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THE SABAN RESEARCH INSTITUTE

Ceded Review

Overview of Relying on Another IRB For Review and Oversight

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Definitions

- **Human Subject Protection Program (HSPP):** An administrative team that provides regulatory expertise, administrative support and serves as the primary contact for investigators and research staff who are submitting research activities and clinical trials for IRB review.
  Comprised of two arms: IRB and Regulatory Affairs. Under Reg Affairs are: Regulatory Specialists, IRB Reliance Admins, QA and CT.gov/NCI-CTRP
- **IRB:** An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities (biomedical research, social behavioral research). Maintains oversight of studies conducted at CHLA.
- **Ceded Study:** a research study that is deferred to an external IRB for review and oversight.
  Example: CHLA would cede review of a study we would like to participate in, to an outside IRB such as Advarra.
  The ceded review submission is reviewed by an HSPP - IRB team member to ensure all CHLA requirements for the conduct of research are confirmed, completed, and the documents to be submitted to the IRB of Record are complete and accurate.
- **Reviewing IRB:** The IRB serving as the IRB of record for all participating sites in a multisite research study. A Reviewing IRB can be a Single IRB or a Central/commercial IRB. *Also described as 'the IRB of Record'.*
- **Relying IRB:** The IRB that is relying on the review of another IRB that is serving as the IRB of record for a multisite research study.
- **Central / Commercial IRB:** an outside review board chosen by the Sponsor, CRO, Foundation, or Consortium to review the study and all/majority of the participating sites.

Definitions (cont.)

- **Single IRB (sIRB):** An Institutional Review Board that oversees all sites participating in a multisite study. "Single IRB" and "sIRB" are terms used in DHHS regulations and NIH grant policy. Can also be called a 'central IRB' or 'IRB of Record'
- **Reliance Agreement:** A document that allows two institutions engaged in research to cede review and oversight to one IRB (central, external, independent, institutional). Both institutions must agree to and sign the Reliance Agreement before the research can begin.
- **Master Agreements:** A standing reliance agreement between two or more institutions or IRBs that can cover future research studies.
- **SMART IRB:** SMART IRB is *not* an IRB, rather it is both a master reliance agreement and an optional web-based **platform** that can be used to organize multi-site reliance

  Intended to help "harmonize and streamline the IRB review process for multi-site studies, while ensuring a high level of protection for research participants"* by enabling reliance on a study-by-study basis, define roles and responsibilities of relying institutions and reviewing IRBs, and eliminates the need to sign individual reliance agreements for each study (e.g., a non-SMART IRB agreement).

  CHLA along with 800+ institutions have already signed onto this agreement and are actively using it as the basis of reliance for multisite projects. See https://smartirb.org/participating-institutions/ for a listing of participating institutions.

* https://smartirb.org/about-us/

Definitions (cont..)

- **Flexibility Agreement:** This is an additional agreement some institutions require to cover missing elements not covered in the SMART master agreement (e.g., indemnification, insurance).
- **Multisite:** two or more sites in a study. Can also be referred to as 'multi-center'.
- **CHLA Clearance:** provides CHLA's okay to submit your study or item to the IRB of Record for review, which indicates that CHLA has conducted a vetting process ensuring that the PI and all study personnel are set to participate in this study.
  Example: Your site receives initial clearance via iStar to submit your study to the IRB of Record for review and approval.
  This does NOT give your site approval to begin any study procedures.
- **CHLA Clearance Letter:** This is a CHLA HSPP letter that is issued after a Ceded review submission is made in iStar.
- **CHLA Approval:** Generally provided to your site AFTER you have received approval from the IRB of Record and submitted the necessary documents to iStar as an amendment. CHLA approval is our agreement with the IRB of Record's determination and approval that study procedures can begin or continue at CHLA.
  This is not a substitute for the IRB of Record's approval.

Overview

- This presentation is intended to provide guidance on CHLA requirements when relying on another IRB for review and oversight of a study.
- A reliance agreement is necessary to allow for only one IRB review of a multisite research study. CHLA has established various reliance agreements to allow an external IRB to serve as the IRB of Record for a research study that is conducted at more than one sites.
  Once all agreements are in place, CHLA has then officially ceded oversight to the study's central IRB.

CHLA Reliance Agreements

The following agreements are in place at CHLA:

- **Master Agreements:** CHLA has reliance agreements for industry initiated and sponsored, multi-center clinical trials with several independent / central / commercial IRBs and consortia groups, which are such as:
  - Advarra IRB
    - authorized by the Therapeutics Development Network of the Cystic Fibrosis Foundation
  - **WIRB-Copernicus Group (WCG IRB)**
  - Sterling IRB
  - University of Southern California (USC) IRB
    - research conducted at both CHLA and USC
  - National Cancer Institute **(NCI) Central IRB (CIRB)**
    - oncology group clinical trials (e.g., COG)
  - **National Marrow Donor Program (NMDP) IRB, BMT-CTN, CIBMTR, Be the Match, Be the Match BioTherapies studies**
    - studies funded and/or supported by NMDP consortia

CHLA Reliance Agreements (cont.)

- **SMART IRB Agreement:** CHLA is a signatory to the SMART IRB master reliance agreement. ***This is the most commonly used reliance agreement for academic and clinical institutions when single IRB review is required for multicenter research.*** CHLA is willing to rely on another institution for IRB review using the SMART IRB agreement.
- **New Master Reliance Agreements and Other Reliance Materials**
  - **All requests for new master reliance agreements or other reliance materials from an IRB of Record must be initiated by the HSPP Director**.
  - Master reliance agreements are negotiated and signed by CHLA Contracts and Clinical Research staff. Fully executed master reliance agreements are kept as IRB records for the CHLA HSPP.
- **Individual IRB Authorization Agreements:** In cases where an institution does not meet the eligibility criteria to sign onto the SMART IRB agreement, CHLA may use an IRB Authorization Agreement to establish a reliance relationship with an external
  - IRB Authorization Agreements must be reviewed by the HSPP Director and are sent to the Contracts and Clinical Research Office for signature. Fully executed reliance agreements are kept as IRB records for the CHLA HSPP.

IMPORTANT NOTE:

Do not use the instructions on the following slides for submitting to Advarra IRB, WCG IRB, Sterling IRB or another central / commercial IRB.

If you have a submission where a central IRB is being used, refer to:
"Instructions for Making a Submission to a Central IRB for Industry Sponsored Multi-Center Clinical Trials"
for details about the submission process.

Please refer to the HSPP website's Ceded Review page for additional resources.

Initial Clearance Overview

All studies ceding review to another IRB 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 CHLA clearance letter is required for submission to any central/commercial IRB as well as any external IRB of Record (hospital/university). Central IRBs will not review a submission without it.

How do I get this clearance letter?

1) Submit a ceded review application in iStar to obtain CHLA HSPP clearance to rely on an external/central/commercial IRB.

2) All department/division/ancillary reviews must be completed before a submission is 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.

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

4) After receiving the clearance notice, the CHLA study team can then submit their application to the IRB of Record for review.

*If the Sponsor is **NOT** using a central/external/commercial IRB, then the study should be submitted for review by the CHLA IRB.*

Steps for Submitting to the CHLA HSPP Office for *Initial* Clearance

1) Contact the lead site or study coordinating center to obtain the approved protocol and the approved consent and assent template forms.

2) Working from the approved consent and assent template forms, add in **all required CHLA consent form language** using tracked (redline) changes. Use one of the following consent form checklists located on the HSPP Ceded Review website to make these additions:
   - "**NMDP IRB Consent Form Checklist**" document for studies that will be reviewed by the NMDP IRB.
   - "**External IRB Consent Form Checklist**" document for all other studies that will be reviewed by an external IRB.
   - You may always reach out to your supervisor or Regulatory Specialist to obtain assistance with your application and consents.
   - **Note:** Advarra IRB and WCG IRB create the **consents** for CHLA, but not the Key Information Summary section (if missing) and the Simplified Assent document.

Initial Clearance (cont.)

3) Be sure to have and include the following information in the CHLA Ceded Review Application:

- Funding source for the study.
- Extramural funding, identify whether CHLA is the prime awardee or a sub-awardee.
- If NIH funded, indicate whether the award requires use of a single IRB.
- Name of the IRB of Record.
- What IRB reliance agreement will be used (e.g., SMART IRB)
- Any additional documentation required by the IRB of Record (e.g., letter to agree to rely, flexibility agreement, indemnification letter; forms to obtain CHLA local context information, CHLA institutional profile information).

Note: CHLA study teams should not sign these documents listed on this slide. They must be reviewed and signed by the HSPP Director or CHLA Contracts and Clinical Research staff.

Initial Clearance (cont..)

4) Include the following *documents* with the CHLA Ceded Review Application:

- The approved or final study protocol that all participating sites will follow.
- IRB of Record study approval letter (if the *study* is approved).
  Note: This is *not* the CHLA site IRB approval letter.
- IRB of Record's approved consent/assent template documents (if available)
- CHLA specific consent/assent forms containing CHLA required language (using redline tracked changes; if available).
- CHLA Conflict of Interest Research Committee (COIRC) management plan (if required).
- Any other CHLA site specific materials to be used by CHLA study team (e.g., ads, flyers, etc.)

Receipt of the initial CHLA Clearance letter **does not approve** your site to begin study procedures.

Study procedures cannot begin until approval is received from the IRB of Record ***AND*** then uploaded to iStar as an Amendment.

All consents should be obtained from the iStar Approved Documents tab, which are not uploaded until *after* the Amendment is approved by CHLA.

If in doubt, reach out to your supervisor to confirm before beginning enrollment.

Submitting to the IRB of Record

After you receive a CHLA clearance letter you can now submit to the IRB of Record.

Include these documents with your ***initial*** submission to the IRB of Record*:

- CHLA HSPP Clearance Notice of Ceded Review Clearance Letter.
- CHLA specific consent/assent forms (versions cleared by CHLA HSPP).
- CHLA specific materials (as applicable; versions cleared by CHLA HSPP).
- CHLA Institutional Profile Information Sheet (CHLA Local Context). This document is located on the CHLA HSPP Website.
- Other IRB of Record documents (e.g., application or submission form) required for review.

*Please note that each IRB may also have additional documents they may require such as site applications, copies of medical licenses, trainings, etc. You are advised to reach out to your IRB of Record contact to inquire further if you are unsure.

Submitting the IRB of Record's approval documents to iStar

Once the IRB of Record's approval is received, the CHLA study team *must* **file an amendment to the study application in iStar to upload the following approved documents:**

- IRB of Record's approval letter(s)
- IRB of Record's final, approved CHLA consent and assent forms
- Any approved CHLA specific recruitment or subject materials

As a reminder: for help with any portion of the application process, whether for the initial study submission or any amendment, we do have resources on the HSPP website.

Initial Clearance Flowchart

1. Sponsor is conducting a study

2. CHLA's Dr. Jones wants to participate

3. Dr. Jones' team submits a ceded review application to CHLA

4. CHLA HSPP office conducts review

5. CHLA issues Dr. Jones a Clearance letter

6. Dr. Jones' team submits that clearance letter to IRB of Record

7. IRB of Record issues Dr. Jones an Approval letter

8. Dr. Jones' team submits that Approval letter to CHLA as an amendment. Amendment #1

9. CHLA reviews the Approvals received and issues Dr. Jones' *their* Approval and posts approved consents/assents in iStar

10. Dr. Jones can now begin study procedures!

Things to keep in mind…

CHLA study teams are responsible for submitting additional amendments to the CHLA ceded review application in iStar, when new approvals and study documents are issued by the IRB of Record, throughout the life of the study (i.e., continuing reviews, protocol modifications, consent updates, enrollment status updates, etc.).

Amendments are processed by the CHLA HSPP staff.

The purpose of filing amendments to the ceded review application is to ensure that the currently approved documents appear in iStar and OnCore.

Clearance vs Approval
what and when

Clearance

- Initial study submission
- PI changes
- Co-I changes

CHLA clearance must be obtained *PRIOR* to submitting to the IRB of Record for approval!

Study Team notifies CHLA of the intended new submission or changes ⇨ CHLA issues a clearance letter ⇨ The study team can then submit that clearance letter to the IRB of Record for Approval.

Approval

- Initial study documents approved by the IRB of Record
- Newly approved modifications (i.e., protocol amendments, consent changes, enrollment status changes)
- Continuing Reviews

CHLA approval is obtained *after* the IRB of Record review and approves changes or updates.

The IRB of Record approves changes to the study or study site documents ⇨ new approval documents are issued to the study team ⇨ The study team MUST notify CHLA via an iStar Amendment ⇨CHLA reviews and provides approval.

** Disclaimer: this is NOT an in-depth list, rather a simple overview. Please refer to the HSPP Ceded Review web page for in depth guides.*

Managing Your Approved Ceded Study:

Responsibilities when relying on an external/outside IRB

The following slides are intended to help touch base on some of the varying responsibilities of the study team, including the PI and IRB of Record.

This is mainly to help ensure that everyone is doing their part to help maintain compliance where needed.

As always, if you are unsure about a specific role, responsibility or action needed – please reach out to your Supervisor, Regulatory Specialist or the IRB team.

IMPORTANT NOTE: These requirements apply to **all ceded studies** that are reviewed by an external or a central / commercial IRB.

CHLA Study Team Responsibilities

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 IRB of Record, so that the correct people receive email correspondence about the study.

3) CHLA study teams are responsible for ensuring that all **CHLA site amendments**, **continuing reviews, and reportable events** are reviewed by the IRB of Record.

4) CHLA study teams are responsible for **understanding the IRB of Record's requirements for review and oversight of the research study**.
These requirements may be different than CHLA IRB requirements. For example, requirements for translation and submission of new information that requires prompt reporting.

5) CHLA study teams are responsible for disbursing copies of Investigator Brochures, Pharmacy manuals, and lab manuals to the appropriate teams and departments. This should take place during the initial study submission as well as whenever updates occur to these items; along with documenting the necessary training that takes place.

6) CHLA study teams must always access the IRB of Record's website and resources from the source to ensure you are referring to the most current versions of the documents.

CHLA Investigator Responsibilities

- **Do not commence research until you have the IRB of Record approval letter and obtain all other required department/division and ancillary approvals.**
- Comply with all requirements and determinations of the IRB of Record.
- Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB of Record.

CHLA Investigator Responsibilities *continued…*

- Protect the rights, safety, and welfare of subjects involved in the research.
- Submit proposed amendments to the IRB of Record prior to their implementation.
- Do not make modifications to the research without prior IRB of Record approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing reviews when requested by the IRB of Record.
- Submit a closure form to the IRB of Record to close research when requested by the IRB of Record.
- If research approval expires, stop all research activities and immediately contact the IRB of Record.
- Promptly report to the IRB of Record any new information that requires prompt reporting (refer to IRB of Record requirements).
- Ensure that pharmacy manuals, lab manuals, Investigator's brochures, etc. are given to the appropriate departments.

IRB of Record Authorities & Responsibilities

The IRB of Record is responsible for review and oversight of the study for all sites conducting the research.

The IRB of Record has authority to:

- Approve, require modifications to secure approval, and disapprove all human subject research activities overseen and conducted under its purview.
- Suspend or terminate approval of human subject research not being conducted in accordance with its requirements or that had been associated with unexpected serious harm to participants.
- Observe, or have a third party observe, the consent process and the conduct of the human subject research activities.
- Decide whether financial interests related to the research and the management (COI), if any, allow approval of the human subjects research.

FAQs for Managing Studies Approved by an Outside IRB / IRB of Record

Q1: When is iStar notification and CHLA clearance required for *Amendments*?

- CHLA iStar notification is required for the following:
  - Change of the CHLA Principal Investigator (PI)
  - Change or addition of CHLA Co-Investigators (Co-I)
- PI and Co-I changes are to be submitted to the CHLA HSPP office to verify human research training requirements are completed and to identify any financial conflicts of interest that require review by the COIRC. Submit this as an amendment in iStar.

NOTE: Personnel changes may or may not require approval from the IRB of Record. CHLA study teams are responsible for understanding and complying with the submission requirements of the IRB of Record for study personnel amendments.

- CHLA *clearance* is not required for amendments initiated by the lead site, sponsor or IRB of Record, prior to submitting for approval.

FAQs (cont.)

Q2. When is an amendment to the Ceded Review Application in iStar required?

- When amendments are approved by the IRB of Record that require changes to the study protocol, CHLA site consent and assents forms, or recruitment materials. The study team will need to submit an amendment in iStar to describe the changes in the research and provide the newly approved documents.

Q3. Is CHLA *Clearance* required for Continuing Reviews and Closure Reports?

- **No.** Continuing reviews and closure reports do not require CHLA clearance before submitting to the IRB of Record for approval. However, the study team must still submit any Continuing Review approvals received to CHLA, along with any documents updated during this time.

Q4: Does CHLA require for a Continuing Review report to be submitted for approval in addition to the one submitted to the IRB of Record?

- **No.** While CHLA does not require a separate Continuing Review report for Ceded studies, the study team is required to submit the renewal approval to CHLA via an amendment in iStar.

FAQs (cont..)

Q5. When is an amendment to the Ceded Review Application in iStar required?

- When a study modification takes place, during the life of the study. This includes changes to the protocol, consent/assent forms, etc.
- When continuing review approval is granted by the IRB of Record, submit an amendment in iStar to indicate continuing review of the study has been performed and upload the new approval letter, approved protocol (if changed), updated consent/assent form(s), and any other documentation provided by the IRB of Record.
- When the study has been closed with the IRB of Record, submit a closure report in iStar (by selecting the "Close IRB" function) for the Ceded Review Application to close the ceded review submission at CHLA.

Q6. Is CHLA Clearance or CHLA IRB Review Required for Reportable New Information and Events?

- **No.** CHLA clearance or CHLA IRB *review* is not required for reportable new information and events.
- **Do not submit any reportable events in iStar.** The CHLA IRB is not the IRB of Record.

FAQs (cont...)

Q7. Does the CHLA HSPP Office require *any* notification of Reportable New Information and Events that occur at CHLA?

- **Yes.** Once a submission for a **CHLA reportable event** has been made to the IRB of Record, send the following information to the CHLA HSPP Office via email to IRB Reliance (irbreliance@chla.usc.edu):
  - Details of the submission made to the IRB of Record.
  - The IRB of Record's review of the event and its determination(s).
- This email submission provides the CHLA HSPP office with information that will be used to communicate with the IRB of Record for events that happen at CHLA. The HSPP Office will ensure any local CHLA requirements are considered by the IRB of Record and will partner with the IRB of Record in the event that any information needs to be reported to federal agencies.

Q8: Do we need to provide CHLA with the Investigator's Brochures, Pharmacy Manuals or Lab manuals via an iStar amendment?

- **No.** These items do not get uploaded to the ceded iStar application. **However!** It is the PI/CRC's responsibility to communicate with the appropriate teams and departments of updates to these documents, including providing them with copies, and document training.

FAQs (cont.…)

Q9. Is there any guidance on creating or editing the consent and assent templates?

- **Yes!** You can refer to the HSPP website for guidance documents. CHLA also has agreements with Advarra and WCG IRBs, in which Advarra and WCG will incorporate CHLA's site specific language into the consents for us as well as be the negotiators with Sponsor, if it is needed, on CHLA's behalf. Keep in mind, that they will not create the Key Info Summary (if it is missing from the template), nor the Simplified Assent form.

Q10. Can I reach out to someone at CHLA for help with my consents or assents?

- **Yes!** You can reach out to your Supervisor and your assigned Regulatory Specialists for help with editing the consents and assents to incorporate CHLA local context. You may also reach out the IRB Reliance Administrators for help with finalizing any edits to the local context language.

Resources:

- HSPP website
- HSPP Ceded Review web page
- CHLA Share Point
- IRB/Regulatory Support Teams Channel
- IRB Reliance (IRBReliance@chla.usc.edu)
- Regulatory Affairs (regulatoryaffairs@chla.usc.edu)
- HSPP office (hspp@chla.usc.edu)

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Thank you for your time and attention!

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The following quizzes will help you test your knowledge

Have fun!

QUIZ

Match the term with the correct definition

1) IRB Authorization Agreement

2) Reliance Agreement

3) Central IRB

4) Single IRB (sIRB)

5) SMART IRB

a) An Institutional Review Board that oversees all sites participating in a multisite study.

b) In cases where an institution does not meet the eligibility criteria to sign onto the SMART IRB agreement, CHLA may use a(n) _____ to establish a reliance relationship with an external institution.

c) A master reliance agreement and optional platform that was created to harmonize and streamline the IRB review process for multisite studies.

d) A formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution.

e) Another term for the IRB chosen by the Sponsor, CRO, Foundation, Consortium to review the study and all the sites that will perform the study.

Answers!

1) IRB Authorization Agreement

2) Reliance Agreement

3) Central IRB

4) Single IRB (sIRB)

5) SMART IRB

a) An Institutional Review Board that oversees all sites participating in a multisite study.

b) In cases where an institution does not meet the eligibility criteria to sign onto the SMART IRB agreement, CHLA may use an _____ to establish a reliance relationship with an external institution.

c) A master reliance agreement an optional platform that was created to harmonize and streamline the IRB review process for multisite studies.

d) A formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution.

e) Another term for the IRB chosen by the Sponsor, CRO, Foundation, Consortium to review the study and all the sites that will perform the study.

#1

After you receive a CHLA IRB clearance letter you can submit to the IRB of Record for review and approval.

#2

After you receive a CHLA clearance letter, you can begin the study and start enrolling.

Which statement is true?

take the QUIZ

#1
After you receive a CHLA IRB clearance letter you can submit to the IRB of Record.

Which statement is true?

Test Your Knowledge

Identify the correct statements:

1) CHLA study teams should **not** sign the CHLA Ceded Review Application. They must be reviewed and signed by the HSPP Director or CHLA Contracts and Clinical Research staff.
2) All studies must first be cleared by the CHLA HSPP office BEFORE submitting to the IRB of Record.
3) Do not submit any reportable events in iStar if CHLA IRB is not the IRB of Record.
4) CHLA clearance is required for amendments initiated by the lead site, sponsor or IRB of Record.
5) CHLA study teams are responsible for assuring all CHLA site amendments, continuing reviews, and reportable events are reviewed by the IRB of Record.
6) To submit to the CHLA HSPP Office for Initial Clearance go to the CHLA HSPP website to download the approved/template consent and assent forms and add all required CHLA consent form language using tracked (redline) changes.
7) Studies approved by external IRBs require CHLA clearance for continuing reviews and closure reports.
8) Once a submission for a CHLA reportable event has been made to the IRB of Record, send the following information to the CHLA HSPP Office.

Answers

Identify the correct statements:

1) CHLA study teams should **not** sign the CHLA Ceded Review Application. They must be reviewed and signed by the HSPP Director or CHLA Contracts and Clinical Research staff.
2) All studies must first be cleared by the CHLA HSPP office BEFORE submitting to the IRB of Record.
3) Do not submit any reportable events in iStar if CHLA IRB is not the IRB of Record.
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