The following updates were made to eIRB on June 10-12, 2016. 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, system functionality, user manuals/quicksheets, IRB Guidance documents, and the supporting software platform. The details of these changes are specified below. The IRB always welcomes feedback on the eIRB system- please feel free to use the eIRB Feedback form.

Please note: Protocols in preparation at the time of the update (not yet submitted to the IRB or those in the comments/contingencies phase) will prompt for new questions (added to the forms in this update) to be answered the next time a form is edited. Newly created “child” forms (e.g., Amendment, Continuing Review) will also prompt for new questions to be answered before submission to the IRB. Use the key below or the published quick charts to find the relevant questions.

Key code:

✔ This symbol indicates a new question which will need to be answered when the next editing action is taken on your IRB protocol (as noted above).

✏ This symbol indicates a question that has changed such that an answer which existed before the update might no longer be adequate and may need to be edited.

⚠️ This symbol indicates a section of the form that was overhauled with major changes and will need specific attention for existing forms.

❗ This symbol indicates a section or question which requires another type of special consideration as detailed below.

واصلة الصورة

Quick Reference Links:
Use the links below to advance to a specific section of the release notes and view changes made to:

- All Forms (BIO Exempt & Expedited/Full; BSS Exempt & Expedited/Full)
- Exempt Forms ONLY
- BIO Expedited/Full Form ONLY
- BSS Expedited/Full Form ONLY
- Continuing Review Form (BIO & BSS)
- Amendment Form (BIO ONLY)
- Report Form (BIO & BSS)
- Serious Adverse Event Form (BIO & BSS)
- Final Report Form (BIO & BSS)

Overall System and System Functionality
All Forms (BIO Exempt & Expedited/Full; BSS Exempt & Expedited/Full):

1. **HELP ICONS:**
   a. **ALL FORMS, Question 1a:** An icon with an application consideration was added to the background information question to describe what is required and why, and what Investigator Initiated studies in particular need to cite.
      i. “Application Consideration: In this question the IRB requires a brief introduction with supporting background information to describe your study. Do not include overly lengthy descriptions. Investigator Initiated studies (i.e., the Principal Investigator has conceived, designed, and is conducting the research) are required to cite references in the response or should upload a referenced bibliography in the Attachments section.”
   b. **ALL FORMS, Personnel Information:** The Research Experience help icon content was edited.
      i. “Application Consideration: In Research Experience, please include information that demonstrates that each research team member has the experience to carry out each duty and work with human subjects. Do not include work experience, a CV or resume, or a publication list. Include the number of years of research experience. If a team member does not have experience, it is required that a mentorship/ supervision plan be included.”
   c. **NEW, Exempt Forms:**
      i. **Research Experience:** Icon was added to all personnel and describes what should be listed in this answer.
      ii. **Question 1a BSS:** Icon was added to the question, “Provide an introduction and background information, including a review of the literature.”
      iii. **Question 2a: BIO:** Application consideration icon regarding how this question (“Describe past findings leading to the formulation of the study.”) should be answered was added.
   d. **Expedited/Full Forms, Waiver of Consent:**
      i. Specific information was added (specific by type of form- BSS v. BIO) to make the pop up more helpful, clarify when a waiver is appropriate, and how it must be justified (see specific sections below).
      ii. The content of the pop-up which was previously cutting off was fixed.
   e. **BIO Expedited/Full Form:**
      i. Minor edits were made on several help icons:
         1. **GENERAL CHECKLIST:** Investigator Initiated Study (punctuation/spacing).
         2. **QUESTION 8e:** Women/minorities/minors (wording/punctuation/spacing).
3. **QUESTION 9.8:** Risk type (“breach of confidentiality” was added).
   ii. **QUESTION 3f:** Important changes were made to the standard of care/standard practice at SLU question (Icon was added to provide clarity on what is now required in this question and to distinguish between standard of care and standard practice at SLU).
   iii. **QUESTION 8c:** “Number of evaluable subjects to be accrued study wide.” (Icon was added for clarity regarding which sites are included and definitions were added regarding a non SLU PI).

2. **PERSONNEL INFORMATION:**
   a. **DEGREE:** The degree field was made mandatory for all personnel.
      i. **NOTE:** Though you will see the mandatory star on the create protocol page, the system will not yet prompt for the degree to be completed there.
   b. **HUMAN SUBJECTS RESEARCH TRAINING:** A note was added to all personnel roles to more clearly emphasize that protocols submitted without proof of training will be returned:
      i. **PI, Administrative Contact, Key Personnel, and Department Chair/Academic Advisor:** “WARNING: Proof of training must show below or the application will be returned. If your training information isn’t showing, upload a copy in the Attachments section.”
      ii. **Non SLU Collaborator:** “WARNING: Proof of training must be attached or the application will be returned”

3. **STUDY LOCATION CHECKLIST:**
   a. “Saint Louis University Hospital (Tenet)” became “SSM Health- Saint Louis University Hospital”. **Note:** SSM and SLU Hospital review processes continue to be separate and unique.

4. **SECTION 2 (STUDY PURPOSE):**
   a. **QUESTION 2a:** The lay summary question now contains a word limit (200 words with a small buffer). Pre-existing answers (longer than the limit) will remain unless edited (i.e., put your cursor in the answer box), in which case the system will cut off the wording at the limit and prompt the user to edit the entry. **If you need to edit your answer for any reason, but wish to maintain the answer-open the protocol in view mode and copy the answer into a word document before editing.** Forms which have been previously submitted will have existing answers in the Event History PDF captures.

5. **OTHER LEVELS OF REVIEW (section 3 BSS/BIO Exempt and BSS Expedited/Full, section 7 BIO Expedited/Full):**
   a. **ALL QUESTIONS:** Problems with the mandatory functionality were fixed.
   b. **SSMSL QUESTION:** Language regarding when to start the SSMSL/RBR process was clarified:
      i. “While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study.”
6. PROCEDURES TO MAINTAIN CONFIDENTIALITY AND PRIVACY (section 6 BSS/BIO Exempt, 7 BSS Expedited/Full, 11 BIO Expedited/Full):

New questions added to one specific form are noted in that form’s section below. Please reference both areas. This section will discuss common changes across all forms.

a. SECTION HEADERS: The header “Data Security” was changed to “Confidentiality”.

b. NEW INSTRUCTION: Instruction was added to the Confidentiality section:
   i. “To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).”

c. NEW INSTRUCTION: Term definitions were updated and included in the new instruction in the Confidentiality section so the definitions are visible and can be used to answer the questions in the section.
   i. “Anonymous/De-identified: data contain no identifiers, including code numbers that investigators can link to individual identities;
   ii. Coded: data in which (1) identifying information, such as name or social security number, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept separately from coded data; AND/OR
   iii. Identifiable: data that includes personal identifiers (e.g., name, social security number), such that information could be readily connected to respective individuals.”

d. ELECTRONIC (COMPUTER) DATA QUESTION:
   i. GENERAL: The previous pick list question was deleted and replaced with a new add box table question.
   ii. INSTRUCTION: “Click “Add” to enter data security information for each type of electronic data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above). To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable security methods.”

e. HARDCOPY (PAPER) DATA:
   i. GENERAL: The previous pick list question was deleted and replaced with a new add box table question.
   ii. INSTRUCTION: “Click “Add” to enter data security information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above). To properly address this question, there should only be one
listing of each type of data in the table. Depending on your project, you
could have up to three types of data.”

f. **NEW QUESTION (6d BSS/BIO Exempt, 7g BSS Expedited/Full, 11i BIO Expedited/Full):** “Are there any information security requirements identified in the project’s RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc. If yes, SLU ITS approval is required. Contact InfoSecurityTeam@slu.edu to start the approval process.”

g. **SECTION HEADERS:** The header “Privacy” was added.

h. **NEW QUESTION (6e BSS/BIO Exempt, 7h BSS Expedited/Full, 11j BIO Expedited/Full):** “Privacy refers to persons having control over the sharing of oneself with others. Please indicate how participant privacy will be protected in this study (select all that apply):”

7. **POTENTIAL CONFLICT OF INTEREST (section 7 BSS/BIO Exempt, 8 BSS Expedited/Full, 12 BIO Expedited/Full):**

   a. **NOTE FROM THE MANAGER, CONFLICT OF INTEREST IN RESEARCH:** “In the Conflict of Interest section, several clarifications have been made to the text. When you complete this section, please keep in mind you are responding for the entire study team. If any study team member has a financial interest with the study sponsor or the manufacturer of a drug or device used in the study, please add the details to this section and remind the study team member to contact coi@slu.edu for additional review.”

   b. **GENERAL:** “Conflict of Interest Committee (COIC)” was changed to “Conflict of Interest in Research Committee (COIRC”).

   c. **INSTRUCTION:** [Conflict of Interest in Research Policy link was fixed.]

   d. **INSTRUCTION:** Edits were made to include information about initiating COI review: “If you have marked #2 or #3, please contact coi@slu.edu to initiate review of this study and provide the following information.”

   e. **QUESTION 3.1:** Wording was added to clarify that answers provided in this section relate only to the specific study: “A Conflict of Interest Management Plan has been approved for all investigators for this study.”

   f. **INSTRUCTION (“Investigator(s) must have”):**

      i. 1: Minor edits: “This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIRC.”

      ii. 2: Minor edits: “You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact coi@slu.edu.”

8. **HIPAA SECTION (section 9 BSS/BIO Exempt, 11 BSS Expedited/Full, 15 BIO Expedited/Full):**

   a. **GENERAL:**
i. **EXEMPT SCREENING QUESTIONS ITEM g:** To support the HIPAA section changes, “Protected Health Information (PHI)” was added and “sensitive data” was underlined.

b. **INSTRUCTION:** Existing instruction was updated:
   i. **NEW:** “Studies that access, receive, or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information visit the IRB HIPAA page or refer to the SLU IRB HIPAA Guidance.”
   ii. **OLD:** “Studies that receive or create protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information see: [HIPAA website] or the SLU HIPAA Tip Sheet.”

c. **QUESTION 1:** Question was edited to include the word “accessed”: “Will health information be accessed, received or collected?”

d. **QUESTION 2:**
   i. The word “recorded” was added to the body of the question: “Which personal identifiers will be received or collected/recorded?”
   ii. The “no identifiers” option received minor edits.
   iii. A new category of identifiers was added: “Limited identifiers will be received or collected/recorded (study will likely require a data use agreement. Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.” The new section allows collection of “city/state/zip codes”, “person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)”, “Age (if subjects are 90+ years)”
   iv. The pre-existing identifier list has a new header “At least one direct identifier will be received or collected/recorded”.
      1. **NOTE:** Direct identifiers which were previously listed in the HIPAA section will remain after the update, but this new header checkbox will not be checked.
   v. A note was added at the end of the section (or in some cases revised) directing users to continue if appropriate: “If you are receiving or collecting/recording health information and at least one personal identifier, please continue to complete the sections, below.”

e. **QUESTION 4:**
   i. **EXEMPT FORMS:** Two options were removed from both Exempt forms:
      1. “Only linkable code that can link data to the identity of the subject. A code access agreement or business associate. . .”
      2. “With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.”

      **NOTE:** Existing Exempt studies which had one of these options marked at the time of the update, will need to re-address the question in order for the section to be recognized as complete.
   ii. **ALL FORMS:** Minor edits were made to: “Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with
other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.”

f. QUESTION 5:
   i. **INSTRUCTION:** Minor edits: “HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.”
   ii. **ADD BOX:**
      1. **INSTRUCTION:** Descriptions of each type of HIPAA item and when they would be used were added to the add box pop-up and are specific by form type (Exempt v. Expedited/Full).
      2. **HIPAA DOCUMENTS:**
         a. The pre-existing “Data Use Agreement” became “Data Use Agreement- EXTERNAL”. **NOTE:** The broken document link was fixed.
         b. A new item was added “Data Use Agreement- INTERNAL”. This drop down is completed on its own and requires no uploaded attachment. It supports the new limited identifiers category. An assurance is on the add box, but a sentence was also added to the PI Obligations page to allow the PI to attest to this item.
         c. The instruction was replaced on the “Waiver of Authorization” option: “Investigators seeking a waiver of authorization must provide justification to all items. Simply restating the criteria in the response box is not acceptable; responses must include a justification as to how/why the study meets each criterion.”
         d. **EXEMPT FORMS:** “HIPAA Authorization” and “Waiver of Authorization” were removed as document options from both Exempt forms. All supporting references were also removed. **NOTE:** Existing Exempt studies which had one of these options completed at the time of the update, will need to re-address the question in order for the section to be recognized as complete. If the item remains, delete it or call the IRB Office.

9. ATTACHMENTS SECTION (section 10 BSS/BIO Exempt, 12, BSS Expedited/Full, 16 BIO Expedited/Full):
   a. Document drop down selections were matched to form-specific documents listed on the page.
   b. Other file type “.tif” was changed to “.tiff” to more accurately reflect the type of acceptable document.
   c. **BIO Expedited/Full only:** “Safety Information” was changed to “Safety Information (DSM information)”.

10. FINAL STEPS/PRE REVIEW COMMENTS:
   a. The Guidelines for Scientific Review link was fixed.
   b. **New INSTRUCTION:** The IRB publishes a document with various policies from around the university on how departments want the pre-review process done in
their unit. This document which has always been on our website and on the “choosing pre-reviewers” page, was added to the final steps page: “Not sure who to select for pre-review? Click here for department/school-specific instructions.”

11. **PI OBLIGATIONS:**
   a. **INSTRUCTION (2nd Paragraph):**
      i. Along with HIPAA changes (noted above) an assurance was added: “PI further assures that the SLU research team will comply with the terms of a Data Use Agreement to PHI (if any).”
      ii. Minor edits were made to the entire paragraph.

**Exempt Forms (BSS and BIO) ONLY:**

1. **PERSONNEL INFORMATION (BIO ONLY):**
   a. **Key Personnel (Research Team):** The ‘Not sure who should be on the research team? Click here.’ pop-up help definition was edited for clarity regarding who should be listed on the research team. Substantive edits include:
      i. **PARAGRAPH 1:** “procedures” was changed to “interventions or interactions”.
      ii. **PARAGRAPH 2:** Wording was added to: “This would include technicians performing standard clinical procedures that may be part of the research protocol, or even persons administering investigational agents that they are accustomed or trained to administer, but not otherwise having any role in the research.”

2. **CLOSURE REQUEST:**
   a. The language on the pop-up confirmation box was edited to more clearly reflect the requirements for closing a study and to reference the SLU Closure Guidance: “Do not close the protocol if you are still using, accessing, or analyzing identifiable information- directly or through a master list at the SLU site. See Closure Guidance.”
   b. **NOTE:** The Closure Guidance was updated with this release, but is not able to be linked in the closure request pop up at this time. See more information about the updated guidance in the last section of these release notes.

3. **EXEMPT SCREENING QUESTIONS:**
   a. Spaces were added to facilitate reading.
   b. **ITEM g:** Along with the HIPAA section changes (as noted above) “Protected Health Information (PHI)” was added and “sensitive data” was underlined.

4. **SECTION 6 (PROCEDURES TO MAINTAIN CONFIDENTIALITY AND PRIVACY):**
The following changes were only made to the Exempt forms. For the complete list of changes made to this section, please see the “all forms” section above.
   a. **GENERAL:** The section was re-ordered (question a became question c).
   b. **QUESTION c:** Previous question was replaced:
      i. **NEW:** “If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b)
how long it will be kept/when it will be destroyed, and c) provide a sample of the code. NOTE: This question is applicable to all exempt categories EXCEPT category 4. Chart/Record review research at the exempt level CANNOT involve a link between subject identity and data to be collected."

ii. **OLD:** “Describe the procedures in place which protect the privacy of the subjects and maintain the anonymity or confidentiality of the data, as required by the federal regulations. If a linked master list is used, explain when the linked master list will be destroyed and provide a sample of the code.”

**BIO Expedited/Full Form ONLY:**

1. **PERSONNEL INFORMATION:**
   - a. **Key Personnel (Research Team):** The ‘Not sure who should be on the research team? Click here.’ pop-up help definition was edited for clarity regarding who should be listed on the research team. Substantive edits include:
     - i. **PARAGRAPH 1:** “procedures” was changed to “interventions or interactions”.
     - ii. **PARAGRAPH 2:** Wording was added to: “This would include technicians performing standard clinical procedures that may be part of the research protocol, or even persons administering investigational agents that they are accustomed or trained to administer, but not otherwise having any role in the research.”

2. **GENERAL CHECKLIST:**
   - a. **NEW ITEM:** “Dietary Supplements, Vitamins, and Other Food Agents” was added and connects to the new drug sub-listing in Section 6 (see below).
   - b. **NEW ITEM:** “International Research or Research on International Populations” was added and connects with the new three-part question in section 9 (see below).

3. **SECTION 1-3 (BACKGROUND, STUDY PURPOSE, PROCEDURES):**
   - a. **QUESTION 3f:** Question altered to include standard practice at SLU, not just standard of care in general: “Is there an accepted standard of care and/or standard practice at SLU for the condition/disease/situation being studied? This information will assist in comparing the risk/benefit ratio of study procedures relevant to usual care that would be received outside of the research context. *?HELP?* If yes, please describe the standard of care and standard practice at SLU for the condition/disease/situation being studied.”
   - b. **NEW QUESTION 3g:** “Does this study involve any diagnostic imaging, labwork or genetic testing that could result in clinical discovery (diagnose, genetic mutations, etc.)? Note that this could include discovery that is expected (related to the research) or incidental (not related to research aims, but possible, like a mass/shadow found in imaging despite not looking for it). If yes, please describe and include whether there are plans to share findings with study participants.”
c. **NEW QUESTION 3h:** “Is this study subject to the NIH Genomic Data Sharing Policy? The NIH GDS policy applies to all NIH-funded research that generates large-scale human genomic data as well as the use of these data for subsequent research and includes: genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic and gene expression data, irrespective of NIH funding mechanism. Click here for more specific examples.”
   i. Question also contains a pop up (“Click here”) to provide more information regarding when the policy is applicable.

4. **SECTION 4 (RADIATION SAFETY):** The Duke website links were fixed and re-linked to wording: “CLICK HERE”.

5. **SECTION 5a (INVESTIGATIONAL DEVICES):**
   a. **GENERAL:**
      i. Questions were reordered and numbered.
      ii. Minor edits were made to the color and text of some items.
      iii. Previously non mandatory questions were made mandatory (#4, 5).
      iv. Stop/Start functionality was added to question #5. Your answer to this question will determine how the rest of the section needs to be completed.
   b. **QUESTION 3:**
      i. Minor edits were made: “Describe the device to be used and attach the device manual in section #16.”
      ii. Help icon was added with the definition of a device manual: “A device manual (also known as “Instructions for Use”) should include a description of the device, the purpose of the device (indications for use), general warnings and cautions related to use of the device and device operating instructions.”
   c. **QUESTION 5:**
      i. Question text was replaced:
         1. **NEW:** “This device research is: [choose one]. Note: Attach documentation/justification in section #16.”
         2. **OLD:** “Indicated level of risk per sponsor or FDA determination”
      ii. The answer selections were modified:
         1. “Significant risk” and “Non-Significant risk” were reordered and a third option, “Exempt from IDE regulations” was added.
         2. Linked pop up definitions were added, describing the risk level and required attachments for each option.
      iii. **NOTE:** The note was edited (some text was deleted): “Note: See level of risk per FDA regulations and guidance and upload supporting documentation for the determination.”
   d. **QUESTION 6:** Some wording was removed from the question. “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.”
e. **QUESTION 7**: Previous question was replaced:
   i. **NEW**: “Who holds the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the ‘sponsor’).”
   ii. **OLD**: “Name of sponsor (the sponsor could be a device manufacturer, company, or an individual investigator acting as the ‘sponsor’).”

f. **QUESTION 8**: Minor edits were made to the question: “If a SLU Investigator is serving as sponsor-investigator of the IDE, click “Yes” to assure that the additional FDA requirements will be followed.”

6. **SECTION 5b (FDA APPROVED DEVICES):**

   a. **GENERAL:**
   i. Questions were reordered and numbered.
   ii. Minor edits were made to the color and text of some items.
   iii. Previously non mandatory questions were made mandatory.
   iv. Stop/Start functionality was added to question #6. Your answer to this question will determine how the rest of the section needs to be completed. (NOTE: question 5 previously had this type of functionality).

   b. **QUESTION 3**: Minor edits were made: “Describe the device to be used and attach the device manual in section #16.”
   i. Help icon was added with the definition of a device manual: “A device manual (also known as “Instructions for Use”) should include a description of the device, the purpose of the device (indications for use), general warnings and cautions related to use of the device and device operating instructions.”

   c. **NEW QUESTION 4**: “Provide the PMA approval or 510(k) clearance number or attach letters in section #16.”

   d. **NEW QUESTION 5**:
   i. **QUESTION TEXT**: “This device research is: [choose one]. Note: Attach documentation/justification in section #16.”
   ii. **ANSWER SELECTIONS**:
      1. “Exempt from IDE regulations”, “Non-Significant risk”, and “Significant risk” were added.
      2. Linked pop up definitions were added, describing the risk level and required attachments for each option.
   iii. **NEW NOTE**: “The risk determination should be based on the proposed use of a device in an investigation and not on the device alone.”

   e. **QUESTION 7**: Some wording was removed from the question. “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.”

   f. **QUESTION 8**: Previous question was replaced:
   i. **NEW**: “Who hold the IDE? (Could be manufacturer, study sponsor, or an individual investigator acting as the ‘sponsor’).”
   ii. **OLD**: “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.”

g. QUESTION 9: Some wording was added to and deleted from the question: “If a SLU Investigator is serving as sponsor-investigator of the IDE, [and this study is not ‘exempt’ from IDE regulations], click “Yes” to assure that the additional FDA requirements will be followed.”

7. SECTION 6b (INVESTIGATIONAL DRUGS):
   a. GENERAL:
      i. ITEM B: Instruction was added to the main page: “Attach all applicable Investigator Brochures in section #16 (Attachments).”
      ii. Questions were reordered and numbered.
      iii. Minor edits were made to the color and text of some items.
      iv. Previously non mandatory questions were made mandatory: Questions 2 (manufacturer), 4 (source), 5 (dosage), 6 (admin route), 7 (premixed), and 8 (IND #) were made mandatory. These questions will need to be addressed on existing protocols at the time of next editing, but eIRB will not otherwise directly prompt for completion.
   b. NEW QUESTION 9: Three questions regarding who holds the IND were deleted and replaced with new question: “Who holds the IND?”.
      i. A note was added at the end of the section regarding attachment requirements.

8. SECTION 6c (FDA APPROVED DRUGS):
   a. GENERAL:
      i. ITEM C: Instruction was added to the main page: “Attach all applicable package inserts in section #16 (Attachments).”
      ii. Questions were reordered and numbered.
      iii. Minor edits were made to the color and text of some items.
      iv. Previously non mandatory questions were made mandatory: Questions 2 (manufacturer), 4 (dosage), 5 (admin route), 6 (premixed) were made mandatory. These questions will need to be addressed on existing protocols at the time of next editing, but eIRB will not otherwise directly prompt for completion.
      v. Two questions regarding drug accountability were deleted.

9. NEW SECTION 6d (DIETARY SUPPLEMENTS, VITAMINS, AND OTHER FOOD AGENTS):
   a. GENERAL:
      i. This section was added to allow for items to be added which previously didn’t have a place in the existing two sections. Researchers who have existing information in another section (Investigational or FDA Approved) which would better fit in the new section are not required to relocate the information.
      ii. Stop/Start functionality was added to the section letting users know when to continue with the section and when it is complete.

10. SECTION 7 (OTHER LEVELS OF REVIEW):
a. **QUESTION 2, Institutional Biosafety:** Mandatory functionality was fixed.

b. **QUESTION 3, PTNT Committee:**
   i. Wording was updated to reflect Tenet change over and more clearly reflect processes: “Saint Louis University Hospital requires that all research involving the administration of medications within the hospital (including outpatient areas such as the Emergency Department, Outpatient Center, Saint Louis University Hospital-South Campus, etc.) be reviewed and approved by the [PTNT] Committee and that study drugs are received, stored, prepared, and dispensed by the Hospital’s Department of Pharmacy Services. Please contact the Investigational Drug Services Clinical Pharmacist at 268-7156 or SLUH-IDS@ssmsluh.com for more information.”
   ii. Mandatory functionality was fixed.

c. **QUESTION 4, SLU Hospital:**
   i. Wording was updated to reflect Tenet change over.
   ii. Contact email address was updated (sluh.research@ssmsluh.com).
   iii. Mandatory functionality was fixed.

d. **QUESTION 5, SSMSL:**
   i. Language regarding when to start the SSMSL/RBR process was clarified: “While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study.”
   ii. Mandatory functionality was fixed.

11. **SECTION 8 (SUBJECT POPULATION):**
   a. **QUESTION 8b:** Question was edited to clearly reflect which sites are accounted for. “Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI)”
   b. **QUESTION 8c:** Help icon (providing clarity regarding which sites are included and definitions were added regarding a non SLU PI) was added to question: “Number of evaluable subjects to be accrued study wide.”

12. **SECTION 9 (RISKS):**
   a. **GENERAL:** A large paragraph of instruction (which was previously incorporated into the first few questions of the section) was removed allowing the section to be renumbered (or numbered for some questions previously without) promoting simplicity.
   b. **QUESTION 11 (Data Safety Monitoring):**
      i. **POLICY CHANGE:** Researchers are no longer required to provide a DSM charter, if all applicable information can be provided in the answer to the questions. Watch the video for complete details on how to answer this question.
      ii. **NEW INSTRUCTION:** “Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could range from no plan needed to an independent data safety monitoring
board. Please refer to SLU Guidelines for Data and Safety Monitoring as you complete the questions below.

iii. **11a (now numbered):** “Is there a Data Monitoring Committee (DMC) or Board (DSMB)?”
   1. Deleted from question: “If DSM charter is submitted initially, please reference charter.”
   2. **If yes** answer box: Question text was replaced:
      a. “If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor or research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time (MD or DO), and g) stopping/halting rules (if any exist). A DSM charter can be referenced for all items except for “f) who is reviewing SAEs in real time.”

iv. **11b (now numbered):** “Is there a Data Safety Monitoring Plan (DSMP)?”
   1. **NEW NOTE:** “Note, if all relevant plan information is included in DSMB question above, select ‘Yes’ and state “see above” in the answer box.”
   2. **If yes** answer box: Question text was replaced:
      a. “If yes, provide details (labeled a-e) including: a) what types of data or events are captured and how are they documented, b) who is monitoring the data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, d) who is reviewing SAEs in real time (MD or DO), and e) stopping/halting rules (if any exist).”

### NEW QUESTION 12:
A new three-part question was introduced and links to an item in the General Checklist (i.e., it will only be answered if applicable).

i. **12:** “In case of international research (research outside of the U.S. or research on international populations [non-U.S.]), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risk to subjects. Include whether research is sensitive given cultural norms.”

ii. **12a:** “State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.”

iii. **12b:** “Will there be language barriers and if so, how will they be addressed? Note: if materials are to be distributed to subjects in their native language, please follow SLU’s Guidance For Studies Involving Non-English Speaking Subjects.”
iv. **NEW NOTE:** An export control note was added to remind investigators that research conducted outside of the US may require Export Control Review:

1. **NOTE:** Export control laws include the transfer of technical information and data, as well as information and technology to foreign nationals. If this study has international components, contact the [SLU Export Control Officer](#) for direction on whether export control policies apply.

### 13. SECTION 11 (PROCEDURES TO MAINTAIN CONFIDENTIALITY AND PRIVACY):

The following changes were only made to the BIO Expedited/Full form. For the complete list of changes made to this section, please see the “all forms” section above.

a. **INSTRUCTION:** Minor edits were made to the paragraph regarding record retention:

i. “Federal regulations require that **research materials** be kept for a minimum of three (3) years, and HIPAA documents be kept for a minimum of six (6) years after the **closure** of the study. For **FDA-regulated projects**, the PI may be required to keep the data and documents for a longer time period.”

b. **QUESTION 11c:** Previous question was replaced:

i. **NEW:** “If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.”

ii. **OLD:** “Describe measures employed to protect the identity of the subjects, their responses, and any data that you obtain from private records (e.g., identifiers will be stripped so data cannot be linked to subjects, or code numbers will be used, etc.). If data will be coded, specify the procedures for coding the data so that confidentiality of individual subjects is protected. If you will keep a master list linking study codes to subject identifiers, explain why this is necessary, how and where you will secure the master list, and how long it will be kept.”

c. **QUESTION 11f:** Minor edits were made to the question: “If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be [protected during electronic transmission and how data will be] recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).”

d. **QUESTION 11g:** Previous question was replaced:

i. **NEW:** “If you will be audio/video recording or photographing subjects, provide a rationale as voiceprints and images of faces/unique body markings are considered identifiers. Describe confidentiality procedures, including any restricted access to images and/or the final disposition of the recordings/photos (destruction, archiving, etc.).”

ii. **OLD:** “If you will be audio/video recording or photographing subjects, provide a rationale for recording/photographing. Describe confidentiality procedures, including the final disposition of the recordings/photos (destruction, archiving, etc.) and a reasonable timeline by which this
disposition will occur. Please note audio or video recordings of voice and pictures or video recordings of a face or a unique body marking would be considered identifiers. Please address this in your response.”

14. **SECTION 13 (INFORMED CONSENT):**
   e. **WAIVER OF CONSENT ADD BOX:**
      i. **INSTRUCTION:** The existing instructions were replaced: “Investigators seeking a waiver of consent must provide justification to all items. Simply restating the criteria in the response box is not acceptable, responses must include a justification as to how/why the study meets each criterion.”
      ii. **HELP** ICON:
         1. Help icon content cut-off issue was fixed.
         2. Major (and important) edits were made to the content and are specific by type of form (BSS Expedited/Full v. BIO Expedited/Full):
            a. “Application Consideration: Certain studies, such as large scale, retrospective chart reviews, are designed such that obtaining consent may not be possible or practicable. Investigators seeking a waiver of consent must provide justification to the points below. Simply restating the criteria in the response box is not acceptable; responses must include a justification as to how/why the study meets each criterion. In considering practicability of obtaining consent (item 3), per federal guidance, the IRB does not take into account consideration of time or financial burdens placed on investigators. Instead, appropriate ethical or scientific rationales might include. . . . .” Refer to the form for complete content.

**BSS Expedited/Full Form ONLY:**

1. **GENERAL CHECKLIST:** Existing item “International Research” now reads “International Research or Research on International Populations” and now connects to section 5 Question C (a three-part question). The question is now only mandatory if applicable.

2. **SUBJECT POPULATION CHECKLIST:** “(specifically targeted)” was added to Employees and Students for clarity.

3. **SECTION 5 (RISKS):**
   a. **QUESTION 5e (Data Safety Monitoring):**
      i. **POLICY CHANGE:** Researchers are no longer required to provide a DSM charter, if all applicable information can be provided in the answer to the questions. Watch the video for complete details on how to answer this question.
      ii. **NEW INSTRUCTION:** “Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could
range from no plan needed to an independent data safety monitoring board. Typically, data and safety monitoring is not required for minimal risk studies, not for the majority of behavioral and social sciences research. Please see the SLU Guidelines for Data and Safety Monitoring for more information.

iii. **5e1 (now numbered):** “Is there a Data Monitoring Committee (DMC) or Board (DSMB)?”
   1. Deleted from question: “If DSM charter is submitted initially, please reference charter.”
   2. “If yes” answer box: Question was replaced:
      a. “If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor or research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time, and g) conditions which would result in the stoppage of the study.”

iv. **5e2 (now numbered):** “Is there a Data Safety Monitoring Plan (DSMP)?”
   1. **NEW NOTE:** “Note, if all relevant plan information is included in DSMB question above, select ‘Yes’ and state “see above” in the answer box.”
   2. “If yes” answer box: Question was replaced:
      a. “If yes, provide details (labeled a-d) including: a) what types of data or events are captured and how are they documented, b) who is monitoring the data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, and e) conditions which would result in the stoppage of the study.”

b. **QUESTION 5c:**
   Existing international research question was replaced with a three part question (now 5c, 5c1, and 5c2):
   i. **5c:** Question was edited, “In case of international research (research outside of the U.S. or research on international populations (non-U.S.)), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risk to subjects. Include whether research is sensitive given cultural norms.”
   ii. **NEW QUESTION 5c1:** “State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.”
   iii. **NEW QUESTION 5c2:** “Will there be language barriers and if so, how will they be addressed? Note: if materials are to be distributed to subjects in
their native language, please follow SLU’s Guidance For Studies Involving Non-English Speaking Subjects.”

iv. NEW NOTE: An export control note was added to remind investigators that research conducted outside of the US may require Export Control Review.

1. “NOTE: Export control laws include the transfer of technical information and data, as well as information and technology to foreign nationals. If this study has international components, contact the SLU Export Control Officer for direction on whether export control policies apply.”

4. SECTION 7 (PROCEDURES TO MAINTAIN CONFIDENTIALITY AND PRIVACY):
   a. INSTRUCTION: Minor edits were made to the paragraph regarding record retention:
      i. “Federal regulations require that research materials be kept for a minimum of three (3) years, and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated projects, the PI may be required to keep the data and documents for a longer time period.”

b. QUESTION 7c: Previous question was replaced:
   i. NEW: “If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.”
   ii. OLD: “Describe the procedures in place that protect the privacy of the subjects and maintain the anonymity or confidentiality of the data. If a linked master list is used, explain when the linked master list will be destroyed and provide a sample of the code.”

c. QUESTION 7d: Previous question was replaced:
   i. NEW: “If data or specimens are being shared outside of the research team, indicate who will receive the material and specifically what they will receive (data or specimens).”
   ii. OLD: “Specify who has access to the data, and what will be available and to whom. State how confidentiality of that information will be maintained (e.g., identifiers will be removed).”

d. NEW QUESTION 7e: “If samples or data will be provided from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected.”

e. QUESTION 7f: “If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be [protected during electronic transmission and how data will be] recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).”

15. SECTION 9 (INFORMED CONSENT):
   a. WAIVER OF CONSENT ADD BOX:
      i. INSTRUCTION: The existing instructions were replaced: “Investigators seeking a waiver of consent must provide justification to all items. Simply
restating the criteria in the response box is not acceptable, responses must include a justification as to how/why the study meets each criterion.”

ii. *HELP* ICON:
   1. Help icon content cut-off issue was fixed.
   2. Major (and important) edits were made to the content and are specific by type of form (BSS Expedited/Full v. BIO Expedited/Full):
      a. “Application Consideration: Certain studies, such as large scale, retrospective chart reviews, are designed such that obtaining consent may not be possible or practicable. Investigators seeking a waiver of consent must provide justification to the points below. Simply restating the criteria in the response box is not acceptable; responses must include a justification as to how/why the study meets each criterion. In considering practicability of obtaining consent (item 3), per federal guidance, the IRB does not take into account consideration of time or financial burdens placed on investigators. Instead, appropriate ethical or scientific rationales might include. . . . .” Refer to the form for complete content.

Continuing Review Form (BIO and BSS):
1. **QUESTION 9 (BSS)**: Note was added to the reportables question: “Note: Descriptions of SAEs here should be consistent with the cumulative table, which should also be attached in section #12.”

2. **QUESTION 11c (BIO)**: Note was added to SAE reporting question: “Note: Information here should be consistent with the cumulative table, which should also be attached in section #16.”

Amendment Form (BIO ONLY):
1. **NEW QUESTION 6**: “For sponsor amendments, when did the SLU site receive notification of changes? [n/a option] [calendar box]. Note: Amendments submitted outside of reporting requirement windows will require submission of a Report Form (as a Protocol Violation).”

Report Form (BIO and BSS):
1. **ITEM A.1, UNANTICIPATED PROBLEM (UP)**:  
   a. Uploading a related document is no longer mandatory on the add box. The mandatory star was removed.

2. **ITEM A.2, PROTOCOL DEVIATION/VIOLATION**:
   a. **QUESTION 1**: Functionality was introduced so that only questions pertaining to the answer given in this question (protocol deviation or violation) must be answered. Deviation submissions will only be required to answer questions 1, 2, 3, 6, and 7. Violation submissions will only be required to answer questions 1, 2,
3, 4, 5, and 7. **NOTE**: questions unfortunately do not grey out at this time, but will in the future. Notes were added to indicate the new functionality.

b. **QUESTION 2**: An opt out function was added to the existing date question to allow users to not have to add a date for planned deviations which have not occurred: “N/A, this is a planned deviation (not yet occurred).”

c. **QUESTION 4, Provide a full description...**:
   i. “Deviation” was removed from the question as it is now only required for violation submissions.
   ii. A note was added: “**NOTE**: Response not mandatory for deviation submissions.”

d. **QUESTION 5, What will be done in the future...**:
   i. “Deviation” was removed from the question as it is now only required for violation submissions.
   ii. The following was added to the question text: “If this was a consent/HIPAA documentation error, describe plans for re-obtaining consent/HIPAA Authorization or provide justification if no such plans exist.”
   iii. A note was added: “**NOTE**: Response not mandatory for deviation submissions.”

e. **NEW QUESTION 6**: “Provide a full description of the protocol deviation, including how it is different from the approved protocol, and why it is necessary.”
   i. A note was added: “**NOTE**: response not mandatory for violation submissions.”

f. **NEW QUESTION 7**: “Will this result in a change to the protocol? If no, please justify.”

g. **QUESTION 8**: Uploading a related document is no longer mandatory. The mandatory star was removed.

3. **INSTRUCTIONS ITEM B**: Instructions were modified to correctly reflect which items (3-7) require section B of the Report Form to be completed.

**Serious Adverse Event (SAE) Form (BIO and BSS):**

1. **Add Box**:
   a. **QUESTION 5**: A sentence was added to the question: “Modifications to the protocol/consent form are not required”: “If modifications are not required, please justify. Include any relevant information about the classification of the SAE by the PI/Study Sponsor”.

   b. **QUESTION 7**:
      i. “Did this event occur at SLU Hospital (inpatient or outpatient)?” was changed to “Please state the location where the SAE occurred/the patient/subject presented.”
      ii. Existing answers to this question will not remain.

   c. **QUESTION 8**:
      i. “Did this event occur at a SSM facility (inpatient or outpatient)?” was changed to “Please indicate if the study is being conducted at one of the
Following sites. Note this should be consistent with the Study Location Section of your approved protocol.”

ii. Existing answers to this question will not remain.

d. FUNCTIONALITY: For expired protocols, immediate availability of the form will be limited, as noted below in the Final Report section. The form will only become available after the Final Report form is created for these protocols.

Final Report Form (BIO and BSS):

1. GENERAL: Both forms were updated to more accurately match the IRB guidance (as noted below).

2. INTRODUCTION PAGE: The guidance link was fixed (both forms).

3. QUESTION 1 BSS (ONLY): Minor edits were made:
   a. 1a: “Is enrollment at the SLU-approved site(s) closed?”
   b. 1b: “Have all participants completed all research-related interventions and/or follow-up at the SLU-approved site(s)?”
   c. 1c: “Has data analysis or manuscript preparation that requires use of or access to personally identifiable information (directly or through a master list at the SLU site) been completed?”

4. QUESTION 1 BIO (ONLY): Substantial edits were made:
   a. 1a: “Is enrollment at the SLU-approved site(s) closed?”
   b. 1b: “Have all participants completed all research-related interventions and/or follow-up at the SLU-approved site(s)?”
   c. 1c: “Biological specimens associated with the research meet one of the following:
      i. 1) Specimens are de-identified (i.e., there is no personally identifiable information, including through a master list at the SLU site);
      ii. 2) As approved by the IRB, specimens have been transferred to a SLU repository that has ongoing IRB approval;
      iii. 3) As approved by the IRB, specimens were transferred to a non-SLU entity.”
   d. 1e: “Has data analysis or manuscript preparation that requires use of or access to personally identifiable information (directly or through a master list at the SLU site) been completed?”
      i. *On a multi-site study where SLU is not the lead site, a sponsor or coordinating center/statistical center at another institution can still be conducting analysis after the SLU study is closed. Local analysis must be complete prior to closing the study (i.e., the SLU site has had its final (close out) visit by the sponsor (even if the database is not locked). Note that simply responding to sponsor/statistical center requests for data verification at the SLU site does not require a study to remain open or to re-open.”

5. QUESTION 3 (BOTH FORMS): The definition pop up for “accrued” was temporarily disabled due to technical issues. The definition was added to the question text:
   a. “. . . accrued (subjects who have given consent and whose participation yields evaluable data).”
6. **FUNCTIONALITY**: The form (both) will now be available after protocol expiration to allow users to properly close the study without having to first re-initiate via Continuing Review form. **NOTE**: With this new availability the Serious Adverse Event (SAE) form will only become available after the Final Report form is created.

**CHANGES MADE TO OVERALL SYSTEM AND SYSTEM FUNCTIONALITY:**

1. **GENERAL:**
   a. A verification pop up was added to the “close” function on all forms. Now when you click “close” users are asked to confirm that they intend to close the form.
   
   b. **INTERNET BROSWER:**
      
      - The Linux platform will now allow users to use the system with the Google Chrome, which previously did not allow users to submit forms or assign pre-reviewers.
      
      - eIRB will no longer support the use of Internet Explorer (IE). **NOTE**: At this time (after testing) there are no known functionality issues with IE. Users who continue to use IE may note visual incompatibility. The IRB Office no longer recommends IE usage.
   
   c. **CHECK FOR COMPLETENESS**: The Check For Completeness feature may be more specific in directing users to incomplete sections.

2. **APPROVAL AND ACKNOWLEDGMENT LETTERS**: Sentence was added: “The Saint Louis University Institutional Review Board complies with the regulations outlined in 45 CFR 46, 45 CFR 164, 21 CFR 50 and 21 CFR 56 and has determined the specific components above to be in compliance with these regulations, as applicable.”

3. **FINAL REPORT FORM**: The form will now be available after protocol expiration to allow users to properly close the study without having to first re-initiate via Continuing Review form. **NOTE**: With this new availability the Serious Adverse Event (SAE) form will only become available after the Final Report form is created.

4. **SEARCH FEATURE (all roles):**
   a. Two new search parameter items (department and protocol status) were added to the search feature.
   b. The sponsor search parameter item was fixed and is working now.

5. **TENET NAME CHANGE**: References to “Tenet” were updated to SSM Saint Louis University Hospital, including contact email addresses. **NOTE**: SSM and SLU Hospital review processes continue to be separate and unique.

6. **PRE-REVIEW PROCESS**: The protocol event status on the Investigator dashboard currently reads: “Pre-Approval/Scientific Review Required.” The pre-review process/policy has not changed. Scientific/PPC Review is only required as applicable per IRB guidelines.

7. **EVENT HISTORY:**
a. The display order was reversed allowing the most recent action on the protocol to appear at the top.

b. This item is now automatically checked in the print view menu, removing a step to add it to the generated PDF.

8. EMAIL HISTORY: The Attachment column was removed.

**CHANGES MADE TO SUPPORTING SOFTWARE PLATFORM:**

1. eIRB was previously supported by the Windows platform, and will now be supported by the Linux platform. Users will notice slight visual differences and several upgrades (noted above, when appropriate). The Linux platform also allows users to use the system with the Internet browser Google Chrome, which previously did not allow users to submit forms or assign pre-reviewers.

**CHANGES MADE TO USER GUIDES/MANUALS/EXTERNAL HELP INFO:**

The following items will be released in the coming week(s) after the update:

1. eIRB Investigator User Guide *(updated version)*
2. New Protocol Submission Quick Sheet *(updated version)*
3. eIRB Pre-Review (Dept Chair/Faculty Advisor Approval) Guide *(updated version)*
4. eIRB Pre-Review (Dept Chair/Faculty Advisor Approval) Quick Sheet *(updated version)*
5. eIRB Department-Specific Viewer Guide *(NEW)*
6. eIRB Department-Specific Viewer Quick Sheet *(NEW)*

The following items will be released in the coming month(s) after the update:

7. PDF System Clarification Document *(updated version)*
8. Approval Letter System Clarification Document *(updated version)*
10. eIRB Tip of the Month web page reorganization
11. Instruction additions to the log in page

**GUIDANCE DOCUMENTS UPDATED WITH RELEASE:**

1. Data Safety Monitoring Guidelines
   a. Guidelines substantially changed to reflect the IRB’s current thinking on the topic. Covers important considerations for studies that need to include a data safety monitoring plan, including what details to include in IRB Applications.

2. Confidentiality Guidelines
   a. Guidelines substantially changed to include SLU ITS, Privacy Office and IRB’s current thinking on the topic. Covers important considerations for forming a data security plan for research projects, links to ITS websites that show allowable storage locations for research data, and describes details to include in IRB Applications.
3. **Study Closure Guidelines**  
   a. Guidelines underwent minor changes to clarify when studies with specimens and multi-site studies can be closed.

4. **Post-Approval Submission Requirements**  
   a. Minor revisions to reflect policy changes for submission of Protocol Deviations and DSMB Charters.

5. **Safety Reporting Guidelines**  
   a. Minor revisions to reflect policy changes for Protocol Deviations.

6. **IND/IDE Guidelines**  
   a. Guidelines substantially changed to reflect the IRB’s current thinking on the topic. Covers considerations for investigators doing clinical investigations involving investigational drugs/devices, or investigational uses of FDA approved drugs/devices and determinations of whether IND/IDE regulations apply.

7. **HIPAA Guidance Documents Revised on SLU IRB’s HIPAA webpage**  
   a. **Guidelines for HIPAA in Research**  
      i. New Guidance Covers considerations for studies that involve use of, access to, obtaining, collecting or recording protected health information.
   
   b. **Internal Data Use Agreement**  
      i. Created for projects that do not require IRB review, but use internal (SLU & SSM affiliate sites) limited PHI (limited datasets).
   
   c. Other minor HIPAA document revisions on the IRB webpage  
      i. Changes to reflect the new limited dataset option. Modified forms include:
         1. **Decision Tree for HIPAA in Research**  
         2. **Examples of PHI Identifiers**  
         3. **Limited Datasets and Data Use Agreements**

8. **Human Subjects Research Determination Form (HSR Determination Form)**  
   a. Minor revisions to reflect that research involving newborn blood spots is considered human subjects research and to reflect the new limited dataset option.