

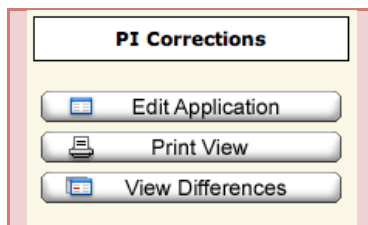


## New Study Application Changes

### Format and Design

- A significant amount of help text has been added to the application. Blue help text has been added underneath many questions. More extensive help text has been added to pop-up windows that can be accessed by clicking the **HELP?** button that is now associated with many questions.
- Many of the text boxes throughout the application are now formatting-capable. This means that you can format the text much like you would in Microsoft Word. For example, you can add bullets, numbering, bolded text, underlining, etc. Formatting-capable text boxes are distinguishable by the  icon in the upper right corner of the text box. By clicking on this icon, a menu of formatting options will appear.
- Most of the text boxes in the application are resizable, allowing you to see more of the text without scrolling inside the text box. This is useful for viewing large amounts of text entered into a text box. To resize a text box, click and drag the  icon in the lower right corner of the text box.
- Changes made to the new study or update study application are now automatically tracked via the View Differences button available on the application workspace. This button is found under the Print View button on the workspace:



- ERICA will maintain a read-only copy of your most recently approved protocol/research summary. This will be accessible to you via the Documents page in ERICA.

ERICA will also maintain an up-to-date e-version of a protocol summary. This e-version is different than the protocol/research summary template used prior to 1/17/2012. This e-version will compile information you provide in your application into a summary view and will include the following sections:

- A title page, with study title, investigator names, IRB approval date, and IRB number
- Background and Introduction
- Purpose and Objectives
- Study Population description, with age of participant and inclusion/exclusion criteria
- Design
- Study Procedures description, including recruitment, informed consent process, and procedures conducted with participants/data

- Statistical Methods, Data Analysis and Interpretation

This will also be accessible to you via the Documents page in ERICA.

### **Contacts and Title Page**

- Persons obtaining consent can be indicated for individuals listed in questions 1 and 3.
- Question 10 was added, allowing for inclusion of text for the background and introduction of the study. This was formerly collected in the Protocol/Research Summary.

### **Study Location and Sponsors Page**

- Information about the sponsor is now paired with information about the location of the study. Formerly, sponsor information was paired with information about the participant.
- Question 2 allows for Intermountain Healthcare hospitals to be listed.
- Question 4 was redesigned to better capture information about other locations/sites that are participating in the study for which the applying PI is responsible. Contact information, procedures conducted at each site, and reporting oversight information are now collected. This was formerly collected in the Protocol/Research Summary.
- Question 5 allows for multiple sponsors to be added to an application. Contact information for sponsors is now collected, as was formerly collected in the Protocol/Research Summary.
- Question 6 is new and collects information about the study's relationship with a Contract Research Organization (CRO). This was formerly collected in the Protocol/Research Summary.
- Question 7 asks about use of the Utah Population Database. This question was formerly asked on the HIPAA page, but has been relocated to accommodate non-HIPAA studies.

### **Participants Page**

- Question 3 separates "Pregnant Women and Fetuses" from "Neonates".
- Questions 4, 5, and 6 have been moved to this page for better grouping of information about participants. These questions were formerly included on the Study Information page.

### **Study Information Page**

- Question 4 is new and collects information about the recruitment process or participant identification process. This was formerly collected in the Protocol/Research Summary.
- Question 5 has been moved to this page for better grouping of information about study procedures and process. This question was formerly included on the Participants page.
- Question 6 is new and collects information about the study procedures. This was formerly collected in the Protocol/Research Summary.
- Question 7 is new and collects information about which procedures may be considered research-only versus non-standard or non-standard of care procedures. This was formerly collected in the Protocol/Research Summary.

- Question 8 is new and triggers information to be collected about safety monitoring for studies that are greater than minimal risk. Safety monitoring information is to be collected on a separate page. This was formerly collected in the Protocol/Research Summary.
- Question 9 is new and collects information about the statistical methods, data analysis, and data interpretation for the study. This was formerly collected in the Protocol/Research Summary.

#### **Request for Waiver or Alteration of Consent Page**

- This page allows for multiple waiver requests of different types to be added to an application.
- This page now collects information about the purpose of the waiver request.

#### **Consent Process Page**

- Question 1 has been modified to display persons obtaining consent who were selected on the Contacts and Title page. Persons affiliated with the study through the University of Utah, the VA, PCMC, or Shriners Hospital should be listed on the Contacts and Title page if they will be obtaining consent.

#### **Data Monitoring Plan Page**

- This is a new page in the new study application. This new page is required for all studies.
- Questions 1 and 2 have been moved to this page for better grouping of information about data monitoring. These questions were formerly included on the Risks and Benefits page. These two questions now provide check-box options for selecting privacy and confidentiality protections.
- Question 3 is new and collects information about images and recordings of participants that may be used in the study. This was formerly collected in the Protocol/Research Summary.
- Question 4 is new and collects information about how study data and documentation will be monitored throughout the study.
- Question 5 is new and collects information about who will be the primary data monitor for the study data and documentation.
- Question 6 is new and collects information about the frequency of monitoring for study data and documentation.

#### **Safety Monitoring Plan Page**

- This is a new page in the new study application. Information on this page was formerly collected in the Protocol/Research Summary. This new page is required for greater than minimal risk studies.
- Question 1 is new and collects information about who will monitor the safety aspects of the study.
- Question 2 is new and collects information about the safety information that will be monitored throughout the study.
- Question 3 is new and collects information about the types of reports that will be produced as the result of safety monitoring.
- Question 4 is new and collects information about the stopping rules for the study.
- Question 5 is new and collects information about the frequency safety monitoring.

### **Risks and Benefits Page**

- This page no longer collects information about privacy and confidentiality protections. These questions have been moved to the Data Monitoring Plan page.

### **HIPAA and the Covered Entity Page**

- Question 2 has been reordered and now includes questions about the following, which were formerly collected in the Protocol/Research Summary:
  - Investigator-initiated drug and device trials
  - Use of data from the UUHSC Enterprise Data Warehouse (EDW)
  - Creating or sending samples to a tissue bank/repository (this triggers a new page called Tissue Banking)

### **Request for Waiver or Alteration of Authorization Page**

- This page allows for multiple waiver requests of different types to be added to an application.
- This page now collects information about the purpose of the waiver request.
- This page allows for an alteration of authorization to be requested.

### **Limited Data Set Statement of Assurance**

- This page now requires that disclosure applicability be indicated.
- This page now requires that the PI accept the Statement of Assurance on the “submit” activity when the PI submits the application to the IRB for review.

### **Non-Human Subject Research Page**

- Question 1 collects information about the type of project being conducted.
- Question 2 collects information about the number of participants to be enrolled in the project.

### **Investigational Use of a Drug Page**

- Column 1 allows for multiple IND numbers to be added to an application.
- Column 1 now also collects information about the investigational drug name and IND holder.
- Column 2 now collects information about the drug name and the IND exemption pathway.
- This page now requires that the PI accept the Statement of Assurance on the “submit” activity when the PI submits the application to the IRB for review.

### **Investigational Drug Data Form Page**

- This page allows for multiple investigational drugs with corresponding drug information to be added to the application.
- Question 10 is new and collects information about the plan to control, store, and dispense the investigational drug. This was formerly collected in the Protocol/Research Summary.

### **Investigational Use of a Device Page**

- This page allows for multiple IDE numbers to be added to an application.

- Question 1a now collects information about the investigational device name and IDE holder.
- Question 2 is new and collects information about the plan to control, store, and dispense the investigational device. This was formerly collected in the Protocol/Research Summary.

#### **Non-Significant Risk Device Page**

- Question 1 is new and collects information about how the investigational device meets the definition of a non-significant risk device.

#### **Device Exempt from IDE Requirements Page**

- The option for Post Approval Device Studies was added.

#### **Tissue Banking Page**

- This is a new page in the new study application. Information on this page was formerly collected in the Protocol/Research Summary. This new page is required for studies that indicate that samples collected from participants will be sent to a tissue bank for future research.
- Question 1 is new and collects information about the type(s) of samples to be collected.
- Question 2 is new and collects information about the type(s) of future research that will be allowed on the samples.
- Question 3 is new and collects information about the management of the tissue bank and storage of the samples.
- Question 4 is new and collects information about the identifiability of the samples, as well as the confidentiality protections used for the samples.
- Question 5 is new and collects information about the data that will be collected and use with the sample.
- Question 6 is new and collects information about how the participants can withdraw their samples from the tissue bank.
- Question 7 is new and collects information about how future research results will be disseminated to participants.
- Question 8 is new and collects information about how other researchers can obtain tissues from the bank.

#### **Resources and Responsibilities Page**

- This is a new page in the new study application. Information on this page was formerly collected in the Protocol/Research Summary. This new page is required for all studies.
- Questions 1 and 2 are new and collect information about the qualifications and training of the study team.
- Question 3 is new and collects information about the facilities to be used for the research activities.
- Question 4 is new and collects information about the resources available to participants as a result of the research.

#### **Documents and Attachments Page**

- The section for attaching a Protocol/Research Summary is no longer active and has been changed to read-only.
- The Consent Documents section has been modified to include consent documents, consent cover letters, consent information sheets, consent scripts, etc.
- The Company Protocol section was changed to the Full Protocol section, which includes company protocols, sponsor protocols, investigator-initiated protocols, etc.
- A section was added for attaching Literature Cited and References.
- A section was added for attaching Recruitment Materials, Advertisements, etc.

## Ancillary Application Changes

*Ancillary applications are sub-components of the new study application.*

### CCIC Application Page

- Question 4e now longer requests a typed answer, but displays components of the safety monitoring plan as completed in the IRB application.
- Question 6 is new and collects information about the HCI institutional databases that will be used to track patient accrual.

### PCMC Administrative Research Questions Page

- Question 4 is new and collects information about the need for an Intermountain or PCMC database query.
- Question 5 is new and collects information about gaining access to PCMC or Intermountain information systems.
- Question 7 is new and collects information about the purchase of computer hardware to be used at PCMC.
- Question 9 is new and collects information about disclosing Intermountain patient data or samples outside of Intermountain Healthcare.
- Question 10 is new and collects information the possibility of inventions being developed from the research.
- Question 17 now requests billing information to be included.

### uTRAC Page

The requirements for requiring a uTRAC application via the ERICA application have changed. All University of Utah Covered Entity studies that have a prospective study design or are collecting PHI with a consent and authorization process are required to link their uTRAC application to their ERICA application.

With the uTRAC-ERICA linkage, the following questions/answers from the ERICA application are shared with the uTRAC application:

- PI name
- Study Title
- Faculty Sponsor
- Investigators and Internal Staff / Clinical Research Contacts
- Purpose and Objectives / Brief Summary
- Background and Introduction / Detailed Description
- Indication if a study is multi-centered
- Participant Inclusion and Exclusion Criteria

## Continuing Review Application Changes

### Safety Monitoring Plan Page

- This is a new page in the continuing review application. This new page is required for greater than minimal risk studies. This page will display information about your safety monitoring plan from your original application.
- Question 1 is new and collects information about the findings identified since last IRB review through the conduct of the safety monitoring plan.
- Question 2 was moved from the Events page.

## Approval Letter Changes

As part of the IRB review process, the IRB must make specific determinations for components of the study that support final IRB approval. The approval letters for new studies will now include the specific IRB determinations for the following items:

- Waivers/Alterations of consent
- Waivers/Alterations of authorization
- Investigational device determinations
- Investigational drug determinations
- Vulnerable population inclusion determinations
  - Children
  - Pregnant women and fetuses
  - Neonates
  - Cognitively impaired or mentally disabled adults
  - Prisoners

Often these determinations include stipulations for the consent process, so carefully read the instructions included in each letter.

These determinations will also be included in amendment and continuing review letters if a new component is added to the study that involves one of these determinations.