7.1 SPECIAL SAFETY PRECAUTIONS

Not Applicable.

7.2 Self-Assessment

7.2.1 At end of first quarter of the grant year, the Quality Working Group will initiate the self-audit process of the OC, EC, HIIRS and Working Groups.

7.2.2 Each organizational component will perform the self-audit utilizing the specific documentation for assessment of the entity and submit the report to the QWG by the specified date.

7.2.3 The QWG will summarize findings, make recommendations and present to the EC.

7.3 Quality Assurance Reporting

7.3.1 Each ACSR Organizational Unit will provide the QWG a Quality Assurance Summary Report.

7.3.2 The QWG will review self-assessments and provide recommendations to the EC.

7.3.3 The EC will provide guidance for improvement based on the QWG recommendations.

7.3.4 The QWG will summarize the results at the Annual Meeting prior to grant progress report submission.

7.3.5 The QWG or EC may request additional self-auditing of the organization units, to resolve any questions or problems regarding quality assurance.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 NCI Best Practices for Biospecimen Resources
http://biospecimens.cancer.gov/practices/default.asp

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

8.3 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

8.4 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

9.0 APPENDICES

9.1 ACSR Working Group Self Audit Form

ACSR WORKING GROUP SELF AUDIT

Please, keep responses concise and within the constraints of the text box.

Working Group Name: _____ Grant Year: _____

1. Restate the overall purpose of the working group (250 characters)

2. What were the goals of the working group for the grant year?

Briefly summarize the outcomes for each goal and action item.

Goal 1 (250 characters):

Action items for Goal 1 (450 characters):

Goal 2 (250 characters):

Action items for Goal 2 (450 characters):

Goal 3 (250 characters):

ACSR WORKING GROUP SELF AUDIT

Action items for Goal 3 (450 characters):

Goal 4 (250 characters):

Action items for Goal 4 (450 characters):

Goal 5 (250 characters):

Action items for Goal 5 (450 characters):

3. Were the meeting minutes structured to reflect the goals and objectives of the WG as well as action items?

Please either attach the meeting minutes template for your group or attach the minutes of a recent meeting highlighted to show the goals addressed.

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions