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

Clinical Research Informatics Policy

Number: **CRI.POL-001**	**Title: Clinical Research Informatics Quality Management System (QMS)**	
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1.0 Purpose

The mission of Clinical Research Informatics (CRI) at UTHSA is to support knowledge generation toward improvement in human health through provision of data, information systems, and related services to clinical investigators and research teams. Accomplishing this mission requires ensuring the following manifesto:

(1) Data are handled in a manner compliant with applicable laws, regulations, and other requirements including research contracts and that privacy and confidentiality are maintained,

(2) Data are available when needed for use in human subject protection and institutional oversight,

(3) Data are capable of supporting study conclusions and other intended decision-making,

(4) Data are documented sufficiently to support reuse, research reproducibility, and replication, and

(5) Software and other computer programs developed or offered by CRI function as intended.

This policy establishes the CRI Quality Management System (QMS), i.e., the formal system of structure, processes, procedures, roles, responsibilities, resources and culture deemed necessary by our organization to consistently deliver products and services meeting customer, stakeholder and regulatory requirements. The QMS is comprised of those things, tangible and intangible, necessary to meet the CRI mission.

SOPs establish procedures that the institution deems compliant with applicable laws, regulations, and current quality standards. SOPs are intended to ensure consistency in data collection, management and use across projects by specifying required processes including the sequence, timing, documentation, and control of process steps as well as the institutional roles responsible for performing and overseeing them. Process important enough to document and control through SOPs will generate objective evidence that can be used to (1) enforce process steps, sequence and the manner in which they are carried out, (2) to detect when the process steps, sequence or performance diverge from expectations, and (3) to provide opportunity for intervention on a timescale commensurate with risk. This objective evidence, also called process documentation, is the mechanism through which process control and auditability are established.

SOPs are mid-level procedural documentation (Figure 1) in the CRI QMS and as such may be specified or required by institutional, school, department or division policy. In turn, SOPs may specify more detailed, step-by-step procedures. In Clinical Research Informatics (CRI), these more detailed procedures are called project-specific or system-specific work instructions. Work Instructions (WIs) provide step-by step directions to be followed in the performance of process steps. Adherence to SOPs and Work Instructions

is required. Guidelines may also accompany SOPs and suggest rather than require approaches to be followed and criteria to aid decision making about approach and methods.

SOPs, WIs, and guidelines may include as attachments such as documentation templates or job aids such as forms and checklists.

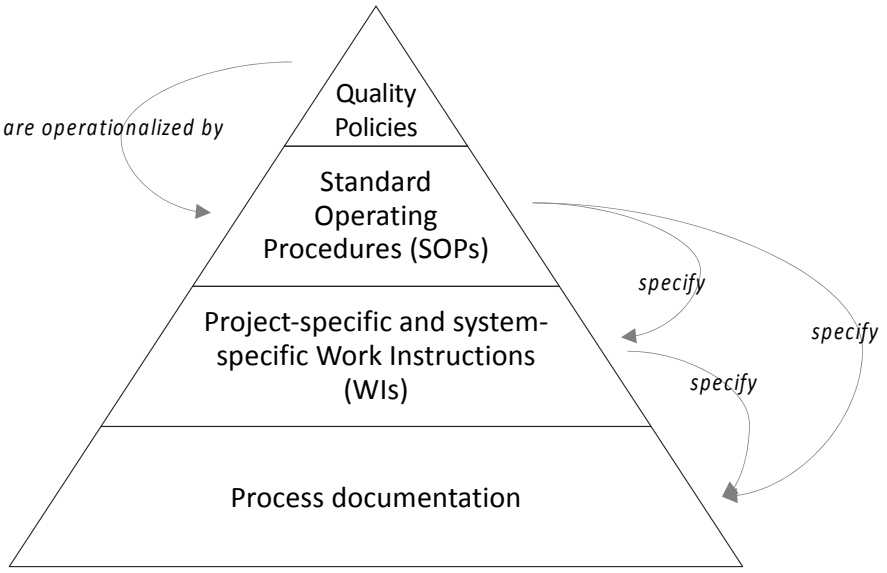


Figure 1: Quality Management System Documentation.

2.0 Scope

This policy establishes the Quality Management System (QMS) deemed necessary to meet the CRI mission. Four core CRI process areas are designated with each specified in a separate policy dedicated to the core process area.

- Human Resources Lifecycle Management (CRI.POL-002)
- Data Lifecycle Management (CRI.POL-003)
- Software Lifecycle Management (CRI.POL-004)
- Project Lifecycle Management (CRI.POL-005)

While having significant potential to impact other process areas, each process area represents a lifecycle that proceeds independently of the other areas. For example, CRI positions are filled and professionals are managed and developed irrespective of progress on data management and software development projects undertaken by the group. It is also the case that problems in any of the four core process areas can impede meeting the CRI mission on individual projects and organizationally. As such, each process area policy enumerates entailed mission critical processes and outlines the managerial, procedural and technical controls employed by CRI to ensure that the mission critical processes perform at the expected level. Together, CRI Policies 001 – 005 comprehensively specify the CRI QMS.

This policy provides for the maintenance and improvement of the CRI QMS over time by designating and specifying the following QMS processes applied across all core process areas.

- Formatting and document control of CRI policy, SOP and associated WI, and guideline documents and attachments
- Review, approval, and revision of CRI policy, SOPs and associated WIs, guidelines and attachments
- Management and documentation of planned and unplanned deviations from CRI SOPs,
- Identifying and undertaking Corrective And Preventative Action (CAPA) for CRI processes,
- Regularly assessing the effectiveness of the CRI QMS, and
- Prompting continuous improvement of the CRI QMS.

3.0 Responsibility

3.1 The CRI Directors are responsible for ensuring that data, information systems, and related services provided to clinical investigators and research teams meet their expectation, applicable regulations and other requirements and that CRI fulfills its mission.

3.2 The CRI Directors have elected a QMS approach to ensuring that CRI meets its mission and are responsible for the performance of the CRI QMS.

3.2.1 In accordance with Good Clinical Practice, ICH E6(R2), the CRI Directors will enumerate processes impacting human safety and research results and will design and document the enumerated processes.

3.2.2 The CRI Directors will assure that SOPs, associated WIs, guidelines and attachments specify processes sufficient for their performance by qualified individuals.

3.2.3 The CRI Directors will assure that SOPs, WIs, and guidelines specify process documentation sufficient for process control and auditability.

3.2.4 The CRI Directors will oversee implementation of and ensure compliance with CRI SOPs and WIs and appropriate application of CRI guidelines.

3.2.5 The CRI Directors will ensure that as essential documentation under ICH E6(R2), CRI SOPs and WIs are managed as version-controlled documents.

3.2.6 The CRI Directors will ensure that CRI Faculty and staff involved in collecting or managing data or in developing or maintaining information system systems used for data collection and management are qualified by education, experience and training for assigned responsibilities and are trained in CRI SOPs, WIs and guidelines relevant to the job tasks performed.

3.3 CRI Faculty and staff will adhere to policies, SOPs and WIs relevant to job tasks they perform and will notify CRI Directors when adherence will not be likely and has lapsed.

3.4 CRI Faculty and staff will use and complete necessary training on current versions of SOPs, WIs and attachments.

3.5 The CRI Directors will ensure that subcontractors and collaborators developing or maintaining information systems used to manage data for UTHSA studies or collecting or managing data for UTHSA studies have processes necessary to and achieve comparable quality.

4.0 References

4.1 ICH E 6, Good Clinical Practice E6(R2), March 2018

4.2 The following regulations are used as the basis for the CRI QMS:

4.2.1 Title 21 CFR Part 11, Electronic Records, Electronic Signatures

4.2.2 Title 21 CFR Parts 50 and 56

4.2.3 Title 21 CFR Part 312 and 314

4.2.4 Title 21 CFR Title 21, Parts 800-1299

4.2.5 Title 45 CFR Part 46, the Common Rule

4.2.6 Title 45 CFR Parts 160, 162, and 164, The Health Insurance Portability and Accountability Act (HIPAA)

4.3 The following QMS standards informed development of the CRI QMS:

4.3.1 International Organization for Standardization (ISO) 9000 family of Quality Management System standards

4.3.2 Software Engineering Institute (SEI) Capability Maturity Model Integration (CMMI™)

4.4 Where noted, definitions for terms used in this SOP were obtained from the following:

4.4.1 American Society for Quality (ASQ) Glossary, https://asq.org/quality-resources/quality-glossary

5.0 Acronyms and Definitions

Term	Definition
Auditability	Whether adherence to a process can be independently and objectively verified.
Audit trail	Secure, time-stamped and immutable records generated by a computer system that independently record the date and time of operator entries and actions that create, modify, or delete electronic records and do not obscure previously recorded information. (Title 21 CFR Part 11)
CAPA	A Corrective And Preventative Action is one or more steps planned and undertaken in response to a quality problem with the intent of correction, remediation, prevention or mitigation of future instances of the problem.
CRI	Clinical Research Informatics
CRIS	Clinical Research Informatics Specialist

DMP	Data Management Plan; comprehensive documentation of data and its handling from definition, collection and processing to final archival or disposal. (ICH E6(R2), March 2018)
GCDMP	Good Clinical Data Management Practices
Managerial controls	Administrative procedures usually involving selection, credentialing, training, and oversight of personnel including performance expectations and corrective action for inadequate performance. Within CRI, managerial controls also include project management.
Note to File	Documentation of an event of consequence to data integrity, data quality or human safety intended to be maintained and archived with the DMP
Procedural controls	Standard procedures specifying process tasks, their sequence, and the roles responsible for performing them. SOPs and WIs are procedural controls.
Process documentation	Records created by or in the performance of a process such as signatures, dates, and computer system audit trails that provide objective evidence against which adherence to procedures can be assessed
Qualified Designee	An individual designated by an individual in the responsible role and directly overseen by the individual in the responsible role or equally qualified by training, education or experience according to the Training SOP to perform a responsibility of the designating role.
QMS	Quality Management System; a formal system that documents the structure, processes, roles, responsibilities and procedures required to achieve effective quality management (ASQ Glossary)
SCDM	Society for Clinical Data Management
SOP	Standard Operating Procedure; text that communicates an organization's requirements for a process including what will be done (process tasks), when (their sequence and timing), and by whom (the institutional roles responsible for performing and overseeing the tasks). In regulated industries, SOPs also commonly specify the documentation generated by a process (process documentation), and how the quality of a process will be controlled.
Substantive changes	Changes to tasks, their sequence, timing, documentation or the roles designated as responsible for tasks.
Technical controls	Functionality in computer systems that constrain operations performed, their sequence and the roles that can perform them.
Unexpected quality problem	Any deviation from the fitness for use of data or computer programming that (1) were not anticipated, i.e., for which detection and control mechanisms were not planned or do not exist, or that (2) occur with a greater severity or frequency than anticipated in such plans.
UTHSA	University of Texas Health Science Center San Antonio
Work Instructions	WIs; Detailed step by step directions for accomplishing process tasks.

6.0 Policy

6.1 Determining processes requiring SOP-level Procedural Control:

6.1.1 The CRI Directors or qualified designee will enumerate work processes impacting the CRI mission as articulated in section 1.0 of this policy.

6.1.2 Processes not having bearing on the CRI mission of the manner in which it is accomplished, i.e., 1-5 in section 1.0 of this policy do not require standardization and control through SOPs. Such processes may be documented in guidelines or left unspecified at the discretion of the CRI Directors.

6.2 Writing a New SOP:

6.2.1 SOPs are intended to be self-contained. As such, SOPs should contain all information needed to understand and implement the process. External references for regulations and methods and referrals to WIs are expected, however, templates and forms needed to carry out the SOP should be included as attachments to SOPs and WIs.

6.2.2 SOP content and format will be standardized using the following template.

6.2.2.1 First and subsequent page headers will contain the fields included in the first and subsequent page headers of this policy.

6.2.2.2 All SOP pages will contain the footer used in this policy.

6.2.2.3 The standard section headings for CRI policy and SOPs include the following:

- A **purpose** section stating the intent of the policy or SOP.
- A **scope** section stating the work processes or roles affected by the policy or SOP.
- A **responsibility** section stating the roles responsible for tasks covered by the policy or SOP.
- A **reference** section listing laws, regulations, regulatory guidance, industry standards, or institutional policies or procedures providing the basis for the policy or SOP or that are pertinent to the execution of the policy or SOP. Specific literature references for methods used in the policy or SOP may be listed in this section.
- A **definitions** section for key terms, acronyms, or phrases required to understand the policy or SOP.
- For SOPs, a **procedure** section stating the following:
    - process tasks,
    - their sequence
    - the institutional role responsible for the tasks
    - required approvals

- process documentation generated in the execution of the process
- process control.

Procedure details should be sufficient to allow personnel qualified for the roles responsible for tasks in the SOP to correctly and consistently execute the procedure. Process validation is not required. Quality is assured through process control and corrective and preventative action taken in response to process problems.

- A **deviations** section stating how planned and unplanned deviations from the SOP are to be handled.
- A **revision history** table like the one included in this policy stating all versions, their effective date and a brief enumeration of the process changes included in the revision or a statement that the revision contains no process changes.
- **Attachments** to policies and SOPs are optional and may include a workflow diagram for processes and job aids such as forms, templates, samples or other documents necessary to execute the policy or SOP.

6.2.3 The CRI Directors or designee will circulate drafts of individual policies and SOPs to other institutional schools, departments or offices groups required to perform and/or supervise the work described in the policy or SOP for review and comment.

6.2.4 The CRI Directors or designee will make updates and modifications to the policy or SOP in accordance with the review comments, as appropriate.

Policy and SOP review is an iterative process and will continue until the policy or SOP is approved.

6.3 CRI Policy and SOP Numbering:

6.3.1 CRI policies and SOPs, WIs and forms will have unique document identifiers to facilitate document control.

6.3.2 The document identifiers, the format of which is specified in Attachment 2, will be modular and designate the document type (POL, SOP, WIN, or FRM) and the higher-level documents to which the document is associated.

6.3.3 Project-specific WIs are those required where applicable by CRI.POL-003 to specify data handling for a particular project. They apply only to a specific project rather than across all projects covered by the CRI QMS. Thus, project-specific WIs are not document controlled at the QMS level. Project-specific WIs are version controlled as specified by the establishing SOP and are maintained with project documentation.

6.3.4 Fillable forms have editable and non-editable areas and are designed to be completed and used in CRI operations. To ensure use of the current version of forms associated with policies, SOPs and WIs, fillable forms are document controlled at the QMS level.

Templates for forms and other templates that are not designed to be completed and used in CRI operations are also provided as attachments to policies, SOPs and WIs but are provided as examples or models and are not document controlled at the QMS level

6.4 Policy, SOP, and WI Review and Approval

6.4.1 Policy review and approval

6.4.1.1 The policy author will circulate drafts of individual policies for developmental review to CRI Leadership and designated reviewers from other schools, departments or offices involved in the policy for review and comment.

6.4.1.2 The policy author will make updates and modifications to the policy in accordance with the review comments, as appropriate.

The developmental review is an iterative process and will continue until the policy is acceptable to the reviewers. Where consensus is not reached in a reasonable number of reviews, a referee decision will be sought from school, departmental, or office leadership of involved reviewers.

6.4.1.3 Following completion of developmental review and approval from CRI leadership, the author will provide the final version to the CRI Document controller to initiate review by the Compliance, IRB, Information Security, Legal (CISIL) group authorized to do so by the UTHSA Patient Data Governance Sub-Committee.

6.4.1.4 The policy author will make updates and modifications to the policy in accordance with the CISIL review comments, as appropriate.

CISIL review and comment will continue until the policy is approved by CISIL.

6.4.1.5 Approved policies will be marked with the date of the CISIL meeting at which they were approved. CISIL approval should be obtained prior to policy implementation.

6.4.2 SOP review and approval

6.4.2.1 SOP development and developmental review will proceed as described for policies.

6.4.2.2 Draft SOPs will be circulated to CISIL for review and comment following developmental review.

6.4.2.3 Two CISIL members will indicate approval for CISIL by signing the SOP header

6.4.3 WI review and approval

6.4.3.1 SOP development and developmental review will proceed as described for policies and SOPs with the addition of including front-line faculty and staffed involved in process execution.

6.4.3.2 Prior to approval by the CRI Directors, WIs will be circulated to CISIL for review and comment.

6.4.3.3 All CISIL comments will be resolved to the satisfaction of CISIL including in the case of disagreement by an agreed trial and evaluation period documented in the CISIL minutes prior to approval by the CRI Directors.

6.4.4 Forms will receive review and approval as part of the establishing policy, SOP or WI

6.4.5 The policy, SOP, and WI review and approval processes will be managed by the CRI Document controller.

6.5 Policy, SOP, WI and Fillable Form Version Control

6.5.1 Substantiative changes to policies, SOPs, and WIs are those that impact the process steps, their sequence, responsibility for performing or overseeing them and process documentation and generally include any changes beyond correction of typos or grammar, or clarification of wording. Substantive revisions require designation of a new version.

6.5.2 The date of the last required approval (required approvals are indicated in the document header of policies, SOPs and WIs) serves as the version date of a new or revised policy, SOP or WI. Separate version numbers are not used.

6.5.3 The date of the last required approval is the earliest date on which the policy, SOP, or WI is eligible for use.

6.5.4 The effective date is the date on which the policy, SOP, or WI is implemented, i.e., put into use.

6.6 SOP Implementation

6.6.1 The effective date of a policy, SOP, or WI is in all cases 30 calendar days from the approval date. The effective date is also documented in the policy, SOP, or WI document header.

6.6.2 The Document Controller will notify all Faculty and staff performing roles designated in a policy, SOP, or WI when the policy, SOP, or WI has received approval. The notification will be provided via email with the read-receipt activated.

6.6.3 New policies, SOPs, or WIs or revisions with substantive changes require documented training.

6.6.3.1 Individuals in roles designated as responsible for policy, SOP, or WI tasks should complete the training prior to independently performing designated tasks.

6.6.3.2 Policy, SOP, and WI training consists of an individual reading the policy, SOP, or WI and completing a five-question quiz about the policy, SOP, or WI with a score of 80% or better.

6.6.3.3 Policy, SOP, and WI training will be completed and documented by electronic testing in the CRI Learning Management System.

6.6.3.4 Individuals not passing policy, SOP, or WI training after three attempts will be required to review the policy, SOP, or WI with a CRI Manager or Director and repeat the quiz attempts. Individuals not passing the training after three repeats will be prohibited from independently performing the process.

6.6.4 The Document controller will notify all Faculty and staff performing roles designated in a policy, SOP, or WI when a new policy, SOP, or WI or a revision is available.

6.6.4.1 The notification will indicate if training or only notification (at the discretion of the CRI Directors) is required.

6.6.4.2 The notification will be sent via email with the read-receipt activated.

6.6.5 The Document controller will place new, approved versions of policies, SOPs, and WIs in the web-based CRI SOP locker. All current policies, SOPs, and WIs in use as well as fillable forms, editable templates and other job aids will be maintained in the web-based CRI SOP locker.

6.6.6 Simultaneously with the previous step, the Document controller will place the replaced, i.e., old, version in the archive in the CRI SOP locker.

6.6.7 The archive will be subject to routine back-up and recovery procedures.

6.6.8 All approved versions will be archived for the longer of ten years or until the last study relying in them has been closed for ten years.

6.6.9 Use of policies, SOPs and WIs prior to the effective date or after the deprecation date may be granted and should be sought with a planned deviation.

7.0 POL, SOP and WI Deviations

7.1 Planned Deviations

7.1.1 Under certain circumstances, a deviation from a policy, SOP, or WI might be necessary and appropriate. If a deviation is anticipated, a Planned Deviation Request Form (Attachment 3) must be submitted.

7.1.2 Planned deviations to policies and SOPs must be approved at the same level as the document type to which the planned deviation is requested.

7.1.3 Planned deviations to WIs must be approved by the CRI Directors.

7.1.4 Planned deviations are sought and documented prior to implementation.

7.2 Non-Planned Deviations

7.2.1 When instances of non-compliance with policies, SOPs or WIs are discovered, they must be reported using the Deviation or Incident Report and Corrective and Preventative Action (DIR-CAPA) form (Attachment 4).

7.2.2 Deviations for infrastructure projects must be completed by the Clinical Research Informaticist (CRIS) or qualified designee leading the infrastructure project and reported by the close of the following business day to a CRI Director.

7.2.3 Deviations for research projects must be completed by the Clinical Research Informaticist (CRIS) or qualified designee leading the informatics work on the project, and reported by the close of the following business day to a CRI Director, the Principal Investigator of the research project, and the project Statistician.

7.2.4 Non-planned deviation forms for research projects must be filed with the Data Management Plan documentation.

7.2.5 Non-planned deviations to policies and SOPs will be reported to CISIL at the next CISIL meeting.

7.2.6 Non-planned deviations also meeting the definition of reportable safety events on clinical studies, non-compliance, or reportable Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO) may also be subject to additional reporting requirements (i.e., reports to the reviewing Institutional Review Board or UTHSA Office of Compliance) separate from and in addition to the non-planned deviation

8.0 Quality Incident Reporting and Handling Including Corrective And Preventative Action (CAPA)

8.1.1 CRI processes are designed to identify and resolve anticipated, impactful problems through process control provisions in policies and SOPs. Anticipated problems detected and resolved as part of routine process control are documented and monitored through such and do not require further reporting.

8.1.2 An unexpected data quality or process problem is any deviation from the fitness for use of data or computer programming that (1) was not anticipated, i.e., for which detection and control mechanisms were not planned or do not exist, or that (2) occur with a greater severity or frequency than anticipated in such plans.

8.1.3 Credible, unexpected data quality or process problems reported by anyone to or unexpected data quality or process problems detected by CRI personnel require incident reports and statement of planned Corrective And Preventative Action (CAPA) using the Deviation or Incident Report and Corrective and Preventative Action (DIR-CAPA) form (Attachment 4).

8.1.3.1 CRI operational faculty and staff must verbally notify a CRI Director by the close of the business day following problem detection.

8.1.3.2 CRI operational faculty and staff should seek guidance from a CRI Director as soon as possible following problem detection if unsure whether an incident or problem requires reporting.

8.1.3.3 The initial version of the DIR-CAPA form should be provided within one week of root cause determination.

8.1.4 Due to the nature of our work, deviations may result in harm to research participants or may risk the ability of the study to answer the research questions. The CRIS is often the first to become aware of a deviation. Deviations for research projects must be reported by the Clinical Research Informaticist (CRIS) or qualified designee leading the informatics work on the project. Preventing harm to research participants and study results should be prioritized over reporting with reporting occurring as soon as possible thereafter. Section 8.0 of the CRI QMS Policy specifies reporting requirements.

8.1.5 For deviations or problems where the impact and remediation are limited to one project or a family of projects managed together, the DIR-CAPA form and planned actions will be completed and undertaken by the project CRIS or designee and maintained in the Project Operational Document System (PODS) with the Data Management Plan documentation for the impacted project/s.

8.1.6 DIR-CAPA forms indicating impact outside an individual project or project family, i.e., impact on underlying CRI technical, managerial or procedural controls, may be completed by any CRI faculty of staff member and will be tracked by CRI until the CAPA is completed. CRI leadership will assign resources to undertake CAPAs on CRI technical, managerial or procedural controls in accordance to their impact, risk and available resources.

8.1.7 DIR-CAPA forms indicating impact outside an individual project, will be reported to CISIL at the next CISIL meeting.

8.1.8 Completed DIR-CAPA forms, progress toward CAPAs and their ultimate completion will be stored in the Project Tracking and Task Management systems.

9.0 Assessing and Prompting Continual Improvement of the CRI QMS

9.1 The CAPA process may result in QMS improvements including policy, SOP or WI revision outside the normal revision cycle.

9.2 CRI polices, SOPs and WIs will be reviewed every three years for accuracy, completeness, reasonableness and opportunities for improvement. The review will include

9.2.1 Planned and unplanned deviations within the effective period of the policy, SOP, or WI.

9.2.2 DIR-CAPA forms filed within the effective period of the policy, SOP, or WI.

9.2.3 Corrective And Preventative Action Requests (CARS) from audits occurring within the effective period of the policy, SOP, or WI.

9.2.4 Review of relevant process and project metrics.

9.2.5 Upon review, CRI policies, SOPs, or WIs may be retired. Retiring of a policy, SOP, or WI is documented by a Planned Deviation Request Form carrying the same approvals as the policy, SOP, or WI to be retired.

9.3 The UTHSA Office of Compliance will determine a schedule for independent auditing of the CRI QMS.

9.3.1 Audit scope and frequency will be determined by the UTHSA Office of Compliance and commensurate with organizational priorities, resources and risk.

9.3.2 CRI Leadership may request audits to assess QMS performance.

9.3.3 If the UTHSA Office of Compliance is unable to accommodate an audit request, a third party of mutual choosing may be contracted at the expense of CRI.

9.3.4 Audits will culminate in an audit report enumeration of findings or observations otherwise requiring Corrective And Preventative Action Requests (CARS).

9.3.5 CARS will be documented on Deviation or Incident Report and Corrective and Preventative Action (DIR-CAPA) forms and tracked as indicated in section 8.0 of this policy.

9.4 Projects undertaken by CRI and taking more than 200 hours will undergo a formal post-mortem as part of project closeout as specified in the CRI Project Management Lifecycle policy (CRI.POL-004). Where these result in meaningful opportunities for QMS improvement, they will be considered and tracked using the DIR-CAPA process.

10.0 Attachments

Attachment 1: QMS Maintenance Workflow Diagram

Attachment 2: Assignment and Structure of QMS Controlled Document Identifiers

Attachment 3: Planned Deviation Request Form

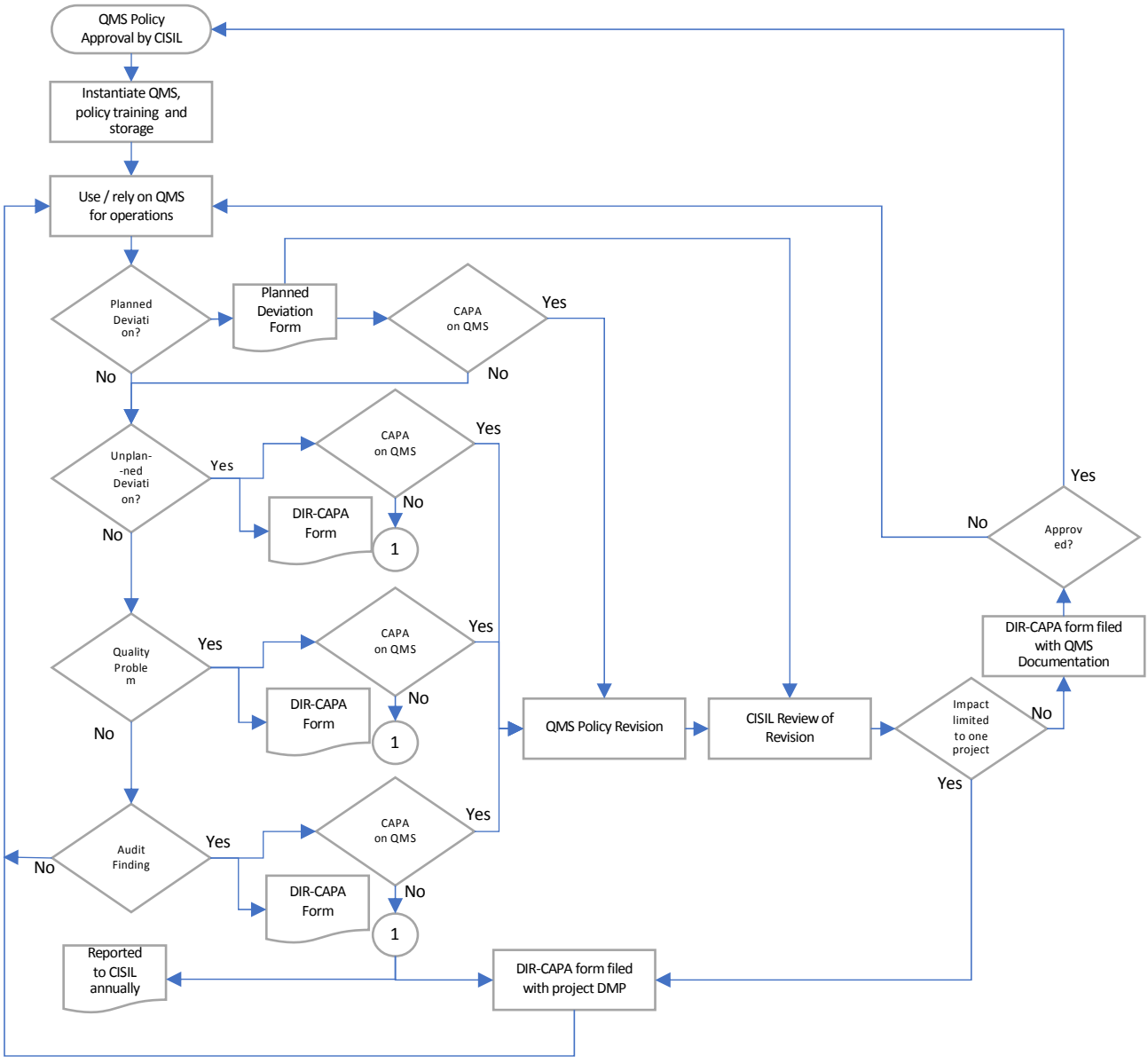
Attachment 4: Deviation or Incident Report and Corrective and Preventative Action Plan (DIR-CAPA) Form

11.0 Revision History (Since Last Version)

The revision history will be documented using the table shown below:

Version No.	Revision Date	Description of Revision
0.0	07/09/2020	This is a draft procedure for trial use.
1.0	05/17/2022	This is the approved policy for dissemination
2.0	06/01/2022	Effective date changed

Attachment 1: QMS Maintenance Workflow Diagram



Attachment 2: Assignment and Structure of QMS Controlled Document Identifiers

I. All CRI controlled document (policies, SOPs, WIs, forms) identifiers will start with the character string "CRI" to distinguish them from controlled documents belonging to other organizational units.

   a. The CRI prefix will be followed by a "." to separate the CRI designation from the document type and number.

   b. The combination of "CRI." and the path of document numbers that follow together comprise the document identifier.

II. CRI Policy Numbering and Identifiers

   a. CRI policy identifiers will be assigned in the format POL-__ __ __ and appear as CRI.POL-__ __ __

   b. The three characters "POL" will designate the document type as a policy.

   c. The 3-character document type will be followed by a 3-character controlled document number assigned sequentially to the policy

   d. Controlled document numbers for policies will be unique over the CRI policies

   e. Controlled document numbers from deprecated policies will not be reused

   f. Controlled document *identifiers* for policies will be unique over the CRI controlled documents

III. CRI SOP Numbering and Identifiers

   a. CRI SOPs are established by and associated with one and only one policy

   b. CRI SOP identifiers will be assigned in the format SOP-__ __ __

      i. The three characters "SOP" will designate the document type as an SOP.

   c. CRI SOP identifiers will appear as CRI.POL-__ __ __.SOP-__ __ __

      i. where the preceding policy identifier is that of the policy establishing the SOP

      ii. The 3-character document type will be followed by a 3-character controlled document number assigned sequentially to SOPs established by and within a policy.

      For example, policies CRI.POL-001 and CRI.POL-002 may each have an SOP with the document number 002 (CRI.POL-001.SOP-002 and CRI.POL-002.SOP-002). By virtue of association with different policies, the aforementioned SOPs are different and are identified as such.

   d. Controlled document *numbers* for SOPs will be unique over the CRI SOPs within a policy

   e. Controlled document *numbers* from deprecated SOPs will not be reused

   f. Controlled document *identifiers* for SOPs will be unique over the CRI controlled documents

IV. CRI System-specific and Process-specific Work Instruction Numbering and Identifiers

a. CRI Work Instructions may be established by and associated with one and only one policy or SOP

b. CRI WI identifiers will be assigned in the format WIN-__ __ __ where the three characters "WIN" designate the document type as a work instruction.

c. CRI WI identifiers will appear as either of the following depending on whether the WI is established by and associated with a CRI policy or an SOP.

CRI.POL-__ __ __.WIN-__ __ __

CRI.POL-__ __ __.SOP-__ __ __.WIN-__ __ __

d. The 3-character document type will be followed by a 3-character controlled document number assigned sequentially to WIs established by and associated with the preceding controlled document.

For example, the CRI policy CRI.POL-005 may establish a system-specific WI with the document number 008. At the same time, SOP-004 under CRI.POL-005 may also establish a WI with the document number 008. By virtue of association with different preceding controlled documents, the aforementioned WIs WIN-008 are different and are identified as such.

CRI.POL-005.WIN-008

CRI.POL-005.SOP-004.WIN-008

e. Controlled document *numbers* for WIs will be unique over the WIs established by and associated with the parent document

f. Controlled document *numbers* from deprecated WIs will not be reused

g. Controlled document *identifiers* for WIs will be unique over the CRI controlled documents

V. CRI Fillable Form Numbering and Identifiers

a. Like system-specific and process-specific WIs, fillable forms may be established by and associated with documents at multiple positions in the CRI QMS controlled document hierarchy

b. CRI fillable forms may be established by and associated with one and only one policy, SOP or WI.

c. CRI fillable form identifiers will be assigned in the format FRM-__ __ __ where the three characters "FRM" designate the document type as a fillable form.

d. CRI fillable form identifiers will appear as either of the following depending on whether the fillable form is established by and associated with a CRI policy, SOP, or non-project-specific WI.

CRI.POL-__ __ __.FRM-__ __ __

CRI.POL-__ __ __.SOP-__ __ __.FRM-__ __ __

CRI.POL-__ __ __.SOP-__ __ __.WIN-__ __ __.FRM-__ __ __

e. The 3-character document type FRM will be followed by a 3-character controlled document number assigned sequentially to forms established by and associated with the preceding controlled document.

f. Controlled document *numbers* for fillable forms will be unique over the fillable forms established by and associated with the parent document

g. Controlled document *numbers* from deprecated fillable forms will not be reused

h. Controlled document *identifiers* for fillable forms will be unique over the CRI controlled documents

Attachment 3: Planned Deviation Request Form

Date of Request: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Policy, SOP or WI from which planned deviation is requested:

SOP or WI number/s:

Explanation of deviation:

Description of how the request deviates from the SOP.

Reason why the deviation is needed:

Quality Control plan:

Statement of how comparable quality will be assured.

Person filing the report: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

CRI Director Approval: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

CISIL Member Approval: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Attachment 4: Deviation or Incident Report and Corrective and Preventative Action Plan (DIR-CAPA) Form

Date/s of Occurrence:

Start date: ___ ___ / ___ ___ ___ / ___ ___ (dd / mon / yy) Stop date: ___ ___ / ___ ___ ___ / ___ ___ (dd / mon / yy) or ☐ Continuing

Date discovered: ___ ___ / ___ ___ ___ / ___ ___ (dd / mon / yy)

Policies, process/s or procedure/s deviated (describe below) or ☐ Not Applicable

SOP or WI numbers or section of the DMP.

Explanation of deviation or quality problem:

Description of what occurred that constituted a deviation.

How the deviation or quality problem was discovered:

Statement of root cause (only one) and contributing factors:

Statement of impact and determination whether event requires additional reporting such as to the IRB, Compliance or the Privacy Officer.

☐ Deviation or problem is limited to the indicated project/s.
☐ Deviation or problem root cause lies in CRI technical, managerial or procedural controls.

Planned Corrective And Preventative Action (CAPA):

Immediate mitigation (describe below or indicate ☐ immediate mitigation not planned)

Remediation or correction of existing data or computer programming (describe below or indicate ☐ data or programming remediation not planned)

Actions to detect, mitigate or prevent future occurrence (describe below or indicate ☐ future mitigating or preventative actions not planned)

☐ CAPA is limited to the indicated project/s.
☐ CAPA involves CRI technical, managerial or procedural controls.

Person making the report: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

CRI Director Approval: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

PI Approval*: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Statistician Approval*: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

*PI and Statistician approval is required where there is impact on data for a project.