

New Study Application Tutorial





*This tutorial is intended to provide you with more in-depth and practical assistance as you complete your **New Study Application** or **Update Study Application** at continuing review.*

Introduction

The New Study Application has been revised to comply with updated policies and procedures, to enhance understanding and readability of the questions, and to eliminate unnecessary duplication.

The application includes help text (in blue font) throughout, and there are also several sections with pop-up guidance (designated by the  icon).

This tutorial is intended to provide you with more in-depth and practical assistance as you complete your New Study Application.

-  Frequently-asked questions and their answers will be designated by this icon.
-  Questions or sections that are brand-new with this update are marked by this icon.

Additional questions or comments about the application or this tutorial should be directed to the IRB in writing at irb@hsc.utah.edu.

Create a New Study Application

- 1) Log into ERICA.

IRB ERICA ONLINE
Electronic Research Integrity & Compliance Administration

uNID:
Password:

Your uNID is your employee/student ID number with a "u" in place of the first 0.
For more information see <http://www.acs.utah.edu/portal/login.html>.

Your password is the password associated with your uNID.
If you do not remember this password please go to the following website for help:
<https://www.acs.utah.edu/uofu/acs/acsselfservice/portal/password/selfservice/ForgottenPasswordHelp.jsp>

For additional help with your uNID or password
please contact the campus help desk at 581-4000

- 2) On the "IRB Studies" tab, click on "Create a New Study Application".

Home IRB Studies IRB Staff Meetings Ancillary Reviews

IRB Studies

Create a New Study Application

In Progress Approved Closed

New Study Applications

Update Study

- **Please note:** This tutorial can also be used to complete the Update Study Application at Continuing Review!

Contacts and Title Page

1. **Principal Investigator:**
[Help?](#)

The Principal Investigator (PI) can create, edit, and submit IRB applications. The PI will also receive all study-related notifications from the ERICA system.

Email Training

a. **Position of Principal Investigator:**

Faculty

Student

Staff

Resident/Fellow

Other


Clear

If Other, describe:

 b. **Will the Principal Investigator consent participants?** Yes No Clear

1. Add the name of the principal investigator (PI) to this section.
 - a. Select the PI's position.
 - b. Indicate whether the PI will obtain consent from participants. If you answer "Yes", the PI's name will automatically appear on the Consent Process Page later in the application.

 **Who can serve as the principal investigator for a study submitted to the University of Utah IRB?**

-  Please see: http://www.research.utah.edu/irb/submissions/submit_study.html and http://www.research.utah.edu/irb/guidelines/pdf/IGS_PrincipalInvestigatorQualifications-D0909.pdf.

Contacts and Title Page

2. Contact Person(s) (if different from the PI):

Contact persons have access to edit the IRB applications and receive all notifications from the ERICA system.

[Help?](#)

Name	Email	Training
There are no items to display		

3. Internal Staff and Sub-Investigator(s) (Within the University of Utah):

Internal Staff and Sub-Investigators have read-only access to the IRB applications and do not receive notifications from the ERICA system. Add persons here who **are responsible for the design, conduct, and reporting of research.**

[Help?](#)

Name	Email	Training	Person Obtaining Consent
There are no items to display			

4. External Sub-Investigator(s) (Investigators outside the University of Utah):

[Help?](#)

External Sub-Investigator cannot view applications in ERICA and will not receive study-related notifications from the ERICA system.

[Add](#)

Last Name	First Name	Affiliation
There are no items to display		

5. Faculty Sponsor (if needed):

[Help?](#)

The Faculty Sponsor has read-only access to applications in ERICA and will receive all study-related notifications from the ERICA system.

Select...

6. Guests:

Guests can view applications in ERICA and will not receive study-related notifications from the ERICA system. If you need read Guest Access for an auditor or monitor, please contact the IRB at 801-581-3655.

[Add](#)

Last Name	First Name	E-Mail
There are no items to display		

2-6. Add your study personnel.



What access does each role have?



The [blue](#) help text under each section explains what view/edit access each role has, and whether the role will receive study-related emails from the ERICA system.



What is the definition of "Internal Staff and Sub-Investigator"?



For additional guidance about how to determine who meets the requirements of this definition, please refer to the Conflict of Interest Guidance for Investigators available at [www.research.utah.edu/irb/news/newsArchive\(PDF\)/Col_GuidanceForInvestigators-Feb2011.doc](http://www.research.utah.edu/irb/news/newsArchive(PDF)/Col_GuidanceForInvestigators-Feb2011.doc), or contact the Conflict of Interest Office at 801-581-6351.

Contacts and Title Page

7. What type of application is being submitted?

[Help?](#)

New Study Application (or Amendment/Continuing Review)

Emergency Use of a Test Article Application

Request for Non-Human Subject Research Review

[Clear](#)

8. Title Of Study:

Ensure the title matches those listed on the Protocol, Consent, and other appropriate documents.

7. Select the type of application you would like to create.
8. Add the title of the study. This title will be used on all IRB correspondence regarding this study.

Contacts and Title Page



9. Study Purposes and Objectives:

The objectives should be stated in such a way that the reader can determine the appropriateness of the study design. If appropriate, state the specific hypotheses being tested and/or study aims.

body p



10. Background and Introduction:

Identify the research area being studied and provide a review of the literature that provides the basis for understanding the objectives of the study. This review should be written such that scientists outside the investigator's area of expertise can understand the issues involved.

Any information about previous research related to this study involving animals and/or humans should be summarized. Include studies on pregnant animals if the research is conducted on pregnant women, fetuses, or neonates.

9. This section replaces the old “Brief Description of the Study” section from the application, and the “Objectives” section from the old Protocol Summary template.
10. This section corresponds with the “Background and Introduction” section from the old Protocol Summary template.

Conflict of Interest

INSTRUCTIONS:

- Please select the **Principal Investigator's** disclosure(s) for this project. In most cases, you will only select **one** disclosure.
- If the Principal Investigator has not completed a disclosure for this project, a new disclosure must be completed. **Do not** select a disclosure that is not relevant to this project.
- All disclosures for responsible staff and sub-investigators will be linked to the Principal Investigator's disclosure. You **do not** need to select multiple disclosures to include these individuals.
- All responsible staff and sub-investigators will be notified that they must complete a disclosure if they have not already done so by the time this IRB application is submitted.
- Every disclosure the PI has made will appear below, with the most recent disclosures appearing first. You may filter this list using the filter drop-down option at the top of the table or scroll through the list using the arrows at the bottom of the table.

For help using the filter option, click here: [Help?](#)

Conflict of Interest Disclosures

Principal Investigator	Title	Sponsor	CoI Disclosure	Disclosure Date
There are no items to display				
⏪ ◀ 0-0 of 0 ▶ ⏩				

- Select the Conflict of Interest Disclosure for the PI. Select only one disclosure, and ensure the title matches the title of the study as it was entered into Section 1.8.
- Read all of the **blue** help text carefully, and contact the Conflict of Interest office if you have any questions about this page.

Study Location and Sponsors

1. Department:

Select only if department listed is not correct.

INSTITUTIONAL REVIEW BOARD

Select...

Clear

2. Location of Study:

[Help?](#)

University of Utah - Main Campus (Outside the Covered Entity)

University of Utah's Covered Entity (Health sciences, hospitals, and clinics)

Primary Children's Medical Center (PCMC)

Veterans Affairs SLC Health Care System (VAMC)

Shriners Hospitals for Children Intermountain

1. Your department will automatically generate based on the information in your ERICA profile.
2. This section has been revised to include more information about what *inside* and *outside the Covered Entity* means. This section should only include locations that the University of Utah IRB is designated to review for on a regular basis. Click the [Help?](#) icon for more detailed information.

Study Location and Sponsors

3. **Is this a Multicenter Study (i.e., the study involves other sites with other PIs):**
[Help?](#)
 Yes No [Clear](#)

a. **If yes, are you the lead investigator of this study, or is this the central location for the study?**
 Yes No [Clear](#)



4. **Indicate other locations that are participating in the study for which you, as the PI, are responsible:**
This section must be completed if the University of Utah is the lead site of a multi-site study or if the University of Utah is acting as the Data Coordinating Center for other sites. Other locations may include: Other colleges or universities; Primary and secondary schools or school districts; other hospitals, clinics, or health care facilities; laboratories; businesses.

Click "Add" to complete information for each participating site. If this study does not have additional sites for which you are responsible, continue to question 5.



[Add](#)

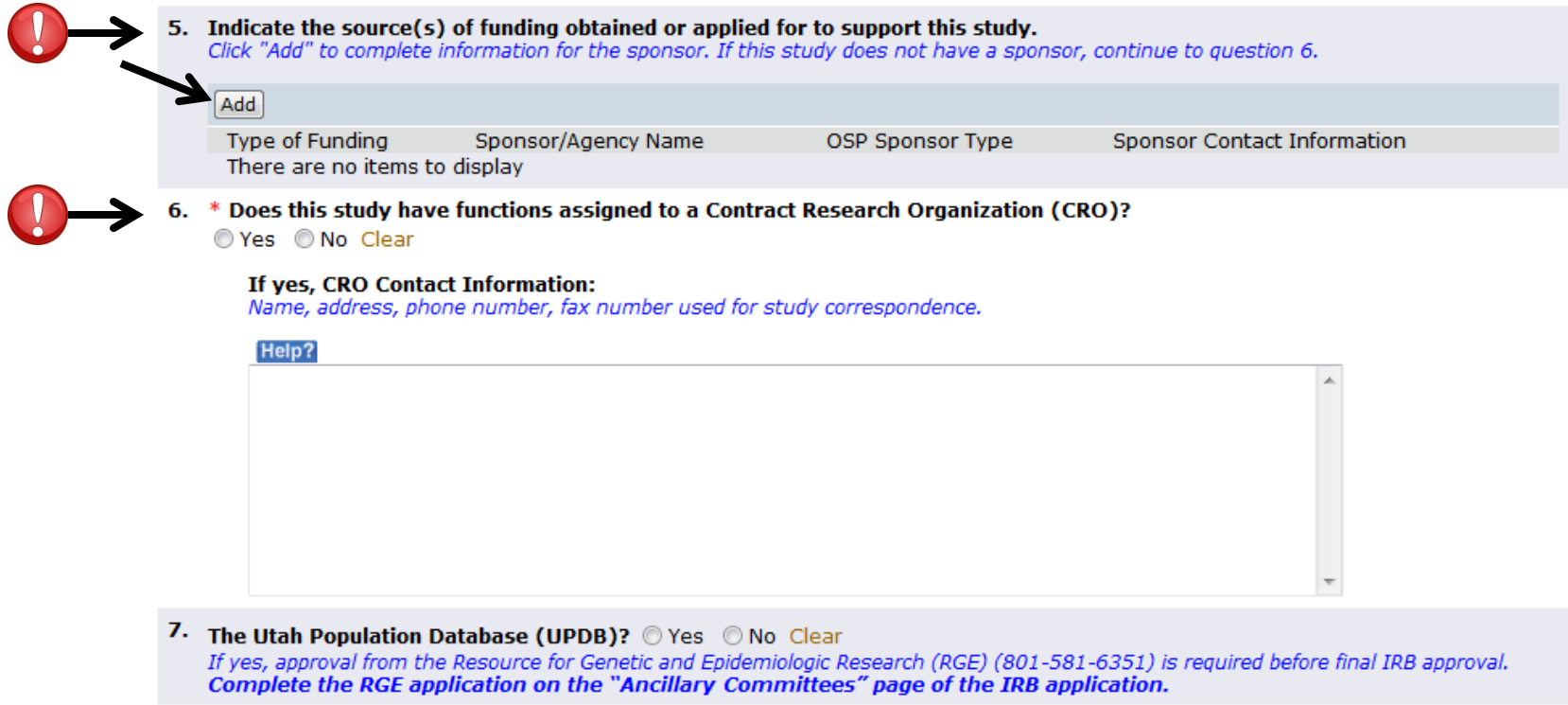
Site Name	Site Investigator	Investigator/Main Contact
There are no items to display		



a. **How will adverse events, unanticipated problems, interim results, and changes to the research be communicated between the participating sites and the Principal Investigator?**

- 3. For a definition of “multicenter study”, click on the **Help?** icon under this question.
- 4. If your study includes other sites outside of the University of Utah, click the “Add” button to add the site. This will activate a **pop-up window** where you can enter information about the site.
- 4a. Add details about the communication plan in place between you and your sites.

Study Location and Sponsors



5. **Indicate the source(s) of funding obtained or applied for to support this study.**
Click "Add" to complete information for the sponsor. If this study does not have a sponsor, continue to question 6.

Type of Funding	Sponsor/Agency Name	OSP Sponsor Type	Sponsor Contact Information
There are no items to display			

6. * **Does this study have functions assigned to a Contract Research Organization (CRO)?**
 Yes No [Clear](#)

If yes, CRO Contact Information:
Name, address, phone number, fax number used for study correspondence.

7. **The Utah Population Database (UPDB)?** Yes No [Clear](#)
If yes, approval from the Resource for Genetic and Epidemiologic Research (RGE) (801-581-6351) is required before final IRB approval. Complete the RGE application on the "Ancillary Committees" page of the IRB application.

- 5. If your study has a sponsor, a **pop-up window** will generate when you click "Add". You can enter data about your sponsor(s) there.
- 6. If you have a CRO, please make sure the contact information entered here is accurate.
- 7. If you click "Yes" to this question, the RGE Application will automatically generate as you click "Continue" through the application.

Emergency Use Description


NOTE: Do not use this form for single patients that are not in life-threatening situations (sometimes called "compassionate use protocols"). For single patient protocols where there is sufficient time to obtain IRB review, you must submit a New Study Application which will be reviewed and approved by the convened IRB. For urgent situations, contact the IRB office 581-3655 to make arrangements for review at the next convened panel.

1. Is this a proposed emergency use or a reported emergency use?

Proposed Emergency Use (notification to the IRB prior to emergency use of a test article.)

Reported Emergency Use (report to the IRB after emergency use of a test article.)

Clear

2. Indicate the date the test article will be (was) administered: 

3. Location of emergency use (e.g. Huntsman Cancer Institute, Moran Eye Center, Primary Children's Medical Center, etc.):

- This page only generates if you have selected “Emergency Use of a Test Article” under “Type of Application” on the **Contacts and Title Page**.
 - If your study does **not** involve a single patient in a life-threatening situation, please go back and change your answer in that section to “New Study Application”.
- Read all of the **blue** help text carefully.
- **Contact the IRB immediately** if you anticipate submitting an Emergency Use application.

Non-Human Subjects Research

The IRB will make the final determination of Non-Human Subject Research on all submitted projects. If the information provided on this page indicates that the project may constitute human subject research, completion of the full New Study Application will be required.

1. Type of Project:

Select all that apply

[HELP?](#)

- Program Evaluation
- Surveillance Activities
- Quality Improvement
- Case Report
(Click Help for IRB policy)
- De-Identified Data/Sample Analysis
- Secondary Analysis of a Publicly Available Dataset
(Click Help for IRB policy)
- Other

If Other, explain:

- This page only generates if you have selected “Request for Non-Human Subjects Research Review” under “Type of Application” on the **Contacts and Title Page**.
 - If your study **does** involve human subject research, please go back and change your answer in that section to “New Study Application”.
- Read all of the **blue** help text carefully.
- The application will skip to the **Documents and Attachments** page after this page is complete.

Participants

1. Ages of Participants:

<input type="checkbox"/> Less than 7 years old	(Parental permission form needed)
<input type="checkbox"/> 7 to 17 years old	(Parental permission and assent form needed)
<input type="checkbox"/> 18 and older	(Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):

3. Indicate any vulnerable participant groups (other than children) included:

Tip?
Select only those groups which you are specifically studying or which have a high likelihood of being included in this project.

None

Pregnant women and fetuses (CFR Part 46, Subpart B)

Neonates (45 CFR Part 46, Subpart B)

Prisoners (CFR Part 46, Subpart)

Mentally disabled

Individuals with Cognitive or Decisional Impairment

Wards of state

Students, staff, or faculty of the research institution

Other

If "Other", please specify:

If "None" and no children are involved, answer the following question.
Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?

Yes No [Clear](#)

- These questions are all the same as the old version of the application.



Why does the IRB ask for the age of the participants twice?

- Selections in Question #1 generate pages specifically related to different requirements for obtaining informed consent, parental permission, and assent. The selection in that section helps the IRB determine which consent forms may be required for your study.
- Question #2 helps the IRB further focus the review. For example, where “18 and older” actually means “60 and older”, or “Less than 7 years old” actually means “0-30 days old”, etc.



I don't want to exclude any potential participants, but my study doesn't specifically focus on any of the listed vulnerable populations. Should I select all of the groups just in case?

- No, only select groups that are either specifically targeted by your inclusion criteria, or that may be vulnerable by virtue of being in your study. For example, “pregnant women” may be vulnerable in a clinical study about pregnancy, but may not be in a survey study about an unrelated condition where the only inclusion criteria is women over age 18.

Participants

4. Number of participants to be enrolled during the entire study:

Provide specific numbers if possible. Use of records and databases containing human information should also be considered in the number of participants.

[Help?](#)

At Utah:

All Centers:

4. Add the number of participants that will be included in your study.

- **Remember:** Data *about* people are still considered “human subjects” by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still should enter the number of charts as your “participants”.
- If your study is **not** multi-center, the “All Centers” total should match the “At Utah” total.
- If the study **is** multicenter, the “All Centers” total should be greater than the “At Utah” total.
- “At Utah” generally means participants who are recruited from or enrolled at University of Utah sites, or it can also refer to participants the University of Utah IRB is responsible for protecting. The definition is intended to be flexible to accommodate unpredictable study designs. The investigator is responsible for ensuring the application defines where participants are coming from.

Participants



5. Characteristics of Participants/Inclusion Criteria:

[Help?](#)

Participant-entry criteria should be as detailed as necessary to define the participant population under study and, for clinical studies, to reduce confounding treatments or diseases. Precise criteria for age, gender, or another other factors (e.g. diagnoses, extremes in signs or symptoms, etc.) should be included.

body p



6. Participants Exclusion Criteria:

[Help?](#)

Specific exclusion criteria should be listed which could interfere with the study design or place a participant at risk during the study. If no exclusion criteria, please state "None."

5-6. These sections correspond with the "Participant Selection Criteria" section from the old Protocol Summary template.

Participants


7. **Is a substantial percentage of the participant population anticipated to be non-English speaking?**

If the question is not applicable (e.g., chart or record review), please select "no."

Yes No [Clear](#)

7. If a substantial percentage of your participants will not speak English, it is probable that the IRB will require full translations of the consent documents and study instruments.

 **What is a “substantial percentage” of the participant population?**

 In general, the IRB considers more than 5% of the local recruitment goal to constitute a “significant percentage”.

Vulnerable Populations

1. How does the nature of the research require or justify using the proposed subject population?

2. Would it be possible to conduct the study with other, less vulnerable subjects?

Yes No [Clear](#)

If yes, justify the inclusion of vulnerable subjects:

3. Is this population being included primarily for the convenience of the researcher?

Yes No [Clear](#)

If yes, explain:

- These questions are all the same as the old version of the application.

Vulnerable Populations

4. Does the scientific merit of the study warrant the inclusion of subjects who may either be susceptible to pressure or who are already burdened?

[HELP?](#)

Yes No [Clear](#)

- This question is the same as the old version of the application.
- The [Help?](#) button on this page includes an explanation of the purpose of this question:

“The purpose of this question is to determine whether the investigator believes the study has enough merit to including potentially vulnerable participants.

*“Answering “Yes” means you **do** believe your study has enough merit to justify including participants who may be vulnerable. Answering “No” means you **do not** believe your study has enough merit to justify including vulnerable participants.*

“If you believe you must answer “No,” you must re-examine the inclusion of vulnerable individuals, as the IRB may not be able to justify approving their inclusion in your research in that case.”

Study Information

1. Design of Study (select all that apply):

- Secondary/Archival Data Analysis
- Survey/Questionnaire Research
- Interviews and Focus Groups
- Oral History
- Observational Research
- Retrospective Chart Review
- Prospective Clinical Research
- Double Blind
- Placebo Controlled
- Randomized
- Phase I Clinical Trial
- Phase II Clinical Trial
- Phase III Clinical Trial
- Phase IV Clinical Trial
- Open- Label
- Other

If Other, describe:

- This question is the same as the old version of the application.

? *How does my answer to this question help the IRB?*

- ?** Selections in this section of the application help the IRB categorize your application for future queries. Also, selecting a design common to clinical trials (e.g. Prospective Clinical Research, Randomized, etc.) will automatically generate the uTRAC application, which is required for projects that may involve billing.

Study Information

2. Does your study involve the use of any placebo?

Yes No [Clear](#)



3. Length of entire study, from initiation through closeout:

Include the amount of time expected to enroll participants and complete all data analysis.

- These questions are the same as the old version of the application.
- 3. This question has been re-worded in an attempt to clarify the purpose of the question. This question is not asking how long the participants will be in the study, or how long it will take a participant to complete the study procedures. The IRB would like an idea of how long it will have oversight over your project.
 - If at continuing review the study is not progressing at a rate that will allow for completion in the anticipated time frame, and amendment may be submitted to increase the length of the study.

Study Information



4. How will participants be recruited or identified for inclusion in the study?

The IRB does not allow cold-calling as a method of recruitment. All recruitment materials must be attached to the Documents and Attachments page.

a. Select all methods that will be used:

- In-person contact (e.g., patients, students, etc.)
- Referrals
- Written or electronic record review
- Written advertising (flyers, brochures, website postings, newspaper ads, etc.)
- Audio advertising (radio and television advertisements, etc.)
The ad script and audio/video recording must be attached to the Documents and Attachments page.
- From a database for which participants have given prior permission to be contracted for research studies
- Other

b. Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):

Indicate that participants will not be contacted if the study only involves a waiver of informed consent for a retrospective chart/data review.

4a. Select all of the methods you will use to recruit or identify participants.

4b. There are several questions that must each be addressed in order for this question to be considered complete. Please read carefully and address each question.

Study Information

5. How will consent be obtained?

If your study uses deception, attach the consent document and debriefing statement to the Documents and Attachments page. Check both Informed Consent Process and Waiver or Alteration of Informed Consent.



- Informed Consent Process (with or without a document)
This process may or may not include a consent document. Also check if requesting that documentation of informed consent be waived (e.g. consent process without signature, questionnaire cover letter, web-based consent, etc.)
- Waiver or Alteration of Informed Consent
Alteration of consent requests that required element(s) of consent template be removed or altered (e.g. use of deception in consent)

5. This question has been modified slightly to account for non-conventional consent processes. The answer is no longer dependent on whether an informed consent document will be used, but rather whether contact with the participant is anticipated. If you will have contact with participants, it is likely “Informed Consent Process” should be selected.
 - You may select both options if they are both applicable to your study.
 - Read all of the [blue](#) help text carefully.

Study Information



6. Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

The investigational activities, treatments, or procedures must be clearly detailed as to how and when they will be performed. For clinical studies, this includes study visits, drug treatments, randomization, and the procedures that are part of standard of care. For clinical studies, a distinction should be made between the procedures for treatment evaluation versus procedures for safety evaluation. Treatment endpoints must be defined as well as interim procedures for dealing with adverse events.



7. Are all procedures for research purposes only (non-standard or non-standard of care procedures)?

Yes No [Clear](#)

If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

6-7. These sections correspond with the “Study Procedures” section from the old Protocol Summary template.

- Read all of the [blue](#) help text carefully.

Study Information



8. Is there a safety monitoring plan for this study?

All studies determined by the IRB to be more than minimal risk must have a safety monitoring plan. Click Help for more information about risk and safety monitoring plans.

[HELP?](#)

Yes No [Clear](#)



9. Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.

8. The [Help?](#) button in this section will help you make a preliminary determination as to whether your study should have a safety plan. If the pre-reviewer or the board disagrees with your assessment, you will be asked to revise this question and provide a plan. You are encouraged to contact the IRB if you are not sure whether your study is minimal risk or greater than minimal risk.
9. This section corresponds with the “Statistical Methods” section from the old Protocol Summary template.

Request for Waiver or Alteration of Consent ←

Request for Waiver or Alteration of Consent

Instructions:

- Click "Add" below to add a new waiver request to this application.
- Click the waiver name link to edit a waiver that has already been created.
- To delete a waiver request, contact the IRB.

Requested Waivers

Add

Date Created	Type of Request
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There are no items to display

Request for Waiver or Alteration of Consent

1. Purpose of the Waiver Request:

Briefly state or summarize the purpose of this waiver (e.g., chart review for all data collection, removing a consent element, using deception procedures, etc.)

- Multiple waivers or alterations can now be requested for one study.
- Click the "Add" button to add a Waiver or Alteration request. A pop-up window will appear where you can fill out the request. Click "OK" at the end of the request to add it to your study.
- Each request must be filled out separately; one page cannot be used for more than one request.

Request for Waiver or Alteration of Consent

4. Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":

- *Example: "If consent were a requirement, the investigator would be unable to obtain consent for about 30% of participants because they have moved and lost to follow-up and the contact information in our database is incorrect. With a loss of 30% of participants, the investigator would be unable to answer the research question."*
- *Example: "If consent were a requirement, the investigator would have to obtain consent on about 100,000 individuals which would require about 10 years of time for the two person staff to accomplish assuming that the staff spend 50% of their time on obtaining consent. The degree of effort would make it not practicable to conduct the research."*

- This question is where you are asked to justify your request for the waiver or alteration of consent.
- This question is critical in assisting the Board with determining whether or not the request is justifiable. Please create a persuasive and detailed argument specific for your study that would demonstrate why it would not be possible to obtain consent and still successfully complete the study.
 - Please note that inconvenience and expense to the research study are not sufficient justification to waive consent. The primary basis of this criterion is related to whether the *scientific validity* of the study will be significantly compromised if consent is required.
 - *For example*, in some cases, it may be argued that if the study team was to attempt to obtain consent from each participant, participant refusals and/or failure to establish in-person contact with participants due to incorrect, outdated, or incomplete contact information would create large gaps in sampling and diminished representativeness of the data.
- The **blue** help text examples should **NOT** routinely be copied verbatim into your waiver request. Justifications for your request should be carefully customized for your study.

Consent Process Page



The RATS Course titled, "Informed Consent", is offered for more instruction about the consent process. Go to <https://education.research.utah.edu/> to register.



1. The following investigators and internal staff will obtain consent (as indicated on the Contacts and Title Page):

There are no items to display

List by name, role, and affiliation any other who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).

In general, persons affiliated with the University of Utah, the VA, PCMC, or Shriners Hospital should be listed in section 1.3 if they will be obtaining consent.

1. The first section of question 1 will display the investigators and internal staff who will obtain consent as indicated on the Contacts and Title page. In order to change the names that display in this list, you must change the investigators and internal staff on the Contacts and Title page.

A text box is also provided so that you can list others who will obtain consent for your study team, if these people cannot be listed on the Contacts and Title page as investigators and internal staff.



Persons obtaining consent must complete Human Subject Research Training. The IRB will not issue final approval on the study until this is complete.



Persons obtaining consent who are affiliated with the University of Utah (faculty, staff, students), must complete a conflict of interest disclosure for the study. The IRB will not complete the review of the study until this is complete.

Consent Process Page

2. Describe the location(s) where consent will be obtained.

3. Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).

- 2. List and describe all of the locations where consent will be obtained. This should include in-person, online, telephone, email, and other consent processes, as applicable.
- 3. Describe the entire consent process from beginning to end. It may be helpful to outline the process as a step-by-step list. Include a description of the timing of consent, including when participants will be approached and how long participants will have to make a decision about dissertation.

Consent Process Page

4. Describe what measures will be taken to minimize the possibility of coercion or undue influence.

5. Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.

4. Describe the measures you will use such that participants do not feel forced or pressured to participate. This may include
 - a. Offering a reasonable amount of compensation
 - b. Emphasizing that participating is voluntary
 - c. Allowing the participant enough time to consider participation – i.e. not rushing him/her into a decision
 - d. Discussing other options available to the participant outside of the research study
5. State how you ensure that participants are given enough time to discuss the study with the a member of the study team. Also state who you will ensure that all of their question are answered during the consent process.

Consent Process Page

6. Will a legally authorized representative (LAR) be used?


Yes No [Clear](#)


If yes, describe when the use of an LAR might arise in this study population and what the frequency of an LAR will be during the enrollment period.

Please include LAR signature block at the end of the consent document.


6. Indicate if a legally authorized representative (LAR) will be asked to provide consent for cognitively impaired or mentally disabled adults who may be enrolled in this study. If the study will not include cognitively impaired or mentally disabled adults, click “No”. If “Yes,” then describe the situation(s) when you will use an LAR to obtain consent, including the anticipated frequency of the situation(s) occurring during your study.

You must also complete the Additional Consent Considerations page in the application, which will automatically generate as you click “Continue” through the application. You must also include a signature block for the LAR on the consent document(s) used in the study. A copy of the signature block can be found in the IRB Consent Template on the IRB website.

 For the purposes of research, an LAR is “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research” (45 CFR 46.102, 21 CFR 50.3(1))


 Utah State Law specifies that the following individuals can act as an LAR for research purposes:

- Any married person for a spouse
- Any person 18 years of age or older for his or her parent who is unable by reason of age, physical or mental condition, to provide such consent
- Any individual given power to make decision for another person through power of attorney documents

 For more information about LARs, refer to the following guidance:

http://www.research.utah.edu/irb/guidelines/investigator_guidance.html

 IGS: Cognitively Impaired Individuals (Non-VA)

 IGS: VA Research Involving Cognitively Impaired Individuals

Consent Process Page

7. Will a language other than English be used to obtain consent?

Yes No [Clear](#)

If yes, complete the following:

a. Please indicate which form will be used:

A consent document must be provided in the language understandable to the subject

- A translated consent document.
- A translated short form with an English long form.

[Clear](#)

If using the short form, please provide justification for why a full, translated consent document will not be used:

b. Describe whether translation services will be used for the consent process and how the consent process will be conducted?

7. Indicate if a language other than English will be used to obtain consent by selecting Yes or No. If yes, see the next pages of the tutorial for help with parts a and b.

Consent Process Page

a. Please indicate which form will be used:

A consent document must be provided in the language understandable to the subject

- A translated consent document.
- A translated short form with an English long form.

Clear

If using the short form, please provide justification for why a full, translated consent document will not be used:

Question 7a:

- Indicate which type of consent form(s) you will use for the consent process with non-English speaking participants. If you choose to use the translated short form option, you must provide justification for its use.

All translations of the full consent form or the short form must be attached on the Documents and Attachments page. You must also attach a copy of the translation certificate, signed by the person providing document translation. A template for the translation certificate is available on the IRB website at <http://www.research.utah.edu/irb/forms/hipaa/index.html>.

- ① Selecting “A translated consent document” means that you will have the full consent form translated from English into the language needed. This is the method preferred by the IRB, as it provides the participant with all of the consent information written in their own language.
- ① Selecting “A translated short form with an English long form” means that you will have a short summary page translated into the language needed, called a “short form”, and will use the full consent form in English as a guide to discuss the consent with the participant. Because this is not the preferred method, you must justify why a full consent document cannot be translated.
 - ① For more information about use of the short form with an English long form, read the Short Form Consent Instructions for Use on the IRB website: <http://www.research.utah.edu/irb/forms/hipaa/index.html>.

Consent Process Page

b. Describe whether translation services will be used for the consent process and how the consent process will be conducted?



Question 7b:

- Describe the translation and interpretation services that will be used to verbally communicate with the participant in his/her language. Include a description of how the study will be explained, how questions will be answered, how the consent form will be signed by the appropriate parties, and how continued communication with the participant will occur. This may include
 - Use of hospital interpreters
 - Use of local authorities and leaders if you are in a foreign country
 - Use of a native speaker or trained interpreter who is a member of the study team

Consent Process Page

8. Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?

If the study is subject to FDA regulation, a waiver of the requirement to obtain documentation of consent is not allowed.

Yes No [Clear](#)

If yes, complete the following:

a. Explain why the waiver of consent documentation is being requested.

b. Justification for the waiver is one of the following:


The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participant's wishes will govern.

You must attach a description of the information that would be disclosed or a consent document for participants who wish to have their consent documented to the documents and attachments page.

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

8. Indicate if you will be using a waiver of **documentation** of consent by selecting Yes or No. Yes means that you will be obtaining consent from participants, but you will **not** be obtaining a signature from the participants.
- If yes, explain why this type of waiver is needed/requested in order to obtain consent from participants.
 - If yes, justify the use of the waiver by selecting the option that is applicable to your study.

Generally, the IRB requires that a written summary (consent cover letter) of the study be provided to the participants, even though signatures will not be obtained. The written summary must be attached to the Documents and Attachments page under the Consent Documents section. A Consent Cover Letter Template is available on the IRB website at <http://www.research.utah.edu/irb/forms/hipaa/index.html>.

 *Waivers of documentation of consent are only allowable for minimal risk studies.*

Additional Consent Considerations Page

Individuals with Cognitive or Decisional Impairment or Mental Disability



For more information about enrolling individuals with cognitive impairment or mental disability, refer to the following guidance:

http://www.research.utah.edu/irb/guidelines/investigator_guidance.html

- IGS: Cognitively Impaired Individuals (Non-VA)
- IGS: VA Research Involving Cognitively

1. Please describe the nature of the cognitive/decisional impairment or mental disability and how this affects decision-making ability:

A large, empty rectangular text box with a thin black border, intended for the respondent to provide details about cognitive or decisional impairment.

1. Describe the nature of the cognitive/decisional impairment or mental disability. Include a description of how will affect a participants ability to make decisions for the study.

It may also be relevant to describe how the investigator will assess the participants ability to understand information about the study and make decisions for the study. In cases of severe mental disability, this assessment will consist of verifying the diagnosis. However, in less severe cases, psychiatric consultation or written assessments of cognitive ability may be used.

Additional Consent Considerations Page

Individuals with Cognitive or Decisional Impairment or Mental Disability

2. In the opinion of the principal investigator, is an assent process appropriate for these individuals, along with informed consent from a legal representative?

Yes No [Clear](#)

Please justify your response:

2. Indicate whether or not an assent process would be appropriate for the individuals with cognitive impairment, along with full informed consent from a legal representative. Assent allows the individual to participate in the decision to participate, while ensuring that a legal representative can assist with the decision utilizing the full information from the consent process. Justify your response in the text box provided.

It may be relevant to describe how the investigator will assess the participants ability to understand information about the study and make decisions for the study. In cases of severe mental disability, this assessment will consist of verifying the diagnosis. However, in less severe cases, psychiatric consultation or written assessments of cognitive ability may be used.

Assent documents used to obtain assent from these individuals must be attached to the Documents and Attachments page.

Additional Consent Considerations Page

Individuals with Cognitive or Decisional Impairment or Mental Disability

3. In the opinion of the principal investigator, is it possible that cognitively/decisionally impaired participants may recover an adequate amount of decision-making capacity during the course of the study (N/A for mentally disabled persons)?

- Yes
 No
 N/A

Clear

If yes, are there plans to obtain full informed consent from the participant at that time?

- Yes No Clear

Please justify your response:

3. Indicate whether or not the cognitively/decisionally impaired participants may recover an adequate amount of decision-making capacity during the course of the study.
- a. If yes, indicate if there are plans to obtain full informed consent from the participant at that time. Justify your response in the text box provided.

Generally, the IRB requires that participants should be given the opportunity to provide consent for themselves if they become cognitively able.

Placebo Justification

Placebo Justification

1. Placebo use may typically only be justified by one of the following situations. Please check the appropriate box:

<input type="checkbox"/>	This trial requires a placebo-only arm although some effective treatment exists <i>(press continue to complete placebo-only justification page)</i>
<input type="checkbox"/>	Any placebo use in this trial is in addition to all usual and standard therapy
<input type="checkbox"/>	The condition being studied is expected to have minimal or no risks for serious suffering, morbidity, or mortality.
<input type="checkbox"/>	Existing therapy previously failed for, or is refused by, all participants <i>(document relevant research below and discuss in consent form)</i>
<input type="checkbox"/>	No effective current therapy exists for the condition under study <i>(document relevant research below)</i>
<input type="checkbox"/>	Best evidence questions the effectiveness of all existing therapy <i>(document relevant research below)</i>
<input type="checkbox"/>	Current therapy is considered to have a negative therapeutic index <i>(document relevant research below)</i>

2. For any choice other than the first (placebo-only design) please provide a simple explanation to justify your rationale. Document relevant research or authoritative expert review if appropriate:

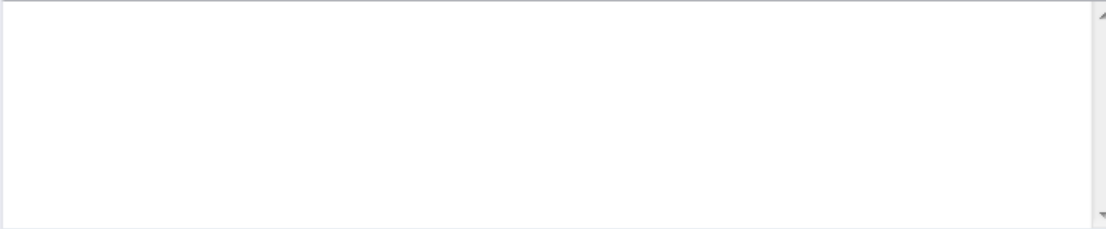
- This page only generates if you have indicated on the Study Information page that your study includes a placebo.
- The IRB may determine that a placebo design is not acceptable if the inclusion of placebo is not adequately justified by the investigator. This page is where justification for the use of placebo should be included.

Placebo-Only Justification

Placebo-Only Justification




Justification Requirements for the Use of a Placebo-Only Design

1. Provide an explicit justification for the use of a placebo-only arm, directed at helping the IRB adequately evaluate the risk/benefit ratio. The justification must include both the scientific rationale for the use of the placebo-only treatment arm and a discussion of possible increased risk to the subjects who will be assigned to that arm. Discussion of risk must include attention to increased severity of disease and complications as well as potential for death, disability, morbidity or significant deterioration of functioning in family, professional/occupational, social and/or significant roles, when relevant.



- Placebo-only designs often elicit discussion from the convened IRB, so additional justification for the use of placebo in these cases is required to provide the IRB with as much information as possible to determine whether the placebo-only design is approvable.
- The IRB may determine that a placebo design is not acceptable if the inclusion of placebo is not adequately justified by the investigator. This page is where justification for the use of placebo should be included.

Data Monitoring Plan Page ← As of 2012: This is a new page with some new questions.

-  *The purpose of data monitoring is ensure the integrity of the research data, adherence to the approved research plan, and that privacy and confidentiality risks are minimized. The complexity of a data monitoring plan depends on the complexity and risk of the study. You should design a monitoring plan that is suitable and realistic for your project.*
-  *The IRB has self-assessment forms available for biomedical and social/behavioral studies to guide you through the process, available at [LINK].*
-  *The RATS Course titled, “Data and Safety Monitoring: Plans, Boards, and Committees”, is offered for more instruction about the monitoring process. Go to <https://education.research.utah.edu/> to register.*


1. Privacy Protections: Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

Select all that apply:

- The research intervention is conducted in a private place
- Discussing the study with participants individually instead of in front of a group
- The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected
(can be used for research with no participant contact, e.g., chart reviews or secondary data analysis)
- De-identification of photos, audio tapes, or video tapes of the participant that will be made during the study
- Allowing for anonymous submission of surveys and questionnaires
- Other or additional details (specify):

Other or additional details (specify):

1. Select and/or describe the privacy protections that will be used for the study.

-  *For more information about the definition of privacy and selecting appropriate privacy protections, refer to the following guidance: Privacy and Confidentiality in Research - http://www.research.utah.edu/irb/guidelines/investigator_guidance.html .*

Data Monitoring Plan Page ← As of 2012: This is a new page with some new questions.

- 2. Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**


Select all that apply:

- Storing research data on password protected computers or in locked cabinets or offices
- Participant identifiers will be stored separately from the coded, participant data
- Complete de-identification of study data
- All data that will be transferred or transported outside of the institution will be encrypted
- Destroying photos, audio tapes, or video tapes at the end of the study
- A Certificate of Confidentiality (from the NIH) will be used
- Other or additional details (specify):

Other or additional details (specify):

2. Select and/or describe the confidentiality protections that will be used for the study.

 *For more information about the definition of confidentiality and selecting appropriate confidentiality protections, refer to the following guidance: [Privacy and Confidentiality in Research - http://www.research.utah.edu/irb/guidelines/investigator_guidance.html](http://www.research.utah.edu/irb/guidelines/investigator_guidance.html).*

Data Monitoring Plan Page ←  As of 2012: This is a new page with some new questions.

3. Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?

Yes No [Clear](#)

If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

3. Indicate if any images or recordings will be made of the participants during the study by selecting Yes or No.
 - a. If yes, describe how the images or recordings will be handled and stored once they are created. It may be helpful to include a step-by-step list of the handling/storage process that will be used until the end of the study.

Data Monitoring Plan Page ← As of 2012: This is a new page with some new questions.

4. How will study data and documentation be monitored throughout the study?

Select all that apply:

[HELP?](#)

Periodic review and confirmation of participant eligibility

Periodic review of informed consent documentation

This may include

- *Verifying there is an original signed and dated consent document for every participant*
 - *Verifying participants signed a non-expired consent document*
 - *Verifying parental permission or consent from a legally authorized representative was obtained correctly*
 - *Verifying the consent process was conducted and documented appropriately for non-English speakers*

Periodic review of the transfer/transcription of data from the original source to the research record

This may include

- *Verifying data was entered correctly into the research database*
 - *Verifying case report forms (CRFs) are completed correctly*
 - *Verifying transcripts were properly recorded*

Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

Other or additional details (specify):

Other additional details (specify):

4. Select and/or describe the how study data and documentation will be monitored throughout the study. Use the blue help text and the HELP? button for more information.

 *The IRB needs to know how study data and documentation will be monitored for the following reasons:*

- To ensure that the study team can identify and correct problems and deviations promptly
- To ensure that the study team can collect valid and accurate data according to the approved protocol
- To ensure that proper problem and deviation reporting can occur throughout the study

Data Monitoring Plan Page ← As of 2012: This is a new page with some new questions.

5. Who will be the primary monitor the study data and documentation?

Select all that apply:

- Principal Investigator
- Study Coordinator or Research Nurse
- Research Assistant
- Study Monitor or Contract Research Organization (CRO)
- Independent Physician, Faculty or Staff Member
- Data (and safety) Monitoring Board or Committee
- Other or additional details (specify):

Other or additional details (specify):

6. How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?

- 5. Select and/or describe who will primarily be responsible for the study data and documentation.
- 6. Indicate how often the study team plans to monitor the data throughout the course of the study.

Safety Monitoring Plan Page ← As of 2012: This is a new page with all new questions.

- ① *A safety monitoring plan must be designed for greater than minimal risk studies in order to minimize threats to the safety and welfare of the research participants.*
- ① *For studies with a Data and Safety Monitoring Board (DSMB), use the DSMB Charter or review plan to complete the questions on this page.*
- ① *For more information about when to use a data and safety monitoring board or committee (DSMB/C) or when to use an independent versus internal DSMB/C, use the HELP? button on question 1.*
- ① *Refer to the following policies, guidance, and resources for more information about safety monitoring:*
 - *Investigator Guidance Series: Data and Safety Monitoring - http://www.research.utah.edu/irb/guidelines/investigator_guidance.html*
 - *VHA Handbook 120005, page 28 - http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2326*
 - *RATS Class: Data and Safety Monitoring – Plans, Boards, and Committees - <https://education.research.utah.edu/classes.jsp>*

Safety Monitoring Plan Page ← As of 2012: This is a new page with all new questions.

1. Describe the safety monitoring entity for this study:

a. Select all that apply:

[HELP?](#)

Principal Investigator

Independent Physician or Faculty Member


Safety Monitor

Data and Safety Monitoring Board or Committee
Click Help for more information about requirements for a board or committee.

Other (specify):

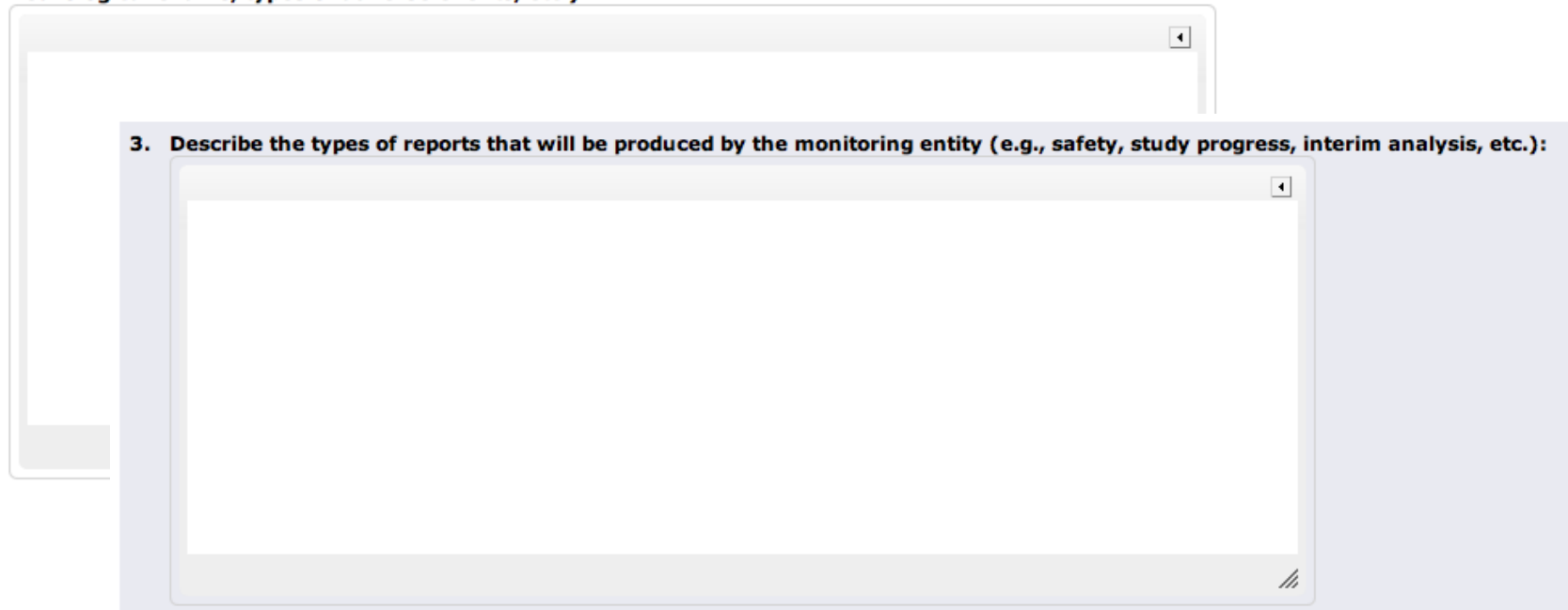
Please specify:

b. Describe the expertise and affiliation of the individual(s) selected above who will monitor the study:

1. Select and/or describe who will primarily be responsible for the safety of the study.
 - a) For each individual responsible for monitoring safety, describe his/her expertise and affiliation
-  *For more information about when to use a data and safety monitoring board or committee (DSMB/C) or when to use an independent versus internal DSMB/C, use the HELP? button on question 1.*

Safety Monitoring Plan Page ← As of 2012: This is a new page with all new questions.

2. Describe the data and events that will be monitored and reviewed (e.g., vital signs, safety blood labs, depression scales, neurological exams, types of adverse events, etc.):



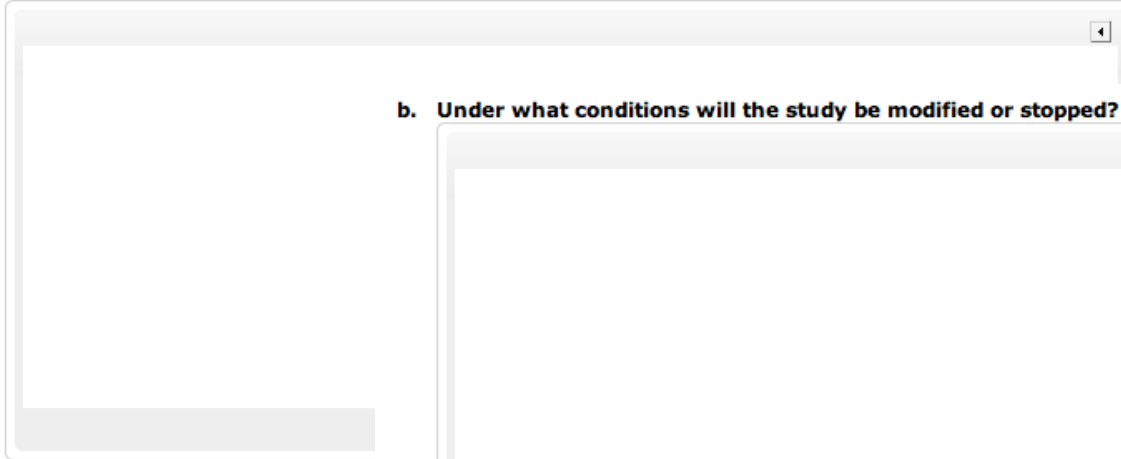
The image shows a screenshot of a web form. The form is titled "3. Describe the types of reports that will be produced by the monitoring entity (e.g., safety, study progress, interim analysis, etc.):". The form is currently empty, with a large white rectangular area for text entry. The form has a light blue border and a small "X" icon in the top right corner. The background of the form is a light blue color.

2. Describe the data and events that will be monitored and reviewed for safety. This should be data points collected during the course of the study.
3. Describe the types of reports that will be produced by the monitoring entity. Note that the monitoring entity may address many items in one report.
 - ❓ Safety reports describe the analysis of adverse events and other items which may affect participant safety.
 - ❓ Study progress reports describe the status of the study, which may include enrollment status, clarification of elements of the protocol, start-up and close-out of participating sites, etc.
 - ❓ Interim analysis reports describe the analysis of data prior to finalizing data collection. This analysis helps to identify if the study is projected to meet its aims and if the results are likely to be positive or negative.

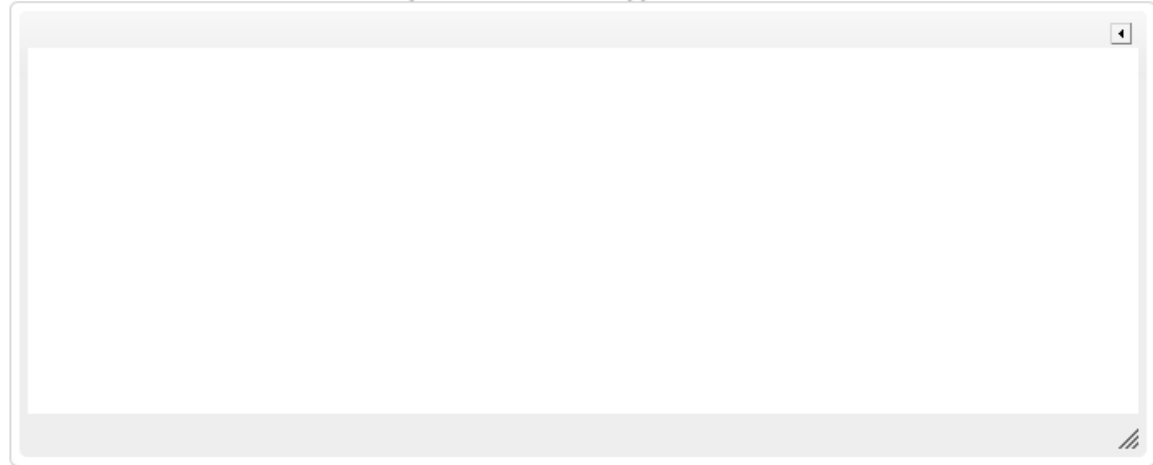
Safety Monitoring Plan Page ← As of 2012: This is a new page with all new questions.

4. Describe the specific triggers or stopping rules for the study:

a. Under what conditions will a participant be withdrawn from the study?







b. Under what conditions will the study be modified or stopped?



4. Describe the specific triggers or stopping rules that would initiate

- a) Withdrawing a participant from the study
- b) Modifying or stopping the study

-  If the protocol has eligibility criteria for a participation to *remain* in a study throughout certain study stages, this should be described in question 4a.
-  At the beginning of a study, it may be unclear exactly which events and problems will cause a participant to be withdrawn or cause the study to be stopped or modified. However, it may be appropriate to state that the following would be considered a stopping rule:
 -  An increase in the frequency, nature, or severity of adverse events beyond what was expected when the protocol was initiated.
 -  No clear benefit to participants can be seen (futility).


Safety Monitoring Plan Page ← As of 2012: This is a new page with all new questions.

5. How often will the data and events be reviewed by the monitoring entity (e.g., after every 5 submits, monthly, quarterly, twice a year, etc.)?

The monitoring frequency should be commensurate with the level of risk to the participants.



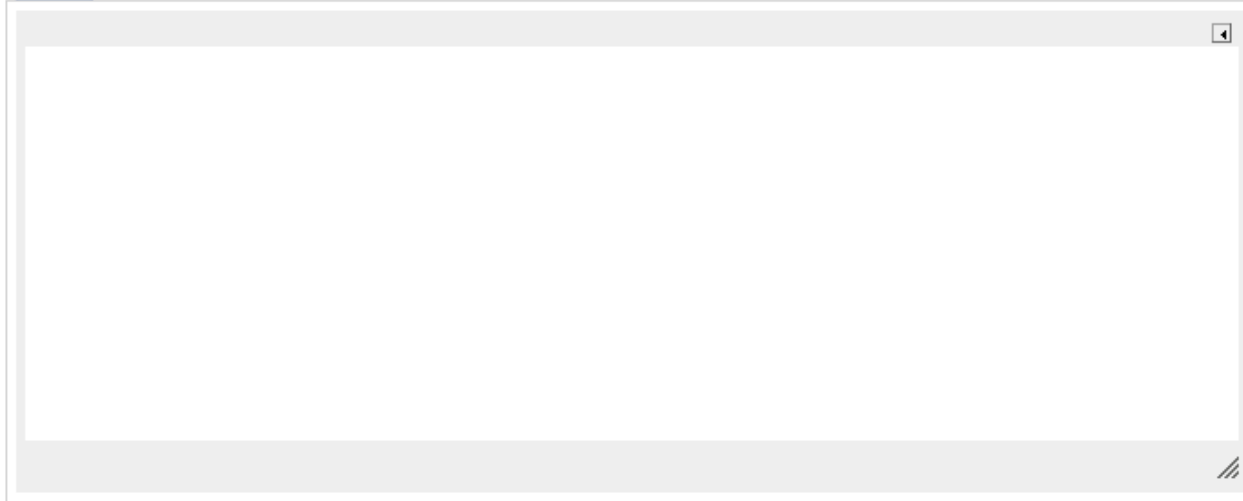
5. Indicate the frequency that safety monitoring will occur by the monitoring entity.

 If the protocol should describe the planned frequency for safety monitoring, however, this frequency may change as the study progresses. Changed to the frequency should be justified and submitted to the IRB via an amendment.

Risks and Benefits

2. Describe the potential benefits to society AND to participants (do not include compensation):

HELP?



- The questions on this page are all the same as the old version of the application. Some questions that previously appeared on this page have been moved to more appropriate sections of the application.
- 2. This question asks the investigator to describe the potential benefits of the research to society **AND** to participants. Please provide information about the potential benefits to both groups. If there is no anticipated direct benefit to participants, please state this.
 - *For example, "Potential benefits to society include an increased understanding about the condition under study. We hope to be able to help patients with this disease in the future by contributing to the general knowledge about the disease. Although we hope participants will benefit eventually, we do not anticipate any direct benefit to participants for being in this study."*

HIPAA and the Covered Entity



For more information about the HIPAA Privacy Rule & Authorization, please review the Investigator Guidance Series (IGS) document titled, "HIPAA Privacy Rule & Authorization" on the A-Z Index.

HIPAA and the Covered Entity

1. Does this study involve Protected Health Information (PHI) or de-identified health information?
[HELP?](#)
 Yes No [Clear](#)

a. If yes, select the method(s) of authorization that will be used:

(Consent and) Authorization Document

Waiver or Alteration of Authorization
(If you are using medical records for screening or recruitment, please request a Waiver of Authorization)

Limited data set

De-identified

If needed, select De-Identification Form:

- This page only generates if you have indicated the study will take place inside the covered entity.
- The [Help?](#) button on this page includes an definition of "PHI" and a copy of the list of 18 identifiers regulated by HIPAA.

1a. Select the method you will use to obtain authorization for the use of the patient's protected health information (PHI). The options listed are specifically defined in the HIPAA Privacy Rule, and each are associated with specific requirements. Please review the Investigator Guidance Series (IGS) document titled, "HIPAA Privacy Rule & Authorization" on the A-Z Index for more information.

HIPAA and the Covered Entity

b. If yes, will PHI be disclosed outside the Covered Entity?
 Yes No [Clear](#)

If so, to whom?

And for what purposes?

- 1b. This question must be consistent with the list of groups who may have access to PHI in the Confidentiality and Authorization sections of the Consent Document. Please check those sections of your documents carefully and ensure they are consistent with this question.
- If your study is sponsored or involves a drug, device, or biologic, it is likely you should list the **sponsor** and **the FDA** in this question. These groups have the right to conduct site audits of the raw data at their discretion to ensure integrity of the research.

HIPAA and the Covered Entity ←

2. Several parts of this question have been modified. Please read the **blue** help text carefully.

2a-2b. If you select “Yes” for either of these questions, additional information about your investigational drug and/or device will be required on subsequent pages, which will automatically generate as you click “Continue” through the application.

- Please note that in vitro diagnostic (IVD) devices are considered to be investigational when developed or used for research in a manner consistent with the Federal definition of an *investigational device*.

2c. This question has been added to designate trials that are initiated by the local investigator. Please read the **blue** help text carefully, and attach your full research protocol to the Documents and Attachments page under “Full Protocol”.

2d. This question is the trigger mechanism for RDRC-HUC review. If your application indicates that data will be collected from radiographic scans which may be prospectively administered, either as part of standard of care, or as part of screening for the study, and/or the study procedures, select “Yes” in this section. The RDRC-HUC does not allow investigators to self-exempt their research from review. Complete the RDRC-HUC application in ERICA for an official determination of approval or an exemption.

2. Does this study involve any of the following:

a. The investigational use of a drug?

Yes No [Clear](#)

b. The investigational use of a medical device?

Yes No [Clear](#)

If medical device requires an IDE or HDE, approval from CMS: Center for Medicare and Medicaid Services is required after final IRB approval is obtained prior to enrolling any Medicare participant. <http://uuhsc.utah.edu/clinicaltrials/Device/index.html>

c. Is this an investigator-initiated drug or device trial lead by the Principal Investigator?

Yes No [Clear](#)

All investigator-initiated drug or device trials are required to have a full research protocol attached to the Documents and Attachments page.

d. Exposure to radioisotopes or ionizing radiation?

Yes No [Clear](#)

*If yes, approval by the Radioactive Drug Research Committee and Human Use Subcommittee (RDRC-HUS) (801-581-6141) is required before final IRB approval. **Complete the RDRC-HUS application on the “Ancillary Committees” page of the IRB application.***



HIPAA and the Covered Entity



- e. **Cancer patients?**
 Yes No [Clear](#)

*All cancer related studies require CCIC (801-587-4670) approval before final IRB approval. **Complete the CCIC application on the CCIC New Project Cover Sheet page of the IRB application.***



- f. **Obtaining data or information from the UUHSC Enterprise Data Warehouse (EDW) in a query outside of the Utah Population Database (UPDB)?**
 Yes No [Clear](#)

Indicate 'Yes' unless the data will be issued by EDW through the UPDB. If yes, please attach a completed Data/Information Request Form (UUHSC): <http://www.research.utah.edu/irb/forms/hipaa/index.html>

- g. **The Center for Clinical and Translational Science (CCTS)?**
 Yes No [Clear](#)

- h. **A Humanitarian Device Exemption (HDE)?**
 Yes No [Clear](#)

If yes, please attach a copy of the letter from the FDA granting the HDE. If medical device requires an IDE or HDE, approval from CMS: Center for Medicare and Medicaid Services is required after final IRB approval is obtained prior to enrolling any Medicare participant. <http://uuhsc.utah.edu/clinicaltrials/Device/index.html>

2. Several parts of this question have been modified. Please read the **blue** help text carefully.

2e. This question has been re-worded. This question is the trigger mechanism for CCIC review.

2f. This question has been re-worded to include the UUHSC EDW. This question is the trigger mechanism for RGE review.

HIPAA and the Covered Entity



i. Creating or sending samples to a tissue bank/repository?

*A tissue bank/repository is established to collect, store, and share tissues for analysis and use in **future** research projects.*

Yes No [Clear](#)

j. The use of human subjects and biological agents (e.g., staphylococcus aureus, adenovirus), or the deliberate transfer of recombinant DNA vectors/plasmids (recombinant DNA, or DNA or RNA derived from recombinant DNA) into human research participants?

Yes No [Clear](#)

If yes, please attach an approval letter from the University of Utah Institutional Biosafety Committee (IBC), biosafety@ehs.utah.edu or 801-581-6590.

k. HIV antibody testing?

Yes No [Clear](#)

2. Several parts of this question have been modified. Please read the **blue** help text carefully.

2i. This question has been added to designated studies that include tissue/specimen banking. If you select “Yes” for this question, additional information about your tissue banking procedures will be required on subsequent pages, which will automatically generate as you click “Continue” through the application.

2j. If you select “Yes” for this question, you should contact the Institutional Biosafety Committee (IBC) for approval. Their application is not built into ERICA, so you should attach the paper approval from IBC to your application following their review.

Request for Waiver or Alteration of Authorization



Request for Waiver or Alteration of Authorization

Instructions:

- Click "Add" below to add a new waiver request to this application.
- Click the waiver name link to edit a waiver that has already been created.
- To delete a waiver request, contact the IRB.

Requested Waivers:

Add

Date Created	Type of Request
There are no items to display	

Request for Waiver or Alteration of Authorization

1. Purpose of the Waiver Request:

Briefly state or summarize the purpose of this waiver (e.g., record review for recruitment, waive signature, chart review for all data collection, etc.)

- Multiple waivers can now be requested for one study.
- Click the "Add" button to add a Waiver request. A pop-up window will appear where you can fill out the request. Click "OK" at the end of the request to add it to your study.
- Each request must be filled out separately; one page cannot be used for more than one request.
- The page has been renamed to include provisions for an Alteration of Authorization.

Request for Waiver or Alteration of Authorization

5. **Explain why the research could not practicably be conducted without the waiver of authorization.** *For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."*



- This question is where you are asked to justify your request for the waiver or alteration of Authorization.
- This question is critical in assisting the Board with determining whether or not the request is justifiable. Please create a persuasive and detailed argument specific for your study that would demonstrate why it would not be possible to obtain a signed authorization and still successfully complete the study.
 - Please note that inconvenience and expense to the research study are not sufficient justification to waive authorization. The primary basis of this criterion is related to whether the *scientific validity* of the study will be significantly compromised if authorization is required.
 - *For example*, in some cases, it may be argued that if the study team was to attempt to obtain a signed authorization from each participant, participant refusals and/or failure to establish in-person contact with participants due to incorrect, outdated, or incomplete contact information would create large gaps in sampling and diminished representativeness of the data.
- Justifications for your request should be carefully customized for your study.

Limited Data Set Statement and Assurance

This assurance applies to the following part(s) of this study (select all that apply):

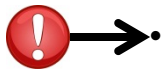
If a limited data set is being received from or disclosed outside of the University of Utah Covered Entity, a completed Data Use Agreement must be attached to the Documents and Attachments page under Other Documents.

<input type="checkbox"/>	All of the information used or disclosed in this study	
<input type="checkbox"/>	The information received or collected from these sources:	<input type="text"/>
<input type="checkbox"/>	The information shared with or disclosed to these groups:	<input type="text"/>

Data Use Assurance:

1. As an employee of the University of Utah and the Principal Investigator for the attached study, I understand that I must comply with the requirements below regarding the permitted uses and disclosure of the limited data set I am receiving from the University.
2. I have described the limited data set with specificity in the Protocol submitted with this form.
3. I have described who will be permitted to use or receive the limited data set in the same Protocol.
4. If I am disclosing the limited data set outside the Covered Entity, I am submitting, in addition to this form, a Limited Data Set Statement and Assurance (if the recipient is within the University of Utah) or a Data Use Agreement (if the recipient is outside the University of Utah) signed by an individual able to bind the entity receiving the limited data set.

- This page generates if you indicate on the **HIPAA and the Covered Entity** page that you will satisfy the requirement to obtain authorization by using a Limited Data Set with a Data Use Agreement (DUA).



A new mechanism for completing assurances in the application has been programmed with the 2012 update. All statements of assurance are now affirmed by the principal investigator upon submission of the application to the IRB.



For more information about the HIPAA Privacy Rule & Authorization, please review the Investigator Guidance Series (IGS) document titled, "HIPAA Privacy Rule & Authorization" on the A-Z Index.

Safe Harbor De-Identification



For more information about the HIPAA Privacy Rule & Authorization, please review the Investigator Guidance Series (IGS) document titled, "HIPAA Privacy Rule & Authorization" on the A-Z Index.

1. This declaration applies to the following part(s) of this study:

A. All of the information used or disclosed in this study.

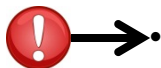
B. The information received or collected from these sources:

C. The information shared with or disclosed to these groups:

2. As the principal investigator for this study, I declare the following:

A. To the best of my knowledge, the information could not be used (alone or with other information) to identify an individual who is a subject of the information, and

- This page generates if you indicate on the **HIPAA and the Covered Entity** page that you will satisfy the requirement to obtain authorization by using a de-identified data set that satisfies the HIPAA requirements for "Safe Harbor" designation.



A new mechanism for completing assurances in the application has been programmed with the 2012 update. All statements of assurance are now affirmed by the principal investigator upon submission of the application to the IRB.

Statistical Analysis De-Identification


1. This declaration applies to the following part(s) of this study:

- A. All of the information used or disclosed in this study:
- B. The information received or collected from these sources:
- C. The information shared with or disclosed to these groups:

2. As the principal investigator for this study, I declare the following:

- A. is a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, and he/she has done the following:
1. Determined that the risk is very small that the information I am using in this protocol could be used, alone or with other reasonably available information, by an anticipated recipient to identify an individual who is the subject of the information, and
 2. Documented the methods and results of the analysis that justifies the determination.
- B. I have attached the following documentation:
1. Documentation that demonstrates that the person listed in A. has the requisite knowledge and experience, and
 2. Documentation that justifies the determination, as required by A.2.

- This page generates if you indicate on the **HIPAA and the Covered Entity** page that you will satisfy the requirement to obtain authorization by using a de-identified data set that satisfies the HIPAA requirements for “Safe Harbor” designation.
- A new mechanism for completing assurances in the application has been programmed with the 2012 update. All statements of assurance are now affirmed by the principal investigator upon submission of the application to the IRB.

 → 2A. The person listed here should be a certified or otherwise qualified statistician. In addition, a report documenting the methods and results of de-identification verification is required. **If you are not giving your data set to a statistician for de-identification, and a report is not attached to the application summarizing the process, chances are you have selected this option in error.**



For more information about the HIPAA Privacy Rule & Authorization, please review the Investigator Guidance Series (IGS) document titled, “HIPAA Privacy Rule & Authorization” on the A-Z Index.

Investigational Use of a Drug Page

#1: Complete this column if an investigational new drug (IND) number is required.



A. Provide IND Number(s):

Add

IND #	Drug name	IND Holder
There are no items to display		

There are no items to display

a. IND #

b. Drug Name

c. IND Holder

B. Attach verification of the IND number to the documents and attachments page. Please check the method by which you choose to verify the IND number:

- FDA letter (this is the actual letter sent to the holder of the IND with the number)
- IND number is printed in protocol
- Letter from the Sponsor
- Other sponsor-generated document

You must:

- Attach a copy of the Investigator Brochure or product insert to the documents and attachments page under the respective section.
- Attach a copy of the FDA Form 1572 to the documents and attachments page under Other Documents.
- Agree to the statement of compliance below.

Column 1 should be completed if the study involves an investigational drug that has received an IND from the FDA. If an IND has not been received, leave this column blank.

- a. Click "Add" to provide the IND number, Drug Name, and IND Holder in a pop-up window. You can add multiple investigational drugs using the "Add" button and the information for each drug will display in this section
- b. Select the documentation method for verifying the IND number as issued by the FDA. On the Documents and Attachments page later in the application, you must attach all required documentation as specified by the blue text in Column 1.

? Who can serve as the principal investigator for a study submitted to the University of Utah IRB?

? Please see: http://www.research.utah.edu/irb/submissions/submit_study.html and http://www.research.utah.edu/irb/guidelines/pdf/IGS_PrincipalInvestigatorQualifications-D0909.pdf.

Investigational Use of a Drug Page

#2: Complete this column if you believe an IND is not required.



A: Drug name:



B. Select one:

FDA Issues IND Exemption
(Attach letter from FDA to the Documents and Attachments page, skip Part C)

IND exemption requested from the IRB
(complete Part C below)

Clear

C. Check all of the following that that apply:

It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug.

It is not intended to support a significant change in the advertising for the product.

It does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

It is conducted in compliance with the requirements for IRB review and informed consent.

It is conducted in compliance with the requirements concerning the promotion and sale of drugs (21 CFR 312.7).

• The sponsor or investigator will not commercially distribute or test market the drug.

• The drug will be provided for free or the FDA has given prior written approval to charge for the drug (please attach documentation to the application).

Exception from informed consent for emergency research will not be invoked.

Column 2 should be completed if the study involves the investigational use of a drug where an IND from the FDA is not required. For example, the off-label investigational use of an FDA approved drug.

- a. Provide the drug name.
- b. Select the method for obtaining an IND exemption for this study.
- c. Complete part C only if an IND exemption is being requested from the IRB. On the Documents and Attachments page later in the application, you must attach all required documentation as specified by the blue text in Column 2.

For more information about Investigational Drug Studies, refer to the following guidance:

IGS

RATS Classes

Investigational Use of a Drug Page

Statement of Compliance

The use of investigational drugs in facilities covered by the University of Utah IRB must follow the policies and procedures of the facility in which the drug(s) will be administered and/or dispensed.

University of Utah Hospitals

If you are conducting inpatient research at the University Health Center or Huntsman Cancer Hospital, please review the [Department of Pharmacy Policies and Procedures](#) and contact the appropriate investigational pharmacist listed below.

University Health Center - **(801)585-2185**

Huntsman Cancer Hospital, **(801)585-0272**

Primary Children's Medical Center

If you are conducting inpatient or outpatient research at Primary Children's Medical Center, please contact the investigational pharmacist at the number listed below:

Primary Children's Medical Center - **(801)662-2655**

Veteran Affairs Medical Center

If you are conducting inpatient or outpatient research at the VA, please contact the investigational pharmacist at the number listed below:

Veteran Affairs Medical Center - **(801)582-1565 ext. 1470**

- I have read and I understand the above information provided.
- I have reviewed the appropriate policies and procedures and/or have contacted the appropriate investigational pharmacist for my research involving an investigational agent.
- I understand the requirements regarding the distribution, storage, and control of investigational agent(s) for research purposes.



The Investigational Drug Statement of Compliance is included at the bottom of this page. This must be reviewed by the PI and then accepted when the PI uses the "Submit" activity to submit the application to the IRB for review. In the "Submit" activity window, a checkbox to accept this statement of assurance will be available.

Investigational Drug Data Form Page



Add

Drug Name	Drug Accountability	Drug Supply Location
There are no items to display		

1. **Name of Investigational Drug:**

2. **Synonyms:**

10. **Describe the plan to control, store, and dispense the investigational drug. This plan should ensure that the drug is only used by qualified investigator(s) for the participants enrolled in this research project.**

3. **Manufacturer or Other Supplier:**

4. **Other Study Drugs:**

11. **Location of Drug Supply:**

An Investigational Drug Data Form (IDDF) must be completed for each investigational drug (with or without IND) that is used in the study. Use the investigator brochure or package insert to complete the form.

- a. Click "Add" to complete the form for each investigational drug. You can add multiple investigational drugs using the "Add" button and the summary information for each drug will display in this section. The name of the drug provided in question 1 of the IDDF must match that given on the Investigational Use of a Drug page.
- b. IDDF Question 10: As of 2012, question 10 on the IDDF is new to the application, capturing information that was once captured in the Protocol Summary that has been discontinued. The plan described in question 10 must be in accordance with FDA regulations for control, storage, and dispensation of investigational drugs. If the Location of the Drug Supply (Question 11) indicates the use of an investigational pharmacy at the U of Utah, HCI, PCMC, or the VA, adherence to these regulations is covered by pharmacy policy.

Investigational Use of a Device Page

1. What is the initial risk determination of the device study according to the investigator and/or sponsor?

[Help?](#)

- The study is a non-significant risk (NSR) device study. *Continue to the next page.*
- The study is exempt from IDE requirements. *Continue to the next page.*
- The study is a significant risk (SR) device study and requires an IDE. *Complete the rest of this page.*

Clear

a. Provide IDE Number(s):

Add

IDE #	Device Name	IDE Holder
There are no items to display		

a. IDE #

b. Device Name:

c. IDE Holder:

b. Attach verification of the IDE number to the Documents and attachments page. Please check the method by which you choose to verify the IDE number:

- FDA letter providing the IDE.
- IDE number is printed in protocol
- Letter from the Sponsor
- Other sponsor-generated document



1. Indicate the risk determination of the device study according to the PI, sponsor, and/or FDA.
 - a. Click "Add" to provide the IDE number, Device Name, and IDE Holder in a pop-up window if this study has received a IDE from the FDA. You can add multiple investigational devices using the "Add" button and the information for each device will display in this section
 - b. Select the documentation method for verifying the IDE number as issued by the FDA. On the Documents and Attachments page later in the application, you must attach the selected method of documentation.

Frequently Asked Questions about IRB Review of Medical Devices (FDA):
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>

Significant Risk and Non-Significant Risk Medical Device Studies (FDA):
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>

Investigational Use of a Device Page



- 2. Describe the plan to control, store, and dispense the investigational device. This plan should ensure that the device is only used by qualified investigator(s) for the participants enrolled in this research project.**

2. As of 2012, question 2 is new to the application, capturing information that was once captured in the Protocol Summary that has been discontinued. The plan described must be in accordance with FDA regulations for control, storage, and dispensation of investigational devices.

- ② *Frequently Asked Questions about IRB Review of Medical Devices (FDA):*
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>
- ② *Significant Risk and Non-Significant Risk Medical Device Studies (FDA):*
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>

Non-Significant Risk Device Page

Review the following definition of a non-significant risk (NSR) device:


1. The medical device is not a significant risk device, because all of the following are true:
 1. The medical device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.
 2. The medical device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.
 3. The medical device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.
 4. The medical device is does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
2. The medical device is not banned.




1. **Provide justification of why the investigational medical device used in this study meets the definition of a NSR device.**

The investigational device sponsor is responsible for providing this information. If this is an investigator-initiated trial, the PI is responsible for this information. All documentation from the sponsor in this regard must be attached to the Documents and Attachments page.

1. Use the FDA definition of a NSR device to justify that the investigational device used in this study meets the definition.
 - a) Attach all documentation for the device that is received from the sponsor, manufacturer, and FDA to the Documents and Attachments page.

 *For more information about what constitutes a non-significant risk device or the IRB review process for non-significant risk device studies, you may schedule a consultation with the IRB by calling 801-581-3655.*

 *Significant Risk and Non-Significant Risk Medical Device Studies (FDA):*
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>

Device Exempt from IDE Requirements Page

Select the category of exemption from IDE Requirements:

- Exemption #1**
The medical device was in commercial distribution immediately before May 28, 1976; and the FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976; and the medical device is being used or investigated in accordance with the indications in labeling in effect at that time of commercial distribution.
- Exemption #2**
The medical device was introduced into commercial distribution on or after May 28, 1976; and the FDA has determined the medical device to be substantially equivalent to a medical device in commercial distribution immediately before May 28, 1976; and the FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976; and the medical device is being used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence. (PMA or 510(k) approval)
- Exemption #3**
The medical device is a diagnostic device; and the sponsor will comply with applicable requirements in §809.10(c); and the testing is noninvasive; and the testing does not require an invasive sampling procedure that presents significant risk; and the testing does not by design or intention introduce energy into a subject; and the testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- Exemption #4**
A medical device undergoing one of the following: consumer preference testing, testing of a modification, or testing of a combination of two or more medical devices in commercial distribution; and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
- Exemption #5**
Device intended solely for veterinarian use.
- Exemption #6**
The medical device is shipped solely for research on or with laboratory animals and labeled in accordance with §812.5(c).
- Exemption #7**
The medical device is a custom device meaning all of the following are true: the medical device necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist and the medical device is not generally available to, or generally used by, other physicians or dentists and the medical device is not generally available in finished form for purchase or for dispensing upon prescription and the medical device is not offered for commercial distribution through labeling or advertising and the medical device is intended for use by an individual patient named in the order of a physician or dentist. One of the following is true: 1) the medical device is to be made in a specific form for that patient or the medical device is intended to meet the special needs of the physician or dentist in the course of professional practice. 2) The medical device is NOT being used to determine safety or effectiveness for commercial distribution.
- Post Approval Device Studies**
The medical device has received marketing approval from the FDA; however, the FDA has requested additional testing. The post approval letter specifying this testing must be provided.



1. Indicate the category applicable to the investigational device that allows it to be exempt from IDE requirements.
 - a) Attach all documentation for the device that is received from the sponsor, manufacturer, and FDA to the Documents and Attachments page.



While a device may be exempt from IDE requirements, the FDA still requires that investigations involving a medical device follow regulations concerning IRB review and informed consent: 21 CFR 50 & 56.

HIV Antibody Testing

6. HIV testing will be done whether or not patient will participate in the study. Standard hospital HIV consent will be used:

Yes

No

Clear


- This page generates if you indicate of the **HIPAA and the Covered Entity** page that the study involves HIV testing.
- 6. If patients will be tested for HIV *regardless of whether they are in the study*, select “Yes” in this section. If patients will be tested because they are in the study, select “No”.
- If patients will be tested for HIV **or other reportable diseases*** exclusively for the purposes of this study, you must address the HIV guidelines.

***State Law & Mandatory Reporting:** If testing is performed for any communicable or infectious diseases reportable by Utah State law as a result of study participation, several additional items must be addressed in the application (refer to <http://health.utah.gov/epi/report.html> for a current list of Utah’s reportable diseases).



For more information about HIV testing, please review the Investigator Guidance Series (IGS) document titled, “HIV Antibody Testing” on the A-Z Index.

Genetic Research Page

←  As of 2016: This is a new page with all new questions.

1. **Describe the risks to participants in regard to genetic testing, including applicable risks to privacy and confidentiality, as well as psychological and social risks.**

You have already provided information about risks previously in the IRB application (see below). Revise this information below as needed to address this question about genetic testing. Your answer will be updated throughout the IRB application.

2. **Describe the privacy protections in place for participants in regard to genetic testing. This includes how family member privacy will be protected.**

You have already provided information about privacy protections previously in the IRB application (see below). Revise this information below as needed to address this question about genetic testing. Your answer will be updated throughout the IRB application.

3. **Describe the confidentiality protections in place for participants' genetic information. Discuss if and how data will be shared and protected outside the local study team.**

You have already provided information about confidentiality protections previously in the IRB application (see below). Revise this information below as needed to address this question about genetic testing. Your answer will be updated throughout the IRB application.

- Questions #1 and #2 pull information from the Risks and Benefits Page, and also from the Data Monitoring Page. You just need to add additional information specific to genetic testing.



- **Don't delete** the information already showing; just add a paragraph about genetic testing risks and privacy to the end of each section.

Genetic Research Page (cont.)



As of 2016: This is a new page with all new questions.

4. Will incidental findings relevant to individuals or families be communicated to the participants?

Yes No [Clear](#)

- If you select “Yes”, you must include the required language in the “New Information” section of your consent document regarding re-contact. This language can be found in the IRB consent template, or in the guidance document linked below.

If yes, answer the questions below:

- a. Describe the process for determining which incidental findings will be returned to the participants. Describe the information and expert consultation that will be used to make this determination.**



- To learn more about what “incidental findings” are, and when you should consider communicating them to participants, please review the IRB guidance document titled, “Genetic Research” at <http://irb.utah.edu/guidelines/investigator.php>.

Genetic Research Page (cont.)

←  As of 2016: This is a new page with all new questions.

b. Indicate the process that will be used to return information about incidental finding to participants:



Select all that apply

- Standard institutional process; [click to review the standard process](#)
- Other

If Other, describe and justify the process that will be used:

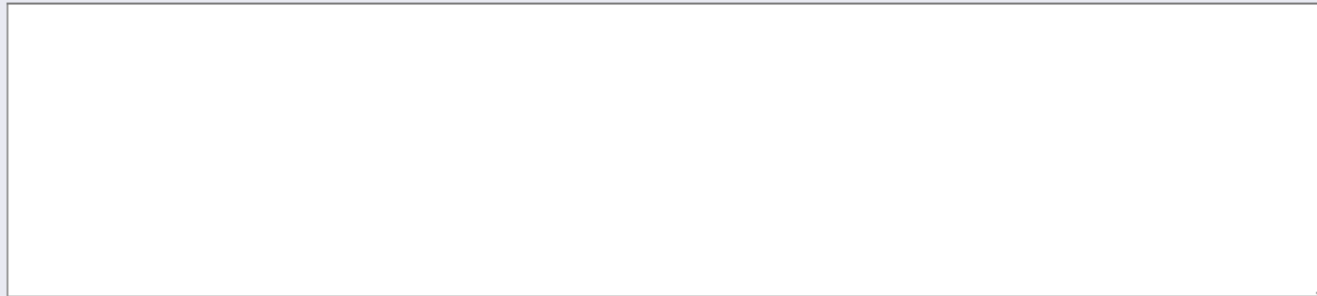
- You can read the “Standard Institutional Process” by clicking the link in the application, or by going to <http://irb.utah.edu/guidelines/disclosure-incident-findings.php>. If you choose to use the standard process, no further information is needed in the application.
- If you select “Other”, describe your re-contact and disclosure process in detail. We will review your process to ensure it is complete, thorough, and meets similar standards as the standard process.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

-  Please review the following policies and procedures to ensure tissue banking compliance for the study: http://www.research.utah.edu/irb/guidelines/topic_pages/tissue_bank.html
-  Ensure that all information provided in the application regarding tissue banking is consistent with all consent forms used for the study.

1. Type(s) of samples to be collected:

Examples: blood, urine, spinal fluid, hair, tumors, skin, organ biopsy, saliva, etc.



1. Indicate the type(s) of samples to be collected. Use the blue help text for examples.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

2. What type(s) of future research will be allowed on these samples?

[Help?](#)

2. Indicate the type(s) of research that may be conducted on these samples by researchers in the future.

 *The rules for allowable future research on banked tissues are as follows:*

1. Tissues collected with participant identifiers can only be used in the future for specific types of research. This must be specified in the IRB application and the consent document.
2. Specific future research is not required if the samples will be completely **de-identified** and cannot be linked back to the participant.
3. For Cooperative Group Trials, specific future research is not required and the cooperative group may keep identifiers, as long as an appropriate plan for maintaining confidentiality is in place.


Tissue Banking Page ← As of 2012: This is a new page with all new questions.

3. Who manages the tissue bank and where will the samples be stores?

If the tissue bank is managed by the University of Utah, a namagement protocol must also be attached to the Documents and Attachments page.



3. Indicate the person/institution that manages the tissue bank (sample and data management), including the location of sample and data storage.

 *All tissue banks managed by the University of Utah must have a management protocol attached to the IRB application. A template for a tissue banking management protocol is on the IRB website on the Forms page.*

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

4. Indicate whether the samples in the tissue bank will be identifiable directly or through a code/link.

Identifiable means that the participant can be identified using information kept with or linked to the sample.

a. Select one of the following options:

[Help?](#)

OPTION 1: All samples will be identifiable to one or more individuals (e.g., PI, sponsor, tissue bank management personnel, etc.) involved with the tissue bank.

Examples:

- *Samples are received into the tissue bank with identifiable information*
 - *The PI will maintain the code or link to identifiable information; however the sponsor's tissue bank will receive a completely de-identified sample.*

OPTION 2: Some samples may be identifiable or de-identified to one or more individuals (e.g., PI, sponsor, tissue bank management personnel, etc.) involved with the tissue bank.

Examples:

- *Participants can choose in the consent form to have their samples identifiable or de-identified.*
 - *Samples are received from many sources and may be identifiable or de-identified; samples received with identifiers will not be de-identified before entering the bank.*

OPTION 3: All samples will be de-identified to all individuals (e.g., PI, sponsor, tissue bank management personnel, etc.) involved with the tissue bank and no link or code will be kept or maintained by the tissue bank.

Examples:

- *Samples are received into the tissue bank without identifiable information.*
 - *Data to be kept with the sample is recorded without identifiers. Only non-identifiable information is recorded.*
 - *Identifiable clinical samples are used for study purposes and are then completely de-identified BEFORE being sent to the tissue bank.*

Clear

4. Question 4a includes 3 options, from which you must select 1 option applicable to your study. Continue on to the next tutorial pages for help with each option.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

OPTION 1: All samples will be identifiable to one or more individuals (e.g., PI, sponsor, tissue bank management personnel, etc.) involved with the tissue bank.


Examples:


- *Samples are received into the tissue bank with identifiable information*
- *The PI will maintain the code or link to identifiable information; however the sponsor's tissue bank will receive a completely de-identified sample.*

Question 4a, OPTION 1:

- Select this option if **all** of the samples are **identifiable** to anyone responsible for conducting the study. People responsible for conducting the study include the PI, members of the study team, tissue banking management personnel, etc.

 *Identifiable means that the participant can be identified in some way.*

 *The sample has identifiers directly on the storage packaging, like name, MRN, DOB, etc.*

 *The sample has an ID number on the storage packaging and a list of ID numbers with identifiers is kept separately which can be used to identify from whom the sample came.*

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

OPTION 2: Some samples may be identifiable or de-identified to one or more individuals (e.g., PI, sponsor, tissue bank management personnel, etc.) involved with the tissue bank.


Examples:

- *Participants can choose in the consent form to have their samples identifiable or de-identified.*
- *Samples are received from many sources and may be identifiable or de-identified; samples received with identifiers will not be de-identified before entering the bank.*


Question 4a, OPTION 2:


- Select this option if
 - **Some** of the samples are **identifiable** to anyone responsible for conducting the study
AND
 - **Some** of the samples are **de-identified** and cannot be re-identified by anyone responsible for conducting the study.
- People responsible for conducting the study include the PI, members of the study team, tissue banking management personnel, etc.


 *Identifiable means that the participant can be identified in some way.*

 *The sample has identifiers directly on the storage packaging, like name, MRN, DOB, etc.*


OR

 *The sample has an ID number on the storage packaging and a list of ID numbers with identifiers is kept separately which can be used to identify from whom the sample came.*


 *De-identified means that the sample cannot be linked back to the participant.*

 *The sample has no information on the storage packaging and no information linked to it.*

OR

 *The sample has an ID number on the storage packaging, but the ID number is not linked to any identifiers. The ID number is kept in a database and is only used to track the sample.*

OR

 *The sample has an ID number on the storage packaging, and the ID number is linked to **de-identified** information about the participant. The ID number and de-identified information about the participant are kept in a database.*

Tissue Banking Page ← As of 2012: This is a new page with all new questions.


OPTION 3: All samples will be de-identified to all individuals (e.g., PI, sponsor, tissue bank management personnel, etc.) involved with the tissue bank and no link or code will be kept or maintained by the tissue bank.

Examples:

- *Samples are received into the tissue bank without identifiable information.*
 - *Data to be kept with the sample is recorded without identifiers. Only non-identifiable information is recorded.*
 - *Identifiable clinical samples are used for study purposes and are then completely de-identified BEFORE being sent to the tissue bank.*


Question 4a, OPTION 3:

- Select this option if **all** of the samples are **de-identified** and cannot be re-identified by anyone responsible for conducting the study. People responsible for conducting the study include the PI, members of the study team, tissue banking management personnel, etc.


 *De-identified means that the sample cannot be linked back to the participant.*

 *The sample has no information on the storage packaging and no information linked to it.*

OR

 *The sample has an ID number on the storage packaging, but the ID number is not linked to any identifiers. The ID number is kept in a database and is only used to track the sample.*

OR

 *The sample has an ID number on the storage packaging, and the ID number is linked to **de-identified** information about the participant. The ID number and de-identified information about the participant are kept in a database.*

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

b. If you selected OPTION 1 or 2 above, describe the process for managing the associated data for identifiable samples:

Who will manage and have access to the identifiable data?

Where will the data be kept?

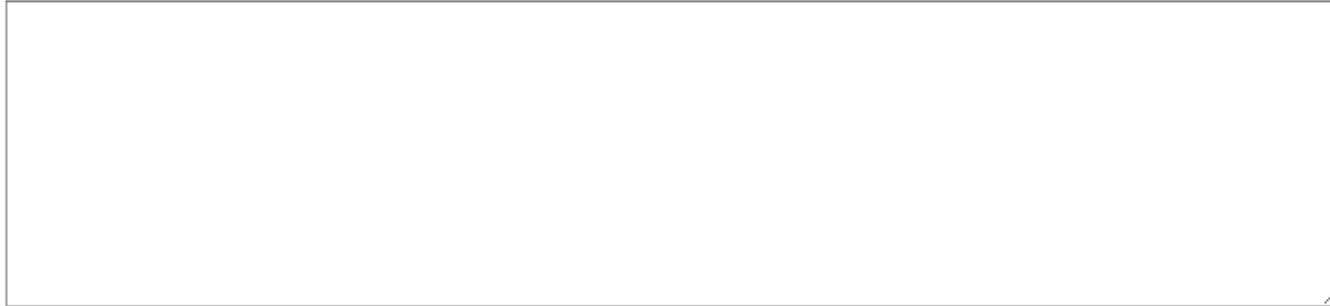
How will the data be kept confidential?

Question 4b:


- Answer the three questions if you selected OPTION 1 or OPTION 2 in section 4a. You can leave these questions blank if you selected OPTION 3. Continue on to the next tutorial pages for help with each option.


Tissue Banking Page ← As of 2012: This is a new page with all new questions.

Who will manage and have access to the identifiable data?



Question 4b, *Who will manage and have access to the identifiable data:*


-  The IRB needs to know who can manage and have access to the identifiable data for the following reasons:
- HIPAA authorization must account for the individuals with access to identifiable data for research purposes.
 - The number of people with access to identifiers for research purposes should be as small as possible in order to protect a participant's privacy.
 - People who are responsible for managing and accessing identifiable data in order to perform their functions of research tissue bank management must be trained to protect confidentiality. They must be trained not to disclose identifiable information to those who are not authorized to receive it.
 - People who are responsible for managing and accessing identifiable data through the research tissue bank are considered to be "engaged in research", even if they did not design the study, obtain consent, collect the data, or perform data analysis. That means that these people cannot be included under a "Non-Human Subject Research" determination. However, if these responsible individuals give out de-identified data, the data recipient may likely be included under a "Non-Human Subject Research" determination.


Tissue Banking Page ←  As of 2012: This is a new page with all new questions.

Where will the data be kept?



Question 4b, *Where will the data be kept:*


-  The IRB needs to know where the data will be kept or stored for the following reasons:
- HIPAA authorization must account for the location of the data.
 - The location of the data must be secure to protect privacy and confidentiality.
 - The institution(s) and investigator(s) who store identifiable data for research purposes are considered to be “engaged in research” and must have IRB approval to keep and use the data.

Tissue Banking Page ←  As of 2012: This is a new page with all new questions.

How will the data be kept confidential?



Question 4b, *How will the data be kept confidential:*

-  The IRB needs to know the confidentiality protections for the following reasons:
 - To ensure that research regulations for approving research are met.
 - To ensure that the data is protected from those individuals who are not allowed to see it. This includes giving only de-identified data if a data recipient is not authorized to have access to identifiers.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

c. If you selected OPTION 2 or 3 above, describe the process for de-identifying the samples:

Who will de-identify the samples?

When will the sample be de-identified?

Question 4c:

- Answer the two questions if you selected OPTION 2 or OPTION 3 in section 4a. You can leave these questions blank if you selected OPTION 1. Continue on to the next tutorial pages for help with each option.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

Who will de-identify the samples?




Question 4c, *Who will de-identify the samples:*

- ④ The IRB needs to know who will de-identify the samples for the following reasons:
 - HIPAA authorization must account for the individuals with access to identifiable data for research purposes. Anyone responsible for sample de-identification will have access to the identifiable data.
 - The number of people with access to identifiers for research purposes should be as small as possible in order to protect a participant's privacy.
 - People who are responsible for de-identifying the samples must be trained to protect confidentiality. They must be trained not to disclose identifiable information to those who are not authorized to receive it.
 - The individual(s) who de-identify the samples may be a member of the tissue bank study team, or may be a person unaffiliated with the study.
 - If an individual performing de-identification is a member of the tissue bank study team, he/she is considered to be "engaged in research", even if he/she did not design the study, obtain consent, collect the data, or perform data analysis. This means that the individual cannot be included under a "Non-Human Subject Research" determination and IRB approval for this individual's activities is needed.
 - If the individual performing de-identification is unaffiliated with the study, the individual is not considered to be "engaged in research", so long as the individual never discloses identifiers to the tissue bank study team. This means that IRB approval is not needed for this individual's activities.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

When will the sample be de-identified?

Question 4c, *When will the sample be de-identified:*

-  The IRB needs to know when the samples will be de-identified for the following reasons:
- The IRB needs to understand at what points in time the samples are identifiable versus de-identified in order to protect privacy and confidentiality appropriately at these time points.
 - Understanding when the samples will be de-identified helps the IRB to know who will have access to identifiers, because some people are only involved in the study at certain points in time.
 - This helps the IRB determine if subsequent studies using tissues from the tissue bank can be considered “Non-Human Subject Research”.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

- 5. List all the specific participants information (identifiable and non-identifiable) that will be recorded with the sample (e.g., name, date of birth, phone number, age, gender, diagnosis, treatment status, outcome, approximate date of collection, etc.):**

- 6. Describe the procedures for participants to withdraw their samples from the bank. If participants will not be able to withdraw their samples, please provide an explanation:**

5. Indicate the data that will be kept with or linked to the sample. Include all identifiable and non-identifiable data points.
6. Indicate the process and procedures that a participant will need to follow if he/she would like a sample and data withdrawn from the tissue bank, such that it cannot be used for future research. If the tissue bank will not allow samples to be withdrawn (e.g. because they are all de-identified), provide an explanation as to why withdrawal is not possible.

Tissue Banking Page ← As of 2012: This is a new page with all new questions.

7. Will future research results or findings be communicated to the participants?
 Yes No **Clear**

If yes, please describe the process for providing these results to participants:

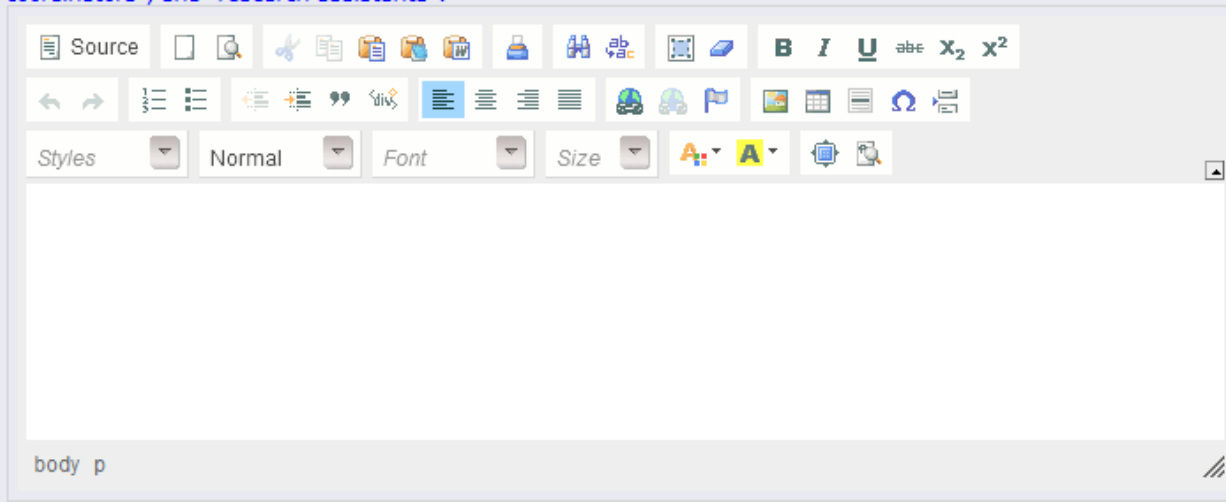
8. Describe the procedures for other researchers to obtain tissues from the bank for use in future research.
(Future research projects using University of Utah tissue banks must be IRB approved before tissues are used):

- 7. Indicate if future research results will be communicated to the participants and what the process for this communication will be, if applicable.
- 8. Give a summary of the procedures the tissue bank will follow to receive and fulfill tissue requests from other researchers. This includes verifying that the other researchers are allowed to receive and use tissues and data for research purposes.

Resources and Responsibilities ← As of 2012: This is a new page with all new questions.

1. State and justify the qualifications of the study staff:

The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience to perform the delegated task. A qualified physician should be responsible for all medical-related decisions and care. You may include a summary of delegated tasks to qualified study staff. You do not need to enter specific staff names, but may use titles such as "sub-investigators", "study coordinators", and "research assistants".



body p

- This page corresponds with the “Administrative Responsibilities” section from the old Protocol Summary template.
- Read the **blue** help text with each question carefully. Make sure you thoroughly answer each question.



- Several of the new questions in the application have been equipped with “Rich Text” editor functions. You are encouraged to use bulleted or numbered lists, different font colors, etc. to clearly format the information on this page.

Documents and Attachments

Protocol or Research Summary: [\(IRB Template - MS Word Format Only\)](#)

Name	Version	Date Created
There are no items to display		

If your application was approved prior to 2012, the most recent, *approved* version of your Protocol/Research Summary will appear here. The document is archival and read-only, so it cannot be updated or deleted.

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

(You must use the current MS Word IRB template to allow watermark approval)

<input type="button" value="Add"/>			
Name	Version	Date Created	Date Modified
There are no items to display			

All consent documents should be attached here. Documents in this section with a blank watermark footer will be processed with an approval stamp.

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, student proposal, etc.):

<input type="button" value="Add"/>			
Name	Version	Date Created	Date Modified
There are no items to display			

A full protocol is required in specific circumstances. Please see the tutorial titled, "Full Protocol Requirements" for more information.

- This page has been revised with more sections and with more detailed sub-titles to help investigators separate their documents more thoroughly.
- **Tip:** Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.



For more information about attaching documents, please review the other tutorials offered on the Tutorials page, including "Attaching Tracked Documents".

Documents and Attachments



For more information about recruitment and advertising, please review the Investigator Guidance Series (IGS) documents titled, “Recruitment” and “Advertising” on the A-Z Index.

Literature Cited/References:

<input type="button" value="Add"/>	
Name	Version
There are no items to display	

This section corresponds with the “References” section from the old Protocol Summary template.

Citations from the literature should be included in the “Background and Introduction” question on the **Contacts and Title** page, and the cited references should be listed in a Word Document and attached here.

This and other supporting information, such as your own publications, should be submitted if you feel it would allow a deeper understanding of the project.

If your study includes a non-traditional design, such as a research registry, quality improvement program, or database, you may include citations that demonstrate a compelling reason to create the registry, improve the program, etc. in the first place (e.g. research that provides a deeper understanding of the disease/disorder the registry is targeting, or the social factors resulting in the need to improve the program, etc.), or previous research that indicates that registries/QI programs are effective in accomplishing the objectives of your design.

Recruitment Materials, Advertisements, etc.:

<input type="button" value="Add"/>		
Name	Version	Date Created
There are no items to display		

Attach materials that will be used for participant recruitment (e.g. recruitment pool announcements, emails, newspaper/internet advertisements and website postings, posters, flyers, letters, etc.).

Please note that the University of Utah IRB does not allow cold-calling as a method of recruitment.

If internet advertisements or social networking sites, etc. will be utilized for recruitment, please review the IRB guidelines regarding internet advertising.

Other Stamped Documents:

<input type="button" value="Add"/>		
Name	Version	Date Created
There are no items to display		

A section titled “Other Stamped Documents” will be included on this page soon. The section will be used for items that are not *consent* documents, but that still require an IRB stamp, such as the “Data/Information Request Form” for the UHSC EDW.

*Do not add documents to this section unless you are familiar with using this section, or unless you are specifically instructed to by the IRB.

Ancillary Applications Page

This page should be used for submitting human research applications to the following ancillary committees:

Resource for Genetic Epidemiology (RGE) for the use of the Utah Population Database (UPDB)

Phone: 801-581-6351

Website: <http://www.research.utah.edu/rge/index.html>

Radiological Drug Research Committee Human Use Subcommittee (RDRC-HUS)

Phone: 801-581-6141

Website: <http://www.rso.utah.edu/using/human.html>

Instructions for Completing Ancillary Application

1. Click on the name of the study below. The ancillary application will appear.
2. Complete all pages of the ancillary application by clicking "Continue" after each page.
3. When you finish the ancillary application, you will be returned to the IRB New Study Application. Complete the remaining pages of the IRB application. If there is more than one ancillary application that needs to be completed, you must complete these steps for each application.
4. Complete the remaining pages of the IRB application.
5. When the PI submits the IRB application, the ancillary application will be submitted also. All ancillary committee reviews will be complete **BEFORE** the study is sent to the IRB for review. Reviews are not conducted concurrently.

ID	Name	Date Submitted	Status
 RGE_00000643	Perceptions about the use of language translation and interpretation in the human subject research setting		Creation
 HUS_00003204	Perceptions about the use of language translation and interpretation in the human subject research setting		Pre Submission

- Follow the instructions provided on this page. For questions about how to complete the ancillary applications, you must contact each office individually.
- When you submit your IRB application, the ancillary applications are submitted as well. Each ancillary committee is required to review their application **BEFORE** IRB review will proceed. Reviews are not conducted concurrently.

Finish

Finish Instructions

1. To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.
 2. Selecting the Finish button will NOT submit the application to the IRB. You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
 3. If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.
- Follow the instructions provided on this page to complete your application.

New Study Application – Workflow Diagram

January 2012

