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August 2015
Form 1 Initial Submission Instructions
Applying for Institutional Review Board (IRB) Approval
Using the UT, Knoxville Application Revised 8/14/15

This guide includes screen-by-screen instructions for completing the application for initial approval of a new project by the UT, Knoxville IRB. You will not see all of the screens shown here; the software will branch you to those appropriate to your application, based on your responses. Please don’t hesitate to contact the IRB if you need further assistance.

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### Application Screen

**Log In**

- **User ID:**
- **Password:**

**System Login Requirements**

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### Completion Instructions

1. **Begin by logging in to the iMedRIS online submission system at** [https://ris01.uthsc.edu](https://ris01.uthsc.edu) **using your UTK netID and password.**

2. **If this is your first time in iMedRIS, it may take 24 hours after your initial log in for the system to set up your account, and for you to have the Study Assistant menu (next screen) available.** (Study Assistant is needed to submit an application.)

3. **Contact the IRB if you have questions or encounter difficulties logging in.**

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### In your Study Assistant menu, select Add a New Project.

When you come back to work on the project once it's been created, you will find it as a "Draft" in My Projects.

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### Please note that help is available whenever there is a question mark icon, throughout the application as well as at the top of your screen.

### Be sure to select UTK IRB Application!!

If you send your application to the Health Sciences Center in Memphis, or to the Graduate School of Medicine, (or to the Biosafety Committee) the UT IRB cannot see it, review it, or approve it.

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### 1.0 General Information

Enter the complete title of your study (same as any funding proposals, if applicable) in the first text box.

"Working Title" is an abbreviated version (and is what you will see in your "My Projects" listing).

### 2.0 Add Department(s)

Your default department (from the UT LDAP directory) is already listed and selected. Please "add" other departments as appropriate, both for yourself and for others affiliated with your project, and then indicate which is the Primary Department i.e., the one that will review and approve, and will have oversight responsibility.
3.0 Assign key study personnel

3.1 The Principal Investigator must be the same as listed on any funding proposals (if applicable). Graduate or undergraduate students serving as PIs must select "Student" and name an Advisor in 3.4.

3.2 Research Staff (NB: Collaborators from outside UTK should not be listed here, but in (650) or (925) below.) There are two categories of research staff:

- **Additional Investigators** include Co-PIs, Co-Investigators and Sub-Investigators at UTK. They must complete CITI training and must sign off on the initial application.
- **Research Support Staff** include Research Assistants, Research Associates, Study Coordinator, Data Analyst, Research Staff, and other individuals (see drop down menu). These individuals must complete CITI training but are not required to sign off on the application.

3.3 Project Contact: The PI will automatically be a project contact, and you should add anyone else whom you wish to receive all automated notifications from iMedRIS. Students must add their Advisors as Project Contacts.

3.4 Students must add their Faculty Advisor

3.5 Departmental Approvals: You must add a Department Review Chair (DRC) and a Department Head (called Department Chair) in iMedRIS. NB: If you are a member of the study staff and the DRC or Dept Head, you must designate someone else to serve as reviewer for you on this study. Approving your own project would present a Conflict of Interest.

3.4 Research Administrative Specialist(s): If there are staff members whose work will be only administrative—they will not enroll or consent participants, or collect or analyze data, or access study records—they may be listed here and do not need CITI training.
### (300) UTK IRB Submission

**Classification:** Indicate if your study is a Research Project, a Dissertation, a Thesis, or an Undergraduate Honors Thesis. Most projects fall into one of these categories; if you believe yours does not, select "other" and specify the category in the text box.

**Submission status:** Leave the default, "I am requesting initial approval for research," unless you have been in conversation with the IRB and have been explicitly told to select the other option.

### (415) UTK Key Project Study Contact Information

Please include in these sections the requested information for the following categories of personnel who are affiliated with the University of Tennessee, Knoxville (as listed in section 3.0 above):

- 3.1 Principal Investigator
- 3.2 Research Staff
- 3.3 Project Contact
- 3.4 Faculty Advisor

You will list collaborators at other institutions in your study design/procedures below: (650) Exempt, (925) Expedited and Full Board.

### (420) Review Board Routing Questions

Please answer these questions carefully as the IRB uses this information to determine whether or not coordination with other compliance offices on campus is needed for your project.

### (468) Funding Source

If you respond, "No," in screen 468, you will not see the rest of the funding screens.

### (470) Funding Source

If you respond, "Yes," in screen 468, you will be asked to name your funding source here.
**Application Screen**

<table>
<thead>
<tr>
<th><strong>(475) Contract Information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* Select the office or institution that is processing the grant or contract for this study/project. If there is no grant or contract for this study/project, enter &quot;Not Applicable.&quot;</td>
</tr>
<tr>
<td>If you selected &quot;Other&quot; please list the office or institution that is processing the grant or contract for this study/project.</td>
</tr>
<tr>
<td>Where is the project/proposal in the funding process?</td>
</tr>
<tr>
<td>- Not submitted (seeking IRB approval as first step)</td>
</tr>
<tr>
<td>- Submitted but not awarded</td>
</tr>
<tr>
<td>- Awarded</td>
</tr>
<tr>
<td>Is the proposal title different from this IRB project application?</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
</tbody>
</table>

**Completion Instructions**

*(475) Contract Information*

If you responded "Yes" to (468), please select from the drop-down menu the office or institution that is processing your grant or contract (or specify "other").

Please indicate where you are in the submission/funding process.

*(The IRB prefers to review your work before you have your funding, to prevent deadline crises later.)*

Proposal titles that are the same help the IRB coordinate with the Office of Sponsored Projects, which facilitates setting up your accounts. (Some sponsors require the IRB application title to match the grant proposal title.)

These Award numbers, when known, are the most efficient way for the IRB to communicate with the Office of Sponsored Programs about your project.

<table>
<thead>
<tr>
<th><strong>(480) Drug, Biologics, and Device Information and Administration</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* Are you requesting full board, expedited or exempt review by the IRB?</td>
</tr>
<tr>
<td>- Full Board</td>
</tr>
<tr>
<td>- Expedited</td>
</tr>
<tr>
<td>- Exempt</td>
</tr>
<tr>
<td>- Not Sure</td>
</tr>
</tbody>
</table>

*(480) Drug, Biologics, and Device Information and Administration*

Please indicate the level of review you believe is required for your study, as well as whether or not you are administering and evaluating a drug, device, and/or biologic as part of your project.

*Your responses here will branch you to the next appropriate screens.*

*(490) Drug, Biologics, and Device Information and Administration*

You will receive this screen if you selected "Yes" above that your study involves a drug, biologic or device.

Please name and describe the relevant items and the training and experience of the persons who will be authorized to administer them in your study.
<table>
<thead>
<tr>
<th>Application Screen</th>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(590) Exempt Screening Questions</strong>&lt;br&gt;☑ The study is an internal evaluation of an institutional program or academic course.&lt;br&gt;☑ The only participants of this study are persons who are deceased.&lt;br&gt;☑ I am NOT able to identify the persons whose information or specimens are being analyzed in the study, either directly or through identifiers linked to the participants.&lt;br&gt;☑ All documents or records used in this research are publicly available.&lt;br&gt;☑ The study involves the review of existing data, and ALL the data to be used in the project are in existence AT THE TIME THIS APPLICATION IS SUBMITTED.&lt;br&gt;☑ The study involves the administration of tests, surveys, interviews or focus groups, or observation of public behavior.&lt;br&gt;☑ All participants doing tests, surveys, interviews or focus groups will be 18 or older.&lt;br&gt;☑ All surveys/interview participants are public officials.&lt;br&gt;☑ The research involves evaluation of a public benefit or service program.&lt;br&gt;☑ The study involves tax, food quality, or consumer acceptance testing.</td>
<td><strong>(590) Exempt Screening Questions</strong>&lt;br&gt;You will receive this screen if you selected &quot;Exempt&quot; or &quot;Not Sure&quot; in (485). Responding carefully will allow iMedRIS to assist you in determining if your study qualifies for Exempt Review. <strong>Please read the selections carefully;</strong> for example, if you are conducting face-to-face interviews, do not select &quot;I am not able to identify the persons whose information or specimens are being analyzed...&quot;</td>
</tr>
<tr>
<td><strong>(638) Not Exempt</strong>&lt;br&gt;Based on your answers to the questions for determination of Exempt Status, your project does not fall under Exempt status according to the Federal Regulations. Please go back to (495) Study/Project Information, and change your answer to &quot;Exempt.&quot; Once you save, you will receive the expeditious questions. You may also call the IRB for assistance (865) 974-7407 if you believe your study is exempt.</td>
<td><strong>(638) (639) (640) Exempt/Not Exempt Determination</strong>&lt;br&gt;If you believe you received &quot;Not Exempt&quot; in error, re-check your responses to (590), or contact the IRB to discuss your application.</td>
</tr>
<tr>
<td><strong>(652) Begin Exempt Application</strong>&lt;br&gt;Study/Project Synopsis and Background/Current Work in Field&lt;br&gt;* Click on the bar below and provide a synopsis of the research study/project addressing the following FOUR Items using these numbered subheadings:&lt;br&gt;1. Purpose/Objectives of the Study/Project&lt;br&gt;2. Study/Project Population&lt;br&gt;3. Study/Project Procedures and&lt;br&gt;4. Outcome Measures. &lt;br&gt;* Provide a discussion of the background and current status of work in the field.</td>
<td><strong>(652) Begin Exempt Application: Study/Project Synopsis</strong>&lt;br&gt;Use the text box (by clicking on the text editor) to describe your research plans using the four subheadings provided. <strong>Item #3 is where you should name any non-UT Knoxville collaborators and their institutions, and describe their roles in your study.</strong> (Many investigators prefer to write this section in a word processor document, and then copy and paste the text into iMedRIS.) <strong>Background/Current Status of Work in the Field</strong>&lt;br&gt;Please provide a summary description of work in your field that should provide—to a lay audience—a scientific rationale for your study. <strong>Please include only the description/discussion here; the reference list to support it will be entered in screen (5000) below.</strong></td>
</tr>
<tr>
<td><strong>(653) Studies Involving Records, Data, Documents 45CFR46.101(b)(4)</strong>&lt;br&gt;* Describe the records, data, or documents to be examined.</td>
<td><strong>(653) Studies Involving Existing Data</strong>&lt;br&gt;If your study involves the review of existing data, this section is where you give the reviewer the information about the data set that is needed to determine if it qualifies for Exempt Category 4. It is important that your use of the data in your study is not in violation of whatever consent the participants gave when the data were first collected, and that whoever owns the data has given you permission to use it for research purposes. Please note that if your data set is listed at <a href="http://irb.utk.edu/public-use-data-sets/">http://irb.utk.edu/public-use-data-sets/</a> and if your study complies with the conditions listed there, you do not need to apply for Exempt review and may begin.</td>
</tr>
</tbody>
</table>
Exempt Screening Questions and Exempt Application

Application Screen

(658) Survey or Interview
45CFR46.101(b)(2) or (b)(3)

* Describe the characteristics of the participant population that will be involved in the survey/interview.

* Explain the circumstances or conditions under which the survey or interview will be conducted.

* Briefly describe the content of the survey or interview:
(At the end of the application, you will be asked to attach a copy of the survey or interview.)

(660) Informed Consent

Indicate which procedure will be used to secure and document the informed consent of prospective participants involved in survey or interview.

Please note that you may use an informed consent statement for survey studies in lieu of a signed consent form. You can choose this option by answering “yes” to option #2.

1) An informed consent interview will be conducted with participants and they will be asked to sign a consent form to document their agreement to participate in the study/project.

2) A brief informed consent statement will be presented orally to participants (for survey or interview) or will be attached (for survey only). Participants will not provide written documentation of consent. Their willingness to respond to the survey or interview will constitute documentation of their consent.

If you answer “yes,” at the end of the application, you will be asked to attach a copy of the informed consent statement prepared in accord with the IRB guidelines for informed consent to survey research (these guidelines should also be followed for interviews, focus groups, etc.)

Yes
No

(662) Exempt Research
(other than or in addition to: Survey / Interview or Records/Data/Documents/Specimens)

* Describe the participant population and explain how the participants will be selected or recruited.

* Describe the procedures used in the study/project for collecting, retrieving, and/or analyzing data.

(663) Secure Informed Consent

Will you secure the informed consent of participants?

Yes
No

Provide details of storage of signed informed consent form and retention for three years beyond the termination of the study.

(665) Informed Consent Process

* Please describe the process that you will use for securing informed consent. You will be asked at the end of the application to attach your informed consent document(s).

Completion Instructions

(658) Survey or Interview

If your study involves the administration of tests, surveys, etc., this is the section where you give the reviewer the information needed to determine if it qualifies for Exempt Category 2 or 3. The review will attend particularly to the relationship between your participant population and the sensitivity of the questions you are asking. Please attach at the end of the application a copy of your instrument, uploading it as an Other Study Document in the "Surveys/Questionnaires/Data Collection Instruments" category.

Do not include the Consent Statement page in the survey, attach it separately—see (660) below.

(660) Informed Consent

Informed Consent procedures are always required before you may collect data from living individuals, even when you do not collect signed forms (in order to keep participation anonymous). Most investigators will select option #2 for Exempt Category 2 studies, and use an Information Sheet/Consent Elements as the first page/screen of their survey. Please see http://irb.utk.edu/forms/ for sample forms including the required elements of Informed Consent. Please attach at the end of the application a clean copy of your consent form to be reviewed, and dated and stamped if IRB approved, uploading it as a Informed Consent Document, and selecting the "Consent Statement/Elements" category.

(662) Exempt Research
(other than Categories 2, 3, 4)

If your study involves procedures that fall into another Exempt category, you will receive this screen to describe your participants and your procedures. The review will attend particularly to the relationship between your participant population and the sensitivity of the questions you are asking.

(663) Secure Informed Consent

If appropriate, you will receive this screen so that you can describe your plans for secure storage of signed informed consent forms, including the UTK campus location at which they are stored. (This information is critical in the event of an audit.)

(665) Informed Consent Process

If appropriate, you will receive this screen to describe your procedures for obtaining informed consent, either via signed forms or via an alteration of consent by the use of an information sheet [see (660) above]. Please be sure that your survey participants must make a proactive decision (e.g., click a "yes" button) to agree to participation after reading your Information Sheet/Consent Elements, as part of this process.
### Application Screen

**667) Informed Consent Not Possible**

* Please explain why it is not possible to secure informed consent:

<table>
<thead>
<tr>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(667) Informed Consent Not Possible</strong></td>
</tr>
<tr>
<td>If appropriate, you will receive this screen to provide your rationale for waiver of informed consent. This is usually only appropriate for studies that are reviews of existing data sets.</td>
</tr>
</tbody>
</table>

**675) Informed Consent**

* Can the study/project practically be conducted if informed consent is required?
  - Yes. The study/project can be carried out even if informed consent is required.
  - No. The study/project CANNOT be carried out without a waiver of informed consent.

If you answered “yes,” please describe the plan to secure and document the informed consent of the participants:

(At the end of the study/project application, you will be asked to attach a copy of the informed consent statement or form.)

**685) Waiver of Informed Consent**

* Why can the research not be practically carried out without the waiver of consent?
  - Funds and personnel do not exist to contact all potential participants to secure their consent.
  - Failure to include all potential participants might result in skewed analyses of the results of the study/project.
  - Other reason:

If you answered “other reason,” please explain:

**1200) Site Information**

* Please list sites and procedures where the study/project will occur.

<table>
<thead>
<tr>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(685) Waiver of Informed Consent</strong></td>
</tr>
<tr>
<td>If appropriate, you will receive this screen to confirm that it is not possible to carry out your study without a waiver of informed consent.</td>
</tr>
<tr>
<td>If it is possible, you will be prompted to describe your consent procedures and instructed to attach your form(s) at the end of the application (as in 660 and 665 above).</td>
</tr>
</tbody>
</table>

**1200) Site Information**

* Is this a multi-site study/project?
  - Yes. This is a multi-site study/project.
  - No. This is NOT a multi-site study/project.
  - Not applicable.

* Are any of the locations listed above non-UTK facilities?

If a project is to be conducted in a non-UT facility, an official letter of permission to use the non-UT facility must accompany the submission. Letters of permission must be on the letterhead of the organization and signed by authorized officials. If public school or school system facilities are to be used, letters of permission from authorized officials to the superintendent of schools office, and possible from school principals must accompany the submission.

<table>
<thead>
<tr>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(1200) Site Information</strong></td>
</tr>
<tr>
<td>Please list in the text box all locations where your study will take place, and information about which procedures will take place at which sites, if more than one.</td>
</tr>
</tbody>
</table>

The IRB must have documentation that you have permission to conduct research at other sites. **These letters**

- **must be on official letterhead of the school/business/organization (not of UT) and**
- **must explicitly be permission for research.**

Please attach them at the end of the application as "Other Study Documents" in the Letter of Support category.
### Application Screen

**Participant Population**

Please state the anticipated number and age range of the participants to be studied. (The first two numbers will be the same if you are not collaborating with other institutions.)

#### Overall number of participants

*Number of participants to be accrued by UTK investigators. (This is the total number of participants you expect to accrue (enroll), including anticipated screen failures and withdrawals. For studies that have been approved for a waiver of consent, participants are considered accrued at the time any study interventions are performed, including medical record abstraction and screening procedures.)*

#### Age range of participants to be accrued locally:

<table>
<thead>
<tr>
<th>Is any racial/ethnic group excluded?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

Provide an explanation if any racial/ethnic group is excluded.

### Completion Instructions

**Participant Population**

It is very important for the IRB to know who your participants will be, and how many of them there will be. **You may not enroll more participants than are approved, so decide carefully what number to enter here.**

- If you responded "No" to multi-site studies in (1200) above, you will enter the same number in the first two boxes.
- If you entered "Yes" to multi-site studies, the first number is determined by adding all of the sites together; the second number is only those to be recruited at UTK. If other PIs are recruiting separately from you, this number will be different than the one above.

**The age range is critical** as research involving minors (anyone under 18 years of age) requires special protections, including parent permission. In addition, depending on the type of study activities, other age groups might be at increased risk. **If you plan to exclude** any racial or ethnic group, you must provide a rationale for doing so.

### Vulnerable Participants

**(1488) Vulnerable Participants**

Please read and complete this section very carefully; many applications are returned for correction in this area.

**In the first box, it is important to select every category of participants who are being actively recruited for your study.** For example, if you are recruiting UT faculty, staff, or students, you must select "Students of a school associated with this project" and/or "Employees of an institution associated with this project." If you are recruiting minors, you must select "Children (0-17 years) who are not wards of the state."

**In the second box, please select every category of participant who might incidentally enroll in your study, even if you have not targeted them.** For example, if you are recruiting UTK faculty, staff, or students, you might inadvertently recruit pregnant females, or international populations. If you are recruiting minors, you might inadvertently enroll children who are wards of the state.

Depending on the category of vulnerable participant, and the design of the study, it may not be the case that any special protections are needed; if so, just explain that in the text box.

If special protections are warranted, you will explain them in your selection and recruitment procedures, and in your inclusion/exclusion criteria.
**Application Screen**

### (1600) Participant Selection and Recruitment

How will you invite individuals to participate in your research?
- via email?
- via posted flyers?
- via visiting meetings and explaining your study?
- via an online recruitment system such as SONA?

The IRB must review your planned procedures and see copies of your materials.

### Recruitment Materials:

Even if you are going to explain the study in face-to-face meetings, we must review the script of what you are going to say. For emails, flyers, online recruitment, we must review the documents themselves. **Please attach these at the end of the application, as "Other Study Documents" in the Recruitment/Advertising Materials category.**

### (3045) Payment (3050) Describe Payment

If you are offering participants any sort of compensation for their participation in your study, you must select "Yes" in (3045) and the describe the payment in (3050).

The IRB—and the participants (via your Consent Form)—must understand:
- the amount of compensation,
- how it will be prorated (for example, will participants receive partial payment if they begin but do not complete the study?),
- to whom it will be given, and
- in what form.

When deciding on an appropriate amount of compensation it is important that you not offer such a large payment that it could exert undue influence and cause persons to volunteer to participate in your study when that might not be in their best interest; i.e., the amount of payment should not be coercive.

Please note that course credit is considered payment!

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**Completion Instructions**

### (1600) Participant Selection and Recruitment

How will you invite individuals to participate in your research?
- via email?
- via posted flyers?
- via visiting meetings and explaining your study?
- via an online recruitment system such as SONA?

The IRB must review your planned procedures and see copies of your materials.

### Recruitment Materials:

Even if you are going to explain the study in face-to-face meetings, we must review the script of what you are going to say. For emails, flyers, online recruitment, we must review the documents themselves. **Please attach these at the end of the application, as "Other Study Documents" in the Recruitment/Advertising Materials category.**

### (3045) Payment (3050) Describe Payment

If you are offering participants any sort of compensation for their participation in your study, you must select "Yes" in (3045) and the describe the payment in (3050).

The IRB—and the participants (via your Consent Form)—must understand:
- the amount of compensation,
- how it will be prorated (for example, will participants receive partial payment if they begin but do not complete the study?),
- to whom it will be given, and
- in what form.

When deciding on an appropriate amount of compensation it is important that you not offer such a large payment that it could exert undue influence and cause persons to volunteer to participate in your study when that might not be in their best interest; i.e., the amount of payment should not be coercive.

Please note that course credit is considered payment!
### Application Screen

<table>
<thead>
<tr>
<th>(701) Define &quot;Expedited&quot; and Minimal Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Expedited Screening Questions</em></td>
</tr>
<tr>
<td><strong>Application Screen</strong></td>
</tr>
<tr>
<td>proposals that may qualify for expedited review include:</td>
</tr>
<tr>
<td>Research activities that</td>
</tr>
<tr>
<td>1) present no more than minimal risk to human participants</td>
</tr>
<tr>
<td>2) involve only procedures listed in one or more of seven expedited review categories.</td>
</tr>
<tr>
<td>By answering the following questions, you will assist the IRB in determining if your proposal will be granted an expedited review.</td>
</tr>
<tr>
<td>* Do the research activities present no more than minimal risk to human participants?</td>
</tr>
<tr>
<td>o Yes. The research activities present no more than minimal risk to human participants.</td>
</tr>
<tr>
<td>o No. The research activities do not present more than minimal risk to human participants.</td>
</tr>
<tr>
<td>* Would identification of the participants and/or identification of their responses reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing?</td>
</tr>
<tr>
<td>o Yes. Identification of participant or participant response COULD place the participant at risk.</td>
</tr>
<tr>
<td>o No. Identification of participant or participant response WOULD NOT place participant at risk.</td>
</tr>
</tbody>
</table>

### Completion Instructions

<table>
<thead>
<tr>
<th>(703) Minimal Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you responded &quot;Yes&quot; in (701) above that identification could place participants at risk, you must implement privacy/confidentiality protections in order to qualify for expedited review.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(706) Classified Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified research is not eligible for expedited review.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(715) Significant Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>If appropriate, you will receive this screen about whether or not your study of a drug, device or biologic will significantly increase its risk, which influence whether or not your study meets the criteria for expedited category 1.</td>
</tr>
</tbody>
</table>
### Application Screen

**Category 2: Blood Collection**

*Does this research involve the collection of blood?*

- Yes. This study/project does involve the collection of blood.
- No. This study/project does not involve the collection of blood.

*Will the collection of blood samples be solely by finger stick, heel stick, ear stick, and/or venipuncture?*

- Yes. Blood will be collected ONLY by the methods listed above.
- No. Blood may be collected by other methods that do not meet requirements for expedited review.

**Completion Instructions**

If your study involves the collection of blood, select "Yes" and then receive the follow-up screens to answer questions that help the IRB determine if your study qualifies for Expedited Category 2.

If your study does not involve collection of blood, select "No" and you will branch to the next category.

### Study/Project Population

*Does the study/project population include the following? Check all that apply.*

- Healthy, non-pregnant adults who weigh at least 110 pounds
- Unhealthy adults, pregnant females, children, and/or persons who weigh less than 110 pounds (please mark the question mark in the right margin to review the definition of 'Children'.)

**Healthy, Non-Pregnant Adult Blood Collection**

*Please check the amount of blood that will be collected from the healthy, non-pregnant adults who weigh at least 110 pounds.*

- No more than 550 ml of blood will be collected in an 8 week period.
- More than 550 ml may be collected in an 8 week period.

*Please check the frequency of blood collection for the healthy, non-pregnant adults who weigh at least 110 pounds.*

- Blood will be collected no more than 2 times per week.
- Blood will be collected more than 2 times per week.

**Vulnerable Population Blood Collection**

*Please check the amount of blood that will be collected from the unhealthy adults, pregnant women, children, and people who weigh less than 110 pounds.*

- No more than the lesser of: 150 ml or (3 ml per kg) of blood will be collected in an 8 week period.
- More than the lesser of: (50 ml or (3 ml per kg) of blood will be collected in an 8 week period.

*Please check the frequency of blood collection for the unhealthy adults, pregnant women, children, and persons who weigh less than 110 pounds.*

- Blood will be collected no more than 2 times per week.
- Blood may be collected more than 2 times per week.

**Category 3: Biological Specimen Collection**

*Does this research entail biological specimen collection other than blood? (This may include DNA, hair, saliva, fingerprint, skin, or any other biological specimen.)*

- Yes. This research includes biological specimen collection other than blood.
- No. This research does not include biological specimen collection other than blood.

**Prospective/Retrospective Specimen Collection**

*Please indicate the type of specimen collection to be used in this research:*

- Retrospective collection means the specimens were "previously collected." "Previously collected" means collected prior to the date that this research is initiated.
- Prospective collection means the specimens will be collected during the course of the research.

- Retrospective Biological Specimen Collection Only
- Prospective Biological Specimen Collection Only
- Both Retrospective and Prospective Biological Specimen Collection

**Non-Invasive Specimen Collection**

*Expedited Review criteria allow the prospective collection of biological specimens through non-invasive means.*

- Are the procedures in this study/project so non-invasive that they are less than those listed?

- Yes. Specimen collection procedures in this research are NO MORE invasive than those listed.
- No. Specimen collection procedures in this research are MORE invasive than those listed.

**Completion Instructions**

If your study involves the collection of biological specimens other than blood, select "Yes" and you will receive the follow-up screens to answer questions that help the IRB determine if your study qualifies for Expedited Category 3. Biological specimens include (but are not limited to):

- cells obtained through swabs or scraping
- hair
- saliva
- fingernail clippings
- skin

If your study does not involve the collection of biological specimens other than blood, select "No" and you will branch to the next category.
**Application Screen**

### (740) Category 4: Non-Invasive Procedures

*If this study/project involves physical diagnostic and/or monitoring procedures, is it true that ALL are NON-INVASIVE and do not include general anesthesia, sedation, x-rays or microwaves?*

- Yes. The study/project involves physical diagnostic and/or monitoring procedures, all of which are non-invasive and do not include general anesthesia, sedation, x-rays or microwaves.
- No. The study/project involves physical diagnostic and/or monitoring procedures, some of which are invasive or include general anesthesia, sedation, x-rays or microwaves.

### (742) List of Non-Invasive Procedures

Expedited Review criteria allow procedures for the collection of data that are NO MORE INVASIVE than the following procedures:

- physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy
- avoidance or testing sensory acuity
- magnetic resonance imaging
- electrocardiography, electroencephalography, thermography, detection of naturally occurring radionuclide, electrotretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- Are the procedures in this research MORE INVASIVE than the procedures above?
  - Yes. The procedures are MORE invasive than the example procedures listed above.
  - No. The procedures are NOT MORE invasive than those listed above.

### (750) Category 5: Use Non-Research Materials

If your study involves using materials that were collected for a non-research purpose, e.g.,

- teaching,
- program evaluation,
- health assessment,
- design,
- business advice,
  and converting them into research data for systematic investigation, select "Yes" and you will branch to (755) to indicate whether or not these materials are medical records.

### (755) Medical Records

*Are these materials medical records?*

- Yes
- No

### (760) Category 6: Recordings

Does this proposal involve the collection of data from voice, video, digital or image recordings made for research purposes?

- Yes. This proposal does involve data from recordings as noted above.
- No. This proposal does NOT involve data from recordings as noted above.

### (770) Category 7: Characteristic, Behavioral, Methodology Research

If you are researching characteristics or behavior, and/or if you are using one of the specified research methodologies, select "Yes."

---

**Completion Instructions**

### (740) f. Category 4: Non-Invasive Procedures

If your study involves physical diagnostic and/or monitoring procedures, you must select "Yes" or "No" to describe them.

- "Yes" will branch you to (742) for confirmation that all procedures are non-invasive, which may indicate that your study qualifies for Expedited Category 4;
- "No" will branch you to Full Board review.

If your study does **not** involve physical diagnostic and/or monitoring procedures, select "Not applicable" and you will branch to the next category.

### (750) f. Category 5: Use Non-Research Materials

If your study involves using materials that were collected for a non-research purpose, e.g.,

- teaching,
- program evaluation,
- health assessment,
- design,
- business advice,

and **converting** them into research data for systematic investigation, select "Yes" and you will branch to (755) to indicate whether or not these materials are medical records.

If your study **does not** involve the use of materials that were collected for non-research purposes, select "No" and you will branch to the next category.

### (760) Category 6: Recordings

Will your study involve audio-, video- or image recording?

### (770) Category 7: Characteristic, Behavioral, Methodology Research

If you are researching characteristics or behavior, and/or if you are using one of the specified research methodologies, select "Yes."
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<tr>
<td><strong>(765) May Be Exempt</strong>&lt;br&gt;Based on your answers to the questions for Determination of Expedited Status, your project may qualify for Exempt status if you are using materials (data, documents, records, or specimens) that have been collected solely for non-research purposes, AND all of these materials are already in existence at the time you submit this application to the IRB.&lt;br&gt;If this is true, you will receive the exempt questions. You may also call the IRB for assistance (974-3466) if you have any questions.</td>
<td><strong>(765) (775) (780) Expedited/Not Expedited Determination</strong>&lt;br&gt;If your responses to the Expedited Screening Questions indicate that your study might be Exempt or Full Board status, you will receive one of these screens, and be prompted to return to (485) and change the status there. If you have been in conversation with the IRB and believe Expedited status is correct, simply continue to the Expedited study application. <strong>Please contact the IRB if you have any questions at (865) 974-7697.</strong></td>
</tr>
<tr>
<td><strong>(775) May Be Exempt</strong>&lt;br&gt;Based on your answers to the questions for Determination of Expedited Status, your project may qualify for Exempt status if you are using materials (data, documents, records, or specimens) that have been collected solely for non-research purposes, AND all of these materials are already in existence at the time you submit this application to the IRB.&lt;br&gt;If this is true, you will receive the exempt questions. You may also call the IRB for assistance (974-3466) if you have any questions. If this is not true, simply save and continue answering the expedited application questions.</td>
<td></td>
</tr>
<tr>
<td><strong>(780) Not Exempt</strong>&lt;br&gt;Based on your answers to the questions for Determination of Expedited status, your project does not fall under Expedited status and should be submitted for Full Board Review according to the Federal Regulations.&lt;br&gt;Please go back to (485) Study/Project Information, and change the chosen option to &quot;Full Board.&quot; You may also call the IRB for assistance (974-3466) if you believe your study is expedited.</td>
<td>If your responses to the Expedited Screening Questions indicate that your study <strong>may</strong> qualify for Expedited Review, you will branch to the study application.</td>
</tr>
</tbody>
</table>
### Application Screen

**925 Study/Project Synopsis**

*Click on the bar below and provide a synopsis of the research study/project addressing the following four items using these numbered subheadings:*

1. Purpose/Objectives of the Study/Project
2. Study/Project Population, and
3. Study/Project Procedures, and
4. Outcome Measures.

*Click here to access the text editor.

### Completion Instructions

**925 Study/Project Synopsis**

Use the text box to describe your research plans using the four subheadings provided. Item #3 is where you should name any non-UTK collaborators and their institutions, and describe their roles in your study. Many investigators prefer to write this section in a word processor document, and then copy and paste the text into iMedRIS.

**1075 Background and Current Status of Work in the Field**

*Provide a discussion of the background and current status of work in the field.*

### Completion Instructions

**1075 Background and Current Status of Work in the Field**

Please provide a summary description of work in your field that should provide—to a lay audience—a scientific rationale for your study. Please include only the description/discussion here; the reference list to support it will be entered in screen (5000) below.

**1200 Site Information**

*Please list in the text box all locations where your study will take place, and information about which procedures will take place at which sites, if more than one.*

The IRB must have documentation that you have permission to conduct research at other sites. **These letters**

- must be on official letterhead of the school/business/organization (not of UT) and
- must explicitly be permission for research.

Please attach them at the end of the application as "Other Study Documents" in the Letter of Support category.
(1400) Participant Population

It is very important for the IRB to know who your participants will be, and how many of them there will be. **You may not enroll more participants than are approved, so decide carefully what number to enter here.**

- If you responded "No" to multi-site studies in (1200) above, you will enter the same number in the first two boxes.
- If you entered "Yes" to multi-site studies, the first number is determined by adding all of the sites together; the second number is only those to be recruited at UTK. If other PIs are recruiting separately from you, this number will be different than the one above.

**The age range is critical** as research involving minors (anyone under 18 years of age) requires special protections, including parent permission. In addition, depending on the type of study activities, other age groups might be at increased risk.

**If you plan to exclude** any racial or ethnic group, you must provide a rationale for doing so.

(1488) Vulnerable Participants

Please read and complete this section very carefully; many applications are returned for correction in this area.

**In the first box, it is important to select every category of participants who are being actively recruited for your study.** For example, if you are recruiting UT faculty, staff, or students, you must select "Students of a school associated with this project" and/or "Employees of an institution associated with this project." If you are recruiting minors, you must select "Children (0-17 years) who are not wards of the state."

**In the second box, please select every category of participant who might incidentally enroll in your study, even if you have not targeted them.** For example, if you are recruiting UTK faculty, staff, or students, you might inadvertently recruit pregnant females, or international populations. If you are recruiting minors, you might inadvertently enroll children who are wards of the state.

Depending on the category of vulnerable participant, and the design of the study, it may not be the case that any special protections are needed; if so, just explain that in the text box.

If special protections are warranted, you will explain them in your selection and recruitment procedures, and in your inclusion/exclusion criteria.
### Application Screen

**[1494] Study/Project Duration**
- What is the anticipated duration of a single participant's participation in the study/project?
- How long will the entire study last?

**[1500] Inclusion Exclusion Criteria**
- Identify inclusion criteria.
- Identify exclusion criteria.

**[1600] Participant Selection and Recruitment**
- How will participants be selected? Check all that apply:
  - Participants identified through medical record screening
  - Participants recruited from among students and/or employees
  - Telephone pre-screening
  - Website pre-screening
  - Advertising
  - Other
- If you selected "Other," please explain:

**[1710] Study/Project Procedures**
- *Describe any procedures that have not already been described in the synopsis.*
- *Describe the procedures that will be performed to determine whether prospective participants satisfy inclusion/exclusion criteria for study/project participation.*

### Completion Instructions

**[1494] Study/Project Duration**
- **In the first box,** tell us how long any individual participant will be involved in your study. This should match what they are told in the consent material.
- **In the second box,** tell the IRB how long your study will last overall, including data analysis and—if dissertation or thesis—final defense.

**[1500] Inclusion Exclusion Criteria**
- How will you determine if individuals are **eligible** to participate in your study (inclusion)?
- How will you determine if individuals are **not eligible** to participate in your study (exclusion)?

**[1600] Participant Selection and Recruitment**
- How will you invite individuals to participate in your research?
  - via email?
  - via posted flyers?
  - via visiting meetings and explaining your study?
  - via an online recruitment system such as SONA?
- The IRB must review your planned procedures and see copies of your materials.

**Recruitment Materials:**
- Even if you are going to explain the study in face-to-face meetings, we must review the script of what you are going to say. For emails, flyers, online recruitment, we must review the documents themselves. **Please attach these at the end of the application, as "Other Study Documents" in the Recruitment/Advertising Materials category.**

**[1710] Study/Project Procedures**
- In the first text box, describe any study procedures that you have not yet explained, either in the synopsis or other screens above.
  - In the second text box, describe how you will screen for your inclusion and exclusion criteria, if screening is necessary for your study.
### Application Screen

**[2000] Risks & Benefits**

* Describe the possible risks to participants (including psychological harm, economic harm, social stigmatization, legal harm and physical harm if applicable). Include justification of those known risks.

Describe ways in which this risk, if any, will be minimized.

**Is there potential for direct benefit to the participant?**
- [ ] Yes
- [ ] No

**Will there be benefit to the class of participants?**
- [ ] Yes
- [ ] No

**Is there societal/scientific benefit?**
- [ ] YES
- [ ] NO

If you are any of the last three questions, explain:

---

### Completion Instructions

#### (2000) Risks & Benefits

Assessing the risk/benefit ratio of a study is one of the IRB’s most important tasks, and this is where you give the information necessary for that assessment. In the first text box, list any/all potential risks, including (but not limited to)

- violation of privacy
- breach of confidentiality
- distress
- physical harm

In the second text box, describe the procedures that you have built in to your study to minimize the risks. **Benefit refers to the good that may result from your study, and there must be a possible societal/scientific benefit**, even if there is not any direct benefit to your individual participants or to the class of participants.

When you describe the potential benefit of your study in the text box, remember that **incentives or compensation that you offer to participants are not considered benefits**, and should be described in (3045) and (3050) below rather than here.

#### (2210) AE’s and Data Monitoring

You should only receive this screen if you responded "Yes" to the drug, device, or biologic item in (485) above.

If so, use this box to explain the arrangements you have made for monitoring the data and the safety of your participants.
### Application Screen

#### (2800) Confidentiality 1

**Completion Instructions**

The first three questions in this screen are asking how you will protect the confidentiality of paper and electronic records, and biological specimens, that are stored locally (at UTK). In each case, you will select either

- "Yes" if there will be secure storage and access only to study personnel,
- "No" if there will not be secure storage and access only for study personnel, or
- "N/A" if this category of data is not included in your study.

The plans you describe here for the IRB will also be included in your Informed Consent process, so that your participants will know how you plan to protect their confidentiality. **Be sure your Informed Consent form is consistent with what is described here.**

The last question is asking whether or not you will transmit any data electronically, including emailing it to yourself.

#### (2810) External Records/Specimens

If appropriate, you will receive screen (2810) asking if the data **to be transmitted** will be coded or not.

If you indicate that some or all of your transmitted data **will not be coded**, you will need to explain your plans in the text box, including how you are going to protect your data.

If you indicate that your transmitted data will be **coded**, you will receive screen (2814) about the key linking the codes to the individuals.

#### (2814) Coded External Records/Specimens

Explanatory note: "Coded" means that identifying information (such as a name or social security number) which would permit easy identification of an individual has been replaced with a number, letter, symbol, or some combination thereof.

- All research records and specimens transmitted to the external site(s) will be coded.
- Some research records or specimens transmitted to the external site(s) will not be coded.
- All research records or specimens transmitted to the external site(s) will not be coded.
- *If the second or third choice is selected, please explain: Otherwise, type "NA."*
Application Screen

(2820) Confidentiality
- Will information obtained from procedures performed only for research purposes be placed in the medical record of the participant?
  - Yes
  - No
  - Not applicable
- Will documentation of the participation of the participant in the research study, such as a copy of the consent form or other notation, be placed in the medical record of the participant?
  - Yes
  - No
  - Not applicable
- For studies/projects that involve a repository: Is it true that specimens or data from the repository will not be labeled in a manner that allows individual investigators to whom the specimens or data are distributed to identify individual participants?
  - True
  - False

(3045) Payment
- Will any type of payment (money, gift card, or other item) be provided to the participant for participation?
  - Yes
  - No

(3050) Describe Payment
- Indicate the AMOUNT of money to be paid (including reimbursement, pay per visit AND total maximum payment, the type of payment (check, cash, gift card and value), as well as the monetary worth of any OTHER taxable item provided as payment for study/project participation.
- To whom will the payment (money, gift certificate, other item) be paid/given?
  - The participant
  - The participant's legally authorized representative
  - Mixed arrangement, depending on the age of the participant
- How will the actual amount of money received by the participants or their legally authorized representative be determined?
- Lump sum payment will be made at completion of the study/project. (Note: if paying per visit, the payment must not be held until the end of the study because of potential undue inducement; the same applies if a rather large sum of money will be paid only at the end of the study.)
- Prorated payments will be processed or issued at the time specific visits and/or procedures are completed
- Prorated payments will be processed or issued at the time specific visits and/or procedures are completed, plus a bonus will be paid for completing the entire study/project
- Course Credit
- Not applicable; no money will be paid to the participants
- If your answer is the second option, “Prorated payments...” please describe the schedule of payments for specific visits and/or procedures.
- If your answer is the third option, “Prorated payments... plus a bonus for completing the entire study,” please describe the schedule of payment for specific visits and/or procedures, as well as the bonus for completing the entire study/project.

Completion Instructions

(2820) Confidentiality 2
These screens contain important questions to be answered by investigators who have access to patients’ medical records as part of their studies. If your study does not involve medical records, select "Not applicable" for all three questions and go on to the next screen.

If your study does involve medical records, please indicate
- whether or not you will put data from your study into the records
- whether or not you will put consent forms or other documentation of participation into the records, and
- how you will label data/specimens if this is a repository study.

While most UTK research does not involve medical records, there are several departments in which it does, and these questions are necessary.

(3045) Payment
If you are offering participants any sort of compensation for their participation in your study, you must select "Yes" in (3045) and the describe the payment in (3050).

The IRB—and the participants (via your Consent Form)—must understand
- the amount of compensation,
- how it will be prorated (for example, will participants receive partial payment if they begin but do not complete the study?),
- to whom it will be given, and
- in what form.

When deciding on an appropriate amount of compensation it is important that you not offer such a large payment that it could exert undue influence and cause persons to volunteer to participate in your study when that might not be in their best interest; i.e., the amount of payment should not be coercive.

Please note that course credit is considered payment!
**Expedited & Full Board Application**

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<td><strong>(3100) Financial Obligations</strong>&lt;br&gt;Are participants going to be responsible for paying for any of the materials, treatments, sessions, etc., that you are asking them to use/receive/attend as part of your study? If you select &quot;Yes,&quot; describe these costs in the text box—and describe them clearly for participants in the Informed Consent form.</td>
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</tr>
<tr>
<td><strong>(3200) Research Injuries</strong>&lt;br&gt;In these screens, you will describe for the IRB how you plan to handle any injuries that might be caused by participation in your study—both physical and non-physical (such as exposure to civil or criminal liability, damage to reputation or employability). If you select &quot;Yes&quot; in (3200) you will receive the follow-up screens to respond to your plans for handling physical injuries.</td>
<td></td>
</tr>
<tr>
<td><strong>(3210) Potential Injuries</strong>&lt;br&gt;Write the &quot;exposure &amp; injury insurance,&quot; or the &quot;participant &amp; exposure insurance,&quot; and the sponsor below, regarding who will be responsible for the costs of treating research-related physical injuries, or specify any other arrangements.</td>
<td></td>
</tr>
<tr>
<td><strong>(3230) Compensation for Non-Physical Injuries</strong>&lt;br&gt;All investigators will be asked to respond to the screens asking about non-physical injuries.</td>
<td></td>
</tr>
<tr>
<td><strong>(3240) Non-Physical Injury: Who Provides Compensation</strong>&lt;br&gt;Write &quot;the sponsor&quot; or &quot;not provided&quot; in the text box below regarding who will provide compensation for non-physical injuries associated with research participation, or specify any other arrangements.</td>
<td></td>
</tr>
</tbody>
</table>
**Informed Consent**

This window and those that follow are very important to IRB review, as the informed consent process is how we demonstrate the *Belmont Report* principle of Respect for Persons.

In (3329), select all statements that are true for your study.

- If you **do not** indicate that you are requesting a waiver and/or alteration of consent, you will branch directly to (3393) Consent Summary.
- If you **do** indicate that you are requesting a waiver and/or an alteration of consent, you will receive screen (3352) to describe the group(s) for which these are being requested.

**Alteration of Consent**

If appropriate, you will receive these screens to describe how you wish to alter the process, and to share your rationale for the request. Alterations of consent can include, but are not limited to,

- not collecting signed informed consent forms and
- not disclosing all of the elements of informed consent before participation (use of deception).

The IRB cannot approve alterations without sufficient rationale and protections in place; **please include as much detail as possible if you are requesting an alteration of consent.**

**Waiver of Consent**

If you indicated in (3329) that you are requesting a waiver of consent for some or all of your participants, you will receive these screens to describe your rationale for this request, and to provide the IRB with the information required to determine if your study meets the criteria for being granted a waiver of consent.

The IRB cannot approve waivers without sufficient rationale and protections in place; **please include as much detail as possible if you are requesting a waiver of consent.**
### (3440) Consent Process

If you are obtaining consent (even with alteration) from any of your participants, you will explain in this text box **when and how consent will be obtained, and by whom**. The IRB will be concerned that the process includes sufficient time for participants to make a thoughtful, voluntary decision that is not unduly influenced by any relationships they might have with the individuals asking for their consent.

**The forms that are to be used should be attached at the end of the application, as "Informed Consent" items in the appropriate categories (e.g., Main Consent Form, Consent Statement/Elements).**

---

### (3442) Non-English Speaking

* Will a consent form (or survey with consent elements) in the primary language of non-English speaking participants and/or non-English speaking legally authorized representatives be attached to the application?

**NOTE:** You may not enroll non-English speaking participants until you have a consent form translated into their primary language.

1. Yes. A consent form (or survey with consent elements) in the primary language of non-English speaking participants and/or non-English speaking legally authorized representatives will be attached to the application.
2. No. After the English consent form (or survey with consent elements) is approved by the IRB, we will obtain a translation. The translation will be submitted at a later date.

**Not Available.** You may ONLY check this button **if you are NOT using survey consent elements or any type of consent form or written document during the informed consent process.**

---

### (3444) Translation Documents

* In this text box, discuss how the informed consent process will be conducted with non-English speaking participants and/or their legally authorized representatives (LARs), and whether a translator (who is fluent in both English and the participant/LAR’s primary language) will be available for all other research interactions with participants/LARs, including but not limited to follow-on visits and phone calls. Indicate the name of the individual among the key study personnel who has been designated to serve as translator, or indicate which other party will serve as translator. If the translator’s name is known, include his/her name below.

---

### (3445) Informed Participants/LARs/Family Members

* Delicate the procedures that will be used to inform, at the earliest feasible opportunity, each participant, or if the participant remains incapacitated, a legally authorized representative of the participant, of such a representative is not reasonably available, a family member, regardless (a) the fact that the participant has been included in the clinical investigation, the details of the investigation and other information contained in the consent document and (b) his or her opportunity to discontinue the participant’s participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

* Characterize the procedures that will be used to locate and inform the participant’s legally authorized representative or family member about the clinical investigation. If feasible, when the participant is enrolled into the clinical investigation with waived consent and the participant dies before a legally authorized representative or family member can be contacted.

---

### (3342) and (3444) Non-English Speaking Participants

If appropriate, you will receive these screens to describe

- your plans for translating your Informed Consent forms into the non-English version, and
- your plans for conducting your consent process with your non-English speaking potential participants.

Please attach both the English and the non-English versions at the end of the application, as "Informed Consent" documents in the appropriate categories as described above.

---

### (3445) Legally-Authorized Representatives for Adults Unable to Consent for Themselves

If appropriate, you will receive these screens to describe the procedures you will undertake to contact and obtain informed consent from their legally-authorized representatives.
(3300) Conflict of Interest
Please read very carefully and indicate whether you or any of your key study personnel (or their families) have a conflict of interest with respect to any sponsor of your research or any entity being studied in your research.

If you select "Yes" for any of these questions, you will need to have a Conflict of Interest Management Plan in place that includes disclosure to participants in the Informed Consent form.

(3450) HIPAA
In this screen, please select "Yes" or "No" to indicate whether or not you are seeking to use Protected Health Information (PHI) without participants' consent. If you select "Yes" you will branch to follow-up screens to provide information that will help the IRB determine if you qualify for a HIPAA recruitment waiver. (see appendix)

If you are not using PHI at all, simply select "No."

(3500) (3505) FERPA
In this screen, please select "Yes" or "No" to indicate whether or not you are seeking to use information protected under the Family Educational Rights & Privacy Act (FERPA) without participants' consent. If you select "Yes" you will need to:
• describe in the text box the FERPA-protected material you wish to use, and
• attach at the end of the application documentation of your permission from the University’s FERPA officer to do so.

(5000) References
Please use this text box to list the citations for your "Background and Current Status of Work in the Field" above.

(10000) Form Completed
In the event that there is more you wish to tell the IRB about your submission, this is the place to do it.

Click on "Save and continue" to advance to the screens for adding attachments, and routing for necessary review and approval.
1.0 **Routing Form**

Once you have completed the application, iMedRIS will take you to the routing form for your submission, where you will be prompted to attach any documents that the IRB needs to review as part of your application. The application you have been working on is already attached. "Save and Continue" unless you wish to attach a different version of the application.

2.0 (555) Consent Form(s)

Please upload your consent documents here, and not as "other study documents." Use the drop down menu (in the dialog window in which you upload) to select the appropriate category of consent form:

- **Main Consent Form**
- **Consent Statement/Elements** (this is the cover sheet used for surveys)

3.0 (575) Additional Study/Project Documents

- **Recruitment/Advertising Materials** (as described in (1600) above)
- **Surveys/Questionnaires/Data Collection Instruments** (attach any instruments here that you will use, including those listed as well as observation checklists, interview protocols, etc.)
- **Letter of Support**
  1. required for any external sites described in (1200) above
  2. required for use of any existing data sets you wish to analyze that you do not own (or attach documentation of their having been made publicly available for research purposes)
  3. this category is where you can upload the IRB approval for your Co-PIs at other institutions that you have listed in Item #3 of your Synopsis (650) or (925) above
- **Other Miscellaneous Documents** (use this category for documents you wish to attach that do not fit into one of the specific categories in the drop down menu)

4.0 (800) UTK Form Completion

When you are sure you have completed your application and all of its attachments, you will click "sign and submit."
### Application Screen

<table>
<thead>
<tr>
<th>Does this submission require additional routing for approval?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ YES - Click YES to select additional personnel for routing.</td>
</tr>
<tr>
<td>○ NO - Click NO to bypass selecting additional personnel for routing.</td>
</tr>
</tbody>
</table>

Be sure to change the radio button to "YES" when submitting a new project for the first time.

The default on this page is "NO" because for most of the life of your study—whenever you modify it or renew it—you will not need to route to additional persons. Only for the initial review must it be signed by all investigators and department approvers as listed to the right.

### Completed Instructions

**Routing**

iMedRIS will prompt you to indicate those to whom your study must be routed for review, approval, and sign off on its way to the IRB. **Select "Yes" the first time you submit a new project,** as all of the following persons **must** sign off before the IRB can begin its review:

- PI
- any/all Co-PIs (or Co-Investigators, or Sub-Investigators)
- Advisor (if a student study)
- DRC (Department Review Chair)
- Department Head (called Department Chair in iMedRIS)

Please check with your Department/College for specific instructions regarding how this is handled—some units have specific arrangements with the IRB that you need to know before you complete screen 3 (above) and route for signatures.

Please view this 10-minute video for specific instructions on routing.

http://utkdms.utk.edu/Mediasite7/Play/a05002db21df4a583d842f84f24cfa81d

The video is also available in the iMedRIS "Help" menu (upper right hand corner of your screen).

Once your routing list is complete, you will "approve" the submission and sign off using your UTK netID and password. Your application will then be sent to each person on your routing list, in order.

**Your application will not be received by the IRB until all have signed off. If you have not routed to everyone listed above, your application will be returned to you for correct routing.**
**Appendix: HIPAA Screens Specific to Studies Using PHI**

### Application Screen

**3455) HIPAA Type of Waiver Requested**

- Waiver of participant authorization is being requested.

- All Protected Health Information (PHI) to be used is from deceased individuals or all Protected Health Information (PHI) to be used is from individuals who were deceased prior to the date when the research proposal was initiated.

- All Protected Health Information (PHI) to be used is a limited data set. A limited data set is a medical record, database, or other source document being accessed for the research which does NOT contain 16 of the 18 HIPAA-specified identifiers. (The 18 identifiers can be found by clicking on the question mark to the right of this section.)

- The health information to be used is de-identified data. De-identified data is a medical record, database, or other source document being accessed for the research which does NOT contain ANY of the 18 HIPAA-specified identifiers. (The 18 identifiers can be found by clicking on the question mark to the right of this section.)

### Completion Instructions

*(3455) ff. HIPAA*

This screen, and those that follow, will be shown only to investigators who have requested in (3450) to access the Protected Health Information (PHI) of participants without securing the participants' explicit informed consent to do so.

### Section A: PHI

* Briefly describe the Protected Health Information (PHI) to be used in the research activity. If this study involves a review of records for which all the records will be in existence and completed at the time that the study is initiated, then specify the beginning and ending dates of those records.

If Protected Health Information (PHI) will be disclosed to the investigator by another covered entity or entities, briefly describe these entities.

* Briefly explain who will receive and use the Protected Health Information (PHI) and where it will be stored.

### Section B: Use of PHI

* Protected Health Information (PHI) will be used:
  - for the conduct of the study itself.
  - to identify potential participants for recruitment.
  - to contact potential participants regarding study participation.

### HIPAA Alteration

* Please describe briefly the proposed alteration of the authorization. At the end of this application, you will be asked to attach a copy of the altered authorization section of the consent form.

Otherwise, type "n/a.

### HIPAA Waiver or Alteration

* Briefly describe the plan to protect the Protected Health Information (PHI) identifiers.

* Briefly describes the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a justification for retaining the identifiers or such retention is otherwise required by law, this should be explained.

* Will the Personal Health Information (PHI) be reused or disclosed to any other person or entity?

- Yes
- No

* Is it true that the Personal Health Information (PHI) will not be reused or disclosed to any other person or entity EXCEPT as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI is approved by the IRB?

- True. PHI will not be reused or disclosed unless as excepted above.
- Not true. PHI may be reused or disclosed as noted below.

If you answered "Not true," please explain:

* Briefly explain why you must have access to the PHI in order to complete your research.
### Appendix: HIPAA Screens Specific to Studies Using PHI

#### Section A: HIPAA Alteration Practicality
* Briefly explain why the research activity could not practically be conducted without alteration of the authorization requirement.

#### Section B: HIPAA Waiver Practicality
* Why can the research not be practically carried out without the waiver of the authorization requirement?
  - A. Needs and personnel do not exist to contact all potential participants to secure their authorization.
  - B. Failure to include all potential participants might result in skewed analysis of the results of the study.
  - C. Other reason.
  * If you answered “Other reason,” please explain: ____________.

#### Section C: PHI from Deceased
* Does adequate documentation exist that all participants whose Protected Health Information (PHI) will be used in this study are deceased?
  - A. Yes. Please describe documentation below.
  - B. No. Please explain why in the following space.

* Explain why the Protected Health Information (PHI) being sought is necessary for the research study.

#### Section D: Limited Data Set
* Will the Protected Health Information (PHI) used in the research study exclude the 16 categories of direct identifiers necessary for the creation of a limited data set?
  - A. Yes. The 16 categories of direct identifiers will be excluded.
  - B. No. Please explain below.

* Has a data use agreement been reached with the covered entity for the use of the Protected Health Information (PHI) in the research study?
  - A. Yes. A data use agreement has been reached.
  - B. No. If no, a data use agreement must be submitted prior to IRB approval of this proposal.

#### Section E: De-identified Data
* The health information to be used in this research has been determined to be de-identified by:
  - A. An appropriate expert has made the determination and a copy of this determination is attached to this proposal.
  - B. The health information excludes all 16 categories of direct identifiers.

* Will the entity that maintains the health information utilize a code or other means to re-identify the records?
  - A. Yes. Records will be re-identified.
  - B. No. Records will not be re-identified.

* Is it true that the code or other means used to re-identify the records is not derived from or related to the individuals or otherwise capable of being translated to identify the individual participants?
  - A. True. Participants will not be able to be identified.
  - B. Not True. Participants may be able to be identified.

* Is it true that the entity maintaining the records will not disclose the means for re-identifying the records?
  - A. True. The maintaining entity will not disclose the means for re-identifying the records.
  - B. Not true. The maintaining entity may disclose the means for re-identifying the records.
### Appendix: HIPAA Screens Specific to Studies Using PHI

#### Section F: Preparatory to Research

- **Is the use or disclosure being sought solely to review Protected Health Information (PHI) as necessary to prepare a research protocol or for similar purposes preparatory to research?**
  - Yes. Disclosure is solely preparatory to research.
  - No. Disclosure may be used for more than research preparation.

- **Is it true that, in the course of the review, the investigator will not copy or remove Protected Health Information (PHI) from the entity maintaining the PHI?**
  - Yes. The PI will not copy or remove PHI from the entity maintaining the PHI.
  - No. The PI may copy or remove PHI from the entity maintaining the PHI.

- **Briefly explain why the use of the Protected Health Information (PHI) is necessary for purposes preparatory to research.**

#### De-Identified Human Cell Lines

- **Briefly describe the purpose of the study.**

- **Briefly describe any cell lines that will be used in this study AND the vendor/sourcing from which they will be received.**

- **Is it true that the investigator will not have or receive any information that would allow cells used in this study to be linked to specific individuals?**
  - Yes, the investigator will not have or receive information that would allow cells used in this study to be linked to specific individuals.
  - No, the investigator will have or receive information that would allow cells used in this study to be linked to specific individuals.

#### Human Cell Lines to be Determined

In order to determine whether your use of human cell lines is exempt from IRB oversight, please check “Exempt” in section 4B3 and answer the subsequent questions that are prompted.