



STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP. SDLC-007	Title: System Downtime	
Version No.: 1.0	Effective Date: February 28, 2023	Page 1 of 3
Supersedes Version: N/A Dated: N/A	REQUIRED APPROVALS BELOW	
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1.0 Purpose

This Standard Operating Procedure (SOP) establishes a process to manage planned and unplanned system downtime.

2.0 Scope

This procedure applies to all server systems and software applications managed by CRI Technical staff regardless of where they may be hosted.

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 outward communication and customer/client liaison, 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 technical related to Division supported applications and servers as well as any technical liaison communication with IMS or Vendor Support.

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 PHS CRI Business Continuity Plan

5.0 Acronyms and Definitions

Term	Definition
SOP	Standard Operating Procedure

This is a controlled document, and it is the recipient's responsibility to assure that they are using the most current version.

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CRI	Clinical Research Informatics
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.
IMS	Information Management Services: UTHSA's central IT Operations
Decommission	To remove, retire, or deactivate from active service
COTS	Commercial Off the Shelf Software/System
Pre Award	Activities that occur prior to the project lifecycle
Post Award	Activities that occur during the project lifecycle

6.0 Procedure

6.1 Planned Vs. Unplanned Downtime

6.1.1 All downtime will be categorized as “Unplanned” or “Planned”.

6.1.1.1 Unplanned: Any application or system downtime (system unavailable to users) initiated through user, system, or power fault.

6.1.1.2 Planned: Any application or system downtime (system unavailable to users) downtime initiated by CRI or CRI notification. It falls into two primary categories:

6.1.1.2.1 Urgent/Immediate: Urgent/Immediate downtime is initiated by the System Administrator in reaction to an anticipated system failure or a security-related event. The expectation is that this downtime will result in minimal system or data loss in the event of a system failure or unplanned downtime

6.1.1.2.2 Routine: Arranged in advance with system owners and used for scheduled events (e.g., upgrades, maintenance, etc.).

6.2 System Downtime, Recovery, and Communication Procedures

6.2.1 All activities related to the system downtime will be managed according to the PHS CRI Business Continuity/Disaster Recovery Plan.

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

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10.0 Revision History

Version No.	Revision Date	Description of Revision