CHLA HSPP Ceded IRB Review Initial Submission Workflow

The following is a general overview, for CHLA study teams, of the workflow for obtaining CHLA HSPP ***clearance to cede IRB review*** to an external/commercial IRB and ***clearance to enroll subjects.*** This workflow ***does not*** apply when submitting revised IRB-approved CHLA-specific consent forms, assent forms, recruitment documents, or updated study protocols.

Please note the IRB of record may have additional steps and/or requirements that are not indicated in this workflow.

The workflow depends on who the IRB of Record is:

- **Click here to view the workflow if the IRB of Record is WCG IRB**
- **Click here to view the workflow if the IRB of Record is NCI CIRB**
- **Click here to view the workflow for all other IRBs (e.g., BRANY IRB, Advarra IRB, Sterling IRB, NMDP IRB, a Hospital IRB (e.g., BCH IRB), a University IRB (UCSD IRB), etc.)**

Please work with the sponsor or IRB of Record to negotiate CHLA-required language. If necessary, contact a Regulatory Specialist for assistance via email, regulatoryaffairs@chla.usc.edu . The Regulatory Specialist may accept minor changes to required language that do not conflict with federal regulations, state laws, and institutional policies. The Regulatory Specialist will determine when it is necessary to involve a CHLA/HSPP Reliance Administrator in negotiations.

Reminders and Tips for Managing Your Approved Study

- When the initial iStar application is created, responses to section 50 are necessary. It will determine the department/division and ancillary reviews that are required before clearance to ceded IRB review may be granted.
- For the life of the study, submission of additional amendments to the CHLA ceded review application in iStar is required when the IRB of Record approves revised CHLA-specific consent forms and assent forms, in addition to revised or new site-specific study documents (e.g., recruitment document, etc.) and updated protocol. The corresponding IRB approval letter(s) must also be submitted.
- If your study contacts change, be sure to revise them with the IRB of Record and in iStar.

IRB of Record: WCG IRB

This workflow applies when the IRB of Record is WCG IRB.

1. IRB OF RECORD

- Issues study-wide approval letter (i.e., Certificate of Action)
- Approves protocol
- Approves consent form and assent form template(s)

2. CHLA STUDY TEAM with support from Reg. Specialits, if needed

- Creates and submits an initial study application in iStar to obtain clearance to cede IRB review to WCG IRB. The application includes:

√ Initial study-wide IRB approval letter (This is not the CHLA site IRB approval letter)
√ Current IRB-approved protocol
√ Current IRB-approved consent and assent form template(s)

When applicable:
√ Current IRB approval letter
√ CHLA specific recruitment material(s) or subject materials
√ Key Information Summary (if no concise summary is in the currently IRB-approved consent template(s))

3. CHLA HSPP RELIANCE ADMINISTRATOR

- Reviews the initial study application to ensure all CHLA requirements for the conduct of research are completed, and the documents to be submitted to the IRB of Record are complete and accurate.
- If necessary, issues contingencies that must be addressed by the study team
- **Issues the *CHLA Notice of Ceded Review Clearance*,** when all contingencies have been addressed

4. CHLA STUDY TEAM with support from Reg. Specialits, if needed

- Submits to the IRB of Record, the CHLA Notice of Ceded Review Clearance, and all applicable documents (e.g., Key Information Summary cleared by Reliance Admins from iStar)

Following IRB approval:
Creates and submits an Amendment application in iStar to upload the following IRB-approved documents to the CHLA ceded review application:
√ Site Level IRB approval letter
√ IRB-approved CHLA consent and assent forms*
√ IRB-approved CHLA specific recruitment or subject materials, if applicable

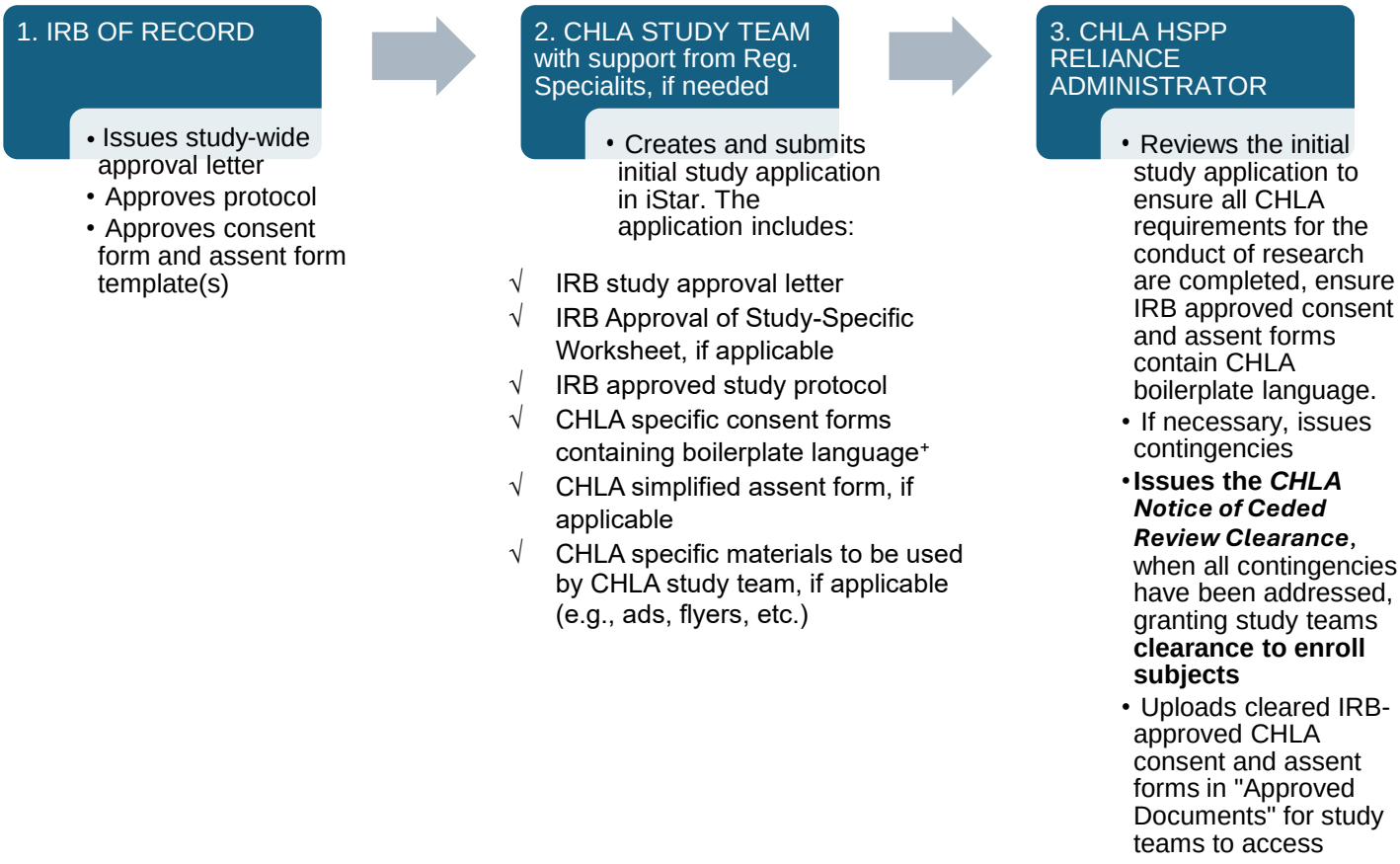
5. CHLA HSPP RELIANCE ADMINISTRATOR

- Reviews the Amendment application to ensure IRB approved consent and assent forms contain CHLA required language
- **Issues the CHLA *Notice of Ceded Review Acceptance of Amendment***, when all contingencies have been addressed, granting study teams **clearance to enroll subjects**
- Uploads cleared IRB-approved CHLA consent and assent forms in "Approved Documents" for study teams to access

* To create CHLA-specific consent and assent forms, WCG IRB will add CHLA specific language to current IRB-approved consent and assent form template.

IRB OF RECORD: NCI CIRB

This workflow applies when the IRB of Record is NCI CIRB.



+ To create CHLA-specific consent forms, only Regulatory Specialists may add CHLA boilerplate language to current IRB-approved consent form templates.

Use this workflow for all other IRBs, such Advarra IRB, BRANY IRB, NMDP IRB, Sterling IRB, a Hospital IRB (e.g., BCH IRB), a University IRB (UCSD IRB), etc.

1. IRB OF RECORD

- Issues study-wide approval letter
- Approves protocol
- Approves consent form and assent form template(s)

2. CHLA STUDY TEAM with support from Reg. Specialits, if needed

- Creates and submits an initial study application in iStar to obtain clearance to cede IRB review. The application includes:

√ Initial study-wide IRB approval letter (This is not the CHLA site IRB approval letter)
√ Current IRB-approved protocol
√ Current IRB-approved consent and assent form template(s)
√ CHLA specific consent/assent forms containing CHLA required language (using redline tracked changes) **

When applicable:
√ Current IRB approval letter
√ CHLA specific recruitment material(s) or subject materials
√ Fully executed reliance documents (does not apply when reliance is documented using the SMART IRB Reliance System or IREx)

3. CHLA HSPP RELIANCE ADMINISTRATOR

- Reviews the initial study application to ensure all CHLA requirements for the conduct of research are completed, and the documents to be submitted to the IRB of record are complete and accurate.
- If necessary, issues contingencies that must be addressed by the study team
- **Issues the *CHLA Notice of Ceded Review Clearance*,** when all contingencies have been addressed

4. CHLA STUDY TEAM with support from Reg. Specialits, if needed

- Submits to the IRB of Record the CHLA Notice of Ceded Review Clearance, CHLA-specific consent and assent forms cleared by Reliance Admins (from iStar), etc.

Following IRB of Record approval:
Creates and submits an Amendment application in iStar to upload the following IRB-approved documents to the CHLA ceded review application:
√ Site Level IRB approval letter
√ IRB-approved CHLA consent and assent forms
√ IRB-approved CHLA specific recruitment or subject materials, if applicable

5. CHLA HSPP RELIANCE ADMINISTRATORS

- Reviews the Amendment application to ensure IRB approved consent and assent forms contain CHLA required language
- **Issues the CHLA *Notice of Ceded Review Acceptance of Amendment***, when all contingencies have been addressed, granting study teams **clearance to enroll subjects**
- Uploads cleared IRB-approved CHLA consent and assent forms in "Approved Documents" for study teams to access

** To create CHLA specific consent and assent forms, use the applicable consent form checklist to add all required CHLA consent form language to current IRB-approved consent and assent form templates. Use either the “NMDP IRB Consent Form Checklist” (for studies that will be reviewed by the NMDP IRB) or the “External IRB Consent Form Checklist” for studies reviewed by all other IRBs. Please use tracked (redline) changes when adding the required language to the templates.