Children's Hospital LOS ANGELES®

THE SABAN RESEARCH INSTITUTE

CEDED REVIEW SUBMISSIONS:

WHAT GUIDANCE DOCUMENTS TO USE AND WHAT TO SUBMIT IN iSTAR

DEEBRA SMITH, MPH, CCRP, CIP

HUMAN SUBJECTS PROTECTION PROGRAM (HSPP)

Learning Objectives

- Overview of the CHLA Ceded Review Process
- Independent (Central) IRBs: Advarra, Sterling, & WCG
- External IRBs: BCH, CHOP, NMDP, UCLA, etc.
- National Cancer Institute Central IRB (CIRB)
- Completing the Initial iStar Application
- Amendment, Continuing Review, & Reportable Event Applications
- Tips & Reminders

Overview of the CHLA ceded review process

- All studies ceding review to another IRB, must first be cleared by the CHLA HSPP office **BEFORE** CHLA investigators can submit to the Reviewing IRB.
- The CHLA clearance process involves:
  - Submitting a ceded review application to CHLA in iStar
  - Ceded Application undergoes any department/division review & approval and are subject to other ancillary reviews & approvals (e.g., Radiation Safety, COIRC, etc.).
  - CHLA HSPP staff performs an **administrative review***
  - CHLA HSPP staff clears the application and issues a **clearance letter**
- CHLA investigators then submit the CHLA clearance letter, and when applicable, cleared documents (e.g., consent forms) to the Reviewing IRB for review & approval
- CHLA investigators submit an Amendment Application to CHLA to submit the Reviewing IRB's approval letter and the approved CHLA site specific materials

Overview of the CHLA ceded review process

Right now, CHLA has 3 paths for ceding review to another IRB. Those paths are:

- Independent IRBs
  - Industry Sponsored Multi-Center Clinical Trials
  - Advarra IRB, Sterling IRB, and WCG IRB
- External IRBs
  - Multi-site studies
  - BCH, CHOP, NMDP, Stanford University, UCLA, & many others
- National Cancer Institute Central IRB (CIRB)
  - Children's Oncology Group (COG) studies
  - Pediatric Brain Tumor Consortium (PBTC) studies

INDEPENDENT IRBs: ADVARRA, STERLING, & WCG

Independent IRBs: Advarra, Sterling, & WCG

- CHLA allows IRB review to be performed by an independent (central) IRB when a Sponsor is using one for **industry sponsored multi-center clinical trials**.

- When you are contacted by a Sponsor to join a study, you should ask them if they are using an independent (central) IRB.
  - If **YES**: Ask what independent (central) IRB they are using.
  - CHLA has master agreements & review procedures in place with **Advarra, Sterling, & WCG**
  - If Advarra, Sterling, or WCG **ARE NOT** being used by the Sponsor, you should email **irbreliance@chla.usc.edu** for details and information to rely on the IRB the Sponsor is using

- If the Sponsor **IS NOT** using an independent (central) IRB, then the study should be submitted for review by the CHLA IRB (not a ceded application).

Independent IRBs: Advarra, Sterling, & WCG

Use these documents to prepare your CHLA submission:

- **Guidance Document**: Instructions for Making a Submission to a Central IRB for Industry Sponsored Multi-Center Clinical Trials

- Template Document: Key Information Summary Section for Consent Forms (if applicable)
  - Only required when the Sponsor's consent templates **DO NOT** include a key information section*
  - CHLA only requires key information in all main study consent forms (not assent forms, pregnancy partner, or sub-study/optional study consent forms)
  - Should only be 1 to 1 ½ pages in length
  - Follow the instructions in the template

- Template Document: Disclosure of Financial Conflicts of Interest Statement for Consent Forms (if applicable)
  - Only required if any member of the study team has a conflict of interest (COI), a Conflict Management Plan (CMP) has been executed, and the CMP requires COI disclosure language in the consent form(s)
  - Follow the instructions in the template

Independent IRBs: Advarra, Sterling, & WCG

Submit these documents (Initial Clearance):

- Protocol (**REQUIRED**)
- Key Information Summary (if applicable)
- Financial Conflict of Interest Statement (if applicable)
- CHLA COIRC Conflict Management Plan (CMP) (if applicable)
- CHLA Site Specific Recruitment Tools (e.g., flyers) (if applicable)
  - Sponsor provided recruitment materials **do not** need to be submitted (e.g., brochures)

Independent IRBs: Advarra, Sterling, & WCG

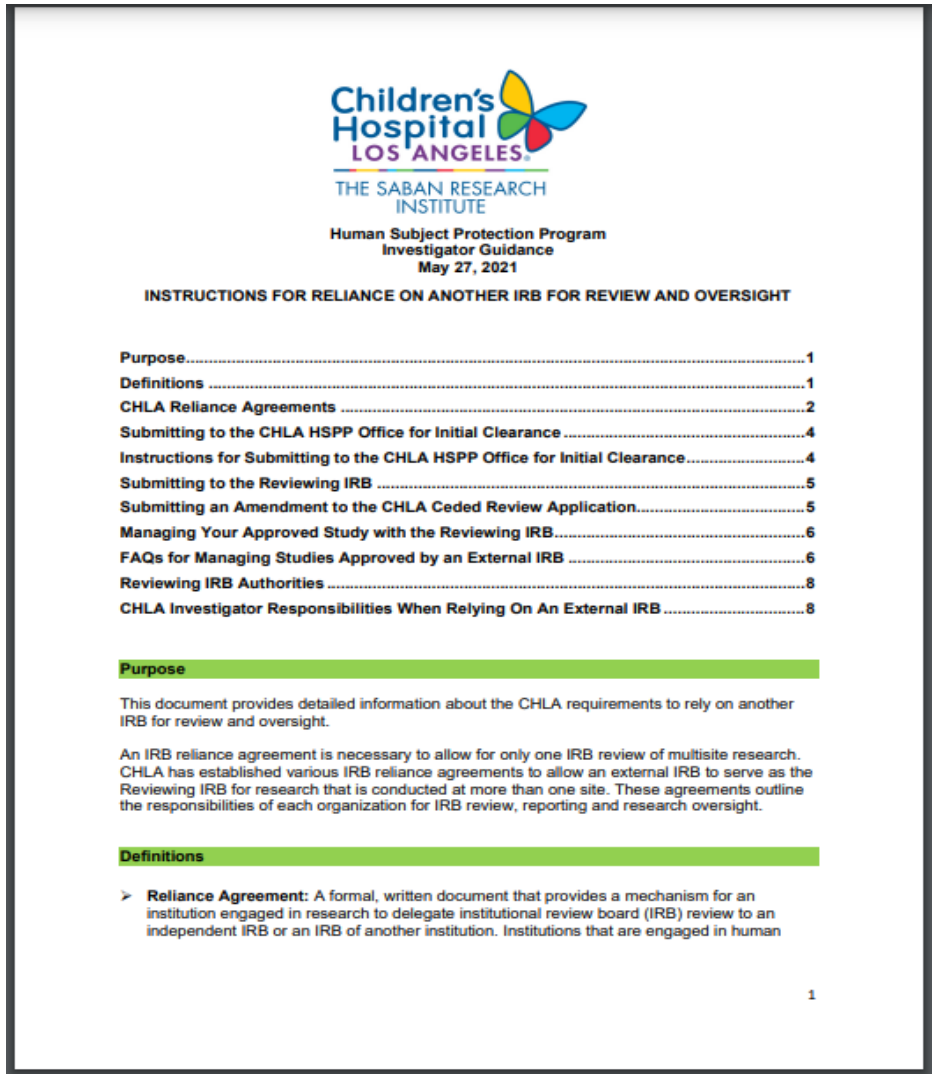
- Study teams **DO NOT** need to upload the Sponsor's consent & assent templates.
- Study teams **DO NOT** need to create consent & assent forms for use at CHLA **IF** the Sponsor has templates.
- Advarra, Sterling, & WCG IRBs will use the Sponsor's templates to create the CHLA forms.
- **QUESTION**: What do I do if the Sponsor doesn't have an assent form template?
  - Use the CHLA Simplified Assent Form Template on the HSPP website. This should only be used if the Sponsor **does not** have an assent form template.
  - Upload the CHLA Simplified Assent Form in iStar so that it can be cleared by HSPP staff

EXTERNAL IRBs: BCH, CHOP, UCLA, Stanford, etc.

External IRBs: BCH, CHOP, & etc.

Use these documents to prepare your CHLA submission:

- **Guidance Document**: Instructions for Reliance on Another IRB for Review and Oversight
- External IRB Consent Form Checklist
- NMDP IRB Consent Form Checklist (NMDP studies only)



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Human Subject Protection Program
Investigator Guidance
May 27, 2021

INSTRUCTIONS FOR RELIANCE ON ANOTHER IRB FOR REVIEW AND OVERSIGHT

Purpose

This document provides detailed information about the CHLA requirements to rely on another IRB for review and oversight.

An IRB reliance agreement is necessary to allow for only one IRB review of multisite research. CHLA has established various IRB reliance agreements to allow an external IRB to serve as the Reviewing IRB for research that is conducted at more than one site. These agreements outline the responsibilities of each organization for IRB review, reporting and research oversight.

Definitions

- **Reliance Agreement:** 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. Institutions that are engaged in human

1

External IRBs: BCH, CHOP, & etc.

Submit these documents (Initial Clearance):

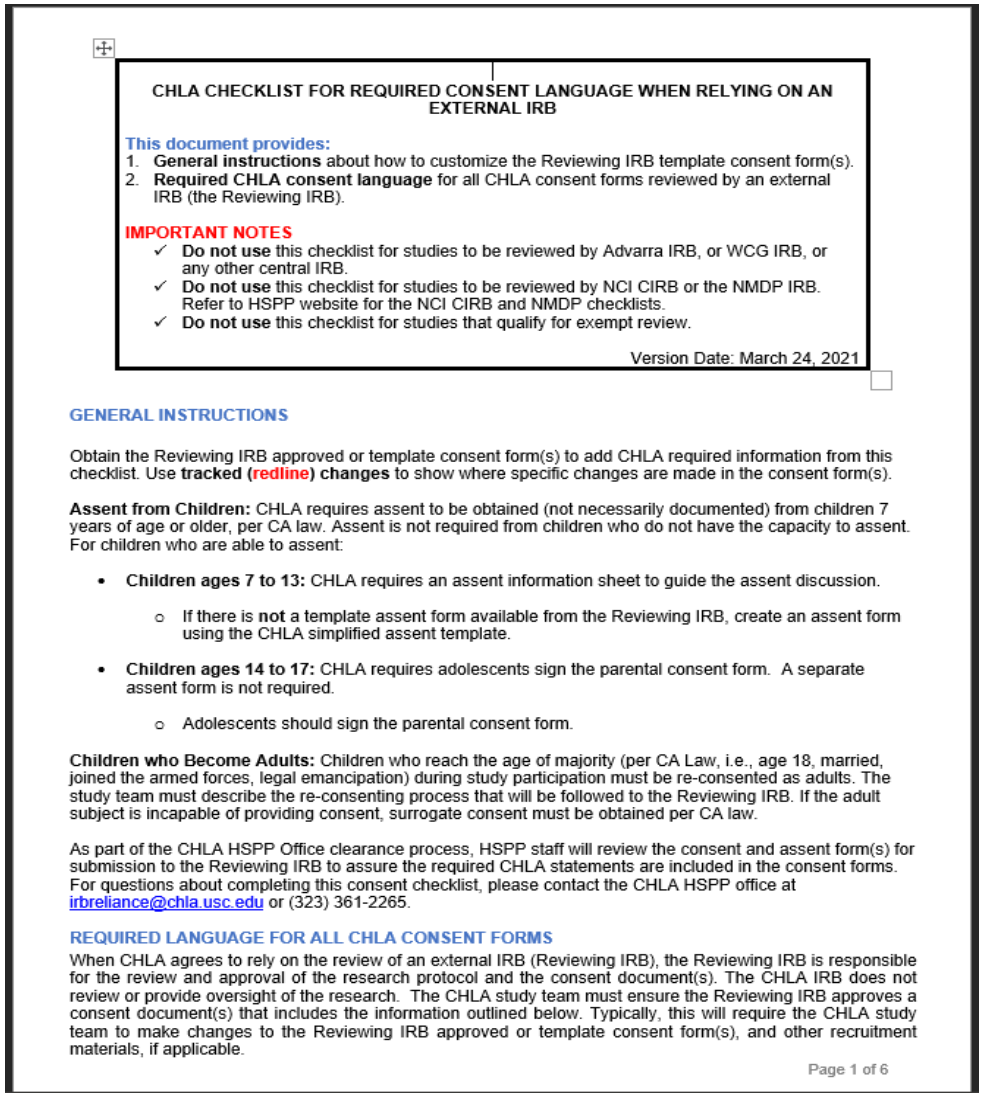
- Protocol (**REQUIRED**)
- Reviewing IRB's Approval Letter (**REQUIRED** if the study is already approved)
- Reviewing IRB's Template Consent and Assent Forms (**REQUIRED**)
- CHLA Site Specific Consent & Assent Forms with required CHLA language (**REQUIRED**)
- CHLA Addendum Form for Subjects turning 18 years old (if applicable)
- CHLA Site Specific Recruitment Tools (e.g., flyers) (if applicable)
- CHLA COIRC Conflict Management Plan (CMP) (if applicable)

External IRBs: BCH, CHOP, & etc.

Customizing the Reviewing IRB's Consent & Assent Forms

- Use the consent and assent templates provided by the Reviewing IRB
  - You should only use the CHLA Simplified Assent Form template, if the Reviewing IRB doesn't have an assent form template

- Use the correct External Consent Form Checklist to customize the CHLA Consent Forms
  - **DO NOT** upload the checklist into iStar



CHLA CHECKLIST FOR REQUIRED CONSENT LANGUAGE WHEN RELYING ON AN EXTERNAL IRB

This document provides:
1. **General instructions** about how to customize the Reviewing IRB template consent form(s).
2. **Required CHLA consent language** for all CHLA consent forms reviewed by an external IRB (the Reviewing IRB).

IMPORTANT NOTES
- ✓ **Do not use** this checklist for studies to be reviewed by Advarra IRB, or WCG IRB, or any other central IRB.
- ✓ **Do not use** this checklist for studies to be reviewed by NCI CIRB or the NMDP IRB. Refer to HSPP website for the NCI CIRB and NMDP checklists.
- ✓ **Do not use** this checklist for studies that qualify for exempt review.

Version Date: March 24, 2021

GENERAL INSTRUCTIONS

Obtain the Reviewing IRB approved or template consent form(s) to add CHLA required information from this checklist. Use **tracked (redline) changes** to show where specific changes are made in the consent form(s).

Assent from Children: CHLA requires assent to be obtained (not necessarily documented) from children 7 years of age or older, per CA law. Assent is not required from children who do not have the capacity to assent. For children who are able to assent:

- **Children ages 7 to 13:** CHLA requires an assent information sheet to guide the assent discussion.
  - If there is **not** a template assent form available from the Reviewing IRB, create an assent form using the CHLA simplified assent template.
- **Children ages 14 to 17:** CHLA requires adolescents sign the parental consent form. A separate assent form is not required.
  - Adolescents should sign the parental consent form.

Children who Become Adults: Children who reach the age of majority (per CA Law, i.e., age 18, married, joined the armed forces, legal emancipation) during study participation must be re-consented as adults. The study team must describe the re-consenting process that will be followed to the Reviewing IRB. If the adult subject is incapable of providing consent, surrogate consent must be obtained per CA law.

As part of the CHLA HSPP Office clearance process, HSPP staff will review the consent and assent form(s) for submission to the Reviewing IRB to assure the required CHLA statements are included in the consent forms. For questions about completing this consent checklist, please contact the CHLA HSPP office at irbreliance@chla.usc.edu or (323) 361-2265.

REQUIRED LANGUAGE FOR ALL CHLA CONSENT FORMS

When CHLA agrees to rely on the review of an external IRB (Reviewing IRB), the Reviewing IRB is responsible for the review and approval of the research protocol and the consent document(s). The CHLA IRB does not review or provide oversight of the research. The CHLA study team must ensure the Reviewing IRB approves a consent document(s) that includes the information outlined below. Typically, this will require the CHLA study team to make changes to the Reviewing IRB approved or template consent form(s), and other recruitment materials, if applicable.

Page 1 of 6

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External IRBs: BCH, CHOP, & etc.

Using the correct **External Consent Form Checklist**, the following edits should be made to the template consent form(s) provided by the Reviewing IRB, as applicable:

Heading: Identifies CHLA as a site

Key Information

Contact Information (PI & CHLA HSPP)

COI Disclosure language

Confidentiality language (remove embedded HIPAA language)

California Subject's Bills of Rights

Research Subject Injury language

Cost language

Pregnancy & HIV/STI language

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External IRBs: BCH, CHOP, & etc.

Customize the Reviewing IRB's Template Assent Form(s):

- Name & contact information for the PI

- Pregnancy and HIV/STI language (if applicable)
  - **Pregnancy**: Your pregnancy test results will not be shared with your parent(s).

  - **HIV/STI**: If your HIV/Sexually Transmitted Infection (STI) test is positive and you are at least 12 years of age, we will not share the results with your parent(s) unless you tell us we can. If your HIV/Sexually Transmitted Infection (STI) test is positive and you are under the age of 12, the results will be shared with your parent(s).

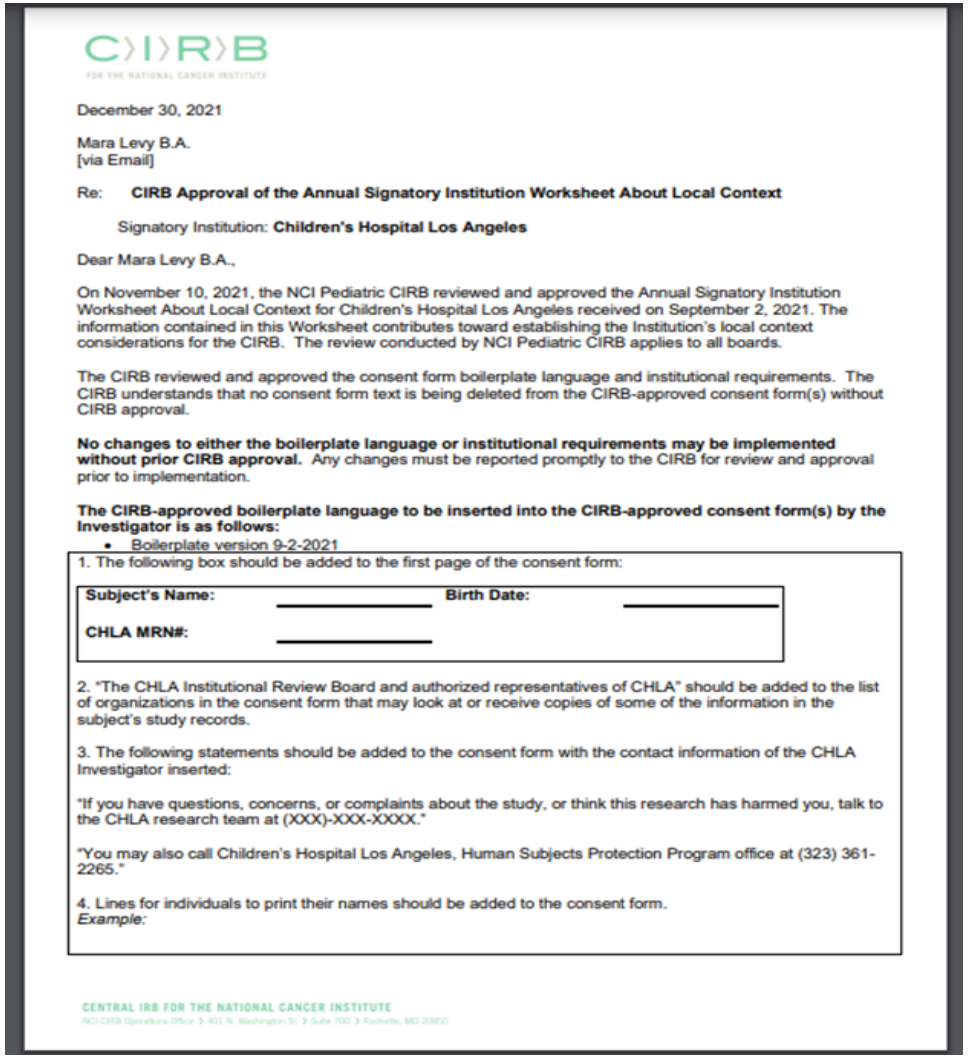
NATIONAL CANCER INSTITUTE CENTRAL IRB (CIRB)

CIRB

Use these documents to prepare for your CHLA submission:

- **Guidance Document**: There is **no** guidance document available for CIRB studies.

- NCI CIRB Boilerplate for Consent Forms (aka Local Context Worksheet)



C)I)R)B

December 30, 2021

Mara Levy B.A.
[via Email]

Re: **CIRB Approval of the Annual Signatory Institution Worksheet About Local Context**

Signatory Institution: **Children's Hospital Los Angeles**

Dear Mara Levy B.A.,

On November 10, 2021, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Children's Hospital Los Angeles received on September 2, 2021. The information contained in this Worksheet contributes toward establishing the Institution's local context considerations for the CIRB. The review conducted by NCI Pediatric CIRB applies to all boards.

The CIRB reviewed and approved the consent form boilerplate language and institutional requirements. The CIRB understands that no consent form text is being deleted from the CIRB-approved consent form(s) without CIRB approval.

No changes to either the boilerplate language or institutional requirements may be implemented without prior CIRB approval. Any changes must be reported promptly to the CIRB for review and approval prior to implementation.

The CIRB-approved boilerplate language to be inserted into the CIRB-approved consent form(s) by the Investigator is as follows:

- Boilerplate version 9-2-2021

1. The following box should be added to the first page of the consent form:

Subject's Name: _____ **Birth Date:** _____

CHLA MRN#: _____

2. "The CHLA Institutional Review Board and authorized representatives of CHLA" should be added to the list of organizations in the consent form that may look at or receive copies of some of the information in the subject's study records.

3. The following statements should be added to the consent form with the contact information of the CHLA Investigator inserted:

"If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team at (XXX)-XXX-XXXX."

"You may also call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265."

4. Lines for individuals to print their names should be added to the consent form.
Example:

CENTRAL IRB FOR THE NATIONAL CANCER INSTITUTE

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CIRB

Submit these documents in the iStar Application (initial clearance):

- CIRB Zip file
- CIRB Approval of Study-Specific Worksheet **(if applicable)**
- CHLA Site Consent Form(s)
- CHLA Simplified Assent Form(s)
- Youth Information Sheet(s) (YIS) - if you are using these **instead** of the CHLA Simplified Assent Form

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CIRB: Customizing the Consent Forms

Use the approved consent templates on the CTSU website

Use the local context worksheet on the HSPP website to make the allowable edits

The CIRB-approved boilerplate language to be inserted into the CIRB-approved consent form(s) by the Investigator is as follows:

- Boilerplate version 9-2-2021

1. The following box should be added to the first page of the consent form:

Subject's Name:	_____	**Birth Date:**	_____
CHLA MRN#:	_____		

2. "The CHLA Institutional Review Board and authorized representatives of CHLA" should be added to the list of organizations in the consent form that may look at or receive copies of some of the information in the subject's study records.

3. The following statements should be added to the consent form with the contact information of the CHLA Investigator inserted:

"If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team at (XXX)-XXX-XXXX."

"You may also call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265."

Customizing the Consent Form(s)

- Add the Subject's Name identifier box on the first page

Subject's Name:	_____	**Birth Date:**	_____
CHLA MRN#:	_____		

- **"What about privacy?"** section

- Children's Oncology Group and research partners
- Representatives of the National Cancer Institute (NCI), Food and Drug Administration (FDA), and other U.S. and international regulatory agencies involves in overseeing research
- **The CHLA Institutional Review Board and authorized representatives of CHLA**
- Pediatric Central Institutional Review Board (CIRB) of the National Cancer Institute
- The study sponsor and any drug company supporting the study now or in the future

Customizing the Consent Form(s)

- Complete the **"Whom do I call if I have questions or problems?"** section

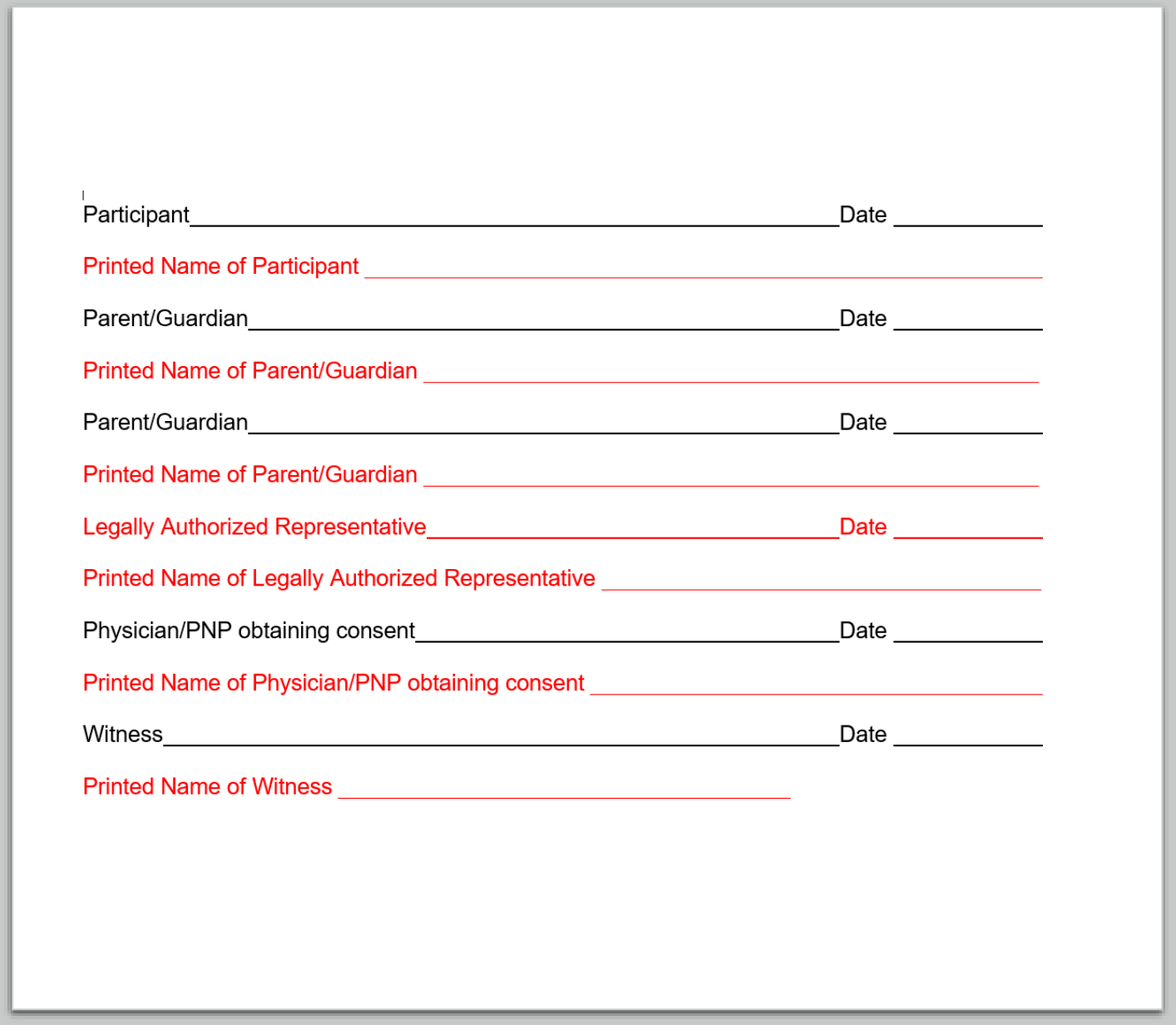
> For questions about the study or if you have a research related problem or if you think you have been injured in this study, you may contact Dr. Jane Doe or your doctor at (323) 111-1111.
>
> If you have any questions about your rights as a research participant or any problems that you feel you cannot discuss with the investigators, you may call the IRB Administrator at Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.
>
> If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Patient Advocate at (323) 361-2265.

- **"Where do I get more information?"** section

> If you have questions, concerns, or complaints about the study, or think the research has harmed you, talk to the CHLA research team at (323) 361-2121.
>
> You may also call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

CIRB: Customizing the Consent Forms

Signature sections: Use the signature sections in the approved CIRB templates. However, you are allowed to add in the "print name line" and any signature sections for special populations that are missing (e.g., legally authorized representatives consenting for adults lacking consent capacity, witnesses for enrolling non-English speaking populations).



Participant _____ Date _____

Printed Name of Participant _____

Parent/Guardian _____ Date _____

Printed Name of Parent/Guardian _____

Parent/Guardian _____ Date _____

Printed Name of Parent/Guardian _____

Legally Authorized Representative _____ Date _____

Printed Name of Legally Authorized Representative _____

Physician/PNP obtaining consent _____ Date _____

Printed Name of Physician/PNP obtaining consent _____

Witness _____ Date _____

Printed Name of Witness _____

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Creating the Assent Form(s) or Customizing the Youth Information Sheets (YIS)

- **CHLA Simplified Assent Form** (version 9-22-2020)
  - This is the version currently approved by CIRB
  - Must be submitted to the CIRB for approval before use

- **Youth Information Sheet(s)**: Can be used when available on the CTSU website and the research involves children 7-13 years old and/or adults lacking the consent capacity.
  - If you choose to use the YIS, if must be the YIS that corresponds to the current protocol version.
    - ➢ Example: If the protocol version is 1/1/22 but is 1/1/21 on the YIS, then the YIS can not be used.
  - You can only add in a signature section (without the checkbox)

Example:

_____ _____

Signature of Subject (if able to sign) Date

COMPLETING THE iStar APPLICATION

Completing the iStar Application

- Ensure that **ALL** study personnel have current CITI certifications
  - The CHLA HSPP office does not monitor/track HIPAA certifications
  - Visit the HSPP website if you have any questions about what training needs to be completed

2.1. **Study Personnel and their roles:**

	Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access Identifiable Data	Manage Audit Access to PHI/ePHI (CHLA Only)
View	Smith	Deebra	CHLA Human Subjects Protection Program	Principal Investigator	HS GCP HIPAA	yes	yes	yes	
View	Smith	Deebra	CHLA Human Subjects Protection Program	Study Contact Person	HS GCP HIPAA	yes	yes	yes	yes

- Identify the funding sources

  - **Item 4.1.1 - Is CHLA the Prime Awardee?**: If "yes", you will need to talk to the IRB Regulatory Manager to determine whether the study can be ceded since CHLA is the primary awardee of the NIH funds. This should be done **before** the iStar application is completed and submitted to the CHLA HSPP.

- Identify the correct reviewing IRB
  - If you select "Other," **DO NOT** list SMART IRB or IREx as the Reviewing IRB. These are **not** IRBs.

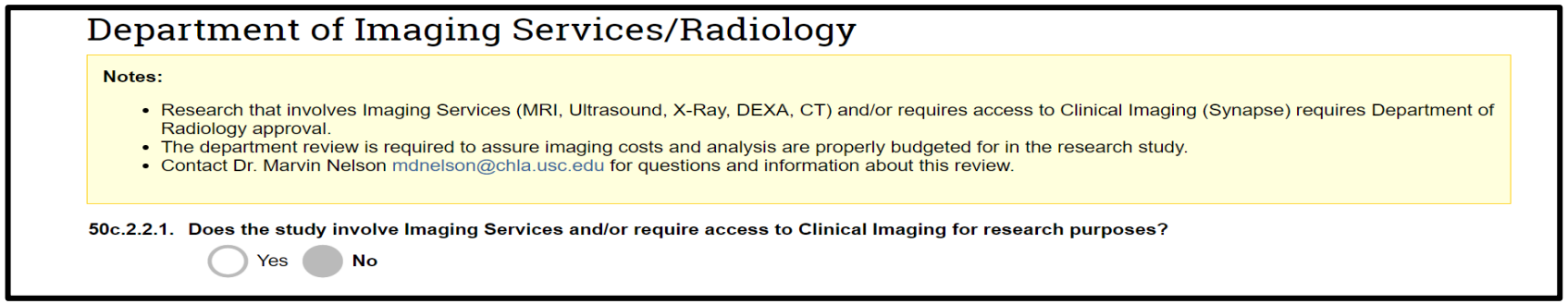
Completing the iStar Application

- Identify any parts of the study or any study procedures CHLA is not participating in (e.g., sub-studies, optional studies, optional procedures)
- Describe the re-consenting plan for minor subjects turning 18 years old while participating in the study
  - CA Law requires that children reaching the age of majority during study participation must be re-consented as adults for their continuing participation.
  - You should consult with the reviewing IRB and describe in the iStar application the re-consenting process that will be followed by the reviewing IRB. They may want these subjects to be re-consented for their continuing participation with the full consent form rather than an addendum form.
- Ensure **ALL** study personnel have a current COI disclosure on file
  - CHLA policy COMP 021.0 requires **ALL** study team members to have a current COI disclosure in DiSClose.
  - Keep your disclosures up to date to prevent delays.

Role	COI Annual Disclosure Status	Conflicts
Principal Investigator	Current: due on 3/25/2023	No conflicts identified
Co-Investigator	Current: due on 3/29/2023	No conflicts identified
Co-Investigator	Current: due on 1/24/2023	No conflicts identified

Completing the iStar Application

- **Item 26.4 – Will identified data/specimens be released to a 3rd party?:** Should be "yes" because it is most likely that coded data/specimens is being released from CHLA.
- Answer **ALL** the questions in Section 50
  - The iStar application will be routed/flagged based on how you answer the questions
  - Contact the department/committee if you have questions or need information about their review process



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**

Completing the iStar Application

- It's impossible to list all the documents that should not be submitted in the iStar application that you receive from the Reviewing IRB.

- However, the following documents are examples of what should **NOT** be submitted in the iStar application:
  - Investigator's Brochure/Package Inserts
  - Questionnaires/surveys, focus group/interview scripts
  - Data Collection Forms
  - Patient Cards
  - Reviewing IRB's roster

- Documents received from the Reviewing IRB must be retained in your study/regulatory binders.

AMENDMENTS, CONTINUING REVIEWS, REPORTABLE EVENTS, & CLOSURES

Amendment Applications

- **Amendment Applications (AM)** are **REQUIRED** for the following:
  - Study personnel updates (PI, Co-PIs, consenting privileges)
  - New/updated protocol(s), ICF(s), CHLA recruitment tool(s), CMPs
  - Enrollment status change
  - When continuing review approval is granted by the Reviewing IRB

- Documents to include in AM applications:
  - New/updated protocol(s), ICF(s)*, CHLA recruitment tool(s), CMPs
    - ICF: Only submit approved/stamped forms. If you are making changes to our required local context, then you will need to submit the requests to irbreliance@chla.usc.edu for review and approval by the IRB Regulatory Manager
  - Reviewing IRBs approval letter(s)

- **FAQ**: Can I use the documents approved by the Reviewing IRB before obtaining clearance of the AM by the CHLA HSPP? →**No**. The documents need to be cleared by the CHLA HSPP office before use so that we can ensure that local context language has not been changed in the ICFs and to ensure that approvals from CHLA departments/divisions (e.g., Lab Medicine) and ancillary committees (e.g., Radiation Safety) are not needed.

Continuing Review & Reportable Event Applications

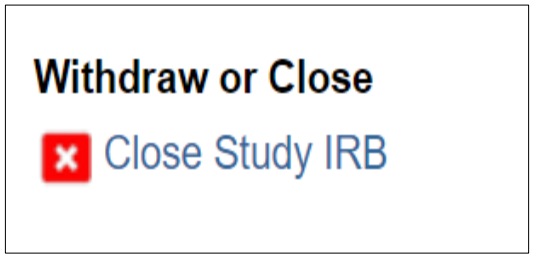
- **Continuing Review (CR)** applications **ARE NOT REQUIRED**
  - CHLA doesn't put an expiration date on the clearance letter or in iStar (except for CIRB studies)
  - When the Reviewing IRB approves a continuing review, an AM must be submitted in iStar

- **Reportable Event** applications **ARE NOT REQUIRED**
  - **Do not** submit any RE applications in iStar for ceded studies
  - CHLA clearance or CHLA IRB review **is not** required for reportable new information or events that occur at CHLA
  - All events should be submitted to the Reviewing IRB according to their requirements

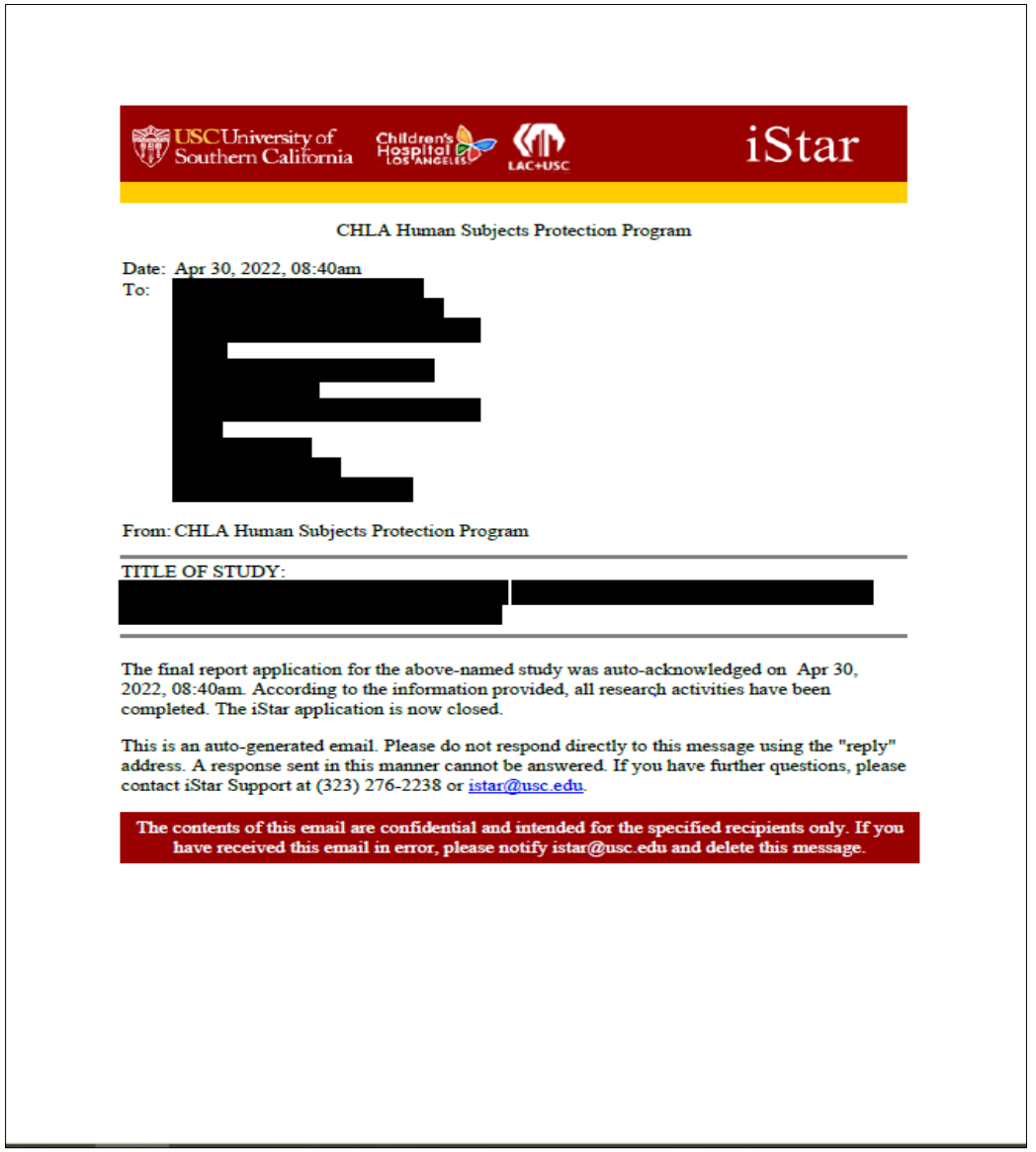
- Once a submission for a reportable event has been made to the Reviewing IRB, you should send an email to irbreliance@chla.usc.edu with the following:
  - Details on the submission made to the Reviewing IRB
  - The Reviewing IRB's review of the event and its determination(s)

Study Closures

- Study closure reports **do not** require CHLA clearance.
- Use the "**Close Study IRB**" function in iStar to close the study.



- iStar will issue a **Close Study Letter**



USC University of Southern California | Children's Hospital Los Angeles | LAC+USC | iStar

CHLA Human Subjects Protection Program

Date: Apr 30, 2022, 08:40am
To: [redacted]

From: CHLA Human Subjects Protection Program

TITLE OF STUDY: [redacted]

The final report application for the above-named study was auto-acknowledged on Apr 30, 2022, 08:40am. According to the information provided, all research activities have been completed. The iStar application is now closed.

This is an auto-generated email. Please do not respond directly to this message using the "reply" address. A response sent in this manner cannot be answered. If you have further questions, please contact iStar Support at (323) 276-2238 or istar@usc.edu.

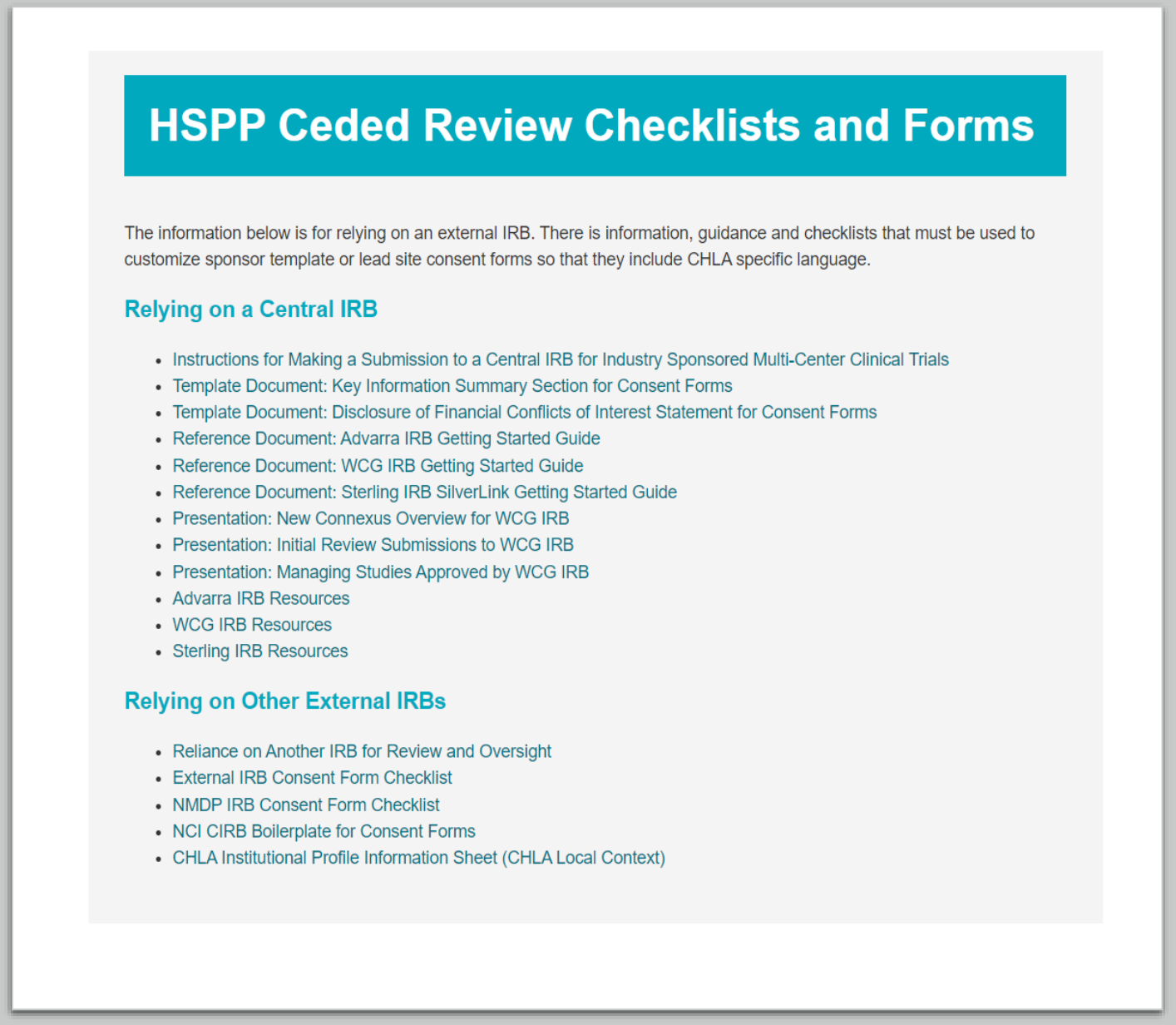
The contents of this email are confidential and intended for the specified recipients only. If you have received this email in error, please notify istar@usc.edu and delete this message.

TIPS & REMINDERS

Tips & Reminders

- Use the current guidance documents, templates, & consent form checklists on the HSPP website
- Have the guidance document & consent form checklist open while working on the iStar application
- When removing embedded HIPAA language, you can use the CHLA Research HIPAA authorization form to help you find HIPAA language
- Make sure you submit the consent and assent forms cleared by the CHLA HSPP to the Reviewing IRB for review and approval
- Check the consent/assent forms once approved by the Reviewing IRB before submitting them in iStar
- Contact your IRBA or the HSPP Office if you have any questions
- Contact the Reviewing IRB if you have any questions about consent, permission, assent, and/or HIPAA and reporting requirements

All the guidance documents, worksheets and templates mentioned today are available on the HSPP website: https://www.chla.org/research/hspp-ceded-review-checklists-and-forms



HSPP Ceded Review Checklists and Forms

The information below is for relying on an external IRB. There is information, guidance and checklists that must be used to customize sponsor template or lead site consent forms so that they include CHLA specific language.

Relying on a Central IRB

- Instructions for Making a Submission to a Central IRB for Industry Sponsored Multi-Center Clinical Trials
- Template Document: Key Information Summary Section for Consent Forms
- Template Document: Disclosure of Financial Conflicts of Interest Statement for Consent Forms
- Reference Document: Advarra IRB Getting Started Guide
- Reference Document: WCG IRB Getting Started Guide
- Reference Document: Sterling IRB SilverLink Getting Started Guide
- Presentation: New Connexus Overview for WCG IRB
- Presentation: Initial Review Submissions to WCG IRB
- Presentation: Managing Studies Approved by WCG IRB
- Advarra IRB Resources
- WCG IRB Resources
- Sterling IRB Resources

Relying on Other External IRBs

- Reliance on Another IRB for Review and Oversight
- External IRB Consent Form Checklist
- NMDP IRB Consent Form Checklist
- NCI CIRB Boilerplate for Consent Forms
- CHLA Institutional Profile Information Sheet (CHLA Local Context)

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	INDEPENDENT IRBS	EXTERNAL IRBS	NCI CIRB
Use these Guidance Documents and templates (as applicable):	• Instructions for Making Submission to a Central IRB for Industry Sponsored Multi-Center Clinical Trials • Template Document: Key Information Summary Section for Consent Forms • Template Document: Disclosure of Financial Conflicts of Interest Statement for Consent Forms	• Instructions for Reliance on Another IRB for Review and Oversight • External IRB Consent Form Checklist • NMDP IRB Consent Form Checklist (NMDP studies only)	• No guidance document available • NCI CIRB Boilerplate for Consent Forms
Submit these documents in iStar for Initial Clearance (as applicable):	• Protocol • Key Information Summary • CHLA Simplified Assent Form • Financial COI Statement • CHLA Recruitment Tools • CHLA CMP	• Protocol • Reviewing IRB's consent & assent templates • Reviewing IRB's recruitment template(s) • CHLA Consent, Permission, Assent, Addendum Forms • CHLA Recruitment Tool(s) • Reviewing IRBs Approval Letter • CHLA CMP	• CIRB zip file • CIRB Site Specific Worksheets • CHLA Consent, Permission, Assent forms • CIRB Youth Information Sheets • CHLA CMP
Submit these documents to CHLA via Amendments (as applicable)	• New/updated protocol • New/updated CHLA Consent, Permission, Assent, Addendum forms • New/updated CHLA Recruitment Tools • Reviewing IRB's Approval Letter(s) • New/updated CHLA CMP	• New/updated protocol • New/updated CHLA Consent, Permission, Assent, Addendum forms • New/updated CHLA Recruitment Tools • Reviewing IRB's Approval Letter(s) • New/updated CHLA CMP	• CIRB zip file • New/updated CHLA Consent, Permission, Assent forms • New/updated CIRB Youth Information Sheets • New/updated CHLA CMP

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