**CHIRB Submission Guide**

Questions? [chirb@catholichealth.net](mailto:chirb@catholichealth.net) : 1-844-626-2299

The mission of the CHIRB is to protect the rights and welfare of our research participants. The CHI core values of Reverence, Integrity, Compassion and Excellence guide our thinking and processes – both in terms of our commitment to upholding the highest ethical standards in the research we oversee, and in maintaining strong relationships with our researchers and research communities. The CHIRB’s administrative offices are housed within the CHI Institute for Research and Innovation at the CHI National Office in Englewood, Colorado. Please note the instructions in this guide apply to all CHI-affiliated sites, including Centura Health. The CHIRB carries out its mission by requiring research proposals to be reviewed and approved by CHIRB prior to being started and by providing oversight of ongoing research studies.

This guide provides useful and necessary information about the CHIRB and how to submit research proposals to the CHIRB for review.

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1. General/Extremely Useful Information (Please Read)

What Is An Institutional Review Board?

An Institutional Review Board (IRB) is a committee of at least 5 individuals with diverse backgrounds and expertise responsible for ensuring human subjects research is conducted in compliance with relevant ethical standards, along with relevant state and federal regulations and institutional policies that set standards for the conduct of human subject’s research and the protection of private information.

What does IRB review involve?

Research proposals are reviewed by the IRB for adherence to relevant regulations, institutional policies and ethical principles. The procedures for review are designed to match the review requirements with the level of risk of harm (physical, psychological, social, or otherwise) to participants. Essentially, the greater the risk of harm to participants the research procedures create for the participant, the more stringent the review requirements are. There are four levels of review which will be touched on in greater detail during your submission to the CHIRB:

1. Not Human Subjects Research Determination: This is a review and determination by the IRB that the proposal submitted to the IRB does not meet the regulatory definition of ‘research with human subjects’. ‘Research’ is defined as a systematic investigation, including research development, designed to contribute to generalizable knowledge. ‘Human subject’ means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. This determination is often made by a designated member of the IRB for proposals that:

   a. Focus on systematic improvement or assessment of operations at a single facility (a ‘quality improvement’ or ‘quality assessment’ project); OR

   b. For proposals that involve only analysis completely of not readily identifiable data which the investigator never had access to the identifiers for and is unable to re-identify.

2. Exempt Review: The regulations that govern the conduct of research include several categories of research that are generally considered of such low risk to participants that they do not require the investigator to provide the CHIRB with an annual update of study progress. Exempt review is generally conducted by a single designated HRPP individual.

3. Expedited Review: Research studies that do not fall into any of the ‘Exempt categories’ but is of low, or ‘minimal’, risk to participants can be reviewed by a single designated member of the IRB. Research studies that qualify for Expedited Review require the investigator to submit to the
CHIRB an update on the current status of the study at least once per year (we call this status update a ‘Continuing Review’).

4. Convened IRB Review: Research studies that present more than minimal risk to participants (for example - clinical trials, HUD’s) require the convened IRB to review the research proposal. Research studies that qualify for Convened IRB Review require the investigator to submit to the CHIRB an update on the current status of the study at least once per year (we call this status update a ‘Continuing Review’).

Once I gain approval from the IRB to start my research study, what information do I have to report to the CHIRB?

Once you have IRB approval to begin your research study, you are required to report any unanticipated problems with your study and any deviations from the protocol. You are also required to obtain IRB approval for any changes to your research study (new personnel, new/revised documents, revised procedures, etc.) before implementing those changes unless the change is to eliminate an immediate hazard to participants. In addition, if your study qualified for Expedited Review or Convened IRB Review, you must submit a status update to CHIRB at least once per year. We call this status update a ‘Continuing Review’.

- **Unanticipated Problems:** The CHIRB requires the investigator to evaluate and report any internal or external Unanticipated Problem to the CHIRB as soon as possible but no later than ten (10) business days after discovery. Unanticipated Problems are 1) unanticipated AND 2) serious or life-threatening or potential for increased risk AND 3) possibly or definitely related to the protocol, as determined by the investigator.

- **Protocol Violations:** A protocol violation is any exception or deviation from the protocol that is not approved by the IRB prior to its initiation or implementation. These protocol violations may be major or minor violations. The CHIRB requires protocol violations to be reported the CHIRB as soon as possible but no later than ten (10) business days after discovery.

Does CHIIRB oversee my research study (and should I be submitting my research study to CHIRB for review)?

It depends. The CHIRB broadly oversees the research conducted at CHI facilities, but in some cases, other IRB’s may have direct oversight of your study. In some cases individual hospitals or medical centers within the CHI family have created their own IRB to oversee research at their facility, in which case the institution’s IRB would provide oversight for research for that facility and you would submit your research proposal to that IRB for review and approval. In other cases, an IRB set up by an institution outside CHI may provide oversight for your study; this is often the case when a CHI facility is participating in a research study that is taking place at multiple research sites both inside and outside the CHI network.
If you are unsure if the CHIRB is responsible for overseeing your research study, we encourage you to contact the research office/manager at your facility:

<table>
<thead>
<tr>
<th>Research Manager</th>
<th>Location</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginger Whisman</td>
<td>CHI Memorial (Chattanooga, TN)</td>
<td><a href="mailto:GingerWhisman@catholichealth.net">GingerWhisman@catholichealth.net</a></td>
<td>253-426-6882</td>
</tr>
<tr>
<td>Rebecca Thomas</td>
<td>KentuckyOne Health (Louisville and Lexington, KY)</td>
<td><a href="mailto:thomasrs@sjhlex.org">thomasrs@sjhlex.org</a></td>
<td>859-313-2960</td>
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<tr>
<td>Paul Edwards</td>
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<td><a href="mailto:PEdwards@stez.org">PEdwards@stez.org</a></td>
<td>402-219-7677</td>
</tr>
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<td>Nebraska Heart Institute (Lincoln, NE)</td>
<td><a href="mailto:cgodfrey@neheart.com">cgodfrey@neheart.com</a></td>
<td>402-328-3930</td>
</tr>
<tr>
<td>Conchita Purchase</td>
<td>CHI Franciscan Health (Tacoma, WA)</td>
<td><a href="mailto:ConchitaPurchase@chifranciscan.org">ConchitaPurchase@chifranciscan.org</a></td>
<td>253-426-6882</td>
</tr>
<tr>
<td>Debbie Lewis</td>
<td>CHI St. Joseph's (Bryan, TX)</td>
<td><a href="mailto:DLewis@st-joseph.org">DLewis@st-joseph.org</a></td>
<td>979-776-5364</td>
</tr>
<tr>
<td>Suzanne Coleman</td>
<td>Centura Health (Colorado, Western Kansas)</td>
<td><a href="mailto:SuzanneColeman@Centura.org">SuzanneColeman@Centura.org</a></td>
<td>303-673-7301</td>
</tr>
<tr>
<td>Joan Gailbraith</td>
<td>CHI St Alexius (Bismark, ND)</td>
<td><a href="mailto:jgalbraith@primecare.org">jgalbraith@primecare.org</a></td>
<td>(701) 530-6954</td>
</tr>
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</table>

If you are unsure or do not see your site above, please contact Andrea Buchmeier for more information AndreaBuchmeier@catholichealth.net 303-383-2620.
2. Creating A Profile In Our Online Document Submission System (IRBNet) So You Can Make Submissions To The CHIRB (All Research Personnel Need A Profile, Even If They Aren’t The One Submitting Documents To The CHIRB)

The CHIRB uses IRBNet, an electronic portal for managing submissions to the CHIRB. Please have each person involved with conducting the research study (i.e. ‘research personnel’) complete the following steps to create a user profile in IRBNet. If on individual already has an IRBNet account, they should not create a new one; they can affiliate their current account with the CHIRB (contact the CHIRB for information on how to do this).

‘Research personnel’ generally includes anyone who engages in research by interacting with participants or their identifiable data for research purposes as defined by the federal Office for Human Research Protections Engagement Guidance. It can be difficult to determine if specific personnel could be considered ‘involved with conducting the research study’ so we ask investigators to use their best judgment and contact the CHIRB if they have questions. Individuals who obtain consent from participants are always considered research personnel.

All research personnel need a profile because having a profile will allow them to access study documents and upload training records.

A. Click here to access IRBNet.

B. Click ‘New User Registration’

C. Add an affiliation by selecting CHI Institute for Research and Innovation.

D. Click the ‘Continue’ button. You will receive a confirmation link in your email which you will need to activate your account.
3. Completing **Required** Training, Uploading a CV, And A Completing Financial Conflicts of Interest (FCOI) Disclosure For All Investigators And Other Staff Involved With Conducting The Research Study.

Conducting research comes with its own set of unique requirements and considerations. To ensure that research personnel have the ability to conduct research according to the highest ethical standards, CHI requires all research personnel (not just investigators) to complete training, upload a CV, and complete a Financial Conflict of Interest Disclosure. Final study approval cannot be given by the IRB unless all research personnel have completed all requirements. Documentation of training and credentials should be uploaded into each individual’s user profile (see letter D below).

**A. Completing Training Requirements:**

<table>
<thead>
<tr>
<th>CHIRB Training Requirements</th>
<th>Acceptable Training Courses (Other courses can be submitted for considered approval*)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Research Personnel Must Complete All Requirements.</strong> Documentation For Completed Training Should Be Uploaded into the user’s IRBNet profile.</td>
<td></td>
</tr>
</tbody>
</table>

1. **Human Subjects Research (HSR) Training**
   - CIRI-specified HSR course through CITIProgram.org (You can create a CITI account affiliated with ‘Catholic Health Initiatives’ to access this course)
   - HSR training through NIH (e.g. NIH Protecting Human Research Participants Course)

2. **HIPAA for Research Training**
   - HIPAA for Research module available through CITI (e.g. CITI Research & HIPAA Privacy Protections Module)

3. **Researcher Financial Conflicts of Interest (COI) Training**
   - **Option 1:** CITI Conflicts of Interest Course through CITIProgram.org containing the following modules (You can create a CITI account affiliated with ‘Catholic Health Initiatives’ to access this course):
     - Module 1 – Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (ID: 15070)
     - Module 2 – Institutional Responsibilities as they Affect Investigators (ID: 15072)
     - Module 3 – Conflicts of Commitment and Conscience (ID: 15073)
     - Module 4 – Institutional Conflicts of Interest (ID: 16765)
   - **Option 2:** CITI Conflicts of Interest module:
     1. Conflicts of Interest in Research Involving Human subjects (ID:488)
   - **Option 3:** Learn Module: *Conflicts of Interest in Research*
     1. CHI Employees can take LEARN course: ‘Conflicts of Interest in Research’. LEARN can be accessed through Inside CHI using the My Tools menu.
   - **Option 4:** NIH Module: *Financial Conflicts of Interest*
4. **Good Clinical Practice (GCP) Training**  
(GCP training is only required if the study involves administering a drug/biologic or investigating a medical device)

- CIRI-specified through CITIProgram.org (You can create a CITI account affiliated with ‘Catholic Health Initiatives’ to access this course)

**B. Upload a CV:**

| Curriculum Vitae, Bio-sketch, or resume | • All research personnel must have a CV, Bio-sketch or resume to inform the IRB that researchers are appropriately qualified and experienced to conduct research. |

**C. Completing Financial Conflict Of Interest (FCOI) Disclosure:**

**Financial Conflict of Interest (FCOI) Disclosure via Health Endeavors**

*Note: Centura Health investigators do not need to complete a disclosure through the Health Endeavors system. Instead, each Centura Health Investigator should complete and submit a copy of the “FORM - CENTURA-AFFILIATED SITES ONLY - Financial Disclosure Form” available in the IRBNet document Library)

**Financial Conflict of Interest (FCOI) Disclosure via Health Endeavors**

*(Please be sure to answer ‘yes’ to Question 5, which asks if you are a researcher.)*

a. Click on this link (note: this link expires October 2017) to access Health Endeavors (If you are a physician not employed by CHI, please use your NPI # in the employee ID section. If you do not have an NPI # use initials and birth month and date in the following format: ABC0101).

b. Attest to the identification information presented and move between questions by clicking ‘Next’ or ‘Previous’ (you will have a chance to review your answers at the end). Please be sure to answer ‘yes’ to Question 5, which asks if you are a researcher.

c. Proceed to the end of the questionnaire and click on ‘Continue’ and finally ‘Attest’ to the Confirmation and Certification of the information provided and click on ‘Submit’ to complete the disclosure process. You may save your questionnaire as a PDF or print for your records.

d. Your Health Endeavors disclosure does not need to be submitted in your user profile in IRBNet. Please include in your cover letter that you have completed the Financial Conflict of Interest declaration via Health Endeavors. This ensures that CHIRB staff is easily able to locate your declaration.
D. Uploading a CV and Training Records Into Your IRBNet Profile:

**Step 1:** Log into IRBNet. Click on user profile on the upper right hand corner of the page.

**Step 2:** At the bottom of the page, under the Training & Credentials sub-header, click on the blue hyperlink – Add a new training & credentials record.

**Step 3:** Pick the appropriate document type, enter description of the course, enter the effective and expiration dates, and upload and attach your completion certificate.

**Note:** When entering the dates, please use the following format XX/XX/20XX.
When submitting your training records please ensure each record/document is submitted separately as shown in this image. Please **DO NOT** submit one attachment with all your training records.

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**Step 4:** Once attached, click on the blue **submit** hyperlink.

**Step 5:** Select the following board: Catholic Health Initiatives Institute for Research and Innovation and click continue (the board will automatically populate).

**Step 6:** Click on the **submit** button. CHIRB will not be able to locate your training records until they have been submitted. Once submitted, the CHIRB will review and approve your training records.
4. Submitting a research study for review to the CHIRB for the first time:

Submitting a research study to the CHIRB for review involves 3 steps:

i. Ensure all research personnel have a IRBNet profile and have completed required training, uploaded a CV, and completed a FCOI Disclosure (see Section 3 of this guide).

ii. Ensure you have necessary institutional approval from your institution’s Research Manager (see Section 1 of this guide). If you are a student/trainee/fellow/resident, you will need a CHI-employed Mentor at the facility you are conducting research at to oversee your research at that facility. This may be in addition to your academic mentor. The CHI-employed Mentor needs to be listed on the CHI – Research Application. Contact the CHIRB with questions.

iii. Submit the necessary documents through IRBNet by:
   A. Creating a New Project and Sharing The Project with all research personnel
   B. Completing the CHIRB SMART Application Form,
   C. Uploading Supporting Documents (Protocol, Consent Form, Etc.), and Linking Training
   D. Signing The Package.
   E. Submitting The Package.

   A. Creating a New Project and Sharing The Project With All Research Personnel:

   By default, the only person who has access to a new project (research study) in IRBNet is the individual who created it. The PI does not automatically have access to the research study unless they are the one who created it in IRBNet. So, the research study needs to be shared through IRBNet with all the Research Personnel working on the study, regardless of whether they will access the documents in IRBNet.

   *For Centura Health of Colorado and Western Kansas Investigators Only – If you are an investigator at a site that is part of the Centura Health network, please also Share Your Project with Suzanne Coleman and Eva Ernevad and give them Read access only.
Click on ‘share this project’

Then click on ‘share’

Please note that CHI will automatically populate. Then click on ‘select organization’
Enter the last name of the person you are giving access to and click ‘search.’

Please note that this person will need to have created an IRBNet account.

Then choose the type of access you would like to grant and click ‘save.’
B. Completing CHIRB SMART Application Form. (Note - HUD submissions do not need to complete this form)

C. Uploading Supporting Documents (Protocol, Consent Form, Etc.), and Linking Training

Supporting documents provide the IRB with essential information. Linking research personnel training to a submission is very important because it allows the CHIRB to see training Research Personnel have uploaded into IRBNet (See Section 3). Below is a table that lists supporting documents and by submission type. Some supporting documents are required while others need only to be submitted if they are applicable to your research study. Protocol and Consent Form Templates, along with other forms and guidance documents researchers, can be found in the IRBNet Document Library:
### D. Signing The Package:

Electronically Signing the Package through IRBNet serves as an attestation on the part of the PI that the research will be conducted in compliance with all relevant regulations, institutional policies, and ethical principles.

<table>
<thead>
<tr>
<th>Supporting Documents By Submission Type</th>
<th>Full Board</th>
<th>Expedited</th>
<th>Exempt</th>
<th>Research Not Involving Human Subjects</th>
<th>Not Research</th>
<th>Request for CHIRB To Cease Oversight To Another IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Link Training Records / Credentials</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Not Required</td>
<td>Not Required</td>
<td>Required</td>
</tr>
<tr>
<td>Protocol - (Template Available In the IRBNet Document Library)</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Requested</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Cover Letter Outlining Your Submission</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Requested</td>
<td>Required</td>
<td>Required</td>
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<tr>
<td>CHIRB Billing Form - (Form Available In the IRBNet Document Library)</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Requested</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Research Routing Form - (Form Available In the IRBNet Document Library)</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Not Required</td>
<td>Not Required</td>
<td>Required</td>
</tr>
<tr>
<td>Documentation of IRB Approval and IRB Authorization Agreement</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>If available</td>
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<tr>
<td>CHIRB – HUD Initial Application</td>
<td>If HUD Submission</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Data Collection Tools</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
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<tr>
<td>Consent Form / Information Sheet - (Template Available In the IRBNet Document Library)</td>
<td>If Applicable</td>
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<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
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<tr>
<td>Documents Used With Subjects (For Example – Advertisements, Surveys, Phone Scripts, Etc.)</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
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<tr>
<td>Other Supporting Documentation (For Example – Grant Application, FDA Documentation, Documentation For Vulnerable Populations, Etc.)</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
<td>If Applicable</td>
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</tbody>
</table>
*If another member of the study team is submitting documents to the CHIRB on behalf of the PI* (meaning the PI does not log in and Sign the Package in IRBNet). The PI can physically sign the ‘FORM - PI Attestation’ available in the IRBNet document library, and this form can be scanned and uploaded as a supporting document.

*If the PI requires a Mentor* because the PI is a student/trainee/fellow/resident, the Mentor must Sign the Package along with the PI.

E. Submitting the Package

After all of the necessary documents have been uploaded into IRBNet, all necessary research personnel training has been completed, and the package has been appropriately signed. The package is ready to be submitted.
CHIRB will not receive your submission until the package has been submitted. To do so, please click on the ‘submit this package’ tab.

Click continue once the Catholic Health Initiatives IRB name is highlighted.
5. Requesting Changes To An Ongoing Research Study (For Example – Adding New Personnel, Changing Research Procedures, Changing Study-Related Documents, Etc.)

Any revision to previously approved materials must be reviewed and approved by the CHIRB prior to implementation unless it is necessary to eliminate an immediate harm to participants. We call changes to an ongoing study ‘Amendments’ or ‘Modifications’. The following documents are required for an Amendment/Modification submission:

- **CHIRB Amendment/Modification Request Form** (found in the Forms and Templates library in IRBNet)
- **Clean & tracked** copies of documents being modified
- For changes in **study personnel**, please add/remove personnel from the CHI-Research Application Form and all other relevant study documents. All **new personnel** need to have created an **IRBNet profile**, completed necessary **training**, uploaded a **CV**, and completed **Financial Conflict of Interest (FCOI) Disclosure** (see **Section 3** above).

Please note that your modification request may require revisions to be made to multiple documents. For example, if you are requesting a change in enrollment number, please revise the CHI-Research Application form, protocol, and consent form (if actively enrolling participants), and any other applicable documents that include information relevant to the requested change. Please be sure clean and tracked copies of documents being modified are submitted.

A. Upload Required Documents

Access your study in IRBNet by going to ‘My Projects.’ Then click on your study title. Once, you are in your study page, click on ‘Create a New Package’.
B. Sign The Package:

Electronically Signing the Package through IRBNet serves as an attestation on the part of the PI that the research will be conducted in compliance with all relevant regulations, institutional policies, and ethical principles.

*If another member of the study team is submitting documents to the CHIRB on behalf of the PI (meaning the PI does not log in and Sign the Package in IRBNet). The PI can physically sign the ‘FORM - PI Attestation’ available in the IRBNet document library, and this form can be scanned and uploaded as a supporting document.

*If the PI requires a Mentor* because the PI is a student/trainee/fellow/resident, the Mentor must Sign the Package along with the PI.
C. Submitting the Package

After all of the necessary documents have been uploaded into IRBNet, all necessary research personnel training has been completed, and the package has been appropriately signed, the package is ready to be submitted.
Click continue once the Catholic Health Initiatives IRB name is highlighted.
6. Submitting a progress report to the CHIRB regarding the status of an ongoing study at least once per year or requesting closure (we call this a ‘Continuing Review’, and it is only required for Expedited research, Full Board research, and HUD’s).

Continuing Reviews (CRs) are required for all projects that are expedited or full board. For Humanitarian Use Device (HUD) submissions, please complete the CHIRB HUD Annual Report Form.

The following documents are required for continuing review submissions.

- CHIRB Application for Continuing Review or Final Report (Part 1 of 2) [Note – if this is an HUD, please use the ‘CHIRB HUD Annual Report Form’ instead]
- CHIRB Application for Continuing Review or Final Report (Part 2 of 2)*
- Most-recently approved version of the protocol and consent form.
- CHI-Research Application**

All research personnel listed on the CHI-Research Application must have completed current training requirements (See Section 3 for all training requirements.)

* If your study has more than one site, the Principal Investigator will need to complete Part 1 of the Continuing Review form on behalf of all sites conducting the study under the CHIRB’s oversight. Each site, including the PI site, must submit Part 2 of the Continuing Review form providing information from that site only.

**If your study was transferred to the CHIRB and your study is active and enrolling, please complete and submit the CHI Initial IRB Application Form at the time of the first continuing review conducted by CHIRB. If your study was transferred to the CHIRB from another IRB and is in long term follow up or data analysis, you are not required to complete the CHIRB Application Form.

A. Submit Required Documents

Access your study in IRBNet by going to ‘My Projects.’ Then click on your study title. Once you are in your study page, click on the ‘Create a New Package’ tab.
B. Signing The Package:

Electronically Signing the Package through IRBNet serves as an attestation on the part of the PI that the research will be conducted in compliance with all relevant regulations, institutional policies, and ethical principles.

*If another member of the study team is submitting documents to the CHIRB on behalf of the PI* (meaning the PI does not log in and Sign the Package in IRBNet). The PI can physically sign the ‘FORM - PI Attestation’ available in the IRBNet document library, and this form can be scanned and uploaded as a supporting document.

*If the PI requires a Mentor* because the PI is a student/trainee/fellow/resident, the Mentor must Sign the Package along with the PI.
C. Submitting the Package

After all of the necessary documents have been uploaded into IRBNet, all necessary research personnel training has been completed, and the package has been appropriately signed. The package is ready to be submitted.

CHIRB will not receive your submission until the package has been submitted. To do so, please click ‘Submit this Package’ tab.
IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the reviewer decision is electronically recorded.

Click continue once the Catholic Health Initiatives IRB name is highlighted.
7. Reporting Problems/Non-Compliance/Concerns/Adverse Events Related To The Research Study.

The CHIRB requires the investigator to evaluate and report any unanticipated problem or protocol violation to the CHIRB as soon as possible but no later than ten (10) business days after discovery.

- **Unanticipated Problems:** The CHIRB requires the investigator to evaluate and report any internal or external Unanticipated Problem to the CHIRB as soon as possible but no later than ten (10) business days after discovery. Unanticipated Problems are 1) unanticipated AND 2) serious or life-threatening or potential for increased risk AND 3) possibly or definitely related to the protocol, as determined by the investigator.

- **Protocol Violations:** A protocol violation is any exception or deviation from the protocol that is not approved by the IRB prior to its initiation or implementation. These protocol violations may be major or minor violations. The CHIRB requires protocol violations to be reported the CHIRB as soon as possible but no later than ten (10) business days after discovery.

The CHIRB requires the investigator to report unanticipated deaths of research participants to the CHIRB within 24 hours of discovery.

A. Upload New Documents:

Access your study in IRBNet by going to ‘My Projects.’ Then click on your study title. Once you are in your study page, click on the project history tab.

Click on create new package.
B. Signing The Package:

Electronically Signing the Package through IRBNet serves as an attestation on the part of the PI that the research will be conducted in compliance with all relevant regulations, institutional policies, and ethical principles.

*If another member of the study team is submitting documents to the CHIRB on behalf of the PI (meaning the PI does not log in and Sign the Package in IRBNet), the PI can physically sign the ‘FORM - PI Attestation’ available in the IRBNet document library, and this form can be scanned and uploaded as a supporting document.

*If the PI requires a Mentor because the PI is a student/trainee/fellow/resident, the Mentor must Sign the Package along with the PI.

Using the ‘Attach New Document’ button, upload a written description of the event including any steps taken to mitigate the issue. Please also upload any supporting documents (reports from the sponsor, etc.)

Click ‘My Projects’ then click the blue link to open the project.

Then, click ‘Sign This Package’.
C. Submitting the Package:

After all of the necessary documents have been uploaded into IRBNet, all necessary research personnel training has been completed, and the package has been appropriately signed. The package is ready to be submitted.

CHIRB will not receive your submission until the package has been submitted. To do so, please click on the ‘submit this package’ tab. Once the Catholic Health Initiatives IRB name is highlighted, select your role, then click ‘Sign’. Click continue once the Catholic Health Initiatives IRB name is highlighted.
8. How To Respond To A Request From The CHIRB Sent Through IRBNet.

The CHIRB requests information from investigators through two avenues:

1. **Informal/Administrative Review** - Your submission becomes ‘Locked’ after your submit to The CHIRB to prevent the researcher from making further changes. In cases where the researcher needs to make a minor change prior to IRB review, an IRB administrator will ‘Unlock’ your submission to allow you to make changes. All you have to do is make changes to your submission, then ‘re-Lock’ the submission. **It is not necessary to create a new package/submission for this type of review.**

2. **Formal Review** - The CHIRB may issue an **information required** letter (Minor Modifications Letter, Deferral Letter, etc.) if more substantial changes are needed. To respond to this type of request for changes, you will need to create a new **Response Package/Submission**. Please follow the instructions below to do this:

   - To respond to the request, ‘create a new package’ in the Project History page as shown. Please **DO NOT** create a new project as this will create an entirely new study in IRBNet.

   - You will get a notification when a letter has been published in IRBNet. To view the letter, click on the ‘My Projects’ tab, select your project, then click on the ‘Reviews’ page and open the letter you wish to view.
If you were requested to provide training and credential documents, please ensure all study personnel have uploaded all CHIRB required training and credential documents in their User Profile in IRBNet. Once that has been done, please link their training and credential documents by clicking on the link/unlink hyperlink.

Once all items have been uploaded, the PI will then be required to sign the package.

Then click on ‘add new document’ to upload items requested by the IRB.
Once the Package has been signed, the Package/submission is then ready to be submitted.

You are now ready to submit. Click on the ‘submit this package’ page and follow all on-screen instructions until submitted. Please be sure to pick ‘response/follow-up’ as your submission type.
9. Uploading Updated Training Documentation Into IRBNet

Step 1: Log into IRBNet. Click on user profile on the upper right hand corner of the page. Scroll down to the bottom of the page where you will be able to see your training records.

Step 2: To upload a new training certificate, please click on ‘add a new training & credentials record.’

In the image below, the CITI Good Clinical Practice course expired on 12/04/2016.

Notice the Doc ID number has a ‘.1’ at the end. Once you upload a new record this number will change to ‘.2’
Step 3: Select the expired course for which you would like to upload a new certificate (in this case, the CITI Good Clinical Practice course) and click ‘continue.’

If you would like to submit completely new training/credential records that have not previously been submitted, select ‘none of these.’

Step 4: Pick the appropriate document type, enter description of the course, enter the effective and expiration dates, and upload and attach your completion certificate.

Note: When entering the dates, please use the following format XX/XX/20XX.

Step 5: Once attached, click on the blue submit hyperlink.

Note that a new version of the CITI GCP training record has been uploaded. The Doc ID now has a ‘.2’ at the end.
Step 6: Select the following board:
Catholic Health Initiatives Institute for Research and Innovation and click continue (the board will automatically populate).

Step 7: Click on the submit button.
CHIRB will not be able to locate your training records until they have been submitted.
Once submitted, the CHIRB will review and approve your training records.
10. Frequently Asked Question - (‘How do I link training?’, etc.)

How do I link research personnel training to a submission?

Linking training is done while you are building a submission to submit to CHIRB. There is a link on the ‘Designer’ page that will allow you to link personnel training to a submission. Please note that you can only link training of personnel you have ‘Shared’ the project with through IRBNet. For information on how new personnel can create an IRBNet profile and upload training into IRBNet so that it is available to be linked, please see Section 3 above.

Make sure the project has been “Shared” with all the research personnel you would like to link training for using the ‘Share this Project’ tab. Then go to the ‘Designer’ tab for the project and click ‘Link / Unlink Training Records’.