Children's Hospital LOS ANGELES®

HUMAN SUBJECTS PROTECTION PROGRAM

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Tea with the IRB: Tips for Successful Submission of Continuing Reviews to the CHLA IRB
February 2021

Presenters: Mara Levy-LaPointe, BA, CIP
&
Dongqing Li, MB, MBS, CIP

Children's Hospital LOS ANGELES
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 more 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

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

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

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.

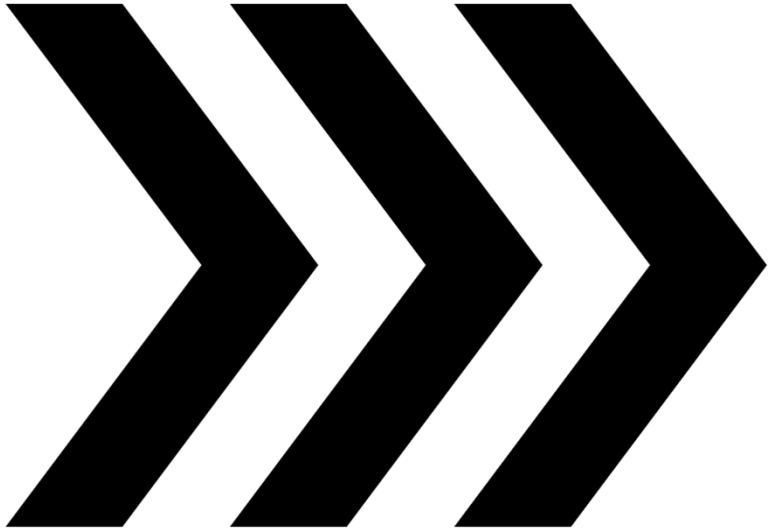
- NOTE: **Any information collected during the lapse in approval may not be used for research.** Failure to maintain current approval may disqualify data intended for submission to the FDA (e.g., studies of investigational drugs and devices), other federal agencies, and sponsors.

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.

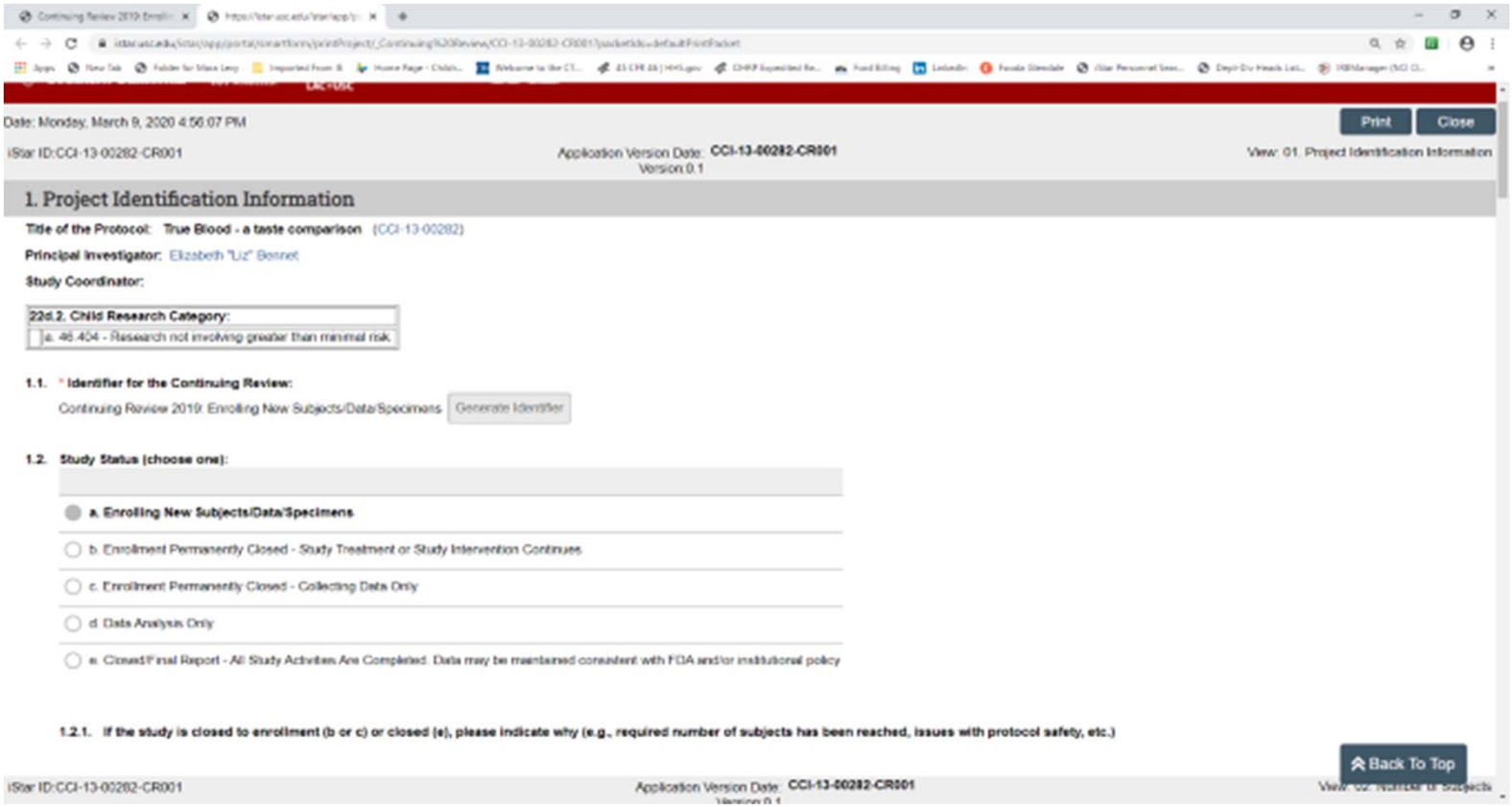
Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

Future Study Status



Future Study Status: Enrolling New Subjects/Data/Specimens

If recruitment and enrollment will continue in the coming year, the study team should select this option. This means the research is open to the enrollment of new subjects, data (i.e. additional medical charts) and/or specimens.



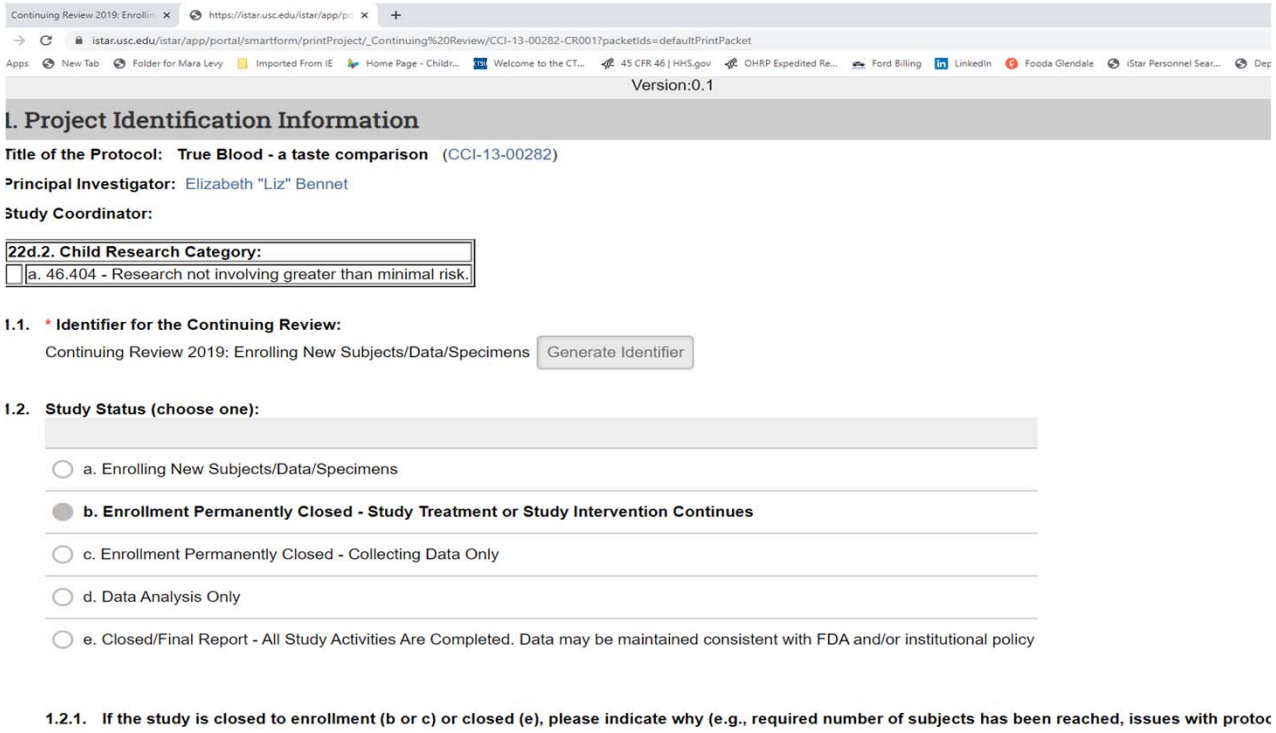
Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

Future Study Status: Enrollment Permanently Closed

- If subject accrual is permanently closing and **no new subjects will EVER be enrolled** into the research (or in the case of a chart review study no additional charts will be identified)…
- BUT further data collection will occur, there are 2 options.

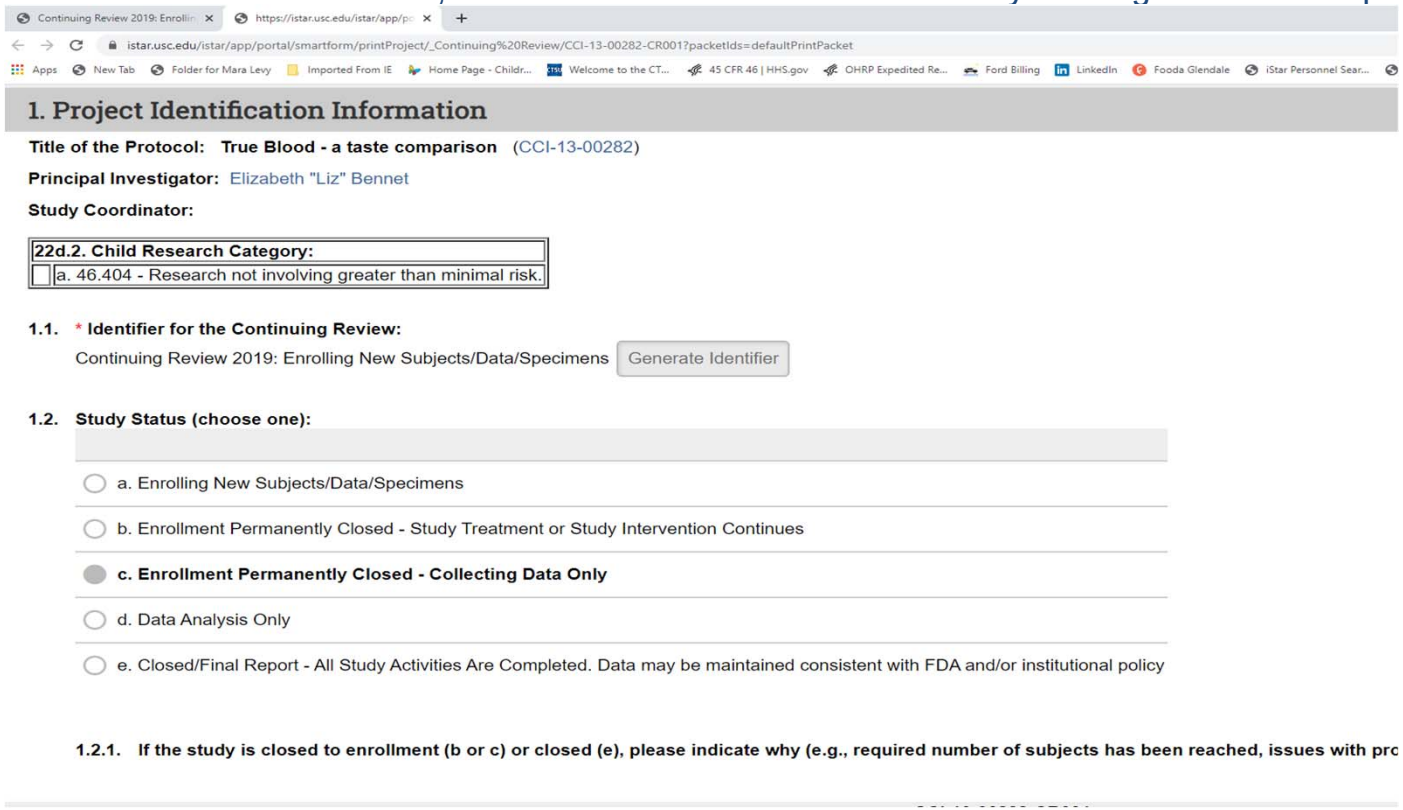
Future Study Status: Enrollment Permanently Closed - Study Treatment or Study Intervention Continues

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. *This option would never apply to a chart review study, because chart reviews do not include any interventions.*



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.



1. Project Identification Information

Title of the Protocol: **True Blood - a taste comparison** (CCI-13-00282)

Principal Investigator: Elizabeth "Liz" Bennet

Study Coordinator:

22d.2. Child Research Category:

☐ a. 46.404 - Research not involving greater than minimal risk.

1.1. * **Identifier for the Continuing Review:**

Continuing Review 2019: Enrolling New Subjects/Data/Specimens [Generate Identifier]

1.2. **Study Status (choose one):**

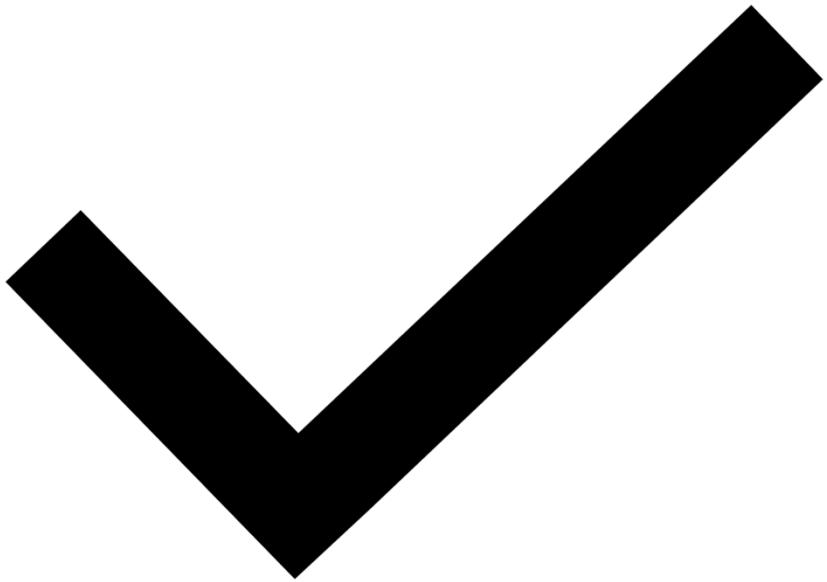
- ○ a. Enrolling New Subjects/Data/Specimens
- ○ b. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- ● **c. Enrollment Permanently Closed - Collecting Data Only**
- ○ d. Data Analysis Only
- ○ e. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

1.2.1. **If the study is closed to enrollment (b or c) or closed (e), please indicate why (e.g., required number of subjects has been reached, issues with prc**

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

Future Study Status: Enrollment Permanently Closed - Collecting Data Only

If the study never involved a treatment or intervention (like in the case of a chart review study), but data collection continues, this is the future status that should be selected.



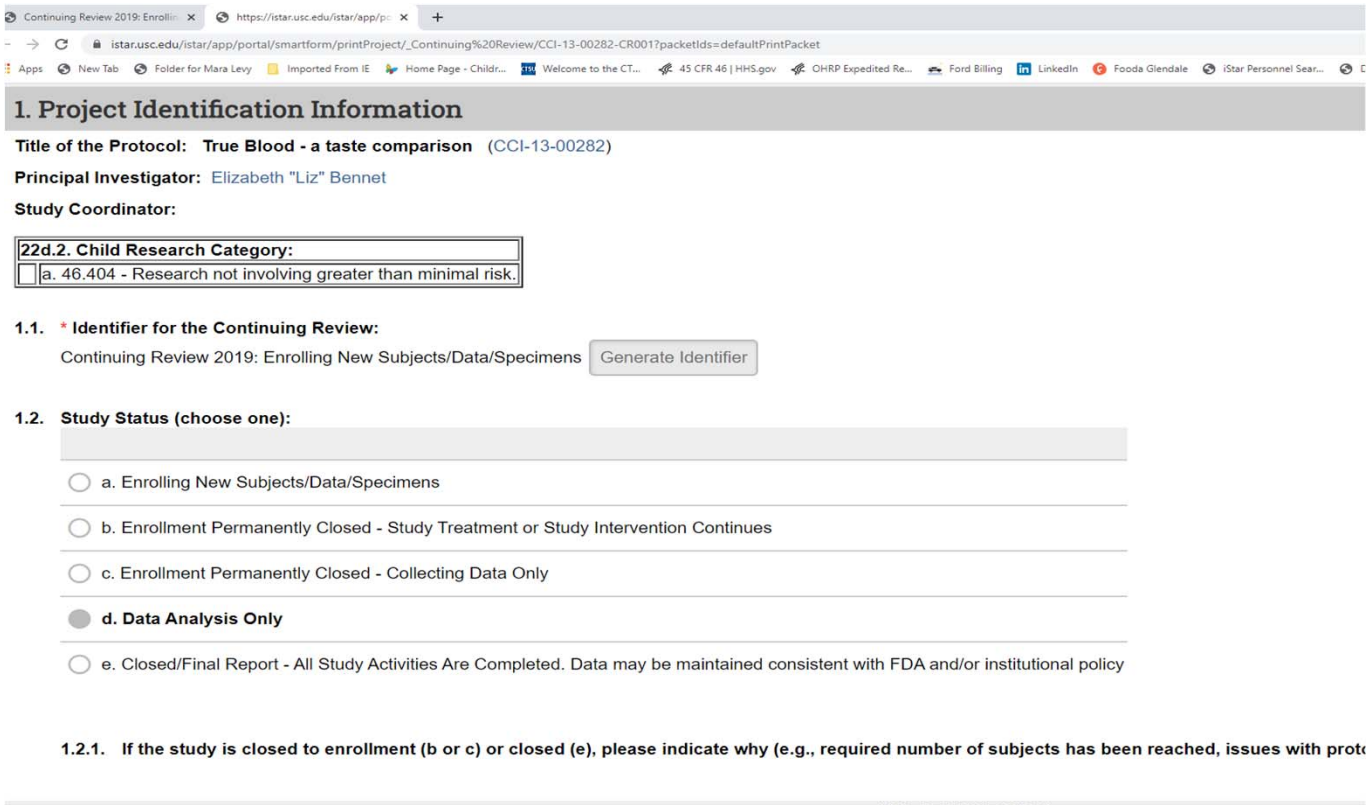
Future Study Status: Enrollment Permanently Closed

Additionally, if the previous status of the research was enrolling new subjects, the study team should explain under item 1.2.1 of the application, the reason why the study is permanently closing to accrual at this time.

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.



1. Project Identification Information

Title of the Protocol: **True Blood - a taste comparison** (CCI-13-00282)

Principal Investigator: Elizabeth "Liz" Bennet

Study Coordinator:

22d.2. Child Research Category:
☐ a. 46.404 - Research not involving greater than minimal risk.

1.1. * **Identifier for the Continuing Review:**

Continuing Review 2019: Enrolling New Subjects/Data/Specimens [Generate Identifier]

1.2. **Study Status (choose one):**

- ○ a. Enrolling New Subjects/Data/Specimens
- ○ b. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- ○ c. Enrollment Permanently Closed - Collecting Data Only
- ● **d. Data Analysis Only**
- ○ e. Closed/Final Report - All Study Activities Are Completed. Data may be maintained consistent with FDA and/or institutional policy

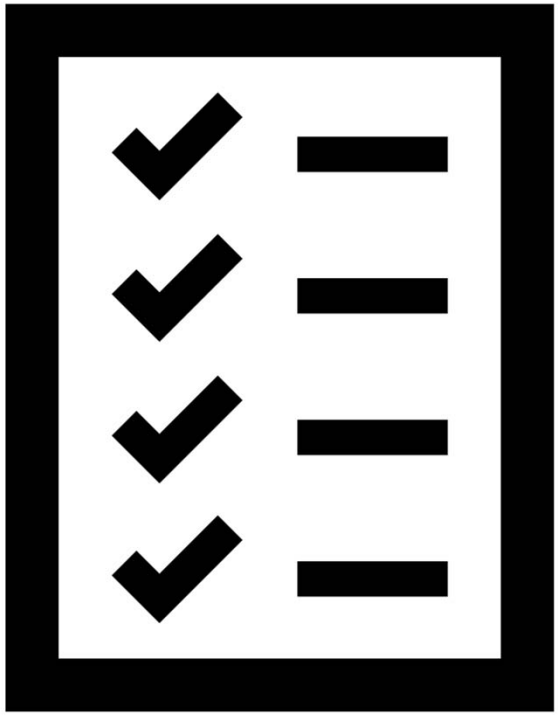
1.2.1. **If the study is closed to enrollment (b or c) or closed (e), please indicate why (e.g., required number of subjects has been reached, issues with prot**

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

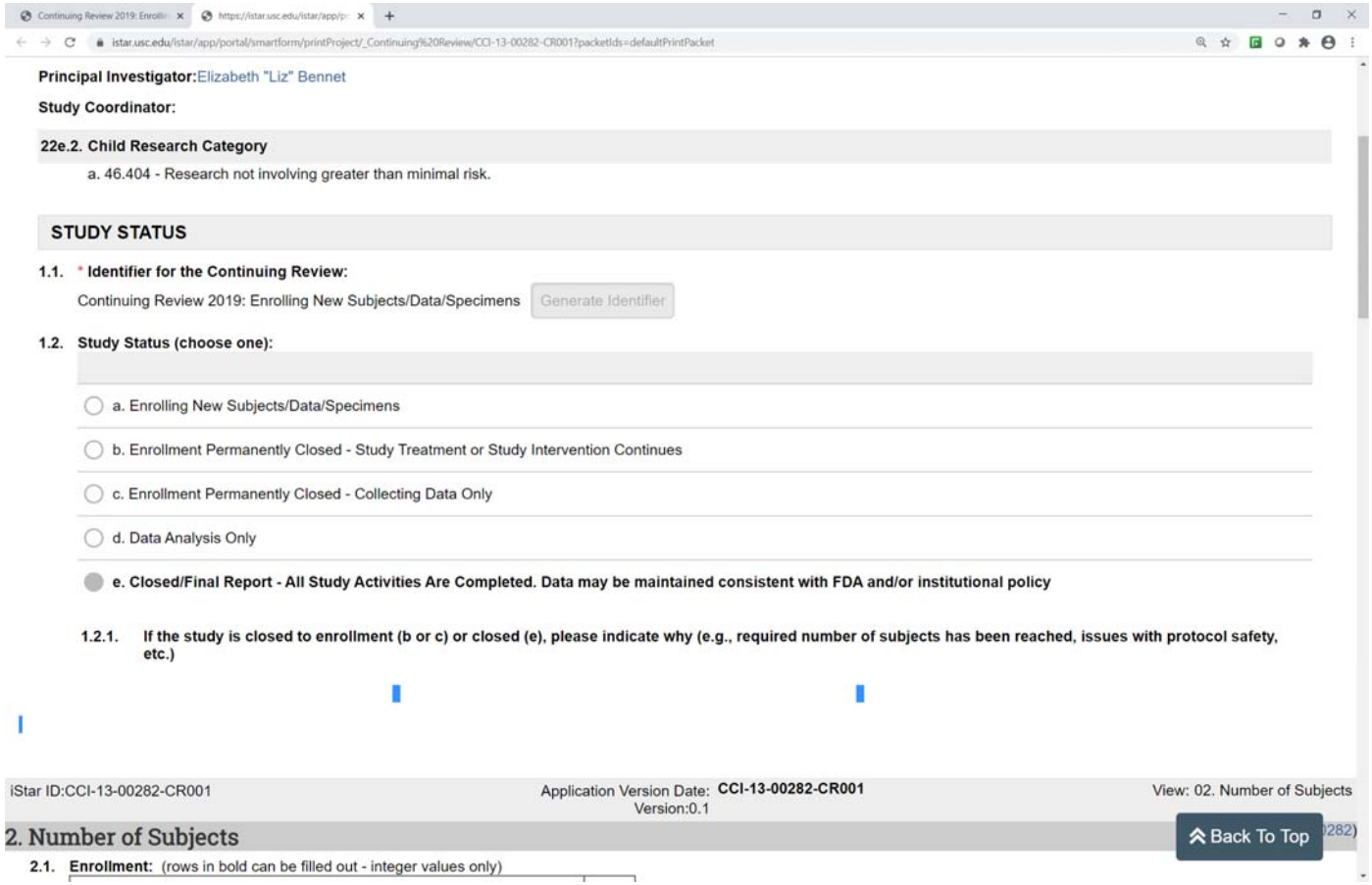
Future Study Status: Data Analysis Only

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 l**ong-**term follow-up of subjects) ha**s** been permanently completed; **and**
- The remaining research activi**ties** are limited to data analysis.



The last option available 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.



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

Principal Investigator: Elizabeth "Liz" Bennet

Study Coordinator:

22e.2. Child Research Category

a. 46.404 - Research not involving greater than minimal risk.

STUDY STATUS

1.1. * **Identifier for the Continuing Review:**

Continuing Review 2019: Enrolling New Subjects/Data/Specimens Generate Identifier

1.2. Study Status (choose one):

- a. Enrolling New Subjects/Data/Specimens
- b. Enrollment Permanently Closed - Study Treatment or Study Intervention Continues
- c. Enrollment Permanently Closed - Collecting Data Only
- d. Data Analysis Only
- **e. 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 closed to enrollment (b or c) or closed (e), please indicate why (e.g., required number of subjects has been reached, issues with protocol safety, etc.)

iStar ID:CCI-13-00282-CR001 Application Version Date: **CCI-13-00282-CR001** Version:0.1 View: 02. Number of Subjects

2. Number of Subjects

Back To Top

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

When Should a Closure Report be Submitted?

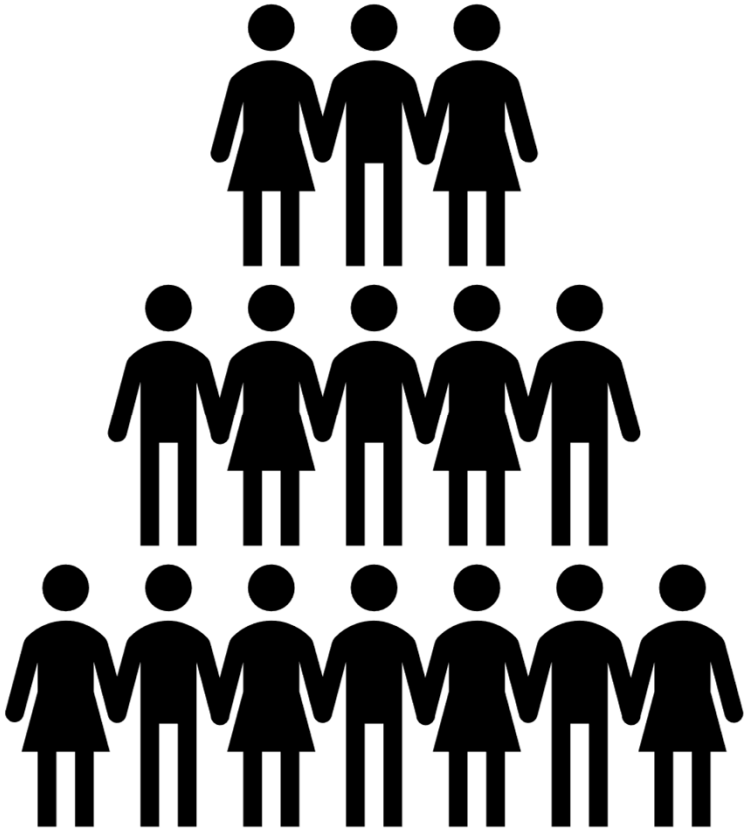
- **Do not** file a study closure report **if any of the following six conditions apply**. Such studies must remain active and continue to receive ongoing IRB review and approval:
  - Enrollment at the CHLA-approved site(s) is ongoing.
  - Research-related interventions and/or follow-up at the CHLA-approved 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).

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

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.

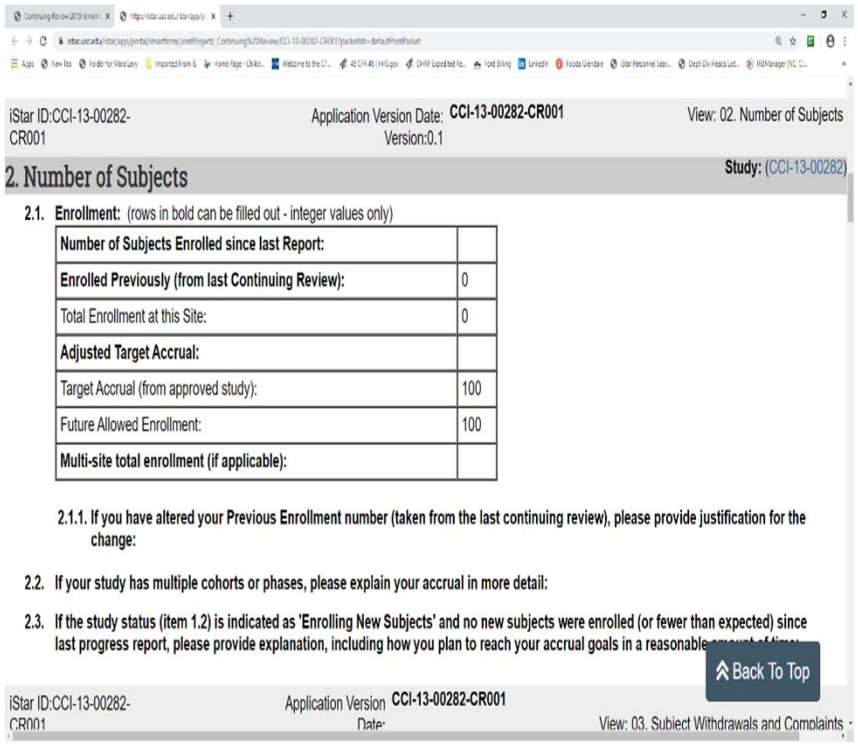
Enrolled Subjects

- 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, or chooses not to continue, 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 (e.g. answering a survey) or have indicated agreement to participate.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

Reporting Accrual Numbers to the IRB

Section 2



iStar ID:CCI-13-00282-CR001 | Application Version Date: CCI-13-00282-CR001 Version:0.1 | View: 02. Number of Subjects

2. Number of Subjects | **Study:** (CCI-13-00282)

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

Number of Subjects Enrolled since last Report:	
Enrolled Previously (from last Continuing Review):	0
Total Enrollment at this Site:	0
Adjusted Target Accrual:	
Target Accrual (from approved study):	100
Future Allowed Enrollment:	100
Multi-site total enrollment (if applicable):	

2.1.1. If you have altered your Previous Enrollment number (taken from the last continuing review), please provide justification for the change:

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 progress report, please provide explanation, including how you plan to reach your accrual goals in a reasonable

Back To Top

iStar ID:CCI-13-00282-CR001 | Application Version Date: CCI-13-00282-CR001 | View: 03. Subject Withdrawals and Complaints

Enrollment Numbers

- Item 2.1 Box 1: Enter the number of subjects that have been enrolled at CHLA over the current approval period (i.e., since the last CR OR, if this is the first CR the number of subjects enrolled since the study was approved).
- Item 2.1 Boxes 2, 3, 5 & 6: Numbers will automatically populate based on the approved Target Accrual number, previous accrual numbers, and the number you enter in Box 1.
- If you are correcting an error from a previous CR, provide a rationale in item 2.1.1.
- 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 each year 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, provide a brief explanation in item 2.3.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

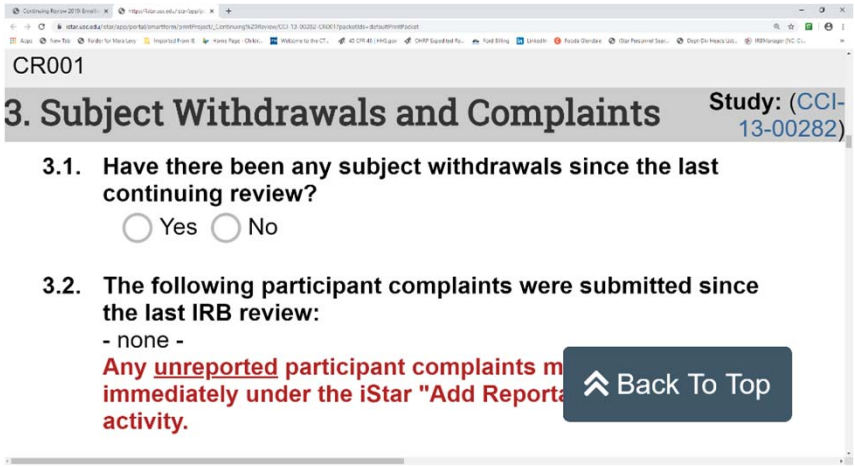
Keep in Mind:

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.



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.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

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.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

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.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

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.

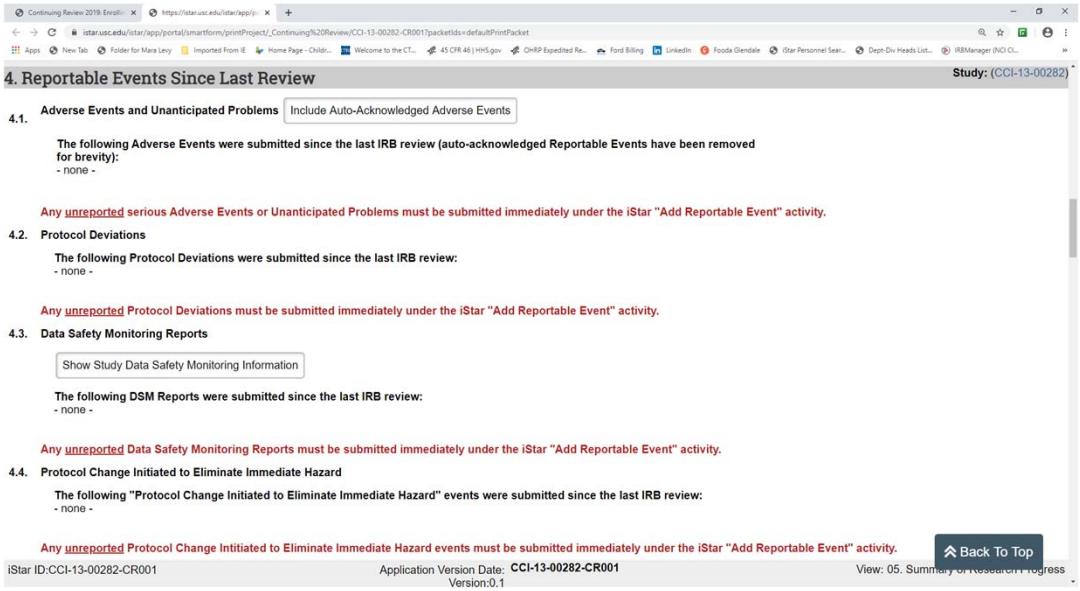
There is a larger number of patients at CHLA with the condition being studied than originally anticipated and the sponsor has agreed to increase the number at CHLA.

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 that have been reported over the approval period by the study team. If there are any AEs, problems, deviations, or data safety monitoring reports that have not yet been submitted, they should be submitted BEFORE you submit the continuing review application.

Data safety monitoring reports should be filed with the IRB as soon as they are received from the sponsor. If you are missing a report, you should contact the sponsor to obtain it before you submit the continuing review application. If the DSMB was scheduled to meet but did not, you should contact the sponsor for a letter about why the meeting was not held.



4. Reportable Events Since Last Review

Study: (CCI-13-00282)

4.1. Adverse Events and Unanticipated Problems — Include Auto-Acknowledged Adverse Events

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

Show Study Data Safety Monitoring Information

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 Intitiated to Eliminate Immediate Hazard events must be submitted immediately under the iStar "Add Reportable Event" activity.

Back To Top

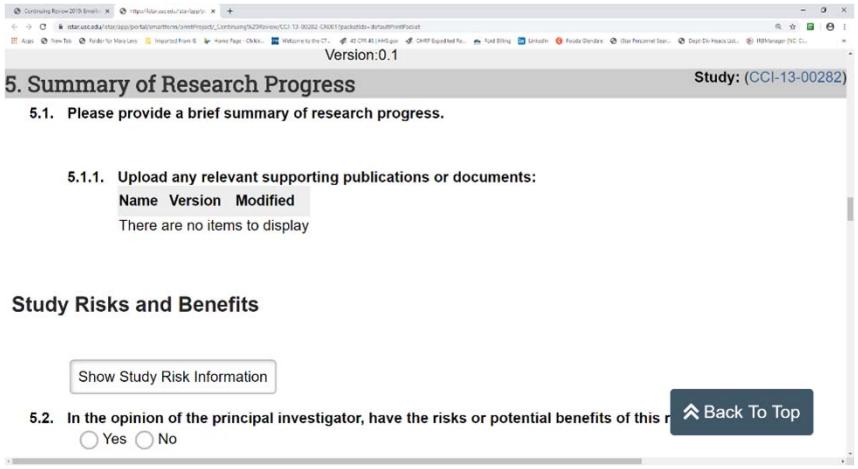
iStar ID:CCI-13-00282-CR001 Application Version Date: CCI-13-00282-CR001 Version:0.1

Section 5:

A brief summary of the study progress thus far 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.



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.

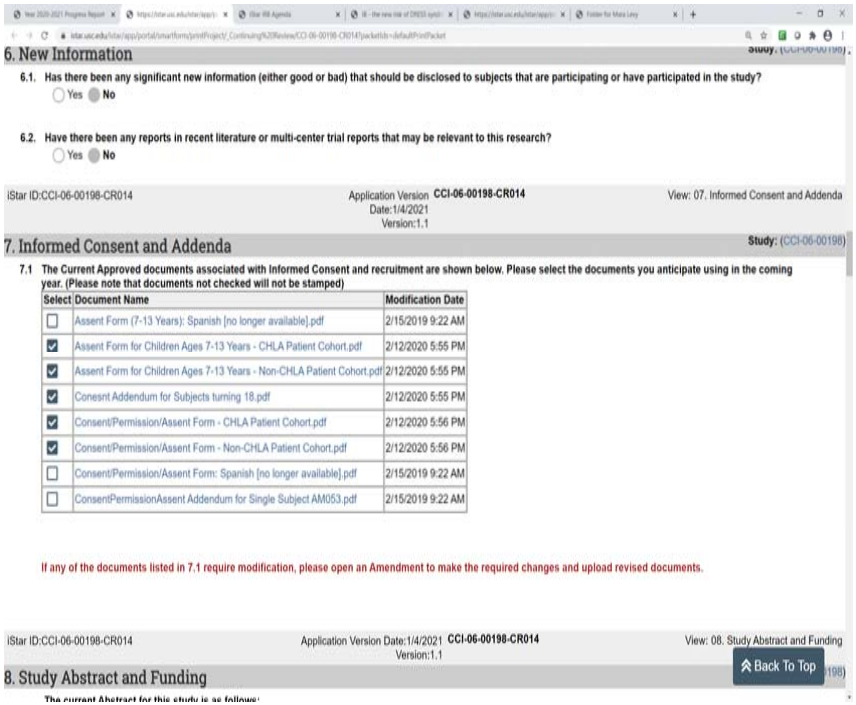
Example: If the IRB previously required reconsent of subjects with a consent addendum that outlined new risks, give the IRB an update on the status of the reconsent plan here

All subjects on study have now been reconsented with the addendum and have decided to continue study participation.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

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.



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 Date:1/4/2021 Version:1.1 View: 07. Informed Consent and Addenda

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
☐	Assent Form (7-13 Years): Spanish [no longer available].pdf	2/15/2019 9:22 AM
☑	Assent Form for Children Ages 7-13 Years - CHLA Patient Cohort.pdf	2/12/2020 5:55 PM
☑	Assent Form for Children Ages 7-13 Years - Non-CHLA Patient Cohort.pdf	2/12/2020 5:55 PM
☑	Conesnt Addendum for Subjects turning 18.pdf	2/12/2020 5:55 PM
☑	Consent/Permission/Assent Form - CHLA Patient Cohort.pdf	2/12/2020 5:56 PM
☑	Consent/Permission/Assent Form - Non-CHLA Patient Cohort.pdf	2/12/2020 5:56 PM
☐	Consent/Permission/Assent Form: Spanish [no longer available].pdf	2/15/2019 9:22 AM
☐	ConsentPermissionAssent 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 Version:1.1 View: 08. Study Abstract and Funding

Back To Top

8. Study Abstract and Funding

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

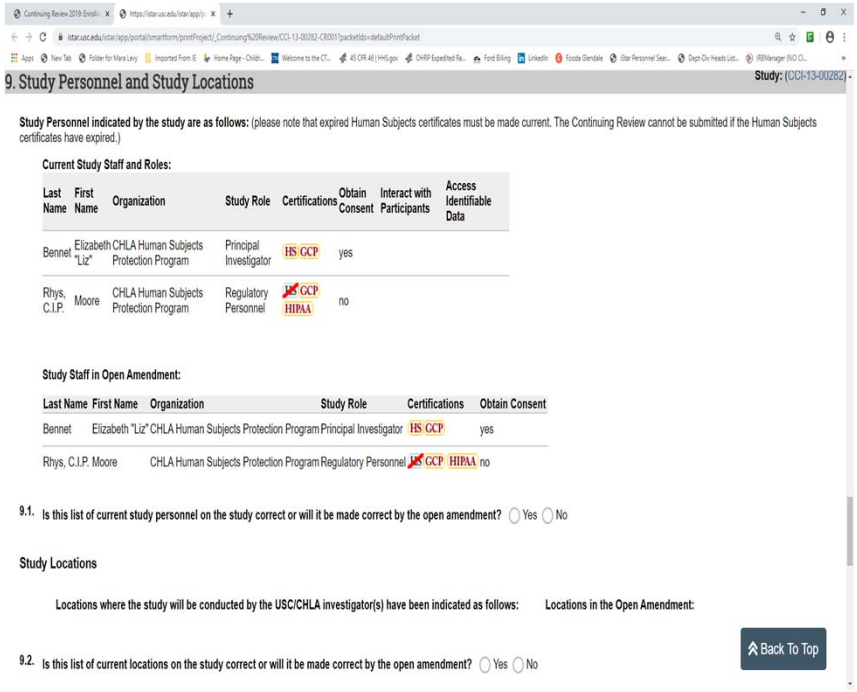
Yes or No Questions

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 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.

Study Personnel



9. Study Personnel and Study Locations

Study: (CCI-13-00282)

Study Personnel indicated by the study are as follows: (please note that expired Human Subjects certificates must be made current. The Continuing Review cannot be submitted if the Human Subjects certificates have expired.)

Current Study Staff and Roles:

Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access Identifiable Data
Bennet	Elizabeth "Liz"	CHLA Human Subjects Protection Program	Principal Investigator	HS GCP	yes		
Rhys, C.I.P.	Moore	CHLA Human Subjects Protection Program	Regulatory Personnel	HS GCP HIPAA	no		

Study Staff in Open Amendment:

Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent
Bennet	Elizabeth "Liz"	CHLA Human Subjects Protection Program	Principal Investigator	HS GCP	yes
Rhys, C.I.P.	Moore	CHLA Human Subjects Protection Program	Regulatory Personnel	HS GCP HIPAA	no

9.1. **Is this list of current study personnel on the study correct or will it be made correct by the open amendment?** ◯ Yes ◯ No

Study Locations

Locations where the study will be conducted by the USC/CHLA investigator(s) have been indicated as follows: **Locations in the Open Amendment:**

Back To Top

9.2. **Is this list of current locations on the study correct or will it be made correct by the open amendment?** ◯ Yes ◯ No

- All study personnel must have current certifications.
- If certification has expired for a team member, they must recertify immediately or be removed from study personnel.
- Section 9 populates the information from the currently approved version of the iStar application (or from the amended main iStar application if an amendment is open).
- If there are changes to study personnel or the study locations, they must be made in the main iStar application.
- Study personnel changes can be made with the "edit study personnel" function or with an amendment (depending on the type of personnel changes needed).

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

If your CR is no longer current (e.g., an additional subject has been enrolled), 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.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

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.

Children's Hospital LOS ANGELES
HUMAN SUBJECTS PROTECTION PROGRAM

Questions and Discussion