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

STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP. SDLC-002	**Title: Study Database Development**	
Version No.: 1.0	**Effective Date: May 5, 2023**	**Page 1 of 5**
Supersedes Version: N/A **Dated:** N/A	REQUIRED APPROVALS BELOW	
CRI Director:	DocuSigned by: Bill Sanns	**Date:** 5/5/2023
CISIL Approver 1:	DocuSigned by: Becki Gerwitz	**Date:** 5/8/2023
CISIL Approver 2:	DocuSigned by: Srinivasa Pandiri	**Date:** 5/8/2023

1.0 Purpose

This procedure describes the process for designing and developing the Case Report Forms (CRF) and associated data collection forms for data collection operations and clinical trials.

2.0 Scope

This procedure pertains to all activities related to the initial design, development, and/or modification of a Case Report Form (CRF), electronic Case Report Form (eCRF), all associated data quality validation rules, Electronic Data Capture (EDC) system functionality (for electronic systems), as well as all manual procedures required for those projects where CRI's role is primary data manager. For this SOP, the CRF and eCRF design, development, and modification process are the same; however, the implementation differs based on the paper or electronic system selected for data collection. Unless otherwise specified, the terms CRF and eCRF may be used interchangeably.

3.0 Responsibility

3.1 CRI Director: responsible for ensuring that all CRF design and development staff are trained on and comply with this procedure.

3.2 Technical Director: responsible for ensuring systems are managed according to federal, state, and local standards.

3.3 Senior Manager: performs all functions related to tracking activities, manages resource allocation required for the software development process, and is the Technical Director's primary backup.

3.4 Clinical Research Informatics Specialist: responsible for including appropriate stakeholders such as the study Principal Investigator (PI), the statistician (if applicable), individuals representative of those involved in the study data collection in the design of the CRFs and eCRFs

3.5 CRI Technical Staff: responsible for providing technical input regarding any electronic implementation of the CRF (CRF → eCRF)

4.0 References

4.1 UT System: UTS 165 Information Resources Use and Security

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

4.3 Title 21 CFR Part 11, Electronic Records, Electronic Signatures Act

4.4 Title 21 CFR Parts 50 and 56

4.5 Title 21 CFR Part 312 and 314

4.6 Title 21 CFR Parts 800-1299

4.7 Title 45 CFR Part 46, The Common Rule

4.8 Title 45 CFR Parts 160, 162, and 164, The Health Insurance Portability and Accountability Act (HIPAA) General Principles of Software Validation: Final Guidance for Industry and FDA Staff, January 11, 2002, FDA

4.9 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
CFR	Code of Federal Regulations
CRF	Case Reporting Form
CRI	Clinical Research Informatics
CRIS	Clinical Research Informatics Specialist
Data-quality management	Data-quality management is a process where protocols and methods are employed to ensure that data are properly collected, handled, processed, used, and maintained at all stages of the scientific data lifecycle.
eCRF	Electronic Case Reporting Form
EDC	Electronic Data Capture
GxP	General abbreviation for the "good practice" quality guidelines and regulations.
PI	Principal Investigator
SOP	Standard Operating Procedure
UTHSA	University of Texas Health San Antonio

6.0 Procedure

The purpose of a CRF is to collect data and to implement data quality controls as early in the data collection process as possible. The CRFs and EDC system are intended to collect protocol-specified data detailed in a clear, concise language with modules and data fields arranged according to usability principles to minimize cognitive load during data collection. To support data reuse, external comparisons of study results, and to decrease development costs, relevant standard data elements, controlled terminology, biomedical ontologies, and common data models are identified and discussed with study leadership as part of the CRF design process.

6.1 <u>Designing a New CRF:</u>

6.1.1 A new CRF is defined as one that does not already exist in the CRI or CRI-approved library. Any changes to a filed CRF will be treated as a "new" CRF and designated with an updated version number from the original form.

6.1.2 The CRIS or Designee:

6.1.2.1 Identifies the readiness for design.

6.1.2.2 Identifies relevant data elements, CRF modules, and EDC functionality required for a study.

6.1.2.3 Discusses relevant standard data elements, controlled terminology, biomedical ontologies, and common data models identified and discussed with study leadership.

6.1.2.4 Develops draft CRF(s).

6.1.2.4.1 The preferred method is to create the draft CRFs on paper or a word processing application (e.g., MS Word, Google Docs, etc.); however, there may be times when using the EDC system may best facilitate the approval process. This is at the discretion of the CRIS and Study Team.

6.1.2.4.2 The CRIS or Designee will circulate/deploy drafts of the individual CRF/eCRF(s) to the stakeholders (e.g., Trial Principal Investigator (PI), Statistician, Clinical Operations Lead, etc.) for review.

6.1.2.5 Defines required operational functionality and needs (e.g., randomization, events, external interfaces, etc.)

The review is an iterative process and will continue until the CRF is considered ready for final approval.

6.2 CRF Approval:

6.2.1 The CRIS or Designee will send the final version of the individual CRFs to the primary stakeholders (e.g., Trial Principal Investigator (PI), Statistician, Clinical Operations Lead, etc.) for final review and approval.

6.2.2 The CRIS or Designee includes CRF Final Review Instructions with the version circulated for approval. Final review instructions include: checking that all necessary data elements are present on the form and that the form adheres to the study schedule of events, checking that the CRF footer reflects the correct version, and checking spelling, punctuation, and formatting corrections necessary. All approvers are responsible for final review checks.

6.2.3 The PI and Statistician (if applicable) must approve, sign, and date the final copy of all CRFs or provide pre-approved documentation to indicate that the CRF(s) are ready for final implementation. This approval covers all associated rules, validations, processes, etc., associated with said CRFs. Any development that occurs before final approval shall be documented within the SOW to address any mitigating circumstances or other logistic issues that may need to be attended to before final CRF approval.

6.3 CRF and EDC Initial Build

6.3.1 The CRIS or Designee will develop the CRF(s) only after approval has been documented to the level specified in the Statement of Work (SOW).

6.3.1.1 Paper forms will be completed via the word processing software specified in the SOW.

6.3.1.2 For eCRFs, implementation depends on the selected system with access ranging from the CRIS/Designee doing the full build to the CRIS/Designee working with the CRI programming team to build the EDC and CRF to specification.

6.4 CRF and EDC Modification

6.4.1 Any change to a CRF after final approval constitutes a modification. Approvals for modifications are identical to that of the initial build. Modification may also represent a change to the SOW requiring cost and time negotiations with the Principal Investigator.

6.5 CRF and EDC Testing

6.5.1 The CRIS or Designee is responsible for final useability testing according to CRI.POL.004 SDLC testing requirements.

6.5.2 The Principal Investigator or Study Team Designee is responsible for final acceptance testing.

6.6 CRF Versioning:

6.6.1 CRFs and any documentation specifying EDC requirements are version-controlled and shall be managed according to the SOW.

6.7 CRF Implementation:

6.7.1 The CRIS or Designee is responsible for assuring the distribution and training on all approved CRFs and any developed EDC system.

6.7.2 Training will be commensurate with the extent of the implementation or changes. For minor changes that do not impact data collection processes or methods, notification rather than training may be more appropriate and is at the discretion of the PI, Statistician, and Data Manager.

6.7.3 All training shall be documented within the CRI Project Tracking and Task Management Systems.

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

10.0 Revision History

Version No.	Revision Date	Description of Revision