Children's Hospital LOS ANGELES®

THE SABAN RESEARCH INSTITUTE

Ceded Review

Tips & Guidance for Submitting an Initial Ceded Study iSTAR Application

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Purpose

The goal of this presentation is to:

- Provide general guidance in completing a **new** initial iStar application for ceded studies.
- Touch on common contingencies, questions and provide clarification on required documentation.
- Provide resources if you have any questions.

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This presentation will **not** cover:

- Reliance Agreements,
- Reliance process or platforms,
- Consent editing,
- Amendment submissions.

Definitions

- 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.
- 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 central, commercial, institutional, independent IRB. A Reviewing IRB is chosen by the Sponsor, CRO, Foundation, Consortium to review the study and all the sites that will perform the study.
    - Interchangeable terms: 'the IRB of Record', 'Central IRB', 'sIRB' or 'single IRB'
    - "Single IRB" and "sIRB" are terms used in DHHS regulations and NIH grant policy.
- Relying IRB: The IRB that is relying on the review of another IRB, to serve as the IRB of Record for a multisite research study.
- Ceded Study: a research study that is deferred to an external IRB for review and oversight.
- CHLA HSPP Clearance to Cede Letter: This is a CHLA HSPP letter that is issued after an initial Ceded Review submission is made in iStar, has undergone all necessary ancillary, dept/divisional reviews, and has been reviewed by a Reliance Administrator. This letter outlines the responsibilities that the Reviewing IRB and the PI must maintain throughout the life of the study.

CHLA HSPP **does not approve** ceded studies.

The initial CHLA HSPP Clearance to Cede letter **does not approve** your PI or site to begin study procedures.

Study procedures cannot begin until full approval is received from the IRB of Record.

The study team is responsible for submitting the IRB of Record's approval documents (i.e., PI approval letter, stamped consents and assents) into iStar as an Amendment for review and clearance.

Reach out to your supervisor if you are unsure of the study status or the next steps.

General Overview of the Process

For the sake of this presentation, we will consider all the back end / administrative reliance processes have been worked on

1. iStar application is opened and completed by the study team.
2. Application gets routed to all the Co-Is and Sub-Is for their acknowledgement (sign off) of their study participation.
3. Routed to the PI for their final review, their attestation and the actual submission of the application.
4. Ancillary, departmental and divisional reviews take place.
5. Once any contingencies have been addressed and cleared, each department will document their review which will move the application forward.
6. Application arrives to the HSPP Office and gets assigned to an IRB Reliance Administrator.
7. Reliance Administrator reviews the application for completeness, ensuring that the above reviews have taken place, and that CHLA's local context language is appropriately captured in the consents and assents.
8. Once all contingencies have been addressed and cleared, Reliance Administrator will issue a CHLA HSPP Clearance Letter to Cede to the PI.
9. Study team is now ready to submit their site application and cleared consents to the IRB of Record.

CHLA study team starts & completes the iStar application.

Sub-Is sign

Co-Is sign

PI signs & submits

Ancillary reviews take place

Committees (RSC, COIRC, etc.)

Departments (IT, Pediatrics, Surgery)

Divisions (Neurology, Dentistry, etc.)

Application arrives at the HSPP office where it is assigned to a Reliance Administrator

Reviews application, consents, applicable recruitment material

Clearance letter issued to PI / study team

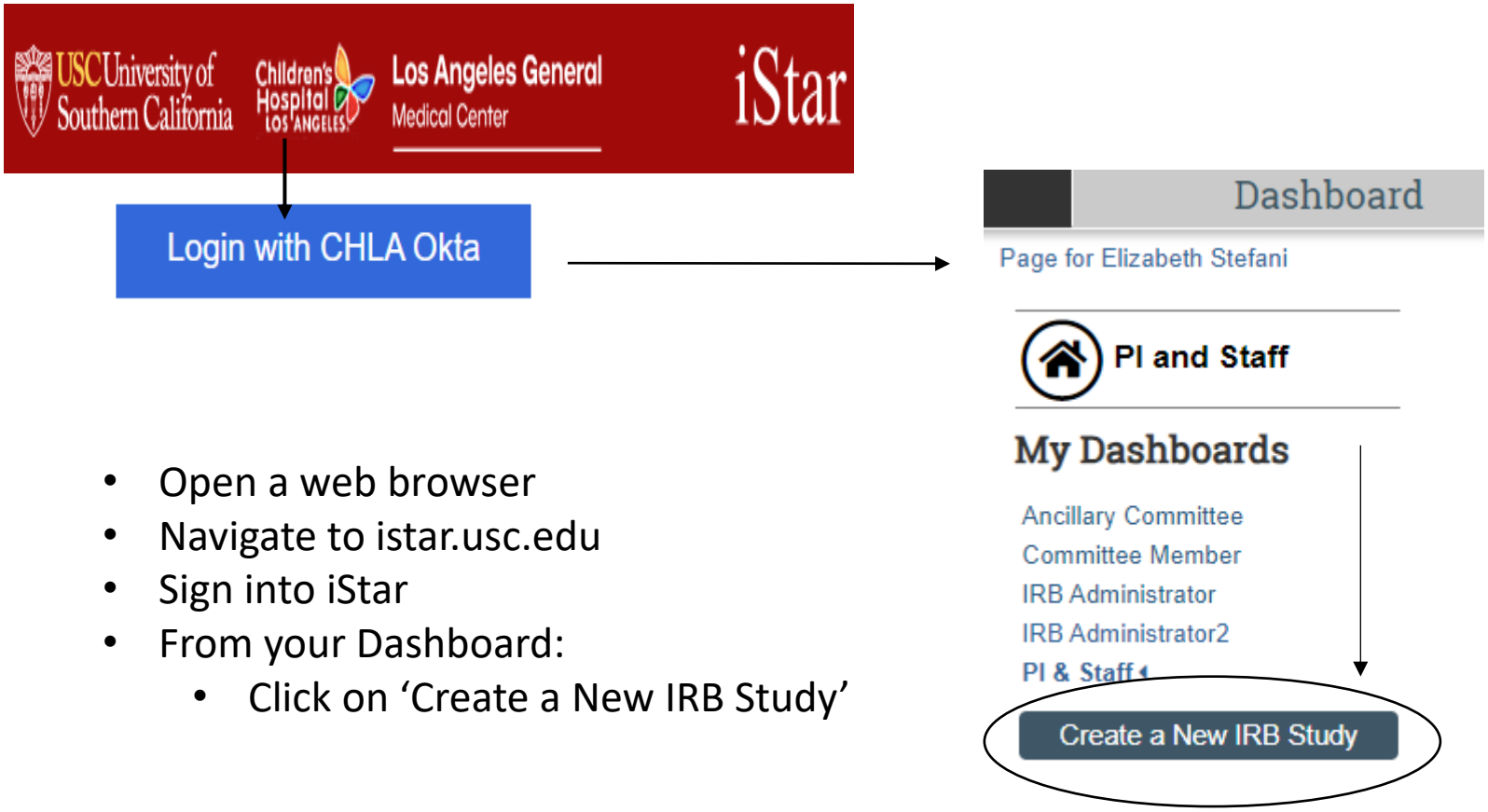
Study team moves forward with submission to the IRB of Record

VISUAL LEARNER

What Do I Need To Complete The Application?

- ❑ IRB approved protocol
  - The final clean version, in either Word of PDF
- ❑ IRB **study** approval letter
  - This should contain the IRB's determinations for the study
- ❑ IRB Approved Consent Template
- ❑ IRB Approved Assent Template
- ❑ Redlined CHLA Consent
  - Must include site specific edits
- ❑ Redlined CHLA Assent
  - Must include site specific edits
- ❑ CHLA created recruitment material (if applicable)
  - Created by CHLA, for use at CHLA **only**
- ❑ Laboratory Letter(s) of Support

First Steps



- Open a web browser
- Navigate to istar.usc.edu
- Sign into iStar
- From your Dashboard:
  - Click on 'Create a New IRB Study'

If you need assistance with obtaining an iStar account, signing in, or navigating the website, email: istar@usc.edu

Project Identification and Abstract

1. Project Identification and Abstract

1.1. * **Type of Submission**:

- ○ Research Protocol or Study on Human Subjects
- ○ Use of Humanitarian Use Device (Not Research)
- ● **Rely on another IRB (Ceded)** ★
- ○ Right To Try

QUICK TIPS

1.2. * **Full Title of Research Protocol**
FOR TRAINING PURPOSES ONLY
-The study title goes here, as it appears in the study protocol document

Item 1.2 is to match the approved protocol document.

1.3. * **Short Title**
TRAINING PURPOSES ONLY (Study acronym, short name, code, etc.)

1.4. * **Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.**
A simple explanation of the study goes here.
Be sure to briefly address each of the following points:
rationale;
intervention;
objectives or purpose;
study population or sample characteristics;
study methodology;
description of study arms (if appropriate);
study endpoints or outcomes;
follow-up;
statistics and plans for analysis.
*If CHLA is only participating in a portion of the study, add that information here.

QUICK TIPS

QUICK TIPS

It is okay to add in other pertinent information that Reliance Administrators should know about CHLA's role in the study.

1.5. **Is this a clinical trial? [The NIH defines a clinical trial as a prospective research study to evaluate the effects of one or more interventions on health-related biomedical or behavioral outcomes.]**

◯ Yes ◯ No

QUICK TIPS This can be verified with Sponsor/CRO.

1.5.1. **Is this a study where the Principal Investigator designed the study, created the protocol, or is responsible for the scientific and technical direction of the study (regardless of funding source)?**

◯ Yes ◯ No

QUICK TIPS Your PI can confirm their involvement with the study design.

1.5.1.1. **Please enter the ClinicalTrials.gov Identifier (also called NCT number).**
#######

1.5.2. **If this is an investigator-initiated drug, biologic, or device study, complete and attach a Sponsor/Investigator Agreement form here. This agreement must be completed and signed by the sponsor/investigator. If the investigator has submitted either an IND or IDE application as the Sponsor/Investigator, attach a copy of the IND or IDE application here.**

1.6. * **Select which IRB you are requesting review from:**

◯ USC - Biomedical IRB

◯ USC - Social Behavioral IRB

● **CHLA - Institutional Review Board (CHLA)** ★

1.7. * **To the investigator's knowledge, does the Institution have financial and/or intellectual property interests in the sponsor or the products used in this project?** *An institutional conflict may occur when a financial interest of the institution has the potential to bias the outcome of research or creates unacceptable risks to human subjects. Please review COMP-022.0 Institutional Conflict of Interest in Research Policy. If you are answering YES – please contact compliance@chla.usc.edu for verification before submitting in iStar.*

◯ Yes ◯ No

QUICK TIPS This question pertains to **CHLA** as an institution.

Save Continue

Best resources to help answer this section:
- Protocol document
- Principal Investigator
- Sponsor/CRO

*** Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.**

A simple explanation of the study goes here.
Be sure to briefly address each of the following points:
rationale;
intervention;
objectives or purpose;
study population or sample characteristics;
study methodology;
description of study arms (if appropriate);
study endpoints or outcomes;
follow-up;
statistics and plans for analysis.
*If CHLA is only participating in a portion of the study, add that information here.

Keep the abstract short, but still touch on these points

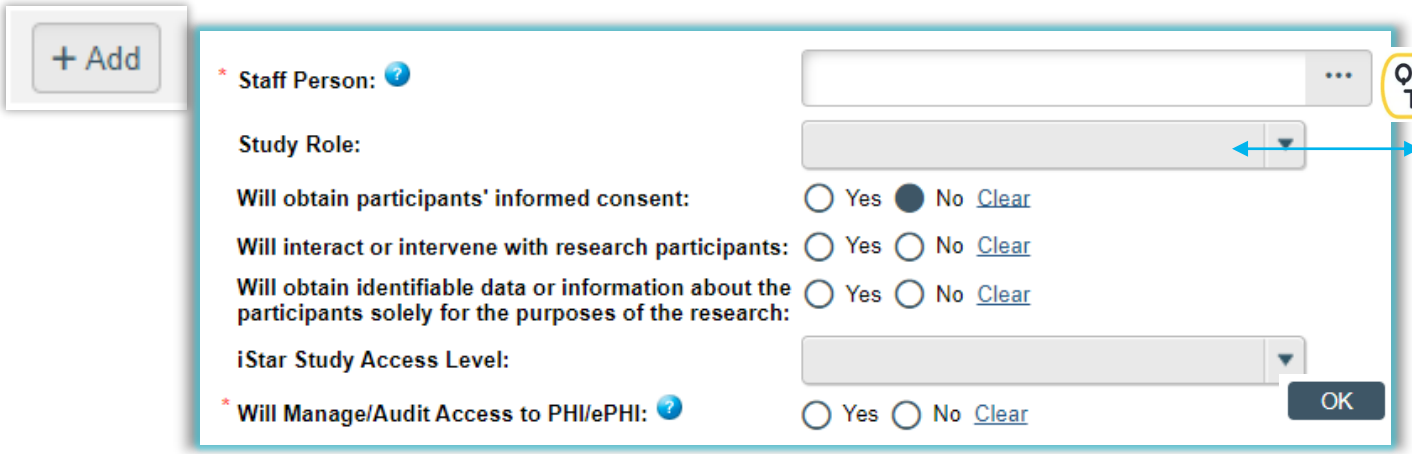
DO NOT:
- copy / paste from the protocol
- state "see protocol"
- leave this section blank

If CHLA will participate in only a portion of the study, please insert a sentence providing this information.

Is this a clinical trial? [The NIH defines a clinical trial as a prospective research study to evaluate the effects of one or more interventions on health-related biomedical or behavioral outcomes.]

Answer all questions in this section.

Study Personnel & Roles



QUICK TIPS

Use this list of agreed upon Study Roles:

- PI,
- Co-I,
- Sub-I,
- Adjunct Co-I
- Faculty Advisor,
- Study Contact,
- Regulatory Personnel,
- Research Assistant/Associate,
- Research Coordinator,
- Data Analyst (Statistician),
- Research Pharmacist,
- Research Nurse,
- Repository Manager/Gatekeeper,
- QA Personnel

QUICK TIPS

Who may be included as "key personnel" on an IRB submission?

Key Personnel are individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. Individuals who should be named on an IRB application are those who engage in the following:

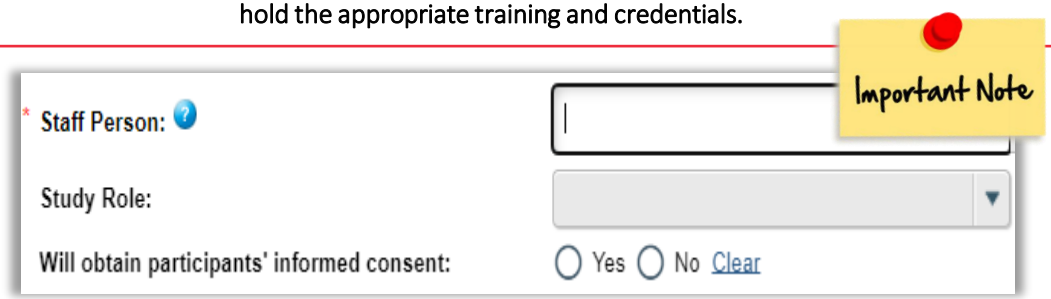
a. conducting research through an interaction or intervention with human subjects for research purposes
b. participating in the consent process by leading it or contributing to it
c. directly recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study

Who should NOT be listed as key personnel on an IRB submission:

Individuals paid by the institution to perform a service not part of or paid by the research project performing services that are typically performed for non-research purposes or fee for service:

- honest broker
- pharmacy employees dispensing investigations drugs
- hospital employees obtaining blood through a blood draw or collect urine and provide such specimens to investigators as a service
- radiology clinic employees performing chest x-rays and sending results to investigators as a service
- routine laboratory analyses of blood samples for investigators as a commercial service
- transcription of research study interviews as a commercial service
- not administering any study intervention being tested or evaluated under the protocol

Consenting privileges in drug or device studies should only be granted to the appropriate personnel who hold the appropriate training and credentials.



"FDA regulations require that the investigator obtain the legally effective informed consent of subjects (21 CFR 50.20, 312.60 and 812.100). If the investigator delegates this responsibility, FDA expects that the individual to whom the responsibility is delegated be qualified by education, training, and experience to perform this activity. The individual obtaining informed consent should be knowledgeable about the clinical investigation and have the appropriate training and credentials to be able to address any questions or concerns the subject may have about the study and/or alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Individuals obtaining consent must be knowledgeable about the protocol. Specifically, they must be able to describe the purpose, procedures, benefits, risks, and alternatives to participation in the study. They must be able to answer subjects' questions about the protocol and about risks of the research procedures and alternatives."

Food & Drug Administration (2003) *Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors* DOI: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent

Organization	Certifications
CHLA Human Subjects Protection Program	HS, GCP, HIPAA
Clinical Translational Science Institute - CHLA	HS, GCP
CHLA - No Department	HS, GCP

Don't forget to verify that the CITI HS and GCP certifications are active, and that all personnel have a home department in their iStar profile.

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Funding Information

4.1. * **What existing or pending support will be used for this study?** (check all that apply)

- ☐ Cooperative Group (SWOG, COG, RTOG, etc.)
- ☐ CTSI
- ☐ Departmental/Institutional Funds
- ☐ Federal Grant/Contract
- ☐ Non-Profit (including Foundations and Universities)
- ☑ **Industry**
- ☐ Intramural/Internal Grant
- ☐ State or Local Grant/Contract
- ☐ No Funding
- ☐ Other

- ☑ Cooperative Group (SWOG, COG, RTOG, etc.)
- ☑ Federal Grant/Contract
- ☑ Non-Profit (including Foundations and Universities)

4.1.2. Will any funds come from the National Institutes of Health (NIH)?
● Yes ○ No Clear

4.1.3. Will any of the funds come (either directly or indirectly) from the Department of Defense (DoD)?
○ Yes ● No Clear

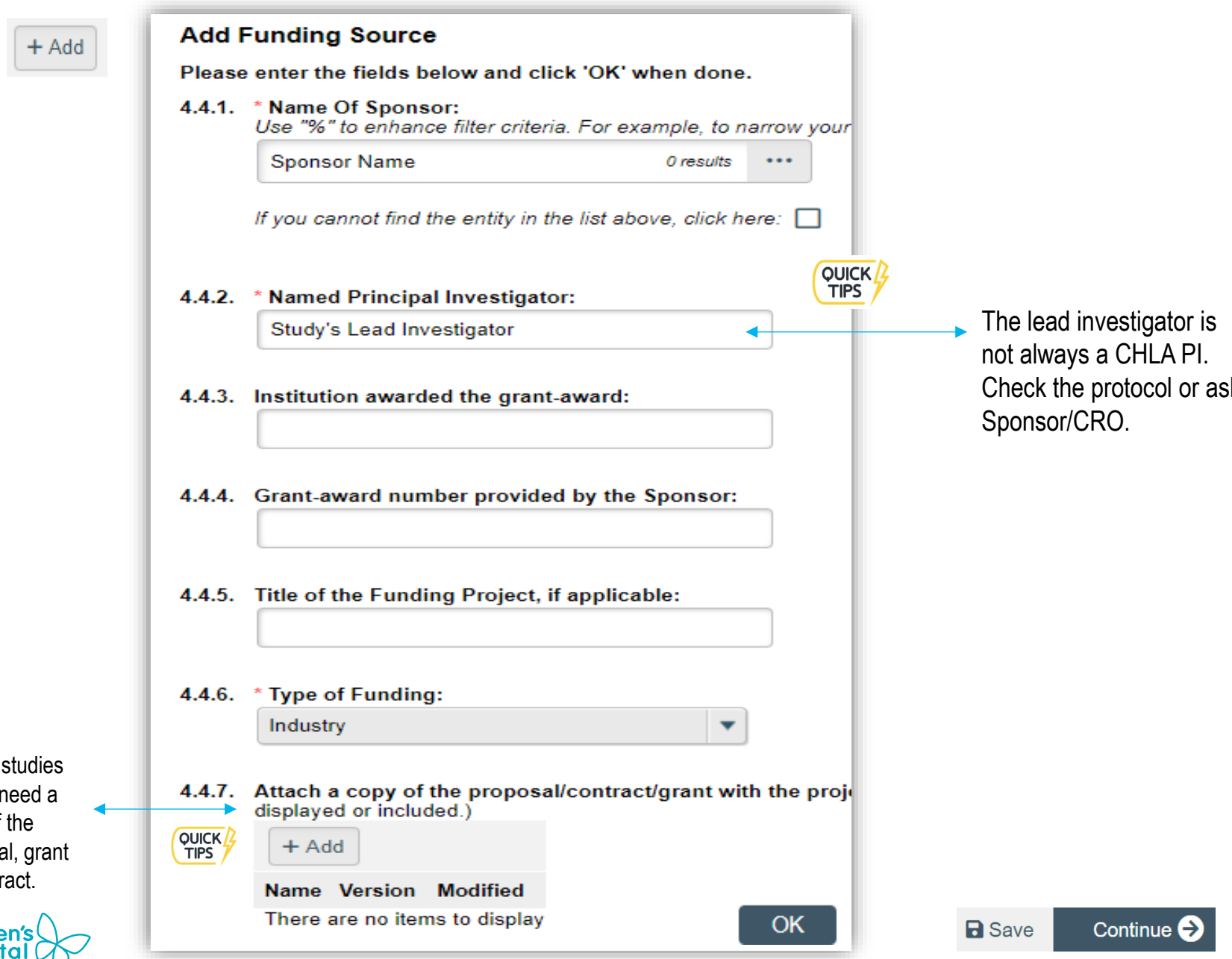
4.1.5. Is CHLA the Prime Awardee?
○ Yes ● No Clear

You must complete the question before submitting.

4.1.3. Will any of the funds come (either directly or indirectly) from the Department of Defense (DoD)?

○ Yes ● **No**

QUICK TIPS If you are unsure how to answer this section reach out to the Sponsor/CRO.



The lead investigator is not always a CHLA PI. Check the protocol or ask Sponsor/CRO.

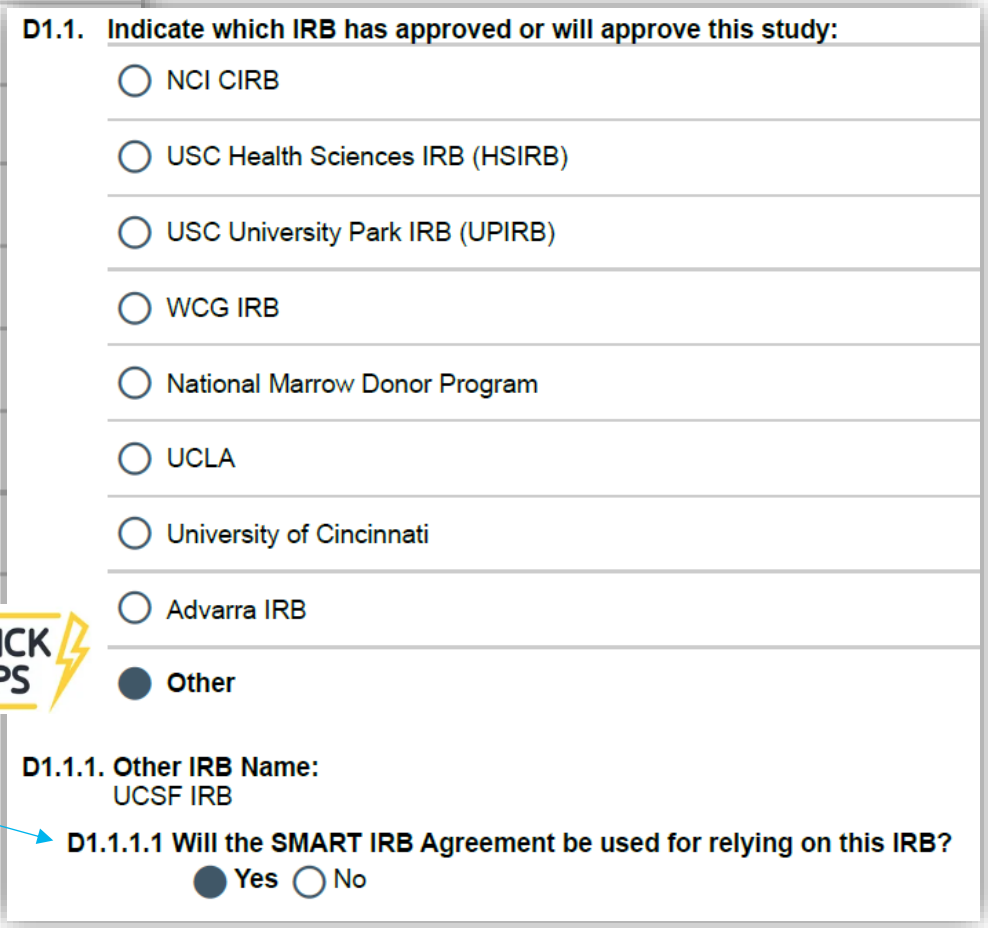
Ceded studies do not need a copy of the proposal, grant or contract.

D1. Ceded Review

QUICK TIPS If you are unsure who the IRB of Record is reach out to the lead study contact, or Sponsor/CRO.

D1.1. Indicate which IRB has approved or will approve this study:

- ○ NCI CIRB
- ○ USC Health Sciences IRB (HSIRB)
- ○ USC University Park IRB (UPIRB)
- ● **WCG IRB**
- ○ National Marrow Donor Program
- ○ UCLA
- ○ University of Cincinnati
- ○ Advarra IRB
- ○ Other



QUICK TIPS

Confirm with the lead study contact or IRB of Record.
CHLA does work with the SmartIRB and IREx platforms.
If a hard-copy is being used, please email forms to: IRBReliance@chla.usc.edu, and submit ***EARLY***.

D1.2 Documents

D1.2. Provide the following as they apply to the study:

- Protocol
- Consent Form(s)
- Approval letter (if available)
- other documents from the reviewing IRB (e.,g. agreement)

NOTE: When approval from the reviewing IRB is received, submit an amendment to submit the approved protocol, consent forms, and any other approved documents. Classify the documents based on document type as you upload them.

+ Add

Name		Version	Document Type	Modified Date
Copy of the IRB Approved Assent Templates.pdf(0.01)	•••	0.01		8/10/2024 10:43 AM
Copy of the IRB Approved Consent Templates.pdf(0.01)	•••	0.01		8/10/2024 10:43 AM
Protocol vFINAL.pdf(0.01)	•••	0.01	Protocol	7/24/2024 4:30 PM
IRB of Record Study Approval Letter.pdf(0.01)	•••	0.01	IRB Approval	7/24/2024 4:30 PM

QUICK TIPS

Do not include:
- Redlined protocol
- Generic study material
- Generic recruitment material

QUICK TIPS

The redlined site-specific consents are to be uploaded to D24.7

*If the study uses a two-part consent (ex.: Part A = study info, Part B = site info) the study info part should be uploaded here.

+ Add

Submit a Document

Title:

If not provided, the name of the file will be used

* File: Choose File

Document Type:

IRB Approval
Protocol
Consent Form
Reliance Documents (Agreements, Local Context Worksheets, etc)
Other Documents

OK

Don't forget to upload your documents!

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D1.3 Study Activities & Who Will Perform Them

D1.3. Briefly describe the study activities to be performed at CHLA, including who will perform them.

A brief and simple list of who will be performing what.
Examples:
Consenting, IP administration: PI, Co-I
Recruiting, data submission, scheduling, vitals, administer pregnancy testing: CRCs
Review concomitant meds, AEs, medical history: Co-I, Sub-Is
Regulatory support: Regulatory Specialists

QUICK TIPS *If your study will be enrolling minors who could turn 18 during their participation - please describe the reconsenting process here with a brief sentence.
Example: Minors who turn 18 will be re-consented with the Main Adult consent.

D1.4. Will CHLA personnel perform research activities at non-CHLA sites?

◯ Yes ◯ No

D1.5. Which study activities occur at CHLA or affiliated sites?

D1.5.1. Will participants' informed consent be obtained at CHLA ?

◯ Yes ◯ No

D1.5.2. Will identifiable data or information about the research participants solely for the purposes of the research project be obtained at CHLA ?

◯ Yes ◯ No

D1.5.3. Will interaction or intervention with research participants occur at CHLA ?

◯ Yes ◯ No

D1.5.4. Is CHLA the Primary Award Recipient of a Federal Grant?

◯ Yes ◯ No

QUICK TIPS Ensure that the responses in this section make sense for the study.
Reach out to your PI for assistance answering if needed.

Save Continue

- Reserved for **non-subject facing** study documents.
- Don't forget to upload the documents.
- Stack like documents.

D1.2. Provide the following as they apply to the study:

- **Protocol**
- **Consent Form(s)**
- **Approval letter (if available)**
- **other documents from the reviewing IRB (e.,g. agreement)**

Be brief. Do not copy/paste the schedule of activities. Use study roles. Only list the activities being done AT CHLA. Describe AOM reconsenting process, if appropriate.

D1.3. Briefly describe the study activities to be performed at CHLA, including who will perform them.

This response should match the Funding information in Item 4.1

D1.5.4. Is CHLA the Primary Award Recipient of a Federal Grant?

◯ Yes ◯ No

4. Funding Information ☑ **Federal Grant/Contract**

Informed Consent & Recruitment Materials

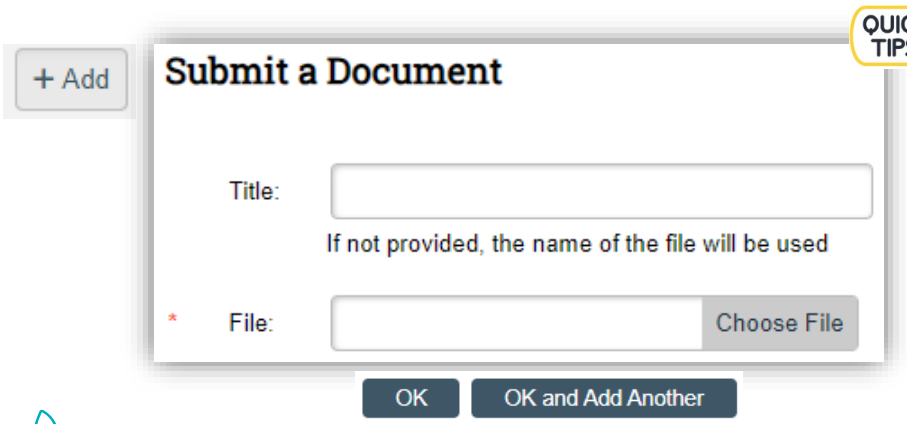
D24. Informed Consent

24.2. Attach copies of all recruitment tools that will be used by the local site. *(Do not attach any advertising or recruitment materials that will not be used at the local site or under control of the local site.)*

Name	Version	Modified
Copy of the CHLA Created Recruitment Material.docx(0.01)	0.01	8/10/2024 10:47 AM

24.7. Please attach any informed consent, assent or parental permission documents, including information sheets to be provided to participants that you intend to use.

Name	Version	Modified
Copy of the CHLA Redlined Assent Forms.docx(0.01)	0.01	8/10/2024 10:54 AM
Copy of the CHLA Redlined Consent Forms.docx(0.01)	0.01	8/10/2024 10:54 AM



QUICK TIPS

Upload the redlined consents and assents here.

If the study utilizes a two-part consent, only the editable site-specific part should be uploaded here.

Material created by CHLA personnel for use at CHLA only.

24.2. Attach copies of all recruitment tools

Upload the Word version of the redlined consent and assent forms to D24.7.
It is the study team's responsibility to edit the consents to include the required local context language.

24.7. Please attach any informed consent, assent or parental permission documents, including information sheets to be provided to participants that you intend to use.

Upload the documents,
Upload to the correct section,
Stack like documents.

Remember, it is the study team's responsibility to edit the consents and assents.
Utilize the checklists found on the HSPP Ceded Review webpage to help with edits.

HSPP Ceded Review Checklists and Forms

- External IRB Consent Form Checklist
- NMDP IRB Consent Form Checklist
- NCI CIRB Boilerplate for Consent Forms

Privacy & Data Confidentiality

26.3. Study data/specimen will be stored:

- [x] **Physically**
- [x] **Electronically**

QUICK TIPS The responses here are typically site specific, depending on the type of study.

Please confirm that, at a minimum, the following measures will be taken and enforced:

- [x] **Information or specimens maintained physically will be stored with appropriate physical safeguards, such as in locked cabinets and/or in restricted areas limited to authorized study personnel**
- [x] **Copying and use of study related materials will be restricted**

Other Measures:

- [x] **Audio and/or video recordings will be transcribed and then will be destroyed**
- [ ] Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified
- [ ] Photos or images will be modified to eliminate the possibility that study participants could be identified

26.4. Will identified data and/or specimens be reviewed and/or accessed by a third party institution (such as a study sponsor, federal agency, or another institution)?

● **Yes** ○ No

QUICK TIPS Sponsor and the IRB of Record are considered a 3rd party for ceded studies

**Note: Releasing Protected Health Information to a third party requires a signed data use agreement

Save Continue

HIPAA Privacy Rule

35.1. Do you intend to access, review, collect, use, or disclose Protected Health Information (PHI/ePHI) which includes either patient and/or participant data, in your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)
    - Name/Initials
    - Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
    - All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
    - Elements of date, including year, for persons 90 or older
    - Telephone number
    - Fax number
    - Electronic mail address
    - Social Security Number
    - Medical record number
    - Health plan identification number
    - Account number
    - Certificate/license number
    - Vehicle identifiers and serial numbers, including license plate number
    - Device identifiers and serial number
    - Web addresses (URLs); Internet IP addresses
    - Biometric identifiers, including finger and voice print
    - Full face photographic images and any comparable images
    - Any other unique identifying number, characteristic, or code*

◯ Yes ◯ No

35.2. Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed above), in your research?

◯ Yes ◯ No

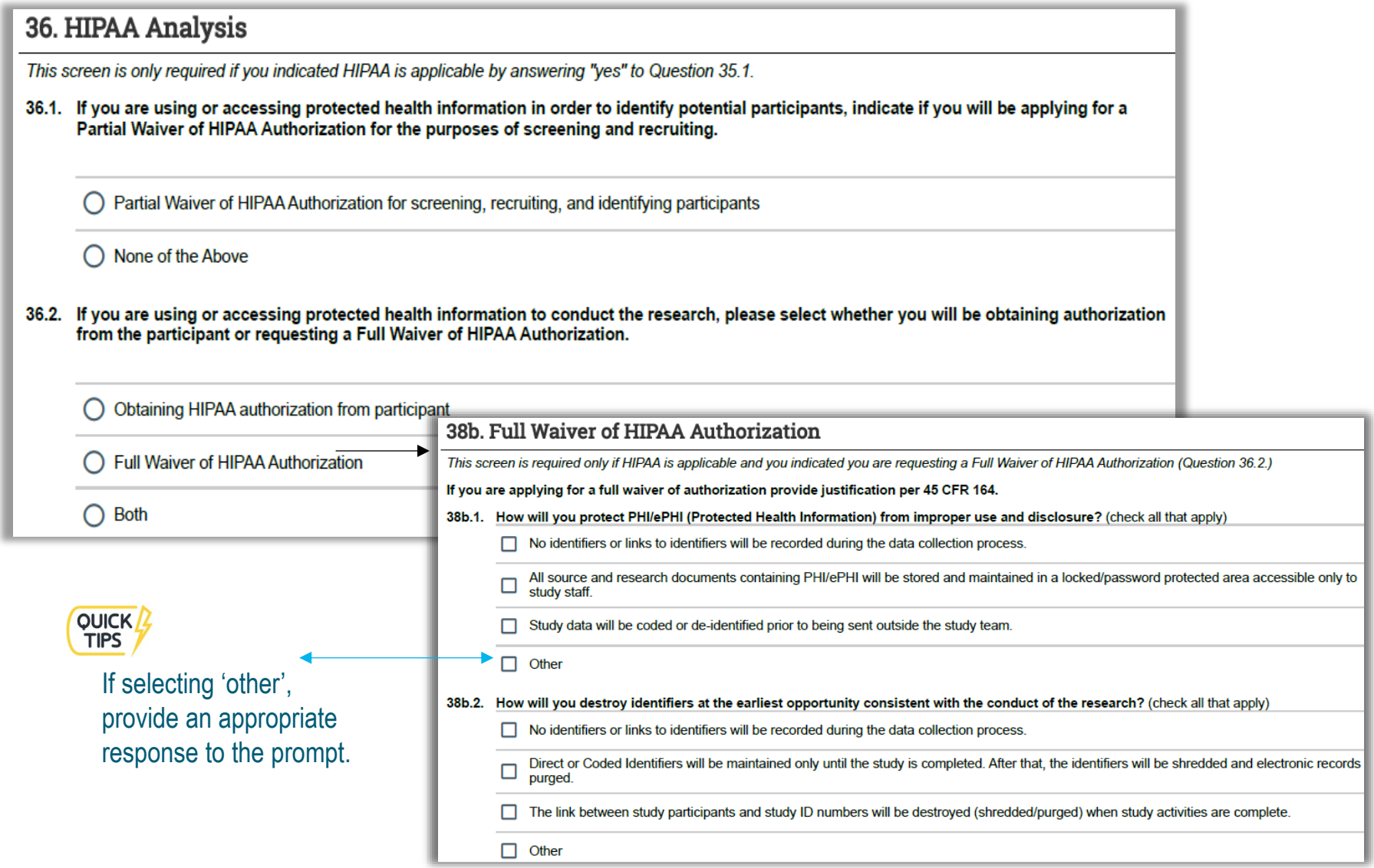
35.3. Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a "limited data set". if you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.

QUICK TIPS

Creating or obtaining a limited data set?
Reach out to Contract@chla.usc.edu for assistance

Save Continue

HIPAA Analysis



36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate if you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting.

- ○ Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying participants
- ○ None of the Above

36.2. If you are using or accessing protected health information to conduct the research, please select whether you will be obtaining authorization from the participant or requesting a Full Waiver of HIPAA Authorization.

- ○ Obtaining HIPAA authorization from participant
- ○ Full Waiver of HIPAA Authorization
- ○ Both

38b. Full Waiver of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Full Waiver of HIPAA Authorization (Question 36.2.)

If you are applying for a full waiver of authorization provide justification per 45 CFR 164.

38b.1. How will you protect PHI/ePHI (Protected Health Information) from improper use and disclosure? (check all that apply)

- ☐ No identifiers or links to identifiers will be recorded during the data collection process.
- ☐ All source and research documents containing PHI/ePHI will be stored and maintained in a locked/password protected area accessible only to study staff.
- ☐ Study data will be coded or de-identified prior to being sent outside the study team.
- ☐ Other

38b.2. How will you destroy identifiers at the earliest opportunity consistent with the conduct of the research? (check all that apply)

- ☐ No identifiers or links to identifiers will be recorded during the data collection process.
- ☐ Direct or Coded Identifiers will be maintained only until the study is completed. After that, the identifiers will be shredded and electronic records purged.
- ☐ The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete.
- ☐ Other

Save | Continue

QUICK TIPS

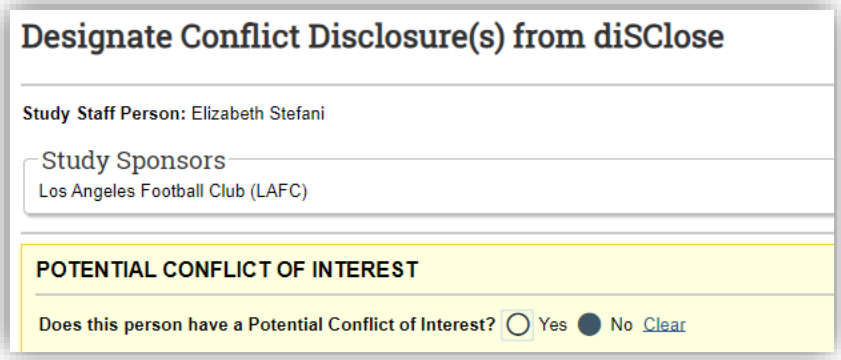
If selecting 'other', provide an appropriate response to the prompt.

Conflict of Interest Information

39.1. Instructions: Click on the name of each study team member and indicate whether they have a potential financial conflict of interest related to this study. If they have a conflict of interest, click on the conflict that has been reported in diSClose. If the conflict is not listed, ask the study team member to update their disclosure information in diSClose before completing this section.

QUICK TIPS

Study Staff	Role	COI Annual Disclosure Status	Conflicts
Jocelyn Pérez	Principal Investigator	Current: due on 8/31/2025	No conflicts identified
Emily Benstead	Co-Investigator	*About to expire: due on 8/31/2024*	No conflicts identified
Nathan Kamel	Co-Investigator	*About to expire: due on 8/31/2024*	No conflicts identified
Consuelo Secules	Data Analyst/Statistician	Current: due on 8/31/2025	No conflicts identified
Joanna Balducci	Quality Assurance Personnel	Current: due on 8/31/2025	No conflicts identified
Nancy Flores	Regulatory Personnel	Current: due on 8/31/2025	No conflicts identified
Andres Vargas Gonzalez	Regulatory Personnel	~~Current: due on 8/31/2025~~	No conflicts identified
Veronica Jimenez	Regulatory Personnel	No disclosure on file	No conflicts identified
Elizabeth Stefani	Regulatory Personnel	No disclosure on file	No conflicts identified



CHLA policy requires all study team members to have a current COI disclosure in DiSClose.
If a study team member has not completed a disclosure form it has expired, a new disclosure must be submitted in DiSClose.

Save Continue

Required Approvals

50.1. Required department/division approvals needed for this study. This list is automatically generated from the home departments/divisions of the listed investigators and the answers to other questions in the application.

Name	Division/Department	Parent Campus
LABORATORY MEDICINE - CHLA	Division	Childrens Hospital Los Angeles (CHLA)
CHLA Human Subjects Protection Program	None	Childrens Hospital Los Angeles (CHLA)
CHLA-CLINICAL INVESTIGATION CENTER	Department	Childrens Hospital Los Angeles (CHLA)
IMAGING SERVICES/RADIOLOGY - CHLA	Department	Childrens Hospital Los Angeles (CHLA)
IT SECURITY - CHLA	Department	Childrens Hospital Los Angeles (CHLA)

QUICK TIPS

This list is automatically generated, but you are able to add in additional departments/divisions.

Department of Clinical Services

Notes:

- Research that involves clinical or bedside nursing, or survey/observation of nursing and advanced proactive providers requires Department of Nursing approval.
- The department review is required to assure appropriate utilization of time and/or nursing services for research.
- Contact Dr. Jennifer Baird, jebaird@chla.usc.edu, for questions and information about this review

50c.2.1.1. Does the study require clinical or bedside nurses to collect data/samples for research?

◯ Yes ◯ No

50c.2.1.2. Does the study involve survey and/or observation of nursing staff and/or advanced practice providers?

◯ Yes ◯ No

Department of Imaging Services/Radiology

Notes:

- Research that involves Imaging Services (MRI, Ultrasound, X-Ray, DEXA, CT) and/or requires access to Clinical Imaging (Synapse) requires Department of Radiology approval.
- The department review is required to assure imaging costs and analysis are properly budgeted for in the research study.
- Contact Dr. Marvin Nelson mdnelson@chla.usc.edu for questions and information about this review.

50c.2.2.1. Does the study involve Imaging Services and/or require access to Clinical Imaging for research purposes?

◯ Yes ◯ No

QUICK TIPS If you are unsure of how to answer these questions, reach out to your PI.

CHLA Radiation Safety Committee (RSC) Review

Notes:

- CHLA RSC review is required for protocols that use ionizing radiation for research purposes (i.e., outside or in addition to standard clinical care).
- This review is done concurrently, but RSC approval is required before IRB approval.
- Examples of ionizing radiation sources include: diagnostic x-rays; computed tomography (CT); cardiac catheterization; electrophysiology, bronchoscopy or endoscopy studies employing x-ray guidance; nuclear medicine procedures (including PET and SPECT); or bone mineral densitometry (DEXA).
- Other examples include: research radiation therapy protocols; novel radioactive drugs, or radioactive drugs developed under an IND.
- Answer "yes" to the question below if any of the above applies to the study.
- Contact Charles Pickering cpickering@chla.usc.edu for questions and information about this review.

50c.2.3.1. Does the study involve the use of ionizing radiation (radioactive materials or radiation producing machines) for research purposes?

◯ Yes ◯ No

Division of Laboratory Medicine

Notes:

- Division of Laboratory Medicine approval is required for clinical laboratory research support services: out-patient phlebotomy, research specimen processing, clinical laboratory testing using research funds, and transfusion medicine services.
- A Laboratory Letter of Support is required.
- Contact **Clinical Lab Research Services** ClinicalLabResearchServices@chla.usc.edu for questions and information about this review.

50c.2.4.1. Does your study require any of the clinical laboratory research support services listed below? (check all that apply)

	Name
☑	**Out-patient Phlebotomy**
☐	Research specimen processing (e.g. specimen aliquots, storage, shipping, serum separation, plasma separation, PBMC isolation, nucleic acid isolation)
☐	Clinical laboratory testing paid by research funds
☐	Services of transfusion medicine (e.g. blood bank, therapeutic apheresis)

50c.2.4.1.1. Please attach the Laboratory Letter of Support from Laboratory Medicine:

Lab Letter of Support.pdf(0.01)

QUICK TIPS If you are unsure of how to answer these questions, reach out to your PI.

Department of Information Security

Notes:

- Information security must approve a data management plan for data that is stored, accessed, shared or viewed electronically.
- IS approval is required before IRB approval.
- Contact IS-Security@chla.usc.edu for questions and information about this review.

50c.2.7.1. Will any devices NOT managed or provided by CHLA I.S. be used to store, transmit, or view study data AT ANY TIME throughout the course of the study (such as local computers, laptops, local servers, tablets, removable storage or USB drives, grant-funded systems, etc.)?

○ Yes ● No

QUICK TIPS

If you are unsure of the appropriate response, reach out to Sponsor/CRO.

50c.2.7.2. Will any data be shared externally (outside CHLA) and/or stored on a 3rd party (Non-CHLA) platform? If so, provide a detailed description (i.e. RedCAP, iMedidata, USC SFTP Server, USC Network Drive) and document the FULL PATH, URL, or IP (I.e. \\server\share\folder, https://redcap.med.usc.edu/, or 172.1.1.250, etc.)

● Yes ○ No

QUICK TIPS

Be sure to provide the correct information and links for IT Security to review.

50c.2.7.2.1. Detailed description of the location where the data will be stored if not at CHLA (i.e. USC RedCAP, iMedidata, USC SFTP Server, USC Network Drive):
DETAILED description of the location of where the data is planned on being stored.

50c.2.7.2.2. Provide the FULL PATH, URL, or IP where the data will reside if not at CHLA (I.e. \\server\share\folder, https://redcap.med.usc.edu/, or 172.1.1.250, etc.):
\\server\share\folder, https://redcap.med.usc.edu

50c.3. Please select any additional approvals that may be needed for this study. Do not specify organizations already listed above. If you do not see a given department or division listed, please contact iStar Support for assistance at istar@usc.edu.

Name	Division/Department	Parent Campus
There are no items to display		

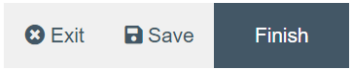
50c.4. Are there other hospital committees that will need to review and approve this protocol? If so, please list the name(s) of the committee(s) and attach approval memos as applicable.

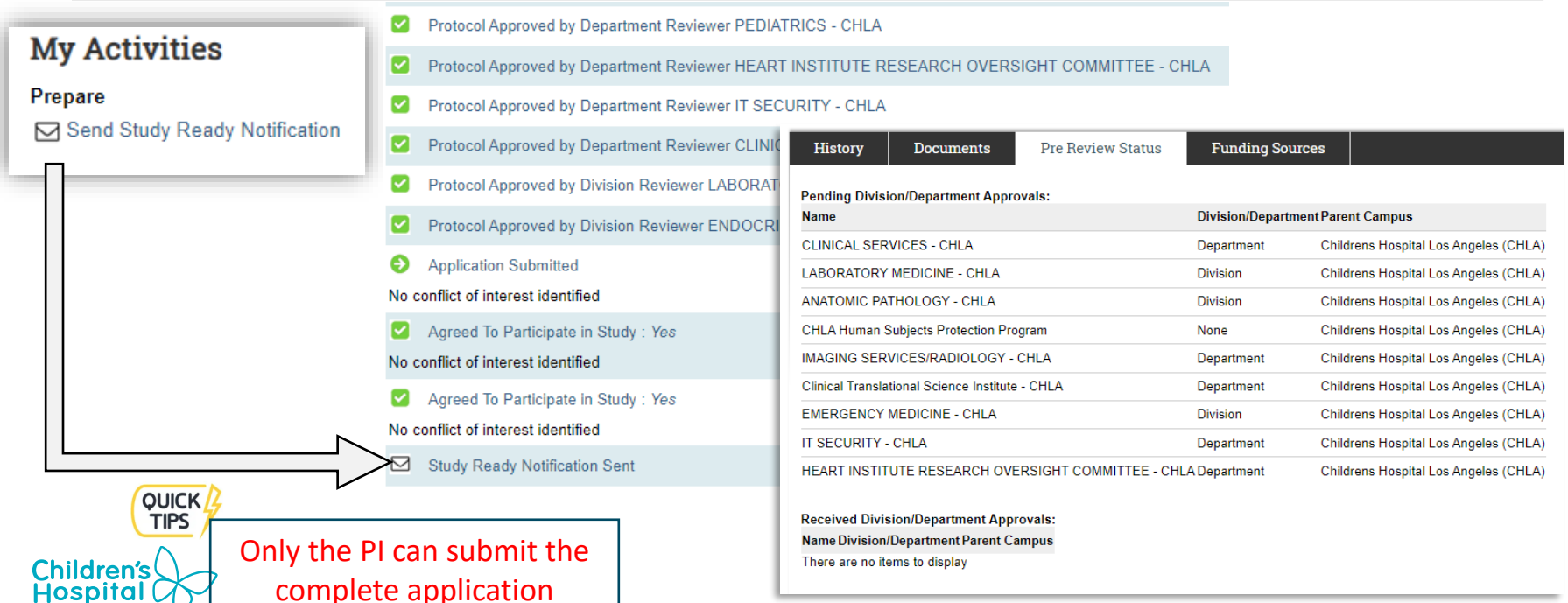
Committee Name	Committee Chair	Approval Memo
There are no items to display		

Submission

You have reached the end of the application. When you are sure of the content, the following steps may be taken to submit your application for review.

1. Click the **"Finish"** button on the top or bottom application navigator bar to return to the workspace.
2. Use the **Hide/Show Errors** above to determine that all sections of the application are filled out correctly.
3. Use the **"Send Study Ready Notification"** activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (indicated in item 2.1.) can submit the application by using the **"Submit Application to ____"**, where ____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The application is submitted. The state indicator in the top left of the workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.





QUICK TIPS

Only the PI can submit the complete application

Common Contingencies

- Upload **ALL** of your documents!
- Provide the final, clean version of the protocol. Redlined versions are not needed.
- Investigator's Brochures, Pharmacy Manuals, and Device Manuals are not needed in ceded applications.
- Do not delete documents unless you are instructed to do so.
- The IRB Administrators, Reliance Administrators and Regulatory Specialists do not have any executive or managerial capabilities in iStar. Please reach out to iStar if technical help is needed.
- Answer all questions, in all sections.
- The study team is responsible for editing the consents and assents to incorporate CHLA local context language.
- Upload the redlined site-specific consents, assents, parental forms, and information sheets.
- Verify that the CITI GCP and HS certificates are up to date for all study personnel.
- Verify that all study personnel have a current disclosure statement on file.
- Do not wait until the last minute to start the application.
- Remember to submit the application!
- Do not use Outlook or Teams to submit study documents to the Reliance Administrators.
- If you would like someone to review your application, including redlined consents, prior to submitting in iStar, request assistance from a study team member or your supervisor first.

Use Your Tools!

Resources

- HSPP website
- HSPP Ceded Review web page
- HSPP Education & Training web page
- CHLA Share Point
- IRB/Regulatory Support Teams Channel
- IRB **Reliance** Inbox (IRBReliance@chla.usc.edu)
- Liz Stefani, Reliance Administrator (estefani@chla.usc.edu)
- Veronica Jimenez, Reliance Administrator (vjimenez@chla.usc.edu)
- Regulatory Affairs (regulatoryaffairs@chla.usc.edu)
- HSPP / CHLA IRB Inbox (hspp@chla.usc.edu)

Resources

- NIH's Definition of a Clinical Trial
- FDA's Informed Consent Guidance Document
- Contracts & Clinical Research Admin
- CHLA Instructions for Making a Submission to a Central IRB for Industry Sponsored Multi-Center Clinical Trials
- CHLA Reliance on Another IRB for Review and Oversight
- iStar – istar@usc.edu or 323-276-2238
- iStar User Reference Guide

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Thank You for Your Time and Attention