



## Clinical Research Informatics Policy

<b>Number:</b> CRI.POL-005	<b>Title: Clinical Research Informatics Project Management Lifecycle (PMLC)</b>	
	<b>Effective Date: June 15,2022</b>	<b>Page 1 of 8</b>
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### 1.0 Purpose

This policy is to ensure that projects undertaken by CRI further our mission of supporting knowledge generation toward improvement in human health through provision of data, information systems, and related services to clinical investigators and research teams. As such, this policy specifies the Project Management Lifecycle (PMLC) through which CRI projects are initiated, planned, executed, managed, and closed. The PMLC ensures that the scope of work for projects is clear, that projects are feasible, that adequate resources are available, and that projects are consistently delivered within the planned cost, quality expectations, and timeline.

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.

### 2.0 Scope

This policy applies to all projects undertaken by CRI. CRI projects to build and maintain infrastructure such as information systems that are configured to support multiple clinical studies and the clinical data warehouse. CRI projects design and develop custom computer programs from complex software applications and simple scripts to support UTHSA studies and other clinical projects. CRI also provides data management services for UTHSA studies and other clinical projects. The PMLC applies equally to this varied eco-system of projects.

This policy covers all project phases: pre-award, post-award and close-out, and emphasizes management within each phase and orderly transition between phases.

### 3.0 Responsibility

- 3.1 The CRI Directors will:

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- 3.1.1 Assure that this policy remains in alignment with UT System and UTHSA policies and procedures.
- 3.1.2 Develop and maintain procedures necessary to implement this policy
- 3.1.3 Assure that projects are feasible and resourced appropriately.
- 3.1.4 Ensure appropriate oversight for CRI work.
- 3.1.5 Serve as the escalation path after the Informatics Project Manager in charge of the project.
- 3.2 Individuals performing CRI tasks will follow this policy and the associated procedures and notify a CRI Director when doing so is not possible or when lapses are detected.
- 3.3 This policy establishes the roles of the Pre Award Manager (PAM), the Informatics Project Manager (IPM), and the Senior Operations Manager (SOM)
  - 3.3.1 The PAM assures all sponsor guidelines, administrative issues, and contract requirements are met. This includes budget preparation, institutional approvals, the project Statement of Work (SOW), and any additional CRI needs prior project start.
  - 3.3.2 The IPM serves as a member of the research team to mitigate risk, facilitates actions to solve project challenges, acts as the liaison between the research team and CRI, as well as coordinates the day-to-day project work. This role is normally filled by a Clinical Research Informatics Specialist (CRIS) or a CRI Technical Lead.
  - 3.3.3 The SOM monitors project progress against their respective budgets, collaborates with the IPM and CRI Management to assign or reposition CRI resources necessary to meet designated priorities, and coordinates with the IPM and Technical Leads and with respect to weekly CRI priorities, schedules work and shifts assignments in collaboration with Informatics Project Manager and technical Team Leads when problems or delays arise from outside the project.

Table 1: Task Ownership Matrix (TOM)

CRI Project Management Roles → ↓ Project Management Tasks	Pre-Award Manager	Senior Operations Manager	Informatics Project Manager	CRI Directors
Select and decline project opportunities				R, A
Serve as CRI contact for project proposal teams	R			
Draft the project SOW, budget and justification	R	P		A
Serve as CRI contact for data queries such as warehouse data			R	
Draft SOW and Data Extraction Form (DEF) for data queries			R	A
Draft sub-contract packet materials such as sub-contract SOW and budget guidelines	R			
Draft Letters of Support (LOS) and Consultant letters	R			
Maintain CRI stock grant package text	R			A
Pre-to-Post-award transition packet	R	P		
Hold pre-post award transition meetings	R	P		

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Set up project in the Project Management System (PMS) and Time Tracking System (TTS)	P	R		
Manage execution of project agreements	R			A
Hold CRI kick-off meeting	P	R	P	P
Coordinate CRI work w/ external team			R	
Manage project risk and scope			R	
Direct and coordinate internal CRI work for project			R	
Ensure quality of CRI work			R	
Track and report project budget		R	P	
Manage CRI Effort allocation		R		A
Create, send and track invoices		R	A	
Schedule CRI work across projects		R		A
Identifies need for amendments to project scope, budget and agreements		P	R	A
Pursue amendments to project scope, budget and agreements	R	P	P	A
Hold Close-out meeting			R	

R: Responsible, P: Participates, A: Approves

#### 4.0 References

A guide to the Project Management Body of Knowledge (PMBOK), 6<sup>th</sup> edition. 2017. Project Management Institute.

#### 5.0 Acronyms and Definitions

Term	Definition
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)
Closing Process Group	Also called project close-out; ... “consists of those processes performed to finalize all activities across all Process Groups to formally close the project or phase.” (PMBOK 6 <sup>th</sup> ed. 2017)
Communication Management	With respect to a project and as a component of project management, ... “includes the processes that are required to ensure timely and appropriate planning, collection, creation, distribution, storage, retrieval, management, control, monitoring, and ultimate disposition of project information.” (PMBOK 6 <sup>th</sup> ed. 2017)
Cost Management	With respect to a project and as a component of project management, ... “includes the processes involved in planning, estimating, budgeting, financing, managing, and controlling costs so that the project can be completed within the approved budget.” (PMBOK 6 <sup>th</sup> ed. 2017)

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Executing Process Group	... “consists of those processes performed to complete the work defined in the project management plan to satisfy the project specifications.” (PMBOK 6 <sup>th</sup> ed. 2017)
Human resource Management	With respect to a project and as a component of project management, ... “includes the processes that organize, manage, and lead the project team. The project team is comprised of the people with assigned roles and responsibilities for completing the project.” (PMBOK 6 <sup>th</sup> ed. 2017)
Initiating Process Group	... “those processes performed to define a new project or a new phase of an existing project by obtaining authorization to start the project or phase.” (PMBOK 6 <sup>th</sup> ed. 2017)
Monitoring and Controlling Process Group	... “consists of those processes required to track, review, and regulate the progress and performance of the project; identify any areas in which changes to the plan are required; and initiate the corresponding changes.” (PMBOK 6 <sup>th</sup> ed. 2017)
Planning Process Group	... “those processes required to establish the scope of the project, refine the objectives, and define the course of action required to attain the objectives that the project was undertaken to achieve.” (PMBOK 6 <sup>th</sup> ed. 2017)
Procurement Management	With respect to a project and as a component of project management, ... “includes the processes necessary to purchase or acquire products, services, or results needed from outside the project team. The organization can be either the buyer or seller of the products, services, or results of a project.” (PMBOK 6 <sup>th</sup> ed. 2017)
PMS	Project Management System
Quality Management	With respect to a project and as a component of project management, ... “includes the processes and activities of the performing organization that determine quality policies, objectives, and responsibilities so that the project will satisfy the needs for which it was undertaken.” (PMBOK 6 <sup>th</sup> ed. 2017)
QMS	Quality Management System; a formal system that documents the structure, processes, roles, responsibilities and procedures required to achieve effective quality management (ASQ Glossary)
Risk Management	With respect to a project and as a component of project management ..., “includes the processes of conducting risk management planning, identification, analysis, response planning, and controlling risk on a project. The objectives of project risk management are to increase the probability and impact of positive events and decrease the probability and impact of negative events in the project.” (PMBOK 6 <sup>th</sup> ed. 2017)
Significant Risk	A risk that if realized would prevent a project milestone or deliverable from successful completion within the planned cost, quality expectations, or timeline.
Scope Management	With respect to a project and as a component of project management, ... “includes the processes required to ensure that the project includes all the work required, and only the work required, to complete the project successfully.” (PMBOK 6 <sup>th</sup> ed. 2017)
SOW	Scope of Work; generally, the products or services that will be provided by an organization.
Stakeholder Management	With respect to a project and as a component of project management, ... “includes the processes required to identify the people, groups, or organizations that impact or be impacted by the project, to analyze stakeholder expectations and their

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	impact on the project, and to develop appropriate management strategies for effectively engaging stakeholders in project decisions and execution.”
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.
Time Management	With respect to a project and as a component of project management, “includes the processes required to manage the timely completion of the project.” (PMBOK 6 <sup>th</sup> ed. 2017)
TTS	Time Tracking System
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 Pre-award

- 6.1.1 A CRI Pre-Award Manager will be assigned to each project and with input from the CRI Senior Operations Manager will use CRI templates to draft project proposal parameters and materials, including but not limited to project scope and budgets. For large proposals, the CRI Informatics Project Manager may draft text portions of the proposal and the budget justification. Where needed, a CRI Director may draft proposal components.
- 6.1.2 All projects undertaken or considered by CRI will be entered into the CRI Project Tracking System with all necessary descriptive data and supporting documents (e.g., SOW, budgets, subcontracts, etc.) uploaded.

## 7.0 Transition to Post-award

- 7.1.1 Transition to Post-award is initiated by a notice of award or other written acceptance of a proposal (the items listed in 6.1.2).
- 7.1.2 As the project transitions from pre-award to post-award, the Senior Operations Manager will assure all necessary information and documentation are entered or uploaded into the Project Management System (PMS). Additionally, the CRI Task Tracking System (TTS) will be loaded with an initial set of projects tasks based on the project type. Reoccurring projects begin with standard set of tasks and custom projects have the initial task list defined by the Informatics Project Manager or Technical Team Leaders.
- 7.1.3 Transition meetings are held regularly during the transition period.

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- 7.1.4 Transition to post-award is complete when the following have occurred:
  - 7.1.4.1 Prime contract is executed or when the proposal is otherwise accepted in writing,
  - 7.1.4.2 Associated agreements such as Data Use Agreements (DUAs) and sub-contracts are executed,
  - 7.1.4.3 The project and associated tasks are set-up in the PMS and TTS
  - 7.1.4.4 Team members have been oriented to the project and have the SOW and budget.
- 7.1.5 At the discretion of a CRI Director and, where allowed by the conditions of the award or agreement, project work may start during the transition period.

## 7.2 Post-award

- 7.2.1 Project management post-award is shared between the assigned Informatics Project Manager and the Sr. Operations Manager and will include the following according to the TOM:
  - 7.2.1.1 Review project work, provide feedback and ensure the quality of CRI work including that CRI policies and procedures are followed.
  - 7.2.1.2 Progress on project deliverables is monitored and tracked.
  - 7.2.1.3 Assigned IPM is responsible for identifying project changes, new requests and out of scope work.
  - 7.2.1.4 The Sr. Operations Manager generates and follows-up on project invoicing as well as reviews and ensures accurate time tracking and management of effort allocation.
  - 7.2.1.5 Significant deviations to project SOWs require Sponsor-approved updates to the SOW, budget and associated agreements which the PM will pursue. Once verbal Sponsor agreement has been received, the Pre-award Manager will pursue amendments to project contractual agreements.

## 7.3 Close-out

- 7.3.1 Projects requiring a Data Management Plan (DMP) will utilize a database lock check-list.
- 7.3.2 The Informatics Project Manager or Technical Lead will coordinate final deliverables, their acceptance, staff transition and archival.
- 7.3.3 The project contract or SOW will specify the CRI archival of project deliverables, interim work products, associated documentation, or any additional requirements where different from or beyond institutional information retention procedures.
- 7.3.4 The Senior Operations Manager will process all final invoices.
- 7.3.5 Any projects with a SOW exceeding 20% of the final estimate will have a formal postmortem to evaluate CRI performance on project tasks and glean opportunities for QMS improvement. Note: projects with significant quality problems will have been reviewed through the Deviation or Incident Report and Corrective and Preventative Action (DIR-CAPA) process described in the QMS Policy (CRI.POL-001).

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7.3.6 The Informatics Project Manager will confirm close out and prepare a planned versus actual report.

## 8.0 SOP Deviations

Planned and non-planned deviations to this policy are handled as described in the CRI QMS Policy (CRI.POL-001).

## 9.0 Review & Revisions

This policy is reviewed as described in the CRI QMS Policy (CRI.POL-001).

## 10.0 Attachments

Attachment: PMLC Workflow Diagram

## 11.0 Revision History

<b>Version No.</b>	<b>Revision Date</b>	<b>Description of Revision</b>
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

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**Attachment 1: PMLC Workflow Diagram**