STANDARD OPERATING PROCEDURE	
Title	Standard Operating Procedure for other IRB of Records
Date Created	November 3, 2017

Purpose
This Standard Operating Procedure outlines the abbreviated process for all current/new, continuing review and study closure submissions where CHRISTUS Health IRB is not the IRB of record.

One of the primary responsibilities of the CHRISTUS Health IRB is to maintain, review and monitor research covered under the Federal Wide Assurance for CHRISTUS Health.

1. The Principal Investigator(PI)/Sub-Investigators(Sub-I)/Clinical Research Coordinators (CRC) will submit all research applications to the CHRISTUS Health IRB via the electronic portal (iRIS), even if CHRISTUS is not the IRB of record: https://christus.imedris.net/. All research study personnel are required to obtain an iRIS account to be listed as key study personnel on the research application.

2. The Principal Investigator (PI)/Sub-Investigators (Sub-I)/Clinical Research Coordinators (CRC) will complete all study applications and upload all essential documents into iRIS. PI sign-off is required in new, continuing review and study closure submissions.

3. All submissions will be assigned to a CHRISTUS Health IRB Coordinator.

4. The following process is listed:

	Responsible Party	Action
Step 1.	PI/ CRC	PI/CRC will submit: • Study application and documents to the IRB of Record. • Study application in iRIS
Step 2.	PI/ CRC	Upon approval from the IRB of Record, the PI/CRC will upload the IRB of Record approved & stamped study research documents and outcome letter into iRIS under Additional Document Upload, if not already provided.
Step 3	CHRISTUS Health IRB	The CHRISTUS Health IRB Coordinator will review the submission and verify that all required documents have been received and that the application is complete.
Step 4.	CHRISTUS Health IRB	Upon completion of the review, a CHRISTUS Health IRB Coordinator will send the submission and acknowledgment letter to the IRB Director.
Step 5.	CHRISTUS Health IRB	The CHRISTUS Health IRB Director will review and acknowledge the research project via iRIS.
Step 6.	CHRISTUS Health IRB	A CHRISTUS Health IRB Coordinator will send an acknowledgment letter to the PI and CRC via iRIS.

5. The study will be reviewed, acknowledged and/or approved by the following departments:

   - Reviewed and acknowledged by the CHRISTUS Health IRB and will then be placed on the Supplemental Agenda.

   During the review process, if any of the CHRISTUS Health Departments have questions and/or concerns the CHRISTUS Health IRB Coordinator will contact the Principal Investigator(PI)/Sub-Investigators(Sub-I)/Clinical Research Coordinators (CRC) directly for clarification and to ensure compliance with all CHRISTUS Health Institutional requirements.

6. Upon approval by the IRB of Record, the Principal Investigator(PI)/Sub-Investigators(Sub-I)/Clinical Research Coordinators (CRC) will forward to CHRISTUS Health IRB all essential approved documents this includes but is not limited to the Study Protocol, Informed Consent and external IRB Approval letter.

7. **CHRISTUS Health and Non-CHRISTUS Health PI/Sub-I/CRCs** will keep CHRISTUS Health IRB informed of the following study amendments within five (5) days. Though the list below is not included in the above submission requirements, the Office of Human Subjects Research Protection Program (OHSRPP) reserve the right to request or require these additional submissions if needed;

    a. FDA Audits and other regulatory agencies (example, OIG)
    b. Unanticipated Problems
    c. Continuing Reviews
    d. Site Amendments (submit to eProposal)

8. During the Continuing Review, the Principal Investigator (PI)/Sub-Investigators (Sub-I)/Clinical Research Coordinators (CRC) will complete the Continuing Review application and provide the external IRB Approval letter.

9. During the closure of the research project, the Principal Investigator (PI)/Sub-Investigators(Sub-I)/Clinical Research Coordinators (CRC) will complete the Closure application and provide the external IRB Closure letter

Please note that the addendum to this document references Quicktips: iRIS Submission Steps for Facilitated Review Studies Flow Chart is a summary of the initial, continuing review and study closure process.