DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

Clinical Research Informatics Policy

Number: CRI.POL-002	**Title: Clinical Research Informatics Human Resources Management Lifecycle (HRMLC)**	
	Effective Date: June 15, 2022	**Page 1 of 12**
Supersedes Version dated: N/A	REQUIRED APPROVALS BELOW	
PDG-CISIL Approval Date: May 17, 2022		
CRI Technical Director Approval:	DocuSigned by: Bill Sarris FB861D8144CB...	Date: 7/26/2022
CRI Scientific Director Approval:	DocuSigned by: Meredith Zozus CE16226E6FE3443...	Date: 7/26/2022

1.0 Purpose

This policy specifies the personnel or Human Resource Management Lifecycle (HRMLC) that we assure that CRI position and personnel management practices are aligned with the University of Texas System and local institutional human resource management policies and procedures and through which we ensure that individuals performing the Clinical Research Informatics (CRI) tasks are qualified by education, training, and experience for the tasks they perform and grow professionally through job training and experience. Ultimately, the HRMLC ensures that CRI job responsibilities are successfully carried out toward 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. 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 relies on the UT System and University of Texas Health Science Center San Antonio (UTHSA) policies and procedures that govern personnel hiring, management and separation. The foundation of the HRMLC is the specification of responsibilities and competencies and minimum qualifications for the job titles used within CRI. For positions using standard institutional job tiles and descriptions, CRI-specific job duties are articulated for CRI positions performing SOP-controlled tasks, such as Clinical Research Informatics Specialists that fill leadership roles on cross-disciplinary study teams often distributes across organizations. This policy also specifies a competency-based approach to ensuring that individuals are qualified through education, training or experience for job duties (responsibilities and competencies) that they perform.

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

3.0 Responsibility

3.1 The CRI Directors will:

3.1.1 Assure that this policy remains in alignment with UT System and UTHSA human resources policy and procedure.

3.1.2 Develop and maintain procedures necessary to implement this policy

3.1.3 Assure that job responsibilities are documented sufficiently to support hiring qualified individuals, determining training and professional development needs and providing oversight of work performed.

3.1.4 Ensure the availability of training and oversight to support needed CRI competencies.

3.1.5 Ensure appropriateness of the content, timing and effectiveness of the training.

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 a CRI training officer to establish qualification records for new employees and conduct internal, routine review of employee training records to ensure employees have the education, training or documented prior experience required for their jobs and projects to which they are assigned.

4.0 References

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

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

5.0 Acronyms and Definitions

Term	Definition
Auditability	Whether adherence to a process can be independently and objectively verified.
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
Job specific training	Training required for a job or role performed irrespective of any project to which an individual is assigned. Job specific training includes role-based organizational training requirements, skills-based training and training on department and division policy, SOPs and WIs that are required irrespective of a project to which a person is assigned. Required Job-specific training is specified on the training matrix for the position.

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

Managerial controls	Administrative procedures usually involve selection, credentialing, training, and oversight of personnel including performance expectations and corrective action for inadequate performance. Within CRI, managerial controls also include project management.
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
Program	When referring to program-specific procedures, program means a group of studies for which procedures are similar enough to be documented in the same DMP
Project specific training	Training required for a specific project. Project specific training includes training in the clinical area of a project and training in procedures that apply only to that project (or program).
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.
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.

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

6.0 Procedure

6.1 The following institutional procedures are in place and determine the **human resources procedures followed** by CRI:

- HOP 4.3 Recruitment, selection and appointment
- HOP 4.4 Background checks
- HOP 4.5 Employment administration
- HOP 4.9 Performance administration
- HOP 4.10 Employee development and training

6.2 All positions within CRI utilize a state position description that describes minimum qualifications and general responsibilities and are used in routine review of work, feedback and HOP 4.9.1 Employee Performance Review Program in support of the state position description.

6.2.1 CRI maintains CRI-specific job duties for all positions.

6.2.2 The CRI-specific job duties are created in alignment with the state position description. In the event of conflict, the state position description will prevail.

6.2.3 The CRI-specific job duties set performance expectations and are used in routine review of work, feedback and HOP 4.9.1 Employee Performance Review Program in support of the state position description.

6.3 Orientation

6.3.1 All new employees attend UTHSA human resources orientation early in their employment, usually during the first month. UTHSA orientation covers human resources procedures, benefits, and institutional policies.

6.3.2 At the time of orientation, employees complete institutionally required compliance training that includes HIPAA training and state requires computer security training.

6.3.3 Within the first month of employment, a job-specific qualification inventory is performed by reviewing the state position description or CRI-specific job duties document against the skills and experience of the employee. Each job duty is reviewed and indicated as one of the following in the employee training record in CRI

- Employee has completed degree program work covering content
- Employee teaches or has previously taught content
- Employee has previously performed the job duty
- Employee satisfactorily completed any training exercises and assessments for the job duty
- Training required prior to independent performance of the job duty.

6.3.4 Training for job duties indicated as training needed prior to independent performance will be sought prior to the employee independently performing the task.

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

6.4 Training on CRI Policy and Procedure

6.4.1 Similar to training for job-specific duties, SOP review shall be completed before or concurrent with the employees first time performing the task.

6.4.2 The employees first time performing an SOP-covered job duty will not be an independent attempt and will be completed with supervision, review and feedback from an experienced preceptor. Precepted tasks are documented on the Training Form (GEN.F1.002).

6.4.3 Training on CRI policies, SOPs and associated documents will be documented by a passing score on a question set designed to test the comprehension of the processes and procedures specified in the policy or SOP.

6.5 Training documentation

6.5.1 Training may be documented on the *Training Form* (GEN.F1.002) where no other documentation mechanism exists.

6.5.2 Certificates or other documentation of completion of training obtained from external training sources may be affixed to the *Training Form* (GEN.F1.002) where no other documentation mechanism exists.

6.5.3 Training session attendance for in-person training may be documented on the Training Session Log Form (GEN.F2.002) where no other documentation mechanism exists.

6.5.4 Other training documentation such as completed assessments may be used to document training completion and are maintained in employee training files.

6.5.5 Employees may receive an exemption from training by demonstrating prior education, training or proficiency for the specific job duty.

6.5.6 If an employee is exempt from training an *Exemption from Training Form* (GEN.F3.002) is completed and stored with the employees training documentation.

6.6 Project Specific Training

6.6.1 Project specific training is dependent on the needs of individual projects and may be needed when an employee is assigned to a new project.

6.6.2 Project specific training is usually required when the CRI Scope of Work on a project includes data processing or exception-handling that requires substantial interaction with the data managed for a project and requires clinical content area knowledge to do so.

6.6.3 Project specific training is completed by the employee and signed-off by a trainer or CRI Director before the employee begins work on project activities.

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

6.6.4 A Faculty investigator, Study Coordinator, the lead Clinical Research Informaticist or lead Developer or other designated trainer trains project team members on the project requirements including the protocol, if applicable, project specific work instructions, guidelines, references and the project Data Management Plan.

6.6.5 The trainer completes the *Training Form* (GEN.F1.002 Attachment 3).

7.0 Deviations

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

8.0 Review & Revisions

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

9.0 Attachments

Attachment 1 Informatics Training Process Flowchart

Attachment 2 Sample Informatics Training Matrix

Attachment 3 Training Form (GEN.F1.002)

Attachment 4 Training Session Log Form (GEN.F2.002)

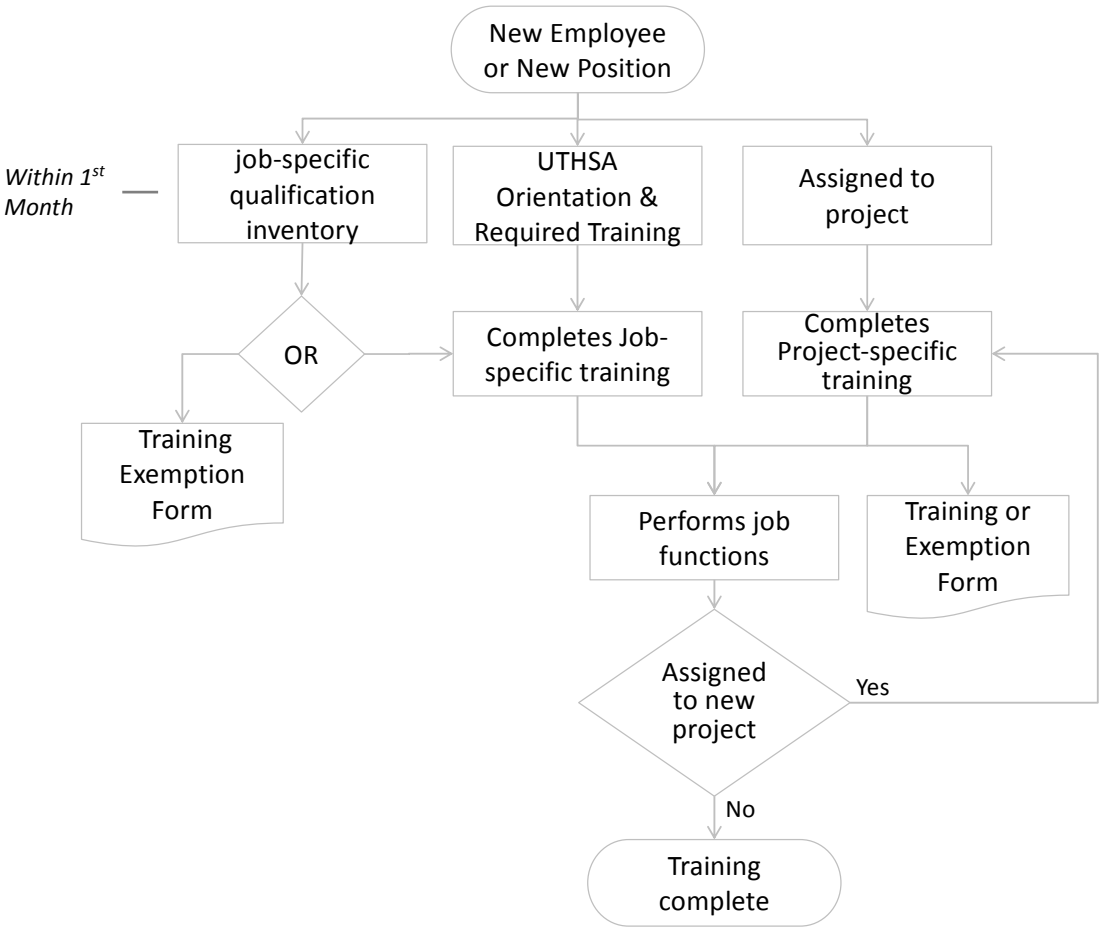
Attachment 5 Exemption from Training Form (GEN.F3.002)

10.0 Revision History (Since Last Version)

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

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

Attachment 1: Informatics Training Matrix



DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

Attachment 2: Sample Informatics Training Matrix

Training	Source	Research Informatics Analyst (CDM) I	Research Informatics Analyst (CDM) II	Research Informati Analyst (CDM) II
SOP Review				
GEN.SOP.001 Developing and Maintaining SOPs	DBMI			
GEN.SOP.002 Training for DCOC Personnel	DBMI			
DMI.SOP.001 Case Report Form Design and Change Control	DBMI			
DMI.002 Data Management Planning and Documentation	DBMI			
…				
Skills-based Training				
REDCap database set-up	ACH	X	X	X
OpenClinica database set-up	Vendor	X	X	X
Data Management Plan Creation and Maintenance	Fundamentals		X	X
Case Report Form Design	Fundamentals		X	X
Data and Workflow Design and Diagramming	Fundamentals	X	X	X
Writing Edit Checks	Fundamentals		X	X
Integration of External Data	Fundamentals		X	X
Clinical Research Data Standards: CDISC SDTM	DBMI		X	X
Clinical Research Data Standards: controlled terminologies	DBMI		X	X
Protocol Review from a Data Management Perspective	DBMI	X	X	X
Creation and Maintenance of Data Management Scope of Work, Timeline and Budget	DBMI		X	X
Capacity Planning	Fundamentals			X

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

Attachment 3 Training Form (GEN.F1.002)

Employee Name: _____

Employee Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

Trainer Name: _____

Trainer Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

Training Module Name: _____

Start date of didactic portion of training: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

End date of didactic portion of training: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

Description of any precepted activities performed in conjunction with training:

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

Attachment 4 Training Session Log Form (GEN.F2.002)

Training Module Name: _____

Trainer Name: _____

Trainer Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

Start date of didactic portion of training: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

End date of didactic portion of training: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

Attendees

Printed Name	Signature	Department	Date

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

DocuSign Envelope ID: BEE5D9B6-2340-4B7C-8483-B84D62614162

Attachment 5 Exemption from Training Form (DM-F3-S-002)

Employee Name: _____

Employee Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

Manager Name: _____

Manager Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___

dd mon yy

Training Module Name: _____

Reason for Exemption:

- ☐ Employee has completed degree program work covering content (prior education documented on resume)
- ☐ Employee teaches or has previously taught content (established expertise documented on resume)
- ☐ Employee has performed the task at UTHSA or a different organization (prior experience documented on resume)
- ☐ Employee satisfactorily completed the training exercises and assessments (tested out)

Description of attached documentation supporting exemption of required training:
