STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP. SDLC-001	**Title: External Software Installation and Verification**	
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Supersedes Version: N/A **Dated:** N/A	REQUIRED APPROVALS BELOW	
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1.0 Purpose

This Standard Operating Procedure (SOP) establishes the life-cycle to guide the design, procurement, configuration, customization, maintenance, and retirement of both open source and commercial offthe-shelf (COTS) software systems Clinical Research Informatics (CRI) at the UT Health San Antonio (UTHSA).

2.0 Scope

This procedure applies to all software applications that interact, manage, process, store, or support, confidential, informatics-related, research, and sensitive data under the stewardship of CRI used within a production environment. This SOP does not pertain to systems used in a prototype, development, or exploratory environment.

3.0 Responsibility

3.1 Technical Director: role bears responsibility for assuring any software written complies with this SOP.

3.2 Senior Manager: role 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: role performs all functions related to establishing, managing, and maintenance related to Population Health Sciences' managed servers, software, network, and security.

3.4 Database Administrator: role performs all functions related to configuration, interfacing, and optimization of any databases included in the installation package.

3.5 Application User: role 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 Good Practices for Computerised Systems in Regulated "GxP" Environments, PIC/S, September, 2007Guidance for Industry: Computerized Systems Used in Clinical Investigations, FDA, May 2007

5.0 Acronyms and Definitions

Term	Definition
COTS	Commercial off the Shelf
CRI	Clinical Research Informatics
CRUD	Create, Read, Update, Delete
DBA	Database Administrator
GxP	General abbreviation for the "good practice" quality guidelines and regulations.
IMS	Information Management Services: UTHSA's central IT Operations
SA	Systems Administrator
SOP	Standard Operating Procedure
UTHSA	University of Texas Health Science Center San Antonio
UTS	University of Texas System
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 Installation Categorization

6.1.1 Prior to project start, the software will be categorized based on its impact to confidential, informatics-related, research, and sensitive data based on **C**reate, **R**ead, **U**pdate, and **D**elete (CRUD) criteria.

6.1.1.1 Create, Update, Delete: Any software that will be configured to directly perform one of these operations will be classified has HIGH risk

6.1.1.2 Read: Any software that will be configured to ONLY perform this operation will be classified as LOW risk.

6.2 Project Tracking

6.2.1 Prior to undertaking any software installation, a project will be created in CRI's **Project Tracking System** by the Senior Resource Manager and the *Installation Categorization* (HIGH/LOW risk) will be logged.

6.2.1.1 Upon successful completion of the project in the tracking system, the appropriate tasks, based on the *Installation Categorization* (HIGH/LOW risk) will be created in CRI's **Task Management System**.

6.2.1.2 Any CRI faculty or staff involved with the software installation are required to track their effort, with notes, into the task tracking system.

6.3 Defining the Installation Environment(s)

6.3.1 Based on vendor license requirements, license restrictions, and CRI needs, software may be installed in Development, Test, and Production environments.

6.3.2 Software environments will be defined and documented in the **Project Tracking System** prior to establishing any hosting environments.

6.4 Establishing a hosting environment (new installation)

6.4.1 University Hosting

6.4.1.1 The system administrator will obtain a standard VM, with the appropriate operating system, from IMS via their ticketing system.

6.4.2 CRI Hosting

6.4.2.1 The system administrator will create and install the necessary VM, with the appropriate operating system, within the CRI server infrastructure

6.4.3 The System Administrator will verify that virtual storage pools and CPU core allocations are correct for the VM being installed.

6.4.4 The System Administrator will verify that the operating system configuration parameters are appropriate for the software package(s) to be installed, based on the installations instructions for the target software package(s)

6.4.5 The System Administrator will verify that the VM is functioning properly.

6.5 Preparing the existing environment (software upgrades, enhancements, components, etc.)

6.5.1 University Hosting

6.5.1.1 The System Administrator may request modifications to existing Universitymanaged system (VM) if required by vendor or application requirements.

6.5.2 CRI Hosting

6.5.2.1 The System Administrator may reconfigure, upgrade, or require additional resources based on vendor or application requirements.

6.6 Installation of Software Packages

6.6.1 The System Administrator will obtain software packages from the appropriate open source repository or, in the case of a vendor product, the vendor's distribution site, or provided media.

6.6.2 The System Administrator will install software packages following installation procedures provided by the vendor or, in the case of open source software, downloaded from the code repository site. All steps for vendor or open source installation are to be documented within the CRI Project Tracking or Task Management system based on the documentation being "Project" or "Task" based.

6.6.3 When multiple software packages are required to support a given application, the System Administrator will install these packages in the order specified in the installation procedure.

6.7 Configuration and Optimization

6.7.1 The Database Administrator, if required, will follow vendor or developer (for open source software) instructions to adjust configuration parameters in order to optimize any installed database management systems for the target application.

6.8 System Verification

6.8.1 A separate System, Database and/or Application User will verify that the installed software is installed as described in the Hardware and Software Component form and

that the installed software functions according to specifications provided by the vendor or open source developer/distributor.

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