

July 6, 2007

Hello,

We are working to improve the human subjects program and, as a component thereof, the IRB review of proposed research activities. As a result, we have made several changes to the iStar application for review of proposed projects involving human subjects. Please note that these changes will go into effect in the afternoon/evening of July 12th. For studies currently under review, if any further information is necessary the IRB will specifically request it. While for many of you these changes will be straight forward, we nevertheless want to briefly highlight them:

1. For HSC and UPC, questions have been revised to include agreements to participate from services, organizations or departments needed to conduct a project, but that are not under immediate control of the investigator (3a & 3b).
2. For projects involving outside sites, additional information concerning outside IRB approval and IRB authorization agreements is now required (6c).
3. For HSC and UPC, FDA regulated studies where the investigator is the sponsor, require an agreement to comply with FDA regulations to be attached. This agreement is available here on the HSIRB website:  
[http://www.usc.edu/admin/provost/oprs/private/docs/hsirb/forms/Invest\\_Sponsor\\_Form.doc](http://www.usc.edu/admin/provost/oprs/private/docs/hsirb/forms/Invest_Sponsor_Form.doc) (9.6).
4. For drugs that are not stored in a pharmacy at one of the campuses, details concerning drug storage are requested (17.2). A similar question has been added for devices (18.3).
5. Questions have been revised to collect information on how individuals assisting with the research are to be trained (23.5).
6. For UPC and HS more information concerning the Data Safety Monitoring Plan is now requested (27.4).
7. For UPC and HS the conflict of interest question has been revised. For all campuses, a question concerning institutional conflict of interest has been added (39).

Attached is a complete list of the wording and question changes with an explanation for the reasons why.

Thank you,  
iStar Technical Support

## **I. iStar “New Study” Application changes:**

3.a.2: alter text on question (HSC and UPC ONLY)

Currently reads:

**3.a.2. Please select any additional department or division approvals that may be needed for this study. Do not specify organizations already listed above.**

Revised to:

**3.a.2. Please select any additional department or division approvals that may be needed for this study. When the conduct of research involves services not under the control of the investigator (such as radiology, pathology or nursing) those departments should be added here. Do not specify organizations already listed above. If the service or organization does not presently have electronic review, attach a written approval or agreement at 3.a.3.**

Rationale and Guidance:

This change clarifies that departments or services that would be called upon to perform services for the study need to be informed and they must agree that they have the resources available to do it. Previously the IRB had limited methods of ensuring that these had agreed.

3.a.3: alter text on question (HSC and UPC ONLY)

Currently reads:

**3.a.3. Are there other campus committees that will need to review and approve this protocol? If so, please list the name(s) of the committee(s) and attach approval memos as applicable**

Revised to:

**3.a.3. Are there any other campus committees, services or organizations that need to review and approve this protocol? If so list the name(s) of the committee(s) and attach approval memos as applicable.**

Rationale and Guidance:

Added “services or organizations” to not restrict this question to committees. For example, some organizations may not have a committee, yet their review and approval are required.

6c.1.5: New question (subpage from 6c.)

**6c.1.5. Does the institution have an IRB?**  
(yes/no)

Rationale and Guidance:

Added question to specify whether the site has an IRB.

6c.1.5: alter text and position for question

Currently reads:

**6c.1.5. Attach a copy of the IRB approval/permission letter from that site here.**

Revised to:

**6c.1.6.** If the site has a local IRB attach the IRB approval here.

Rationale and Guidance:

Removes the assumption that the site has an IRB. Whether the site has an IRB is covered in another question (see above)

6c.1.6: alter text and position for question

Currently reads:

**6c.1.6.** If no, please attach a letter of agreement for conduct of the study from that site.

Revised to:

**6.c.1.7.** If the site does not have an IRB please attach a letter of agreement for the conduct of the study from that site. The IRB will contact that individual to verify authority, and to obtain an IRB authorization agreement from that site. The IRB authorization agreement will define reporting between the study site, the investigators and the IRB. Contact the IRB/CCI director for assistance with the IRB authorization agreement.

Rationale and Guidance:

A letter of agreement authorizes the research to be conducted at the site. Note that the agreement must: (1) be signed by someone who has authority to do so, and (2) include how information (changes, problems, etc.) gets disseminated between the site, study staff, and IRB.

6c.1.8: New question (subpage from 6c.)

**6c.1.8.** If the site has an IRB but they have elected to have USC/CHLA be the IRB of record, please explain why and attach an IRB authorization agreement at 6c.1.6.  
(text box)

Rationale and Guidance:

The rationale for the site's IRB not being involved is requested.

7.1.1: alter text on question

Currently reads:

**7.1.1.** If yes, describe how the information relevant to protecting participants, such as reporting of unexpected problems, protocol modifications, and interim results are managed.

Revised to:

**7.1.1.** If yes, describe how the information relevant to protecting participants, including obtaining local IRB approval at the study sites, reporting of unexpected problems, protocol modifications, and interim results are managed.

Rationale and Guidance:

The question retains its purpose, namely: to elicit how you manage your information related to human subjects protection. What is changed here is that it now includes local site IRB approval as included in that set of information.

8.3.9: New question (subpage from 8a.)

**8.3.9 (HSC ONLY) Attach a copy of the Contract/Study Consistency Checklist completed by HRA.**  
(upload a document)

Rationale and Guidance:

This is a checklist that HRA (Health Research Associates) fills out when examining the contract. Please upload a copy of this checklist here.

9.5: New question on Methods and Procedures form

**9.5. Is this project an investigator initiated drug, biologic or device study?**  
(yes/no)

Rationale and Guidance:

Elicits information on whether the study is investigator initiated.

9.6: New question on Methods and Procedures form

**9.6. (HSC and UPC ONLY) If the investigator is considered a sponsor/investigator he or she must complete and attach a USC Sponsor/Investigator Agreement. This must be completed and signed by the Sponsor/Investigator.**  
(upload document(s))

Rationale and Guidance:

Sponsor/Investigators have a specific agreement they have to complete. Upload a completed and signed copy here.

17.2: alter text on question

Currently reads:

**17.2. Indicate where the drugs will be stored.**

Revised to:

**17.2. Indicate where the drugs will be stored. If not at the pharmacy, indicate where the drugs will be stored, how they will be secured and the inventory will be managed.**

Rationale and Guidance:

This makes it more clear that the IRB needs to review how the drugs will be managed. If this is the pharmacy, the expectation is that this falls under standard pharmacy practices. However, if it is not, more precise information on how the drugs are managed is required.

### 18.3: New Question on Device Information form

**18.3** Indicate where the investigational devices will be stored, how they will be secured and the inventory will be managed.  
(text box)

#### Rationale and Guidance:

As with Drugs, the IRB needs to know how devices are stored and managed to ensure subject protection.

### 18.1.8. New Question on IDE subform:

**18.31.8** Name of the IDE holder:  
(text field)

#### Rationale and Guidance:

Sometimes, the IDE holder and the PI are not the same person. Thus, we must elicit this information specifically.

### 23.5: Alter text on question

Currently reads:

**23.5. Describe how the investigators will ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.**

Revised to:

**23.5. Describe how the investigators will ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions. Include a description of how research staff, research and clinic nurses, other participating physicians, pharmacists, data managers, coordinators and others will receive necessary information and training.**

#### Rationale and Guidance:

This question has been expanded to help ensure that people participating in the study are informed and trained. Since this could differ by role, please explain how each get informed.

### 26.1: Alter text on question

Currently reads:

**26.1. How will the data for this study be collected and recorded? Describe the provisions to protect the privacy of the individual.**

Revised to:

**26.1. How will the data for this study be collected and recorded? Describe the provisions to protect the privacy of the individual.** (e.g. consenting/screening subjects in a private office or area versus a busy hospital waiting room).

#### Rationale and Guidance:

This question has been revised to more particularly seek out information on how confidentiality and privacy are respected in the study.

27.4: Alter text on question

Currently reads:

- 27.4. Data Safety Monitoring Plan: Describe how the studies are monitored for the safety of the participants and for the validity and integrity of the data. (If a DSMB is involved with this study, please describe the composition, plans for monitoring and distributing information to the local IRBs.)**

Revised to:

- 27.4. Data Safety Monitoring Plan: Describe who will monitor the studies for the safety of the participants (investigators, sponsor, independent monitor, DSMB, etc). Provide a plan ( Monitoring provisions) which may include information on: the type of data or events to be captured, who is responsible for monitoring data related to unanticipated problems and adverse events, time frames for reporting adverse events and unanticipated problems to the monitoring entity, the frequency of assessments of data / events captured by monitoring, specific triggers or stopping rules that dictate when an action is required, and procedures for communicating to the IRB, sponsor, investigator, and other appropriate officials the outcome of the reviews by the monitoring entity. For CHLA attach the plan below. For HSC and UPC you may reference the specific sections of the Protocol that provide this information.**

Rationale and Guidance:

This question is expanded to better explain the expectation of what a good DSMB would contain.

39.1: Alter text on question (Initially, this will be for HSC and UPC only).

Currently reads:

- 39.1. 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?**

Revised to:

- 39.1. Do any of the participating study investigators or other research personnel (or their immediate family/domestic 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.**

Rationale and Guidance:

This question makes it more clear what needs to be included in a Conflict of Interest disclosure.

### 39.3: New Question on Conflict of Interest form

**39.3 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?**

(yes/no)

#### Rationale and Guidance:

The institution may have a conflict of interest that requires review from an independent COI committee.