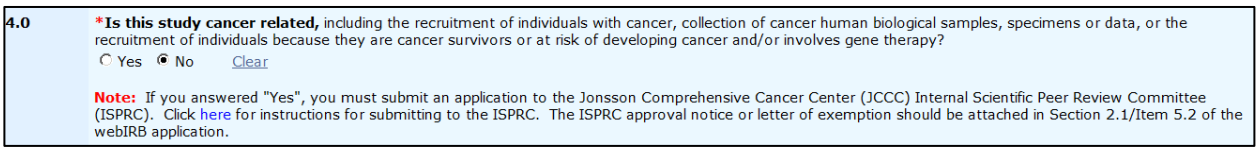
UCLA Office of the Human Research Protection Program

SEPTEMBER 2014 WEBIRB UPDATES

Below is a summary of webIRB updates made this past weekend. Due to this upgrade, if your study is currently in the following states "Pre-Review Request", "Accepted Pending Modification" or "Deferred" states you **may** be asked to answer a few additional questions when you respond to IRB correspondence.

A. UPDATES to Sections

1. Section 2.2/item 3.0 of the main application has been moved to section 2.1 to group the JCCC questions together.



4.0 *Is this study cancer related, including the recruitment of individuals with cancer, collection of cancer human biological samples, specimens or data, or the recruitment of individuals because they are cancer survivors or at risk of developing cancer and/or involves gene therapy?

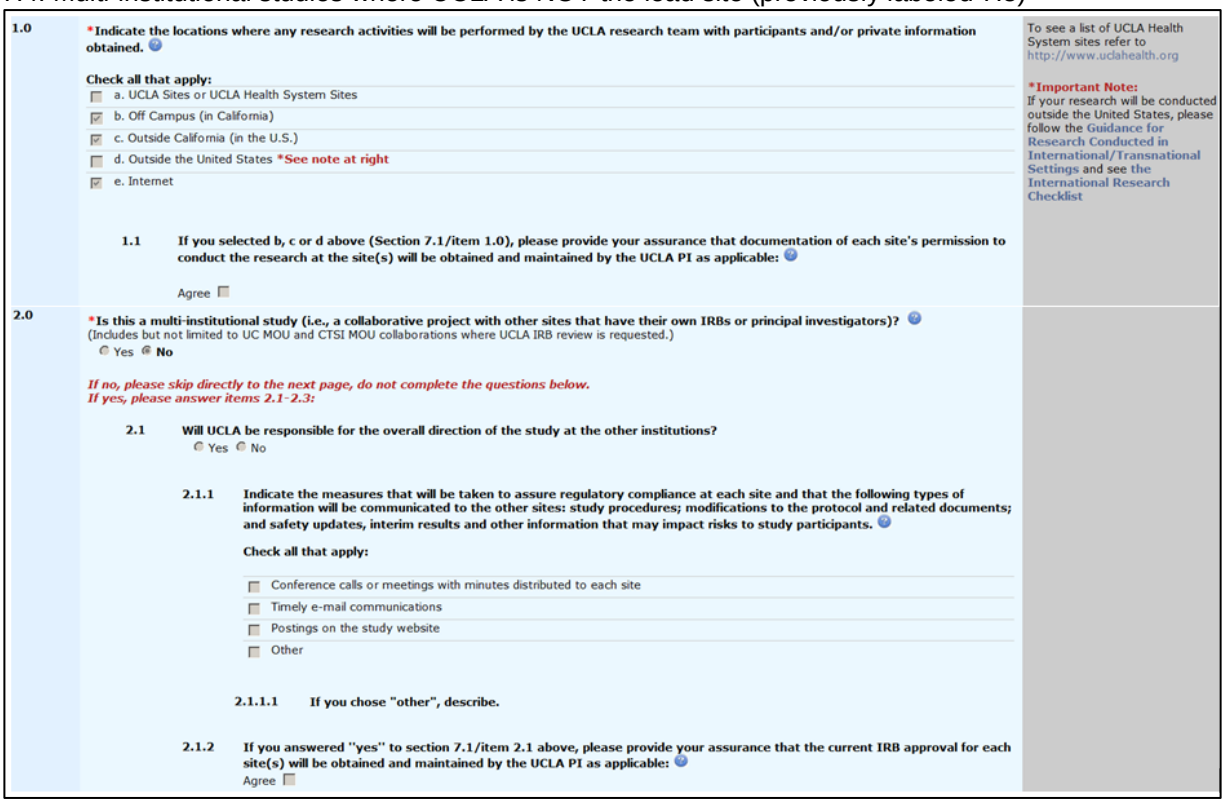
○ Yes ◉ No Clear

Note: If you answered "Yes", you must submit an application to the Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC). Click here for instructions for submitting to the ISPRC. The ISPRC approval notice or letter of exemption should be attached in Section 2.1/Item 5.2 of the webIRB application.

2. The Multi-site sections have been updated and regrouped into 4 sections for clarity.

(*Please note that not all studies will branch out to the following 4 sections)

The multi-site portion of the application has now been consolidated into 4 sections instead of 5:
7.1: Site locations
7.2: UCLA site
7.3: Other than UCLA site locations
7.4: Multi-institutional studies where UCLA is NOT the lead site (previously labeled 7.5)



1.0 *Indicate the locations where any research activities will be performed by the UCLA research team with participants and/or private information obtained.

Check all that apply:

- ☐ a. UCLA Sites or UCLA Health System Sites
- ☑ b. Off Campus (in California)
- ☑ c. Outside California (in the U.S.)
- ☐ d. Outside the United States *See note at right
- ☑ e. Internet

To see a list of UCLA Health System sites refer to http://www.uclahealth.org

*Important Note: If your research will be conducted outside the United States, please follow the Guidance for Research Conducted in International/Transnational Settings and see the International Research Checklist

1.1 If you selected b, c or d above (Section 7.1/item 1.0), please provide your assurance that documentation of each site's permission to conduct the research at the site(s) will be obtained and maintained by the UCLA PI as applicable:

Agree ☐

2.0 *Is this a multi-institutional study (i.e., a collaborative project with other sites that have their own IRBs or principal investigators)? (Includes but not limited to UC MOU and CTSI MOU collaborations where UCLA IRB review is requested.)

○ Yes ◉ No

If no, please skip directly to the next page, do not complete the questions below.
If yes, please answer items 2.1-2.3:

2.1 Will UCLA be responsible for the overall direction of the study at the other institutions?

○ Yes ○ No

2.1.1 Indicate the measures that will be taken to assure regulatory compliance at each site and that the following types of information will be communicated to the other sites: study procedures; modifications to the protocol and related documents; and safety updates, interim results and other information that may impact risks to study participants.

Check all that apply:

- ☐ Conference calls or meetings with minutes distributed to each site
- ☐ Timely e-mail communications
- ☐ Postings on the study website
- ☐ Other

2.1.1.1 If you chose "other", describe.

2.1.2 If you answered "yes" to section 7.1/item 2.1 above, please provide your assurance that the current IRB approval for each site(s) will be obtained and maintained by the UCLA PI as applicable:

Agree ☐

3. The Recruitment sections have been regrouped into 4 sections.

The previous 12 recruitment sections have been combined into 4 sections:
(*Please note that not all studies will branch out to the following 4 sections)

18.1: Type of Identification and Recruitment Method
18.2: Recruitment
18.3: Identification
18.7: Review of medical records to identify potential research participants

A. Selecting any of the following options brings up 18.2
- Advertisements/Flyers/Information Sheet/Internet Postings
- Direct recruitment of potential study participants
- Recruitment Letters/Emails
- Referrals
- Participant pool

B. Selecting any of the following options brings up 18.3
- Random or Other Probability Sampling
- Review of publicly available records
- Review of other records
- Potential Study Participants are identified from another IRB approved study or IRB approved screening protocol
- Other

C. All previous recruitment documents (except for 18.7 which remains in that section) are being moved to 18.2/item 1.0.

4. Attachment extensions in WebIRB.

For security reasons, *.rtf and *.exe files are no longer accepted in the application.

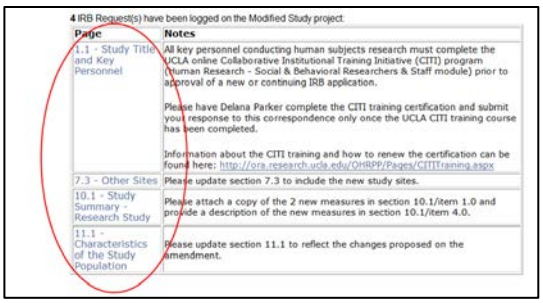
B. FIXES & ENHANCEMENTS

1. Broken links in WebIRB

All known/reported broken links in the application have been fixed.

2. Broken links on Amendment letters

Links have been fixed and now redirect to the correct section of the modified study.



3. Study expiration time

The expiration time has now been set to the end of the day midnight and not 12:00am the day of.

4. Edited notices now appear in the “Notices” tab.