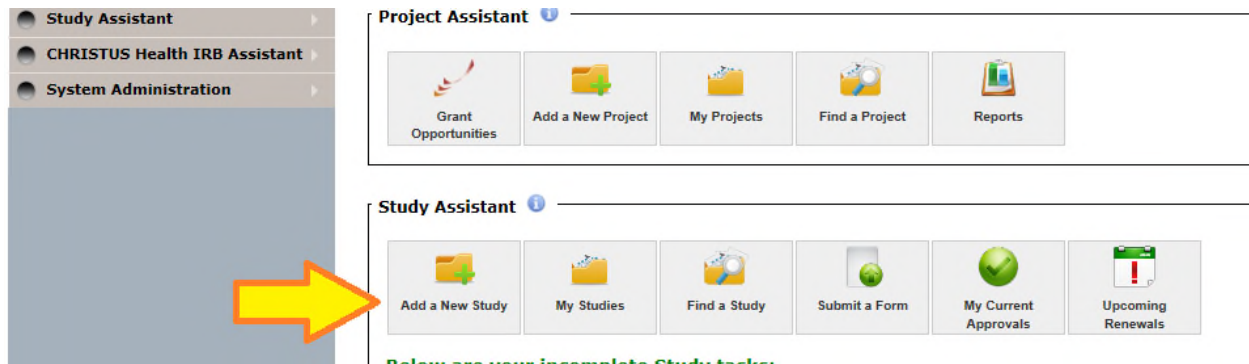


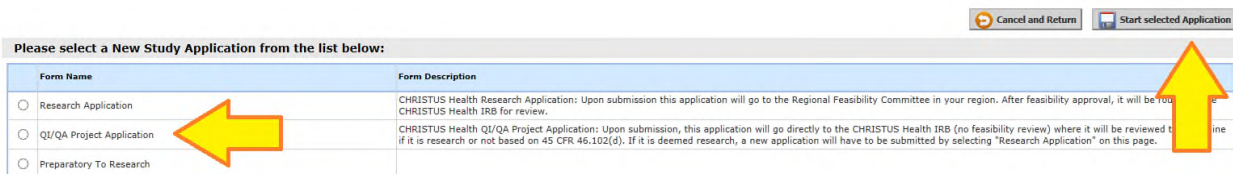
How to submit a QI/QA Project into iRIS

When adding a QI/QA project into iRIS log into your iRIS account. If you do not have an iRIS account please see the reference document titled “How to request an iRIS account”, if you have forgotten your username and/or password please contact CHRISTUS.IRB@christushealth.org.

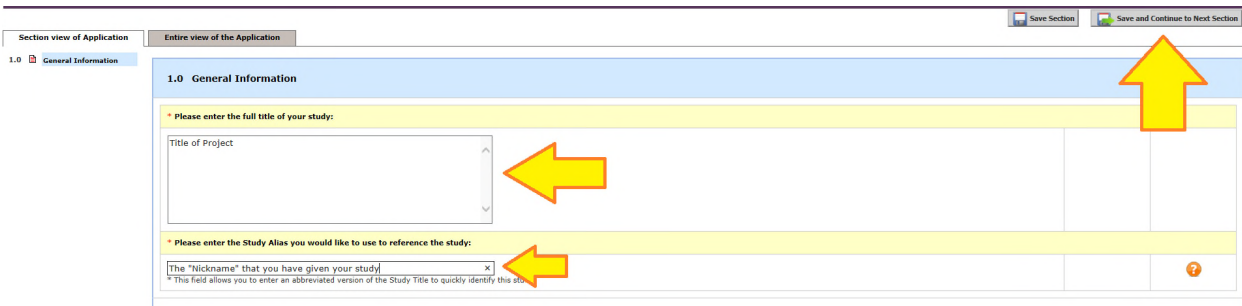
Once you have logged into iRIS please click on “Add New Study” (if your screen looks different from the below image please look at the menu on the left side of the page and hover over “Study Assistant” then click on “Add New Study”).



Then click on QI/QA Project Application and “Start Selected Application”



Complete the section for the study title and the study alias. Then click on Save and Continue to Next Section



How to submit a QI/QA Project into iRIS

On the next screen click on Save and Continue to Next Section

Section view of Application | Entire view of the Application

1.0 General Information
2.0 Setup Facility Name(s) Access
3.0 Grant Key Personnel access to the study

2.0 Add Facility Name(s)

2.1 This field is defaulted to CHRISTUS Institute for Innovation and Advanced Clinical Care. You can leave this default choice, simply recognizing this study will go through our process.

Primary Dept?	Department Name	
<input type="checkbox"/>	CH - CHRISTUS Institute for Innovation and Advanced Clinical Care	+ Add - Remove

Print Friendly | Save Section | Save and Continue to Next Section

Please add the Principal Investigator for the project.

If Sub-Investigators are on the study please add them to this section.

If research staff will be utilized they are added on this page (including Facilitators, Regional Managers, Coordinators, etc.)

Add the study contacts on this page as well. These are people that will receive iRIS notifications and Outcome letters.

PLEASE REMEMBER ALL STUDY/PROJECT PERSONAL THAT WILL BE ADDED TO THE STUDY MUST HAVE AN IRIS ACCOUNT AND SUBMIT THE REQUIRED DOCUMENTATION.

Section view of Application | Entire view of the Application

1.0 General Information
2.0 Setup Facility Name(s) Access
3.0 Grant Key Personnel access to the study

3.0 Assign key study personnel (KSP) access to the study

3.1 Please add a Principal Investigator for the study:

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

3.3 Please add a Study Contact:

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

Print Friendly | Save Section | Save and Continue to Next Section

How to submit a QI/QA Project into iRIS

Once all staff has been added please click on Save and Continue to Next Section

Section view of Application | Entire view of the Application | Print Friendly | Save Section | Save and Continue to Next Section

1.0 General Information
2.0 Setup Facility Name(s) Access
3.0 Grant Key Personnel access to the study

3.0 Assign key study personnel (KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

Demo PI

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

P12_Demo
Sub-Investigator

B) Research Support Staff

P12_Demo
Regional Director

3.3 * Please add a Study Contact:

PI_Demo

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

Please select the CHRISTUS Health Region the study/project will take place in.

Answer if CHRISTUS Health will be the IRB of record – if you answer no – you will be required to provide the name of the IRB of record.

Complete the section for facility name.

Click on QA/QI Project, the page will expand and nine questions will need to be completed. Once all questions are answered click on Save and Continue to Next Section

Section view of Application | Entire view of the Application | Print Friendly | Save Section | Save and Continue to Next Section

1.0 General Information
2.0 Setup Facility Name(s) Access
3.0 Grant Key Personnel access to the study
4.0 QI/QA Project Application

4.0 CHRISTUS Health QI/QA Project and Case Report/Study Application

Request For Determination
Research vs. Quality Improvement vs. Case Report/Study

4.1 * Which region is the QI/QA or Case Report/Study project being proposed in?

Louisiana and Southeast Texas (LA/SETX)
 New Mexico (NM)
 Northeast Texas (NETX - Texarkana)
 Northeast Texas (NETX - Trinity Mother Frances)
 South Texas (STX - Santa Rosa)
 South Texas (STX - Spohn)
 System Office

4.2 * Is CHRISTUS Health IRB the IRB of record for your study?

Yes No

4.3 * Please choose the IRB of record in your region:

Schuman

4.4 * What is the facility name where the QI project or Case Report/Study will be performed?

St Frances Cabrini

4.5 * Is this a QI/QA Project or Case Report/Study?

QA/QI Project
 Case Report/Study

How to submit a QI/QA Project into iRIS

Please answer the questions regarding PHI. Remember to click on Save and Continue to Next Section before continuing to the next page.

Section view of Application: Entire view of the Application

5.0 Use & Disclosure of PHI

5.1 Will PII/PHI be transmitted externally? (Personally Identifiable Information/Protected Health Information)

Yes No

Print Friendly Save Section Save and Continue to Next Section

Please review the information on the next few screens making sure to click on Save and Continue to Next Section between pages.

Once you come to the Master Document Upload Page **PLEASE UPLOAD THE WRITTEN PROJECT PLAN, DATA COLLECTION FORMS, SURVEYS, AND ANY OTHER STUDY RELATED INFORMATION** you can also upload your signed and dated CV/Resume and medical license or certifications and Sub-Investigator conflict of interest forms (if applicable) here as well. Once all documents are loaded please click on Save and Continue to Next Section.

Failure to submit project documentation will result in a delay in IRB review and stipulations being sent to the Principal Investigator and study contacts by the IRB

Section view of the Form: Entire view of the Form

3.0 Master Document Upload

3.1 Attach the Sub-Investigator Conflict of Interest document(s) (if applicable). can download the form from the CRI website here.

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

3.3 Attach any study documents to include with the study packet: Examples would include your full Study Protocol, Drug Brochures, Sponsor Information, Other IRB Approval Documents, or any other miscellaneous documents.

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

3.5 Please click "Save and Continue to Next Section"

Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

How to submit a QI/QA Project into iRIS

Once the form is completed and all documents have been uploaded please sign off on the submission and submit the form to the IRB.

IF you are the Principal Investigator please click on Signoff and Submit.

If you are *not* the Principal Investigator please follow the instructions further down the page.

Section view of the Form | Entire view of the Form

1.0 Application Summary
2.0 Application Attachment
3.0 Master Document Upload

Print Friendly | Signoff and Submit

Form has been Completed!
Instruction of Form has Been Completed Screen

Exit Form | Signoff and Submit

Click on “no” and the Save and Continue

Save and Continue

Does this submission require additional routing for approval?

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

To sign off on the submission click on Approve, enter iRIS user name/ID and password, then click on Save Signoff.

Save Signoff

Printable Version

Study Title: s10ff
Submission Reference Number: 000294

Include in PDF Packet:
Submission Form(s)
Application Summary - (Version 1.0)
QI/QA Project Application - (Version 1.0)

INVESTIGATOR SIGNATURE

Approve | Deny

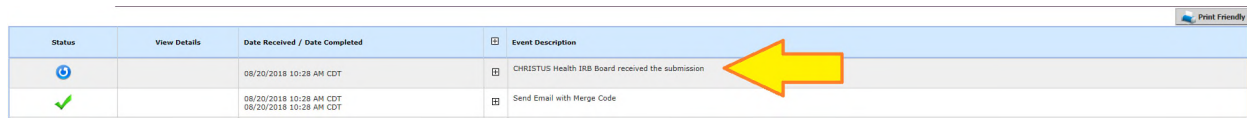
Comments: Click here to add comments.

This form requires your electronic signature. Please enter your User ID & Password:
User ID:
Password:

Save Signoff

How to submit a QI/QA Project into iRIS

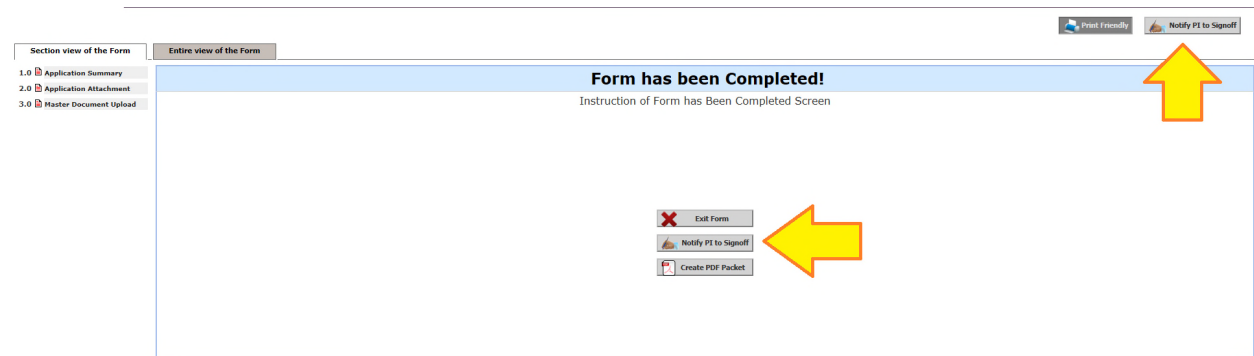
On the next screen you should see the message “CHRISTUS Health IRB Board received the submission”.



Status	View Details	Date Received / Date Completed	Event Description
		08/20/2018 10:28 AM CDT	CHRISTUS Health IRB Board received the submission
		08/20/2018 10:28 AM CDT	Send Email with Merge Code

If you are NOT the Principal Investigator please follow the steps below:

Click on Notify PI to signoff



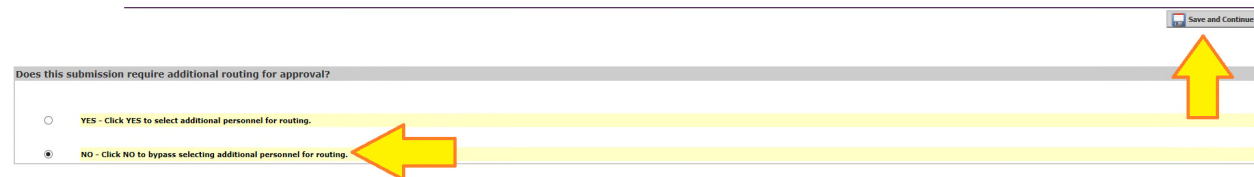
Section view of the Form | Entire view of the Form

1.0 Application Summary
2.0 Application Attachment
3.0 Master Document Upload

Form has been Completed!
Instruction of Form has Been Completed Screen

Exit Form
 Notify PI to Signoff
 Create PDF Packet

On the next page complete the routing question and then click on Save and Continue



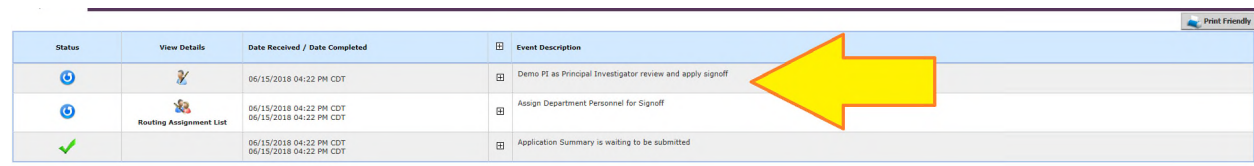
Does this submission require additional routing for approval?

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

On the next screen you should see that the message “Principal Investigator review and apply signoff

Once the Principal investigator logs into iRIS and signs off on the submission it will be routed to the CHRISTUS Health IRB.



Status	View Details	Date Received / Date Completed	Event Description
		06/15/2018 04:22 PM CDT	Demo PI as Principal Investigator review and apply signoff
		06/15/2018 04:22 PM CDT 06/15/2018 04:22 PM CDT	Assign Department Personnel for Signoff
		06/15/2018 04:22 PM CDT 06/15/2018 04:22 PM CDT	Application Summary is waiting to be submitted

THE PRINCIPAL INVESTIGATOR MUST SIGN OFF ON THE SUBMISSION PRIOR TO THE IRB RECEIVING THE SUBMISSION FOR REVIEW