Human Subject Protection Program
Investigator Guidance
June 1, 2022

INSTRUCTIONS FOR MAKING A SUBMISSION TO A CENTRAL IRB FOR INDUSTRY SPONSORED MULTI-CENTER CLINICAL TRIALS

Central IRB Review of Clinical Trials

CHLA allows IRB review to be performed by a central IRB when a Sponsor/CRO is using a central IRB for review of industry sponsored multi-center clinical trials.

This document describes the process for making a submission to the central IRB for review and approval of CHLA to be a performance site for industry sponsored multi-center clinical trials.

1. When a CHLA study team is contacted by the Sponsor/CRO to join a study, ask if the Sponsor/CRO is using a central IRB.

   - Master agreements and CHLA review procedures are in place with three independent IRBs that perform central IRB review: **Advarra IRB, WCG IRB and Sterling IRB**.

   - If you encounter another independent IRB that a Sponsor/CRO is using as the central IRB for a trial, please contact the Executive Director of Clinical Research Operations, Shannen Nelson (shnelson@chla.usc.edu) for more details and information to rely on that IRB.

   - If the Sponsor/CRO is <u>not</u> using a central IRB, the study can be reviewed by the CHLA IRB.

2. When the Sponsor/CRO uses a central IRB for the clinical trial, the Sponsor/CRO submits the protocol for review and approval by the central IRB. A submission to the central IRB is also required to add CHLA as a performance site to conduct the clinical trial.

3. Resources for submitting to Advarra IRB, WCG IRB and Sterling IRB are posted on the HSPP website. Interactive education sessions with Advarra, WCG and Sterling representatives are offered periodically throughout the year. Upcoming sessions are advertised via email to iStar users and the TSRI training and education list.

Submitting to the CHLA HSPP Office for Clearance

All studies must first be cleared by the CHLA HSPP office. The clearance process is an administrative review to ensure all CHLA requirements for the conduct of research are completed, and the documents to be submitted to the central IRB are complete and accurate. The central IRB will not review a submission to add CHLA as a site without a CHLA clearance letter.

1. Submit a ceded review application in iStar to obtain CHLA HSPP clearance to rely on the central IRB for the clinical trial.

2. All department/division and ancillary reviews must be completed **before** a submission may be cleared by the HSPP Office. To avoid delays in the CHLA clearance process, be sure to answer all of the questions in Section 50 of the iStar application – do not leave sections blank.

3. The CHLA HSPP will issue a clearance notice to the Principal Investigator (PI).

4. After receiving the clearance notice, the CHLA study team can submit for review by the central IRB.

Documents to include in the CHLA ceded review application for initial clearance:

1. **Central IRB approved protocol:** Upload a copy of the approved protocol so that department/division and ancillary reviews can complete their reviews.

2. **Key Information Summary (if no concise summary is in the consent template):**

   - Check with the Sponsor/CRO to find out if the approved Sponsor consent template(s) include a concise summary section (also called a key information summary section).

   - CHLA requires that all main study consent forms (not assent forms or sub-study consents) include a concise summary section. **If the Sponsor consent template does not include this, you must create one.**

   - There is a template key information summary statement on the HSPP website. Complete the template and upload it to the ceded review application.

3. **CHLA COIRC Conflict Management Plan (CMP):** If any of the CHLA study team members have a financial conflict of interest related to the clinical trial, upload a copy(ies) of the CHLA conflict management plan(s) to the ceded review application. If the COIRC has not issued a

conflict management plan (when one is required), the study cannot be cleared until the plan is approved and uploaded into iStar.

4. **Financial Conflict of Interest Consent Statement:** If any of the CHLA study team members have a financial conflict of interest related to the clinical trial, **a financial conflict of interest consent statement must be created** and submitted when the executed CMP requires a financial disclosure statement to be included in the consent form and/or recruitment materials.

   - There is a template conflict of interest statement on the HSPP website. Complete the template and upload it to the ceded review application.

5. **CHLA Specific Recruitment Materials (if applicable):** Upload any CHLA specific recruitment or subject materials (e.g. recruitment flyers). Sponsor provided recruitment materials do not need to be submitted for clearance.

NOTES:

- ✓ **Do not** include any CHLA consent form checklists. These are no longer required. The central IRB will create consent and assent forms with required CHLA language using the approved Sponsor template documents.
- ✓ **Do not** include any simplified assent templates or addendum consents for these submissions. These documents may not be used for relying on a central IRB.

Submitting to Advarra IRB

Follow these instructions when the central IRB is Advarra IRB. This submission can be made by the CHLA study team or the Sponsor/CRO.

After you receive a CHLA clearance letter you can submit to Advarra IRB. The Advarra IRB uses a submission platform called the Center for IRB Intelligence (CIRBI). You will complete an application and **upload all of the documents that have been cleared by the CHLA HSPP office**. Refer to the reference documents on the HSPP website for helpful tips for completing the CIRBI application.

1. The website for submitting to the Advarra IRB is: www.advarra.com. Click on the "IRB CIRBI LOGIN" link at the top of the page.

2. First time users will need to complete an initial registration process. Once registered, an activation link will be emailed. Follow the instructions in the email to activate your CIRBI account.

3. Use your CHLA email account for CIRBI registration. No personal email accounts may be used.

4. Existing users may go directly to http://www.cirbi.net and login with their CHLA email and password.

Documents to include with your Advarra IRB submission:

- ❑ CHLA HSPP Clearance Notice
- ❑ PI Curriculum Vitae (CV)
- ❑ Key Information Summary document, if required
- ❑ CHLA COIRC Conflict Management Plan(s), if required
- ❑ Financial Conflict of Interest Consent Statement document, if required
- ❑ Any CHLA specific recruitment or subject materials, when applicable

5. **Questions about Submitting?** You can email or phone Advarra IRB: cirbi@advarra.com or 866-99CIRBI (866-992-4724). You also may contact CHLA's Institutional Contact, Andrew Saunders at Andrew.Saunders@advarra.com or 206-436-3266, if you have any questions or problems with submitting to Advarra IRB.

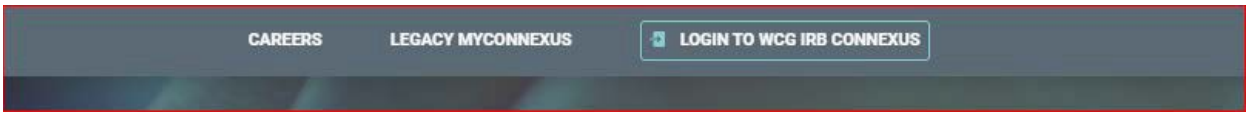
Submitting to the WCG IRB

Follow these instructions when the central IRB is the WCG IRB. This submission can be made by the CHLA study team or the Sponsor/CRO.

The Western IRB (WIRB) is now called the WIRB-Copernicus Group IRB (WCG IRB). WCG has combined its five IRBs into a single IRB called the "WCG IRB." This includes Western IRB, Copernicus Group IRB, Aspire IRB, New England IRB, and Midlands IRB.

After you receive a CHLA clearance letter you can submit to the WCG IRB. The WCG IRB uses a submission platform called Connexus. You will complete an online application and upload all of the documents that have been cleared by the CHLA HSPP office. Refer to the reference documents on the HSPP website for helpful tips for using Connexus.

1. The website for submitting to the WCG IRB is: https://www.wcgirb.com/how-to-submit/. Click on the "LOGIN TO WCG IRB CONNEXUS" link at the top of the page.



2. First time users will need to "Create a New Account" by completing the registration process. Once registered, an activation link will be emailed. Follow the instructions in the email to activate your WCG IRB Connexus account.

NOTES: The WCG IRB is transitioning to a new Connexus platform that is used to submit studies for review. However, not all user accounts have been transitioned yet.

- ❑ **New Users:** Use your CHLA email account to register for a **WCG IRB Connexus** account. No personal email accounts may be used.

- ✓ Refer to the WCG IRB Website for detailed instructions and helpful "How To" videos: https://www.wcgirb.com/how-to-submit/.

❑ **Existing Users:** Do not create a new user account if you have a **Legacy MyConnexus** account. You will need to transition your account to avoid problems with viewing existing submissions. To transition your account from **Legacy MyConnexus** to **WCG IRB Connexus** you will need to select the "Forgot Password?" link the first time you access WCG IRB Connexus. Use the same email address from **Legacy MyConnexus** and follow the instructions to reset your password.

- ✓ Refer to the WCG IRB Website for detailed instructions and helpful "How To" videos: https://www.wcgirb.com/how-to-submit/.

3. **Questions about Submitting?** You can "live chat" with Client Services in Connexus or email or phone Client Services at clientservices@wcgirb.com or 855-818-2289. You also may contact CHLA's Account Manager, Carmen Thompson at CBThompson@wirb.com or 360-252-2447, if you have any questions or problems with submitting to the WCG IRB.

Documents to include with your WCG IRB submission:

- ❑ CHLA HSPP Clearance Notice
- ❑ PI medical license - for PIs who have not previously submitted to WCG
- ❑ PI Curriculum Vitae (CV) - for PIs who have not previously submitted to WCG
- ❑ Key Information Summary document, if required
- ❑ CHLA COIRC Conflict Management Plan(s), if required
- ❑ Financial Conflict of Interest Consent Statement document, if required
- ❑ Any CHLA specific recruitment or subject materials, when applicable

Submitting to Sterling IRB

Follow these instructions when the central IRB is Sterling IRB. This submission can be made by the CHLA study team or the Sponsor/CRO. After you receive a CHLA clearance letter you can submit to Sterling IRB.

The Sterling IRB uses a web submission portal called SilverLINK. You will complete an application and **upload all of the documents that have been cleared by the CHLA HSPP office**. Refer to the reference documents on the HSPP website for helpful tips for completing the SilverLINK application. **Important Note:** Do not complete a New Study Submission Application. You will need to request access to the Sponsor's study to add CHLA as a participating site.

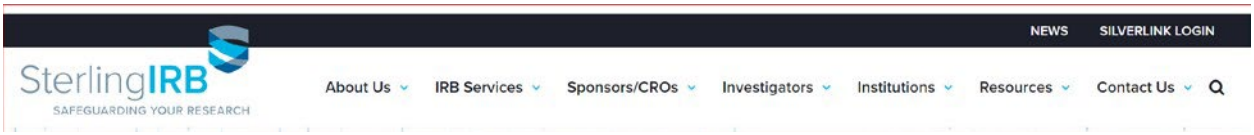
Request access to SilverLink using one of the following options:

1. Visit this website to request access or contact admin support in SilverLINK to request access. You will need to ask the Sponsor/CRO for the study protocol number or Sterling IRB ID number. Complete the form and submit to be granted access to a specific study.

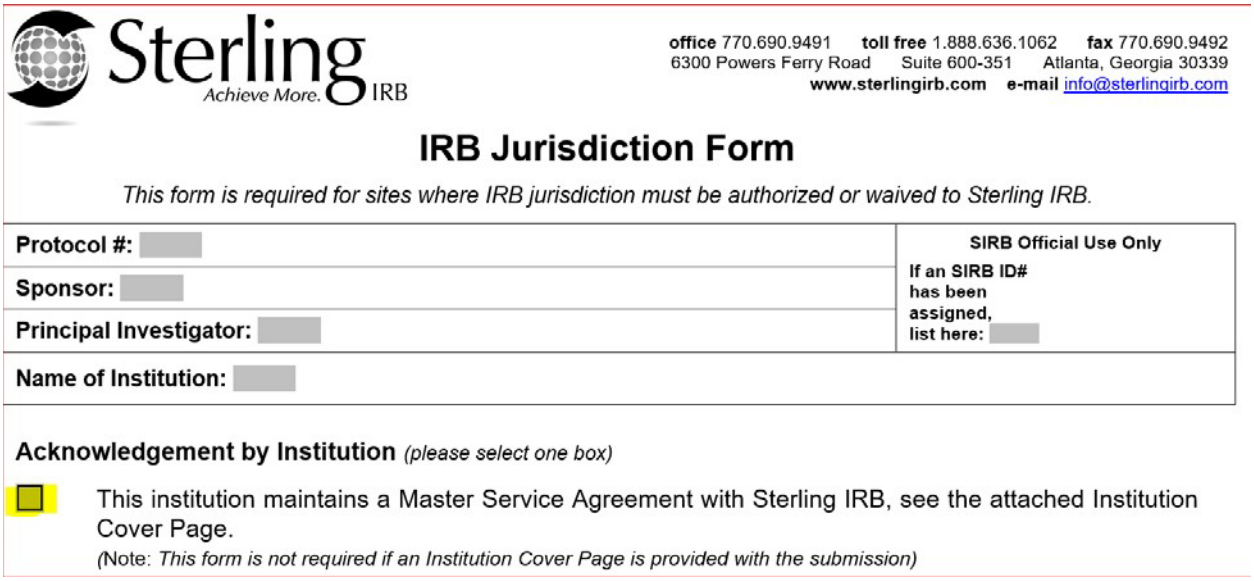
2. You can also email support@sterlingirb.com with the following information: a) Lead PI's name and email address.

3. A welcome email will be sent to you once CHLA has been added to SilverLink. Use your CHLA email account for SilverLINK registration. No personal email accounts may be used.

4. Existing users can access SilverLINK at: https://www.sterlingirb.com/. Click on the "SLIVERLINK LOGIN" link at the top of the page.



5. SilverLINK will prompt you to fill out an IRB Jurisdiction form. **Important Note:** Check the **first box** on this form. The "Institution Cover Page" is the CHLA HSPP Clearance Notice:



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6300 Powers Ferry Road Suite 600-351 Atlanta, Georgia 30339
www.sterlingirb.com **e-mail** info@sterlingirb.com

IRB Jurisdiction Form

This form is required for sites where IRB jurisdiction must be authorized or waived to Sterling IRB.

Protocol #:	**SIRB Official Use Only**
Sponsor:	**If an SIRB ID# has been assigned, list here:**
Principal Investigator:	
Name of Institution:	

Acknowledgement by Institution *(please select one box)*

☐ This institution maintains a Master Service Agreement with Sterling IRB, see the attached Institution Cover Page.
(Note: *This form is not required if an Institution Cover Page is provided with the submission)*

Documents to include with your Sterling IRB submission:

- ❑ CHLA HSPP Clearance Notice
- ❑ PI Curriculum Vitae (CV) - signed, dated and current within two years
- ❑ Key Information Summary document, if required
- ❑ CHLA COIRC Conflict Management Plan(s), if required
- ❑ Financial Conflict of Interest Consent Statement document, if required
- ❑ Any CHLA specific recruitment or subject materials, when applicable

6. **Questions about Submitting?** You can email or phone Sterling IRB: support@sterlingirb.com or 888-636-1062. You also may contact CHLA's Institutional Contact at Sterling IRB, Becky Ramkissoon at becky.Ramkissoon@sterlingirb.com or 678-501-7836, if you have any questions or problems with submitting to Sterling IRB.

What to Expect After Submission to the Central IRB

1. Once you have made a submission it is **very important to check your email for messages about your submission**.

2. Draft consent and assent forms will **not** be sent to you by the central IRB. However, drafts may be sent to the Sponsor/CRO for pre-review if required by the Sponsor/CRO.

NOTES:

- ✓ Any requests to change CHLA required language needs approval from the CHLA HSPP. The central IRB will notify the CHLA study team and the CHLA IRB reliance email (irbreliance@chla.usc.edu) when a Sponsor/CRO requests changes to CHLA required language.

- ✓ The HSPP Director will review the changes to CHLA language and decide if they may be approved. The Director will let you and the central IRB know via email if the changes are approved.

3. When central IRB approval and study documents are issued, you will receive an email with instructions about how to access them.

4. The central IRB will notify you when revised study documents are issued. For example, new versions of the approved protocol, investigator brochure (IB), revised consent documents.

Submitting an Amendment to the CHLA Ceded Review Application

1. Once the central IRB approval is received, the CHLA study team will need to **file an amendment in iStar** to upload the following approved documents to the CHLA ceded review application:

   - ❑ Central IRB approval letter
   - ❑ Central IRB approved CHLA consent and assent forms
   - ❑ Any approved CHLA specific recruitment or subject materials

2. CHLA study teams also are responsible for submitting **additional amendments** to the CHLA ceded review application in iStar when **new approval letters and study documents** are issued by the central IRB.

3. Amendments are processed by the CHLA HSPP staff. The purpose of filing amendments to the CHLA ceded review application is to ensure currently approved documents appear in iStar and OnCore for use by the CHLA study team.

Tips for Managing Your Approved Study with the Central IRB

1. CHLA study teams are responsible for keeping **all the IRB approved protocol documents and information** in the research regulatory binder/e-Reg for the study.

2. If your **study contacts change**, be sure to revise them with the central IRB, so that the correct people receive email correspondence about the study.

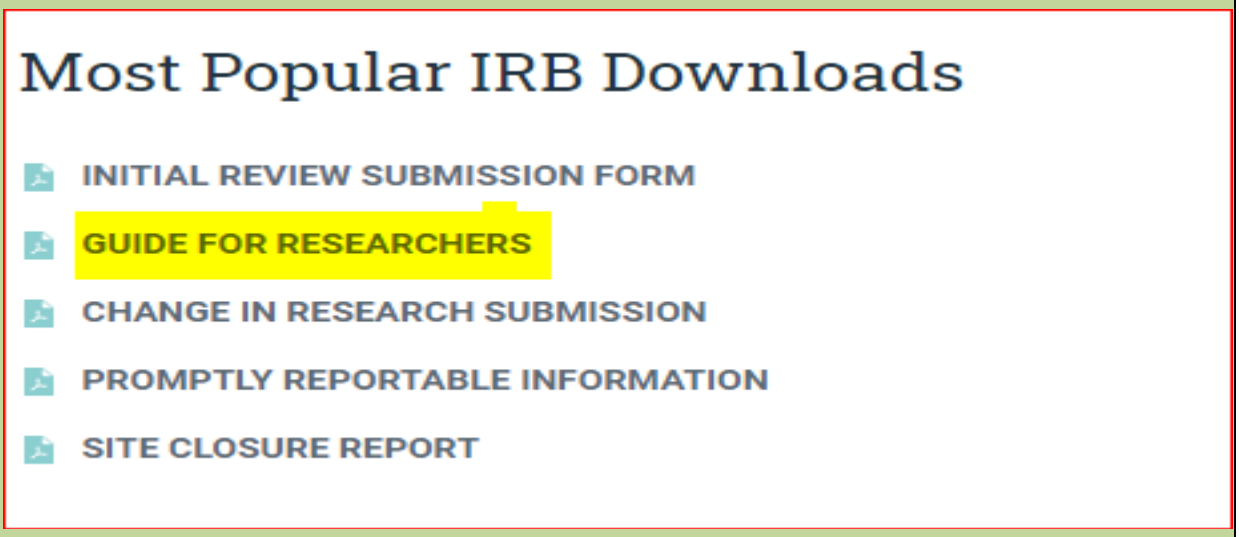
3. CHLA study teams are responsible for assuring all **CHLA site amendments, continuing reviews, and reportable events** are reviewed by the central IRB.

4. CHLA study teams are responsible for **understanding the central IRB's requirements for review and oversight of the research**. These requirements may be different than CHLA IRB requirements. For example, requirements for translation and submission of new information that requires prompt reporting. **NOTE:** Always access the central IRB's references and resources **from the source** to ensure you are referring to the most current versions of the documents.

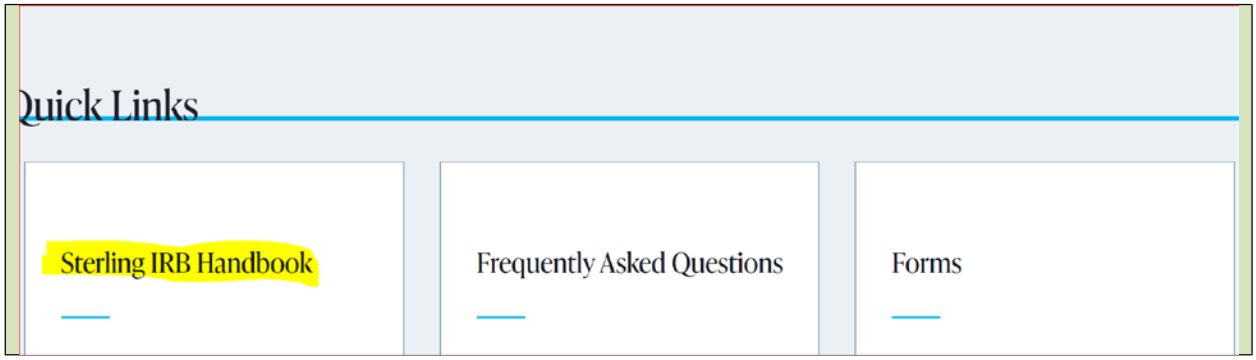
Investigator Resources for Advarra IRB, WCG IRB and Sterling IRB

Advarra IRB: See the Advarra IRB Handbook for Investigators, Institutions, Sponsors, and Sponsors' Representatives. This is located under "Reference Materials" in CIRBI.

WCG IRB: See the Guide for Researchers at https://www.wcgirb.com/how-to-submit/irb-forms/.



Sterling IRB: See the Sterling IRB Handbook at https://www.sterlingirb.com/resources/.


Quick Links
Sterling IRB Handbook
Frequently Asked Questions
Forms