

eIRB User Release Notes
July 31, 2014 eProtocol Release

The following updates were made to eIRB on July 31, 2014. Please e-mail irb@slu.edu if you have any questions. The changes made to the system in this release include changes to the forms and system functionality. The details of these changes are specified below. The IRB welcomes feedback on the eIRB system- please feel free to use the [eIRB Feedback form](#).

Please note: Protocols in preparation, not yet submitted to the IRB (at the time of the update) will prompt for new questions (added to the forms in this update) to be answered.

CHANGES MADE TO FORMS:

All Forms (BIO Exempt & Expedited/Full; BSS Exempt & Expedited/Full):

1. PROCEDURES TO MAINTAIN CONFIDENTIALITY (6 BSS/BIO Exempt, 7 BSS, 11 BIO): The broken link to SLU IT Security Policies was repaired.
2. POTENTIAL CONFLICT OF INTEREST SECTION:
 - a. Items under “Note to Investigator(s) Reporting a Potential Conflict of Interest” were modified to reflect current policy.
3. FINAL STEPS/PRE REVIEW COMMENTS SECTION:
 - a. New instructional wording was added, “While the protocol in undergoing pre-review it will not be available in edit mode. The protocol will be available for editing once the assigned pre-reviews have been completed.” AND “The protocol will not automatically be submitted to the IRB.”
4. ATTACHMENTS SECTION:
 - a. “Archived Consent Materials (Office Use Only)” attachment drop down selection was deleted. Archived consent materials will no longer be saved on the attachments page, but can be located in the Event History.
 - b. Unstamped versions of all stamped documents (on consent, assent, HIPAA, and Attachments page) will also be removed from the Attachments page at time of approval.

Exempt Forms ONLY:

1. SECTION 1-3 (BACKGROUND, STUDY PURPOSE, PROCEDURES): Two new questions were added (3c and 3d) regarding the involvement of SSMSL or Saint Louis University Hospital.

Expedited Forms ONLY:

1. NEW HELP LINK FEATURE: A new pop-up help feature was added to provide two types of instruction “Application Consideration” and/or “Ethical Consideration”. Links were added to the following questions:
 - a. BOTH FORMS:
 - i. **Personnel Information (all team members)**, research experience
 - ii. **Procedures to Maintain Confidentiality**, definition links
 - iii. **Informed Consent**, waiver of consent
 - b. BIO ONLY:
 - i. **General Checklist**, Investigator Initiated, University Indemnified

- ii. **Question 2d**, placebo use
 - iii. **Question 3f**, accepted standard of care
 - iv. **Question 8c**, subjects study-wide
 - v. **Question 8e**, exclusion of women, minorities, or minors
 - vi. **Question 9.7**, investigational compound/drug/device
 - vii. **Question 9.8a**, additional/other risks
2. **SUBJECT POPULATION(S) CHECKLIST**: Item “Adult Volunteers” was changed to “Adults”.
 3. **PROCEDURES TO MAINTAIN CONFIDENTIALITY (7 BSS, 11 BIO)**: A new instructional note was added, “NOTE: A specific data set may not be designated as more than one of these items: ‘Coded’, ‘Data collected anonymously’, and ‘Data are de-identified’. If you have multiple data sets with different protections, please check ‘Other’ in addition and explain.”
 4. **INFORMED CONSENT (9 BSS, 13 BIO)**:
 - a. **Question 2**: “Explain how risks, benefits, and alternatives will be discussed” was deleted.
 - b. **Waiver of Written Consent Pop-Up**: Instruction referencing the paper to electronic conversion process was deleted.

BIO Expedited/Full Form ONLY:

1. **FUNDING SECTION**: A new question was added to the Industry Sponsor funding tab, “Billing Note (e.g., does the billing for this study deviate from the standard IRB Fee schedule or billing process, or is there anything else unique to the billing for this study?)”
2. **SECTION 1-3 (BACKGROUND, STUDY PURPOSE, PROCEDURES)**:
 - a. **Question 1a**: Question was modified to include new wording, “Provide an introduction and background information” and “Investigator Initiated studies must cite references in the response provided or attach a bibliography”.
 - b. **Question 3a**: The first sub question was modified with additional wording, “OR does this study involve conduct of research at multiple sites?” The second sub question was also modified with additional wording, “OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the [Supplemental Application for Coordinating Center Activities \[Linked document\]](#).”
3. **SECTION 5a (INVESTIGATIONAL DEVICE)**:
 - a. **Question 4**: Question “IDE #. . .” was modified with new wording, “Provide IDE # or state whether sponsor deems this as nonsignificant risk or “exempt” research. Documentation of IDE # required unless imprinted on sponsor protocol (attach in section #16). [See Guidance \[Link to Additional Criteria Checklist\]](#).”
 - b. **Question 5**: Question “Name of sponsor. . .” was modified with new wording, “Name of sponsor (the sponsor could be a device manufacturer, company or an individual investigator acting as the ‘sponsor’).”
 - c. **Question 6**: New wording- “sponsor or” was added to the question “Indicated level of risk. . .”
 - d. **Line 7**: Note was edited. “(device information or documentation from FDA indicating it is exempt from IDE requirements)” was replaced with “for the determination”.

- e. NEW Question 8: New question was added, “Describe location and procedures for storage and control of the device. Include information on how access will be limited to authorized personnel.”
 - f. NEW Assurance 9: New question/assurance was added, “If a SLU Investigator is serving as sponsor-investigator, click “Yes” to assure that the [additional FDA requirements \[Link to document\]](#) will be followed.”
4. SECTION 5b (FDA APPROVED DEVICE):
- a. NEW Question 4: New question was added, “Does the research involve use of a commercially available device for an unapproved purpose?” If answered with “yes” the rest of the questions in the pop-up will apply.
 - b. Question 5 (formerly #4): Question “IDE #. . .” was modified with new wording, “Provide IDE # or state whether sponsor deems this as nonsignificant risk or “exempt” research. [See Guidance \[Link to Additional Criteria Checklist\]](#).”
 - c. Question 6 (formerly #5- a note): Note “Attach documentation of IDE #. . .” was modified with new wording and became an answerable question, “Attach documentation of IDE # if not imprinted on sponsor protocol. If an IDE # is not provided, you must justify nonsignificant risk or exempt determination and/or attach supporting documentation from the FDA.”
 - d. Question 7 (formerly #6): Question “Name of sponsor. . .” was modified with new wording, “Name of sponsor (the sponsor could be a device manufacturer, company or an individual investigator acting as the ‘sponsor’).”
 - e. NEW Question 8: New question was added, “Describe location and procedures for storage and control of the device. Include information on how access will be limited to authorized personnel.”
 - f. NEW Assurance 9: New question/assurance was added, “If a SLU Investigator is serving as sponsor-investigator, click “Yes” to assure that the [additional FDA requirements \[Link to document\]](#) will be followed.”
5. SECTION 6 (DRUGS):
- a. Instructions were added regarding the listing of placebo in this section.
 - b. 6a (INVESTIGATIONAL DRUG):
 - i. Question 5: Additional wording was added to this question (“Is IND held by. . .”), “Sponsor-investigators must also follow [additional FDA requirements \[Link to document\]](#).”
 - ii. NEW Question 11: New question was added, “Describe location and procedures for storage and control of the device. Include information on how access will be limited to authorized personnel.”
 - c. 6b (FDA APPROVED DRUG):
 - i. NEW Section: New section header was added to the end of the pop-up, “Drug Accountability (if IND is required).”
 - ii. NEW Question: New question was added in the new Drug Accountability section, “Describe location and procedures for storage and control of the device. Include information on how access will be limited to authorized personnel.”
 - iii. NEW Assurance: New question/assurance was added in the new Drug Accountability section, “If a SLU Investigator is serving as sponsor-investigator, click “Yes” to assure that the [additional FDA requirements \[Link to document\]](#) will be followed.”

6. SECTION 7 (OTHER LEVELS OF REVIEW):
 - a. Question 1 (RADIATION SAFETY): Question was previously grandfathered/disabled and in this update was reactivated. Question will now need to be completed (or completed again). Question text was updated to reflect current policy. Completion options were altered and now include “Not Applicable” or “Study involves. . .”
 - b. Questions 2 through 5: Completion options were altered and now include “Not Applicable” or “Study involves. . .”
7. SECTION 9 (RISKS): Question 9.8.a was edited to remove other physical risks.
8. SECTION 11 (PROCEDURES TO MAINTAIN CONFIDENTIALITY):
 - a. NEW Question 11h: Question was added, “Describe any study-specific (non standard of care) information or documentation that will be put in the participants’ medical record for this research (e.g., study visit notes, lab results, etc.) If none, state “not applicable”.
 - i. If the response is not applicable, no further action is required.
 - ii. If study data/information will be put in the medical record, there will be a new requirement (policy memo forthcoming) to incorporate new template language into the consent form unless comparable language already exists. The new language will be released in a policy memo to the research community and incorporated into the SLU model consent template shortly.
 - iii. At time of next submission, please do the following or you will be sent contingencies from the IRB to do so:
 1. For New Protocols/Responses to Contingencies: investigators are asked to include new template language into section 7 (Confidentiality Section) of the consent and ensure 11c of the protocol includes that study information is in Epic, thus, is accessible by authorized SLU/Hospital staff.
 2. For Amendments/Continuing Reviews: if not already clear in your IRB protocol and consent form, include new language in Section 7 (Confidentiality Section) of the consent and review 11c of the protocol to ensure the response addresses that study information is in Epic, thus is accessible by authorized SLU/Hospital staff. In the amendment/continuing review form, please describe this as an official change and answer the question about re-consent, describing that subjects will be re-consented at next visit, but those who’ve completed all study visits will not be re-consented.

BSS Expedited/Full Form ONLY:

1. SECTION 1-3 (BACKGROUND, STUDY PURPOSE, PROCEDURES):
 - a. NEW Question 3a: New question was added regarding research at multiple sites. “Does this study involve conduct of research at multiple sites and the SLU PI is the direct recipient of a federal grant for this research? If yes, please complete and attach the [Supplemental Application for Coordinating Center Activities \[Linked document\]](#).”
 - b. Question 3e and 3f (now 3f and 3g): Completion options were altered and now include “Not Applicable” or “Study involves. . .”

Continuing Review Form (BIO and BSS):

1. INSTRUCTIONS 1.b.iv: Instructions were edited to accurately reflect current practices.
2. QUESTION 4: Question was modified, “Total number of participants/records/specimens you are approved to enroll.”
3. QUESTIONS 6 & 7: Definition pop-up links were made blue to increase visibility. The definition for accrued was modified to more accurately reflect IRB guidance.
4. STUDY PROGRESS QUESTION: (BIO- #13, BSS- #11), wording was added, “Provide a status of participants in study, for example, where is the most recently accrued participant in terms of timeline in the study? If participants are in long-term follow-up, explain what this consists of in terms of data collection and/or intervention. Provide any new information in regard to risks. Summarize or attach publications or presentations.”
5. RECENT FINDINGS QUESTION: (BIO- #16, BSS- #13), question was made mandatory and must be answered before submission.

CHANGES MADE TO SYSTEM FUNCTIONALITY:

1. Enhancements were made to the system to improve alerts to users trying to access a protocol when another user is already editing. Users will continue to have view mode and will be informed which other team member (PI or Administrative Contact) is already editing the form.