

October 10, 2008

Dear iStar users,

We are getting ready to make a major upgrade to the iStar system, which will become live on **October 20th**. **The system (iStar) will be *unavailable* during the weekend prior (October 18 and 19).**

What are we changing and how will it affect you? In addition to the numerous bug fixes and the system upgrade that should help boost performance, there are three areas where you will see significant change:

1. **Continuing Reviews:** The most dramatic change by far is to the Continuing Review form. We have retooled this form to make it easier to fill out and more compliant with current federal regulations. The change will be immediate as of October 20th, so any in process continuing review will show the new form. If your Continuing Review is submitted prior to the 20th, you do not need to complete the new form unless directed to do so by the IRB . All new Continuing Reviews must complete the new application.
2. **Amendments:** You will be directed to make all changes to a study on an amendment in the "Modified Study"; changes to study personnel have to be made on the modified study in the amendment. You are also asked a new question about the accuracy of your abstract in the amendment application.
3. **Studies:** You are will be allowed to designate the iStar access level of staff to the study in iStar. You can continue to give them their current access (where study personnel are allowed to open continuing reviews or amendments, for instance), you can restrict them to read only, or you may give them NO access to the study in iStar.

There are many other changes in addition to those mentioned above. A complete list will be available on iStar after the update.

Please let us know if you have any concerns or issues at [istar@usc.edu](mailto:istar@usc.edu).

Best Regards,

the iStar development team

# iStar Changes of 10/20/08

Spotlight: Continuing Review

## Why Continuing Review?

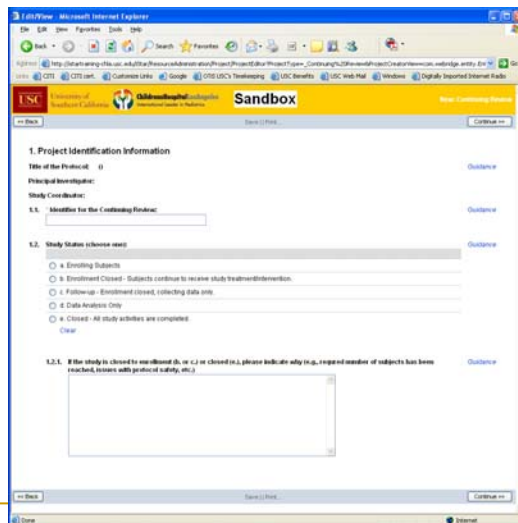
- We have been working on a new review system for the IRB that increases ease, speed and accuracy of review. This made us look again at the data we are collecting.
- Accreditation and Compliance
- Same principles for review of forms is true of someone filling out the form

## Guiding Principle:

- When asking a question, provide whatever information you have to the user to help him/her answer it.
  - We ask questions on the forms, but hardly ever show anyone any information on them.
  - It is cumbersome to have to go hunt down the data in iStar to fill out an iStar form.

## Old Form – Page 1

- Issues
  - Choices at 1.2 can be confusing
- New Form



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## New Form – Page 1

- Identification information
  - If child research, shows research category
- Study Status
  - Retooled to be more consistent and less confusing
  - User requested clarifications

**1. Project Identification Information**

Title of the Protocol: test (APP-00-00003) [Guidance](#)

Principal Investigator: Principal Investigator 1 Test Account-HSC

Study Coordinator:

1.1. Identifier for the Continuing Review:  [Guidance](#)

1.2. Study Status (choose one): [Guidance](#)

a. Enrolling New Subjects/Data/Specimens

b. Enrollment Closed - Study Treatment or Study Intervention Continues

c. Enrollment Closed - Collecting Data Only

d. Data Analysis Only

e. Closed/Final Report - All Study Activities Are Completed

[Clear](#)

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.) [Guidance](#)

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## Old Form – Page 2

- Issues
  - Do your own adding
  - Hunt for your approved Target Accrual and previous Enrollment
  - If not ONLY numbers, messes up
  - IRB also wants to know about low enrollment, not just no enrollment
- New Form

2. Number of Subjects

2.1. Total enrollment at this site since initiation of the study (Integer values only): [Guidance](#)

2.1.1. If this is a multi-site study, the total number of subjects enrolled study wide (Integer values only): [Guidance](#)

2.2. Number of subjects enrolled at this site since the last progress report (Integer values only): [Guidance](#)

2.2.1. If study status (IT) is indicated as "Enrolling Subjects" and no new subjects were enrolled since the last progress report, please provide justification: [Guidance](#)

2.3. Number of subjects of this site to be enrolled in the future (Integer values only): [Guidance](#)



2.4. Target accrual for this site as listed in the application (Integer values only): [Guidance](#)

2.4.1. Please indicate if this is a change from the previously approved target accrual. If yes, please submit an amendment for this change. [Guidance](#)

Yes  No [Clear](#)

(Previously approved target accrual, site: (null) (enter total, if applicable) )

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## New Form – Page 2

- Number of Subjects
  - Easy to read/understand
  - Does the addition for you
  - Pulls data from study and last CR (if exists)
  - Warns about over-enrollment or near complete enrollment
  - If change previous enrollment, then asks why
  - Provides ability to explain complicated enrollment issues
  - Low enrollment clarified

### 2. Number of Subjects



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

Number of Subjects Enrolled since last Report:	8
Enrolled Previously (from last continuing Review):	0
Total Enrollment at this Site:	8
Target Accrual (from approved study):	50
Future Allowed Enrollment:	42
Multi-site total enrollment (if applicable):	

2.2 If your study has multiple cohorts, phases, or is otherwise complicated, please explain your accrual in more detail: [Guidance](#)


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 amount of time: [Guidance](#)

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## Old Form – Page 3

- Changes
  - Textual clarification at 3.2
- New Form



3. Subject Withdrawal

3.1. Please indicate the number of subjects that withdrew from the study since the last progress report and the reasons for the withdrawal. [Guidance](#)

3.2. If applicable, please provide a summary of any difficulties recruiting/staying subjects or obtaining informed consent during the last approval period. Additionally, please indicate if there have been any complaints about the research. [Guidance](#)

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## New Form – Page 3

- Complaints and Withdrawal
  - 3.2 focuses on complaints
  - Asking in 3.2 about difficulties retaining subjects is duplicative (3.1)

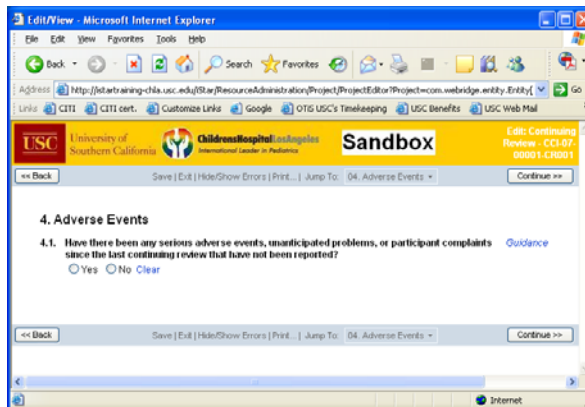
### 3. Complaints and Subject Withdrawal

3.1. Please indicate the number of subjects that withdrew from the study since the last progress report and the reasons for the withdrawal. [Guidance](#)

3.2. Please summarize any complaints about the research since last IRB review. [Guidance](#)

## Old Form – Page 4

- Issues
  - Difficult to answer – need to navigate away to find out
  - Not specific
  - 4a not useful – need to submit RE, not describe here
- New Form



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## New Form – Page 4

- Reportable Events
  - Show REs since last review
  - Specifically ask about each type of RE
  - Show DSM information
  - If “yes” directs to submit RE

#### 4. Reportable Events Since Last Review

##### 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):

ID	Type of Event	Date Submitted	Status
4.1. Are there any Adverse Events or Unanticipated Problems since the last review that have yet to be reported? <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a> <a href="#">Guidance</a>			

##### Protocol Deviations

The following Protocol Deviations were submitted since the last IRB review:

ID	Type of Event	Date Submitted	Status
4.2. Are there any Protocol Deviations since the last review that have yet to be reported? <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a> <a href="#">Guidance</a>			

##### Data Safety Monitoring Reports

[Show Study Data Safety Monitoring Information](#)

The following DSM Reports were submitted since the last IRB review:

ID	Type of Event	Date Submitted	Status
4.3. Are there any Data Safety Monitoring Reports since the last review that have yet to be reported? <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a> <a href="#">Guidance</a>			

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## Old Form – Page 5

- Issues
  - Not always have “results”
  - Odd place to look for Abstract changes
  - No way to add documents
  - Sometimes hard to answer about risks without having the Study risks in front of you
- New Form

5. Summary of Research Results



5.1. Please provide a brief summary of the research results to date. [Guidance](#)

5.2. In the opinion of the principal investigator, have the risks or potential benefits of this research changed?  Yes  No [Clear](#) [Guidance](#)

5.2.1. If yes, provide a necessary delineating these changes. [Guidance](#)

5.3. Please update the study abstract in LEXLANSAGE if necessary. A copy of the current approved abstract is provided below. If there are no changes, you must copy and paste the abstract into this box. [Guidance](#)

Current Abstract: Please provide a brief (1 to 2 paragraph) description of the study in LEXLANSAGE. This should not be a scientific abstract.

## New Form – Page 5

- Research Progress
  - Not just asking about results!
  - Can add documents
- Study Risks
  - Show risks and Protocol from main study
- Abstract has its own page (new page 8)

**5. Summary of Research Progress**

5.1. Please provide a brief summary of research progress.

5.1.1. Upload any relevant supporting publications or documents:

Add	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 research changed?

Yes  No

5.2.1. If yes, provide a summary detailing those changes.

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## Old Form – Page 6

- Issues
  - What about new Information? Does it qualify as new Findings?
  - No ability to upload documents
- New Form

**6. New Findings**

6.1. Have there been any significant new findings (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 that affect the risks associated with this research?

Yes  No

6.3. If you answered yes to any of the questions above (6.1. or 6.2.), please describe and submit an amendment form with the progress report.

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## New Form – Page 6

- New Information
  - ❑ “Findings” was too narrow, so use information
  - ❑ OHRP uses “Information”
  - ❑ Can Add documents

### 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? [Guidance](#)

Yes  No [Clear](#)

6.2. Have there been any reports in recent literature or multi-center trial reports that may be relevant to this research? [Guidance](#)

Yes  No [Clear](#)

6.3. If you answered yes to any of the questions above (6.1 or 6.2), please describe below or upload a document in 6.3.1: [Guidance](#)

6.3.1. Upload any necessary supporting information:

[Add](#)

There are no items to display

## New Form – Page 7

- Informed Consent Page
  - ❑ Shows current approved ICs
  - ❑ Can select which ones you will use (cleans up stamped form section)
  - ❑ Link to current IRB consent form template

### 7. Informed Consent and Addenda

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 checked="" type="checkbox"/>	Consent Form 10-23-08	10/28/2008 2:21 PM
<input checked="" type="checkbox"/>	Spanish IC 10-23-08	10/28/2008 2:23 PM

7.2. Do any of the above documents require modification?  Yes  No [Clear](#) [Guidance](#)

If you answered “yes” to 7.2 above, please open an Amendment to make the required changes.

[IRB Informed Consent Templates and Forms](#)

## New Form – Page 8

- Study Abstract page
  - ❑ Show current study information
  - ❑ Does not automatically update abstract (only when you say “no”)
  - ❑ Easy paste into box for editing

### 8. Study Abstract

The current Abstract for this study is as follows:  
 This is a test abstract made only to show that the abstract does populate from the main study. It should work out well. This is a test abstract made only to show that the abstract does populate from the main study. It should work out well. This is a test abstract made only to show that the abstract does populate from the main study. It should work out well. This is a test abstract made only to show that the abstract does populate from the main study. It should work out well. This is a test abstract made only to show that the abstract does populate from the main study. It should work out well. This is a test abstract made only to show that the abstract does populate from the main study. It should work out well.

[Hide Study Information](#)

#### 4.2 Protocol Documents:

name	Version Modified
Protocol Test 10-10-08 0.01	10/28/2008 2:25 PM

#### 29.1.1 Informed Consent Documents:

name	Version Modified
Informed Consent 10-10-08 0.03	10/29/2008 2:29 PM
Spanish IC 10-10-08 0.01	10/29/2008 2:29 PM

[Hide Study Information](#)

8.1 Does the above abstract accurately summarize the current study? The abstract should provide a simple explanation of the study and should have 1 or 2 sentences written to address each of the following points: background and rationale; objectives or purpose; selection criteria or sample characteristics; study methodology; description of study arms if appropriate; study endpoints or outcomes; intervention and follow-up; statistics and plans for analysis. [Guidance](#)

Yes  No [Clear](#)

8.1.1 Please update the study abstract in simple language. Ensure that it continues to correctly describe the study given any [Guidance](#) and all amendments.

[Paste in Current Study Abstract](#)

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## New Form – Page 9

- Study Personnel and Locations
  - ❑ Shows current study personnel and asks if the list is current
  - ❑ Shows current study locations and asks if current

### 9. Study Personnel and Study Locations

Study Personnel indicated by the study are as follows: (please note that expired Human subjects certificates must be made current)

Principal Investigator:  Principal Investigator 1 TestAccount:HSC HS Certification: 0

Study Contact Person:  HS Certification: 0

Co-Investigator:  Last Name First Name Organization HS Certification Expiration

There are no items to display

Study Staff and Roles:

Last Name First Name Organization Study Role HS Certification Expiration Obtain Consent

There are no items to display

9.1 Is this list of people on the study current?  Yes  No [Clear](#) [Guidance](#)

#### Study Locations

Study Locations indicated by the study are as follows:

HSC Locations:
<input type="text"/> LAC+USC General Hospital (does not include GCRC)
<input type="text"/> USC University Hospital
<input type="text"/> USC Medical School
<input type="text"/> LAC+USC Outpatient Building

9.2 Is this set of locations current?  Yes  No [Clear](#) [Guidance](#)

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# Old Form – Page 7

- Issues
  - “Other Materials” question just tacked on at the end
- New Form

**7. Conflict of Interest and Other Materials**

7.1. Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project? (See Guidance for CHLA Conflicts of Interest and Commitment in Research policy.) Guidance  
 Yes  No

7.1.1. If yes, attach a completed Financial and Intellectual Interest Disclosure Form for each person who has a potential conflict to be managed. (download the form here)  
  

name	Version	Modified
There are no items to display		

7.2. To the investigator's knowledge does the institution have financial and or intellectual property interests in the sponsor or the products used in this project? Guidance  
 Yes  No

7.3. Please attach the current versions of any applicable documents not already located on this site. Do not attach copies of Informed Consents, Protocols, Interim Reports, or Recruitment Materials. Only submit publications of other appropriate documents. Guidance  
  

name	Version	Modified
There are no items to display		

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# New Form – Page 10

- Conflict of Interest Page
  - Own page
  - Substantially the same
- If “Other Materials has data, then on its own page, page 11.
  - Deprecated, so won't show up on new forms

**10. Conflict of Interest**

10.1. Do any of the participating study investigators or other research personnel (or their immediate family/significant partner) have a financial interest (equal to or exceeding \$10,000 per year) and/or intellectual property interest in the sponsor or products used with this project? Conflicts of interest may include (but are not limited to) any of the following items below: equity (stocks or options, do not include mutual funds); consulting fees; speaking fees; gifts; a position as a Corporate Officer or on the Board of Directors; other employment relationships; trademarks or copyrights; licensing agreements; royalty rights; or patent holdings; or compensation that will be affected by the outcome of the study. If so, describe which party or parties have a conflict of interest and indicate the nature and extent of the conflict of interest. Note: recruitment bonuses of any amount must be disclosed. Guidance  
 No  Yes

10.1.1. If yes, attach a completed Financial and Intellectual Interest Disclosure Form for each person who has a potential conflict to be managed. (download the form here)  
  

name	Version	Modified
There are no items to display		

10.2. To the investigator's knowledge does the institution have financial and or intellectual property interests in the sponsor or the products used in this project? Guidance  
 Yes  No

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# New Form – Last Page

## ■ Reminders!

### 99. Instructions for Submission

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

1. Click the "Finish" button on the top or bottom application navigator bar to return to the continuing review folderspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Any of the study personnel can submit the continuing review by using the "Submit to IRB" activity.
4. The continuing review is submitted. The state indicator in the top left of the continuing review folderspace will no longer display Pre Submission.

### Reminders:

Please remember that some of the answers you have provided may require an Amendment or the submission of a Reportable Event. From your responses, the following must be done:

1. You have indicated that there is at least one Adverse Event that has yet to be submitted to the IRB. Please submit it under Reportable Events for the study.
2. You have indicated that there is at least one Data Safety Monitoring Report that has yet to be submitted to the IRB. Please submit it under Reportable Events for the study.
3. You have indicated that the risks or potential benefits of the research has changed. Study risks/benefits must be revised via an Amendment.
4. You have indicated that Informed Consent documents must be changed. Consent documents must be revised via an Amendment.
5. You have indicated that the study personnel list is not current. Study personnel must be revised via an Amendment.

\*\*Please note that all items requiring an Amendment may be combined into one Amendment comprising all of the changes.