



**Tea with the IRB: Tips for Successful
Submission of Continuing Reviews to the CHLA
IRB**

February 2024

**Presenter: Mara Levy-LaPointe, BA, CIP
Manager, IRB
Human Subjects Protection Program**

CHLA HSPP & IRB Website



Visit our website! <https://www.chla.org/research/hspp>



Review Investigator Guidance: [Continuing Review Requirements and Submission of Closure Reports](#)

Federal Requirements for Continuing Review

DHHS and FDA regulations require the IRB to continually review ongoing research at intervals appropriate to the potential risk to participants, **but at least annually.**

- Research that involves **greater than minimal risk to subjects**
- Research that is **FDA regulated**:
 - ✓ Clinical investigations of drugs or biologics
 - ✓ Clinical investigations of devices
- The IRB determined that continuing review of this research would **enhance protection of research subjects.**
- Research that involves **no greater than minimal risk to subjects and was initially approved on or before January 20, 2019.**

If an Investigator does not wish to continue a research study, then a study closure or final report must be submitted in iStar.

For How Long is Continuing Review Required?

- Investigators are responsible for submitting a continuing protocol in iStar and maintaining current IRB approval **until all of the following occur**:
 - **Subject recruitment has concluded** (i.e., no subject recruitment is in progress or anticipated)
 - **All subject specimens, records, data have been collected** (i.e., no further collection of data/information from or about living individuals is needed)
 - **All interactions or interventions with subjects are completed** (i.e., no further contact with subjects is necessary or anticipated)
 - **Analyses of subject identifiable data, records, specimens are finished** (i.e., use or access to subject identifiable data is no longer necessary).

Common Errors

- Late Submissions
- Incorrect Future Study Status selected
- Incorrect Enrollment & Withdrawal Reporting
- Missing Reportable Events & DSM Reports
- Contradictory Information provided in item 5.1
- Future Use of Consent & Assent Forms - Documents needed in years ahead are not checked
- Yes or No Questions - Skipped or answered “No” without amending the main application
- Study Personnel - Expired certifications and personnel listed are not current (or have been updated but question 9.1 is answered “No”)
- Updates Not Made - Information is no longer current and IRB is not notified

Remember to submit your continuing review application (CR) well before the study is due to expire.

- Federal regulations **make no provision for any grace period** extending the conduct of research beyond the expiration of IRB approval.
 - Continuing review and re-approval of research must occur **on or before** the date when IRB approval expires.
- Continuation of research activities without IRB review and approval is a violation of federal regulations and **represents protocol noncompliance.**

In order to avoid a lapse in IRB approval, it is recommended that continuing review applications be submitted to the CHLA IRB **60 days before the expiration date.**

What happens if IRB approval expires before the continuing review is approved?

Expirations and Lapses in Approval

- Investigators must plan ahead to meet required continuing review requirements.
- If an investigator fails to submit a continuing protocol application to the IRB or the IRB does not approve the continuation of the research before the date of expiration, the **research must stop**.
- All of the following research procedures must stop (even if the continuing review application has been submitted to the IRB, all activities must stop until IRB approval is granted):
 - Subject recruitment or enrollment
 - Collection of data/information from or about living individuals
 - All research-related interventions or interactions with currently enrolled subjects*
 - Data analyses involving subject identifiable data

Additional Requirements When IRB Approval Expires

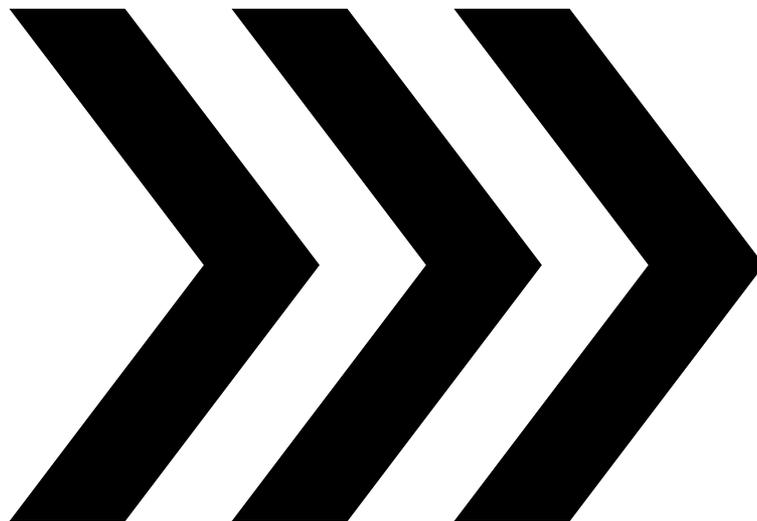
- For studies that are allowed to expire, investigators must include the following information in the continuing review application:
 - Confirmation that all research activities have stopped.
 - An explanation of why the study was allowed to expire.
 - A corrective action plan for preventing lapses in approval and protocol expiration in the future.

Rights & Welfare of Subjects

***Exception:** Research-related interventions or interactions with currently enrolled subjects can continue **only if stopping the research would jeopardize the rights or welfare of current subjects.**

- The IRB must make this determination and decide which subjects should continue with the intervention during the lapse. Investigators who think that currently enrolled subjects are at risk of harm by stopping research procedures, must provide the following information to the IRB:
 - **Prepare a written description of subjects who will be harmed.**
 - **Identify the research procedures that need to continue.**
 - **Describe the reasons that these procedures need to continue.**
- An IRB chair will decide whether there is an over-riding safety concern or ethical issue involved such that it is in the best interest of individual subjects to continue to be followed for safety.
- **NOTE: Any information collected during the lapse in approval may not be used for research.** Failure to maintain current approval may disqualify data intended for submission to the FDA (e.g., studies of investigational drugs and devices), other federal agencies, and sponsors.

Future Study Status



Future Study Status: Enrolling New Subjects/Data/Specimens

If recruitment and enrollment will continue, the study team should select this option.

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

Generate Identifier

1.2. Overall Study Status (choose one):

- a. Enrolling New Subjects/Data/Specimens
- b. Enrollment temporarily halted consistent with the IRB approved protocol/study design
- c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- d. Enrollment Permanently Closed - Collecting Data Only
- e. Data Analysis Only
- f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

Future Study Status: Enrolling temporarily halted consistent with the IRB approved protocol/study design

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

Generate Identifier

1.2. Overall Study Status (choose one):

a. Enrolling New Subjects/Data/Specimens

b. Enrollment temporarily halted consistent with the IRB approved protocol/study design

c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues

d. Enrollment Permanently Closed - Collecting Data Only

e. Data Analysis Only

f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

Future Study Status

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

1.2. Overall Study Status (choose one):

a. Enrolling New Subjects/Data/Specimens

b. Enrollment temporarily halted consistent with the IRB approved protocol/study design

c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues

d. Enrollment Permanently Closed - Collecting Data Only

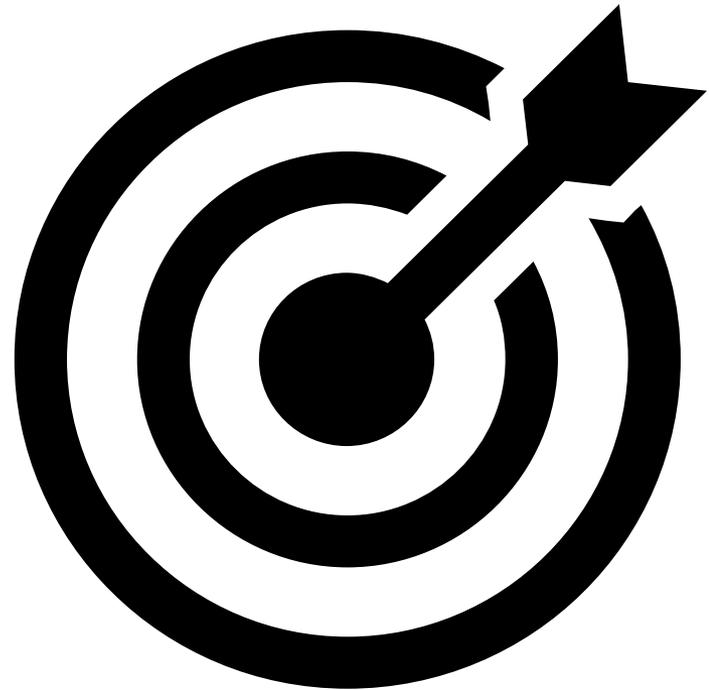
e. Data Analysis Only

f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy



Future Study Status: Enrollment Permanently Closed

- If subject accrual is permanently closing and **no new subjects will EVER be enrolled again** into the research
- **BUT** further data collection will occur...



OHRP Continuing Review Guidance

Expedited Review Category (8)

Under category (8), an expedited review procedure may be used for the continuing review of research previously approved by the IRB at a convened meeting as follows:

- (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; **OR**
- (b) Where no subjects have been enrolled and no additional risks have been identified; **OR**
- (c) Where the remaining research activities are limited to data analysis.

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html#section-e2>

Future Study Status: Enrollment Permanently Closed - Study Treatment or Study Intervention Continues

In the case where the subjects have **NOT** completed all research-related treatments and/or interventions (including research only tests during follow-up study visits), the study team should be selecting this option.

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

Generate Identifier

1.2. Overall Study Status (choose one):

- a. Enrolling New Subjects/Data/Specimens
- b. Enrollment temporarily halted consistent with the IRB approved protocol/study design
- c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- d. Enrollment Permanently Closed - Collecting Data Only
- e. Data Analysis Only
- f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

1.2.1. If the study is permanently closed to enrollment (c, d, e, or f) please indicate why (e.g., required number of subjects has been reached, issues with protocol safety, etc.)

Future Study Status: Enrollment Permanently Closed - Collecting Data Only

The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related treatments/interventions; and the research remains active only for long-term follow-up of subjects.

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

1.2. Overall Study Status (choose one):

- a. Enrolling New Subjects/Data/Specimens
- b. Enrollment temporarily halted consistent with the IRB approved protocol/study design
- c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- d. Enrollment Permanently Closed - Collecting Data Only
- e. Data Analysis Only
- f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

1.2.1. If the study is permanently closed to enrollment (c, d, e, or f) please indicate why (e.g., required number of subjects has been reached, issues with protocol safety, etc.)

OHRP Continuing Review Guidance

Expedited Review Category (8)

Expedited review category (8)(a) and the meaning of “long-term follow-up”

Under expedited review category (8)(a), OHRP interprets “long-term follow-up” to include:

- Research **interactions** that involve no more than minimal risk to subjects (e.g., quality of life surveys); and
- **Collection of follow-up data** from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol

In contrast, OHRP interprets “long-term follow-up” to exclude:

- Research **interventions** that would **not** have been performed for clinical purposes, even if the research interventions involve no more than minimal risk (e.g. research blood draws)

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html#section-e2>

Future Study Status: Enrollment Permanently Closed - Collecting Data Only

The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related treatments/interventions; and the research remains active only for long-term follow-up of subjects.

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

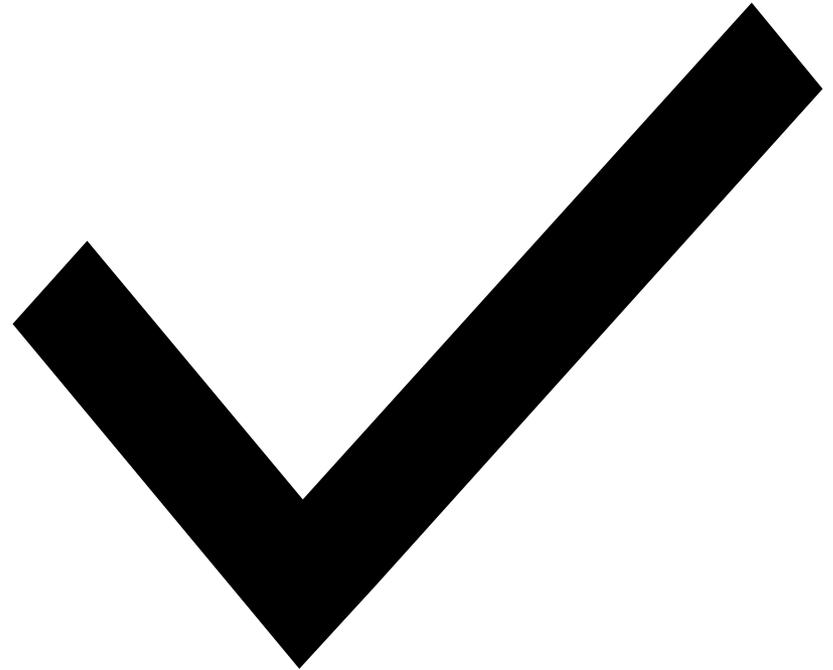
1.2. Overall Study Status (choose one):

- a. Enrolling New Subjects/Data/Specimens
- b. Enrollment temporarily halted consistent with the IRB approved protocol/study design
- c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- d. Enrollment Permanently Closed - Collecting Data Only
- e. Data Analysis Only
- f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

1.2.1. If the study is permanently closed to enrollment (c, d, e, or f) please indicate why (e.g., required number of subjects has been reached, issues with protocol safety, etc.)

Future Study Status: Enrollment Permanently Closed - Collecting Data Only

If the study never involved a treatment or intervention, but data collection continues, this is the future status that should be selected.



Future Study Status: Enrollment Permanently Closed



If the previous status was **enrolling new subjects**, explain under item **1.2.1** of the application, the reason why enrollment is permanently closing now.



Example: *The target number has been reached and all subjects have completed the study treatment and all research related interventions.*

Future Study Status: Data Analysis Only

Once all data and specimen collection has been completed and the remaining research will be limited to analysis of the data, the study team may select this option.

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

Generate Identifier

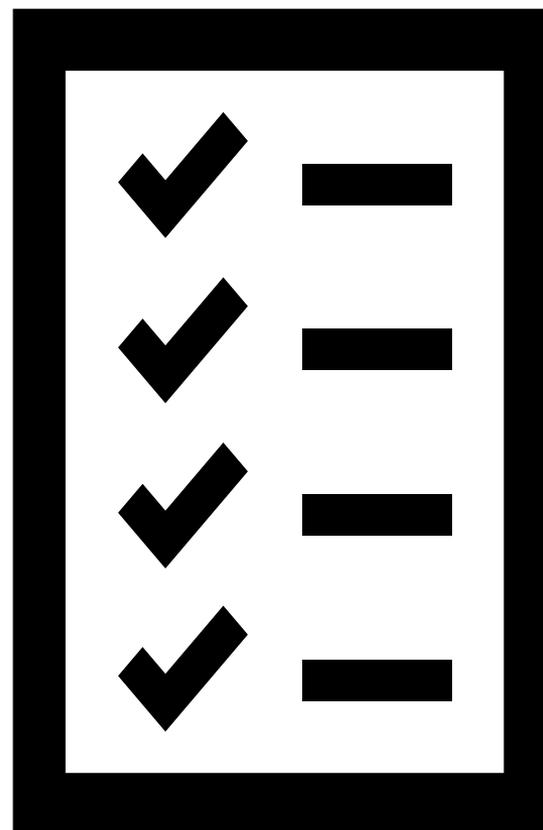
1.2. Overall Study Status (choose one):

- a. Enrolling New Subjects/Data/Specimens
- b. Enrollment temporarily halted consistent with the IRB approved protocol/study design
- c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- d. Enrollment Permanently Closed - Collecting Data Only
- e. **Data Analysis Only**
- f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

Future Study Status: Data Analysis Only

This status should **NOT** be selected until everything else is complete. Once you select this status, you are telling the IRB that:

- **All subjects have completed all research-related treatments/interventions;**
- **All data collection (including long-term follow-up of subjects) has been permanently completed; and**
- **The remaining research activities are limited to data analysis.**



The last option is a study closure report. This is one of 2 ways in iStar to close a study. The other option does not require a continuing review application.

STUDY STATUS

1.1. * Identifier for the Continuing Review:

test CR

1.2. Overall Study Status (choose one):

- a. Enrolling New Subjects/Data/Specimens
- b. Enrollment temporarily halted consistent with the IRB approved protocol/study design
- c. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- d. Enrollment Permanently Closed - Collecting Data Only
- e. Data Analysis Only
- f. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

1.2.1. If the study is permanently closed to enrollment (c, d, e, or f) please indicate why (e.g., required number of subjects has been reached, issues with protocol safety, etc.)

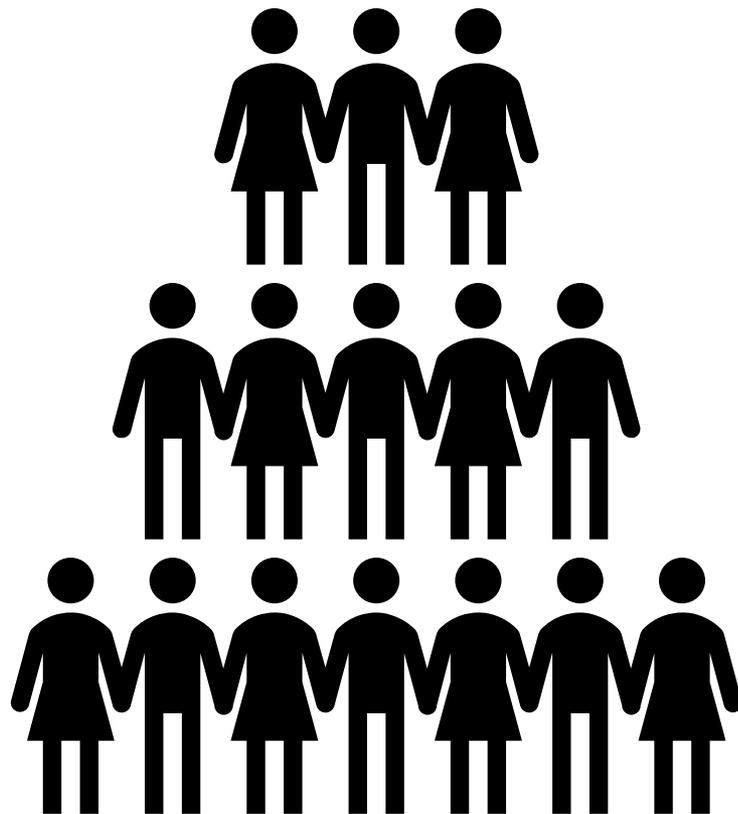
When Should a Closure Report be Submitted?

- **Do not** file a study closure report **if any of the following six conditions apply**. Such studies must remain active and continue to receive ongoing IRB review and approval:
 - Enrollment at the CHLA-approved site(s) is ongoing.
 - Research-related interventions and/or follow-up at the CHLA-approved site(s) is ongoing.
 - Participant follow-up at the CHLA-approved site(s) is ongoing.
 - Identifiable biological specimens are being maintained or analyzed.
 - Data analysis or manuscript preparation that involves the use or access to personally identifiable information is ongoing.
 - If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.**

** Closing Sponsor-Initiated Clinical Trials

- After study enrollment is closed and interventions with subjects are complete, do not submit a study closure or final report **until the sponsor has closed CHLA as a study site**. This includes:
 - Sponsor close-out visit is complete, and all outstanding issues have been addressed.
 - Access to PHI or identifiable data and records (e.g., source documentation) is no longer needed by the CHLA study team, sponsor or sponsor representatives.
 - All contractual and budgetary issues are complete (e.g., payments to subjects; billing to sponsor or third party insurance).

Enrollment & Withdrawal Reporting



Definitions

Target Accrual Number: The proposed total number of participants needed to participate in a research study in order for the study to contribute to generalizable knowledge.

Enrolled Subjects: Individuals who have provided informed consent to participate in the research study. Investigators should include these individuals in the accrual number reported to the IRB at continuing review.

Enrolled Subjects

- An enrolled subject is **anyone who has signed an Informed Consent Document**, whether or not that individual actually completes the study.
- Therefore, someone who signs a consent document but is determined during screening to be ineligible, chooses not to continue and withdraws from the study before they complete the study, or is withdrawn from the study at any point before they complete the study, must still be counted as an enrolled subject.
- For studies granted a waiver of documentation of consent, a subject is considered enrolled when they have returned information to the research team or have indicated agreement to participate.

Reporting Accrual Numbers to the IRB

Study: (CCI-13-0028)

2. Number of Subjects

2.1. **Enrollment:** (rows in bold can be filled out - integer values only)

| | |
|--|-----|
| Number of Subjects Enrolled at this site since last Report: | |
| Enrolled Previously at this site (from last Continuing Review): | 0 |
| Total Enrollment at this Site: | 0 |
| Adjusted Target Accrual at this site: | |
| Target Accrual at this site (from approved study): | 100 |
| Future Allowed Enrollment at this site: | 100 |
| Multi-site total enrollment (if applicable): | |
| <input type="text"/> | |



2.2. If your study has multiple cohorts or phases, please explain your accrual in more detail:

2.3. If the study status (item 1.2) is indicated as "Enrolling New Subjects" and no new subjects were enrolled (or fewer than expected) since last continuing review, please provide explanation, including how you plan to reach your accrual goals in a reasonable amount of time:

Item 2.1 Box 1: Enter the number of subjects that have been enrolled at CHLA over the current approval period.

Item 2.1 Boxes 2, 3, 5 & 6: Numbers will automatically populate.

If you are correcting an error from a previous CR, provide a rationale in item 2.1.1 (item is triggered by changing the number).

The last box (**Box 7**) may be skipped unless CHLA is the **coordinating center and/or the IRB of record** of additional sites of a multi-site study.

If CHLA is the **IRB of record** for additional sites, break down your accrual numbers by site under item 2.2. Details about enrollment as it relates to specific cohorts or phases of the research may also be provided in item 2.2.

If the study is open to enrollment and no subjects have been enrolled over the approval period, explain why in item 2.3.

Keep in Mind:

The IRB definition of accrual/enrollment may differ from that of the study sponsor.

Remember to use the IRB's definition when corresponding with the IRB.

Reporting Subject Withdrawals to the IRB

- ❑ If this is the first continuing review, have there been any withdrawals since the study was approved at CHLA, and if so, how many and why were they withdrawn?
- ❑ If this is NOT the first continuing review, have there been any withdrawals since the last continuing review, and if so, how many and why?
- ❑ If CHLA is the IRB of record for additional sites, provide withdrawal information for each site each year.

The screenshot shows a web browser window with a form titled "CR001" and "3. Subject Withdrawals and Complaints" for "Study: (CCI-13-00282)". The form contains two questions:

3.1. Have there been any subject withdrawals since the last continuing review?
 Yes No

3.2. The following participant complaints were submitted since the last IRB review:
- none -
Any **unreported** participant complaints must be reported immediately under the iStar "Add Report" activity.

A "Back To Top" button is visible in the bottom right corner of the form area.

Definitions

- **Screen Failures:** Individuals who have provided informed consent to participate in the study and undergone screening procedures, but do not qualify to continue participation.
 - Investigators should include these individuals in the accrual number reported to the IRB at continuing review.
 - Screen failures should also be reported to the IRB as subject withdrawals in the continuing review report.
- **Subject Withdrawals:** Individuals who have given informed consent but who withdrew or were withdrawn from the research at any point in the study before their participation was complete. This includes when a subject is initially eligible but then meets the criteria for the stopping rules subsequently during their participation and is withdrawn from further participation.

Subject Enrollment

The number of participants in a study relates to required determinations of whether or not subject selection is equitable and whether the risks to participants are reasonable in relation to the anticipated benefits of the research.



Investigators may **NOT** enroll more participants than the number specified in the application currently approved by the **IRB**.

Target Accrual Exceeded



Exceeding the approved target number is considered **non-compliance** and should be reported to the IRB as soon as it is detected.



Exceeding the target number may involve additional action from the IRB, e.g., submission of periodic reports to the IRB, additional monitoring by the IRB, restrictions on the use of data collected.

Target Accrual Increase



The IRB understands that there are times when the target number must be increased.



Examples:

Preliminary analyses show that initial estimates of subjects needed provide inadequate power to test the hypothesis.

There is a larger number of patients at CHLA with the condition being studied than originally anticipated and the sponsor has agreed to increase the number at CHLA.



Avoid exceeding the approved target number by filing an amendment for IRB approval **before** enrolling additional subjects.

Reportable Events & DSM Reports

Section 4 of the application is entirely populated by reportable event applications and amendments that have been submitted over the approval period by the investigator.

Data safety monitoring reports should be submitted to the IRB as soon as they are received from the sponsor.

Continuing Review 2019: Enrollment | https://istar.usc.edu/istar/app/ | x

istar.usc.edu/istar/app/portal/smartform/printProject/_Continuing%20Review(CCI-13-00282-CR001)?packetId=-defaultPrintPacket

4. Reportable Events Since Last Review Study: (CCI-13-00282)

4.1. Adverse Events and Unanticipated Problems

The following Adverse Events were submitted since the last IRB review (auto-acknowledged Reportable Events have been removed for brevity):
- none -

Any **unreported** serious Adverse Events or Unanticipated Problems must be submitted immediately under the iStar "Add Reportable Event" activity.

4.2. Protocol Deviations

The following Protocol Deviations were submitted since the last IRB review:
- none -

Any **unreported** Protocol Deviations must be submitted immediately under the iStar "Add Reportable Event" activity.

4.3. Data Safety Monitoring Reports

The following DSM Reports were submitted since the last IRB review:
- none -

Any **unreported** Data Safety Monitoring Reports must be submitted immediately under the iStar "Add Reportable Event" activity.

4.4. Protocol Change Initiated to Eliminate Immediate Hazard

The following "Protocol Change Initiated to Eliminate Immediate Hazard" events were submitted since the last IRB review:
- none -

Any **unreported** Protocol Change Initiated to Eliminate Immediate Hazard events must be submitted immediately under the iStar "Add Reportable Event" activity.

iStar ID:CCI-13-00282-CR001 Application Version Date: CCI-13-00282-CR001 View: 05. Summary of research progress
Version:0.1

Section 5:

A brief summary of the study progress should be provided here.

Make sure your summary does not contradict other sections of the CR application.

Example: If “data analysis only” is selected in item 1.2, but it is indicated in item 5.1 that data are still being collected, the CR will be returned to you to reconcile the discrepancy.

Version:0.1

5. Summary of Research Progress Study: (CCI-13-00282)

5.1. Please provide a brief summary of research progress.

5.1.1. Upload any relevant supporting publications or documents:

| Name | Version | Modified |
|-------------------------------|---------|----------|
| There are no items to display | | |

Study Risks and Benefits

Show Study Risk Information

5.2. In the opinion of the principal investigator, have the risks or potential benefits of this r

Yes No

Back To Top

Provide any information resulting from the research, such as any preliminary results or publications based on the current data.

This is also a good place to give the IRB an update on previous events.

Example: If the IRB previously required reconsent of subjects with a consent addendum that outlined new risks, give the IRB an update on the status of the reconsent plan here

Section 6:

Continuing Review 2019: Enrollin x https://istar.usc.edu/istar/app/po x +

istar.usc.edu/istar/app/portal/smartform/printProject/_Continuing%20Review/CCI-13-00282-CR001?packetId=defaultPrintPacket

Apps New Tab Folder for Mara Levy Imported From IE Home Page - Child... Welcome to the CT... 45 CFR 46 | HHS.gov OHRP Expedited Re... Ford Billing LinkedIn Fooda Glendale IStar Personnel Sear... Dept-Div Heads List... IRBManager (NCI CL...

iStar ID:CCI-13-00282-CR001 Application **CCI-13-00282-CR001** Version Date: View: 06. New Information Version:0.1

6. New Information Study: (CCI-13-00282)

6.1. Has there been any significant new information (either good or bad) that should be disclosed to subjects that are participating or have participated in the study?

Yes No

6.2. Have there been any reports in recent literature or multi-center trial reports that may be relevant to this research?

Yes No

iStar ID:CCI-13-00282-CR001 Application **CCI-13-00282-CR001** Version Date: View: 07. Inform [Back To Top](#) enda Version:0.1 Study: (CCI-13-

Consent and Assent Documents

- Remember to check **all documents** needed in the future.
- If you do not check the form, it will not be approved and stamped for use.

Year 2020-2021 Progress Report x | https://istar.usc.edu/istar/iss/ x | Star RB Agenda x | B- the new risk of DRES synd x | https://istar.usc.edu/istar/iss/ x | Folder for Mira Levy x | +

istar.usc.edu/istar/app/portal/smartform/printProject_Contraining%20Review%20L1-08-00198-CR014/packets/defaultPrintPacket

6. New Information

6.1. Has there been any significant new information (either good or bad) that should be disclosed to subjects that are participating or have participated in the study?
 Yes No

6.2. Have there been any reports in recent literature or multi-center trial reports that may be relevant to this research?
 Yes No

iStar ID: CCI-06-00198-CR014 Application Version: CCI-06-00198-CR014 View: 07. Informed Consent and Addenda
Date: 1/4/2021
Version: 1.1

7. Informed Consent and Addenda

Study: (CCI-06-00198)

7.1 The Current Approved documents associated with Informed Consent and recruitment are shown below. Please select the documents you anticipate using in the coming year. (Please note that documents not checked will not be stamped)

| Select | Document Name | Modification Date |
|-------------------------------------|--|-------------------|
| <input type="checkbox"/> | Assent Form (7-13 Years); Spanish [no longer available].pdf | 2/15/2019 9:22 AM |
| <input checked="" type="checkbox"/> | Assent Form for Children Ages 7-13 Years - CHLA Patient Cohort.pdf | 2/12/2020 5:55 PM |
| <input checked="" type="checkbox"/> | Assent Form for Children Ages 7-13 Years - Non-CHLA Patient Cohort.pdf | 2/12/2020 5:55 PM |
| <input checked="" type="checkbox"/> | Consent Addendum for Subjects turning 18.pdf | 2/12/2020 5:55 PM |
| <input checked="" type="checkbox"/> | Consent/Permission/Assent Form - CHLA Patient Cohort.pdf | 2/12/2020 5:56 PM |
| <input checked="" type="checkbox"/> | Consent/Permission/Assent Form - Non-CHLA Patient Cohort.pdf | 2/12/2020 5:56 PM |
| <input type="checkbox"/> | Consent/Permission/Assent Form; Spanish [no longer available].pdf | 2/15/2019 9:22 AM |
| <input type="checkbox"/> | Consent/Permission/Assent Addendum for Single Subject AM053.pdf | 2/15/2019 9:22 AM |

If any of the documents listed in 7.1 require modification, please open an Amendment to make the required changes and upload revised documents.

iStar ID: CCI-06-00198-CR014 Application Version Date: 1/4/2021 CCI-06-00198-CR014 View: 08. Study Abstract and Funding
Version: 1.1

8. Study Abstract and Funding

The current Abstract for this study is as follows:

[Back To Top](#) 198

Yes or No Questions

Do **Not** forget to answer all questions in the CR. If you skip a question, the CR will be returned to the study team.

The responses to Yes or No questions in sections 8 and 9 of the continuing review (CR) application must be Yes, since the iStar CR application populates the information from the main iStar application (or from the amended main iStar application if an amendment is open).

Example: The response under item 9.1 of the CR application must be Yes, since the iStar continuing review (CR) application populates the study personnel information from section 2.1 of the main iStar application (or from the amended main iStar application if an amendment is open). If there are changes to study personnel, please make them via the “edit study personnel” function or via amendment (depending upon the type of study personnel changes required) and then update the response under this item of the CR application.

Conflicts of Interest

Conflict of Interest information must be current.

Study team members with expired disclosures will need to log into **diSClose** to update their information using their Okta single sign on.

39. 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.

| Study Staff | Role | COI Annual Disclosure Status | Conflicts |
|------------------------|------------------------|------------------------------|-------------------------|
| Elizabeth "Liz" Bennet | Principal Investigator | No disclosure on file | No conflicts identified |
| Mara Levy-LaPointe | Co-Investigator | No disclosure on file | No conflicts identified |
| Moore Rhys, C.I.P. | 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 or the disclosure form has expired, you must submit a new disclosure in DiSClose. Hover over the annual disclosure status for more details.

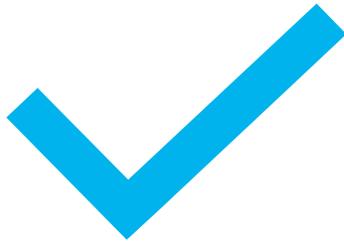
Please note that first time users of diSClose will need to create a diSClose account using the "Login with CHLA Okta" option to ensure disclosure data from diSClose appears in this Section.

If your CR is no longer current, please update it before it is reviewed.



If the information submitted to the IRB changes before the IRB has completed their review, please reach out to the **IRBA** to update the CR.

Does my CR make sense?



Remember to check last year's CR when completing this year's CR. **Make sure this year's CR makes sense in relation to last year's report. If last year's CR included errors, let us know.**



Review your Work!

Remember to review your completed CR application before officially submitting for IRB review.

Questions and Discussion

