UT Health San Antonio
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Department of Population Health Sciences
Clinical Research Informatics Division

STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP. SDLC-008	**Title: System and Data Decommissioning**	
Version No.: 1.0	**Effective Date: April 11, 2023**	**Page 1 of 3**
Supersedes Version: N/A **Dated:** N/A	REQUIRED APPROVALS BELOW	
CRI Director:	DocuSigned by: Bill Sanders	**Date:** 4/17/2023
CISIL Approver 1:	DocuSigned by: Becki Gerwitz	**Date:** 4/17/2023
CISIL Approver 2:	DocuSigned by: Stephen Hargrove 5AEBB2C5776E46A...	**Date:** 4/18/2023

1.0 Purpose

This Standard Operating Procedure (SOP) establishes a process to decommission computer-based systems (applications) or data managed by CRI technical staff.

2.0 Scope

This procedure applies to all software applications and data managed by CRI Technical staff, regardless of where they may be hosted. This SOP does not pertain to physical devices (e.g., servers, PCs, laptops, etc.).

3.0 Responsibility

3.1 Technical Director: Assuring any decommissioned software, applications, and data complies with this SOP.

3.2 Senior Manager: Responsible for understanding any sponsor-required data destruction requirements and performs all functions related to tracking activities, managing resource allocation required for the software development process, and is the Technical Director's primary backup.

3.3 System Administrator: Performs all functions for establishing, managing, and maintaining Population Health Sciences' managed servers, software, network, and security.

3.4 Application User: Performs all functions related to the access and utilization of the installed software.

4.0 References

4.1 UT System: UTS 165 Information Resources Use and Security

4.2 21 CFR Part 11, Electronic Records; Electronic Signatures, March 20, 1997

4.3 General Principles of Software Validation: Final Guidance for Industry and FDA Staff, January 11, 2002, FDA

4.4 Texas State University Records Retention Schedule (URRS) Section 17.3

4.5 UTHSA HOP 2.2.1 Records Retention

5.0 Acronyms and Definitions

Term	Definition
COTS	Commercial Off the Shelf Software/System
CRI	Clinical Research Informatics
Decommission	To remove, retire, or deactivate from active service
HOP	Handbook of Operating Procedures
IMS	Information Management Services: UTHSA's central IT Operations
Post Award	Activities that occur during the project lifecycle
Pre Award	Activities that occur prior to the project lifecycle
SOP	Standard Operating Procedure
UTHSA	University of Texas Health Science Center San Antonio
VM	Virtual Machine: Used as a generic term to describe a server-based container that will host the software application or service.

6.0 Procedure

6.1 Decommission Project and Task Tracking

6.1.1 Before any planning, categorization, archiving, removal, or destruction, the Senior Manager will ensure that the project and tasks are created in the CRI Project Tracking and Task Management Systems.

6.2 Decommission Categorization

6.2.1 **Systems**: Before decommission, the software will be categorized based on if CRI, open source, or commercial COTS created it.

6.2.1.1 Created by CRI: Software will be archived.

6.2.1.2 Open Source: The software may be archived if any data is retained, and it is necessary to use a specific version of the software to read or manage data if required at a future date.

6.2.1.3 COTS: The software will be permanently removed from CRI or CRI-manged servers or VM.

6.2.2 **Data**: All data collected or managed by CRI will have a data management plan documenting any archive or destruction requirements, by UTHSA HOP 2.2.1 and Texas State University Records Retention Schedule (URRS) section 17.3.

6.3 System/Data Access

6.3.1 Once the project has been established and the decommission/destruction date decided, all user access to those systems/data will be severed.

6.4 Removing the System/Data From the Production environment

6.4.1 **Systems**: Based on the Decommission Categorization, the software will be archived to another CRI VM or removed from the hosting server.

6.4.1.1 System Archives are compressed files managed in the appropriate location based on the source system.

6.4.2 **Data:** Data will be removed from the production environment and processed following its data management plan.

6.5 Decommission Verification

6.5.1 The IT Director or project sponsor representative will verify that the system and data have been decommissioned following project requirements.

7.0 SOP Deviations

Deviations from this and all SOPs are handled according to CRI.POL.001 *Clinical Research Informatics Quality Management System (QMS)*.

8.0 Review & Revisions

Review and revisions of this and all SOPs are handled according to CRI.POL.001 *Clinical Research Informatics Quality Management System (QMS)*.

9.0 Attachments

NONE

10.0 Revision History

Version No.	Revision Date	Description of Revision