Institutional Review Board (IRB)
Form 1 Initial Application Step-by-Step Instructions

User ID:
Password:
Log In

updated
July 2016

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July 2016
Form 1 Initial Submission Instructions
Applying for Institutional Review Board (IRB) Approval
Using the UT, Knoxville Application Revised 7/1/2016

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 at utkirb@utk.edu or 974-7697 if you need further assistance.

Table of Contents

Initial Screens (all applications) 4 - 7
  New Application
  Key Study Personnel
  Review Board Routing
  Funding
  Study/Project Information

Exempt Application 8 - 12

Expedited Screening Questions 13

Expedited & Full Board Application 14 - 18

Closing Screens (all applications) 19 - 21
  Conflict of Interest
  HIPAA
  FERPA
  References
  Routing Form
  Attachments

Appendix: HIPAA Screens Specific to Studies using PHI 22 - 24
Begin by logging in to the iMedRIS online submission system at https://ris01.uthsc.edu using your UTK netID and password.

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.)

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

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.

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.

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

(417) UTK Key Study Personnel (KSP) Credentials

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 in (925) Study/Project Synopsis.

(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

**475) Contract Information**

* 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 "Not Applicable."

- [ ] none
- [ ] Contract Information

If you selected "Other" please list the office or institution that is processing the grant or contract for this study/project:

Where is the project/proposal in the funding process?

- [ ] Not submitted (seeking IRS approval as first step)
- [ ] Submitted but not awarded
- [ ] Awarded

Is the proposal title different from this IRB project application?

- [ ] Yes
- [ ] No

If different list below:

List the following information (if applicable):

Note: Please contact the office processing the contract/grant for the appropriate information.

- [ ] UTK - PAMS number or other Institution Log Number / Proposal Number
- [ ] Protocol number for which the contract is handled by UTK Sponsored Programs
- [ ] Request number for which the contract is handled by UTK Sponsored Programs
- [ ] Request number for which the contract is handled by UTK Sponsored Programs

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.

### 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.

**485) Study/Project Information**

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 only 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.
(591) **Exempt Categories**

You will receive this screen if you selected "Exempt" in (485).

Please read the descriptions of each category carefully; and indicate for the IRB if your project fits Category 2, Category 4, or both.

(653) **Studies Involving Existing Data**

You will receive this screen if you selected Category 4 above.

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 [http://irb.utk.edu/public-use-data-sets/](http://irb.utk.edu/public-use-data-sets/) and your study complies with the conditions listed there, you do not need to apply for Exempt review and may begin.

(658) **Survey or Interview**

You will receive this screen if you selected Category 2 above.

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 note that Category 2 does not apply to research with children.

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.
Exempt Application

Application Screen

(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.

* Yes
* No

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 provided 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 consent.

If you answer "yes," at the end of the application, you will be asked to attach a copy of the informed consent statement provided in accord with the IRR guidelines for informed consent to survey research. These guidelines should also be followed for interviews, focus groups, etc.

Informed Consent procedures are always required before you may collect data from living individuals, even when you do not collect signed forms. 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 an Informed Consent Document, and selecting the "Consent Statement/Elements" category.

Completion Instructions

(925) Study/Project Synopsis

Use the text box (by clicking on the text editor) to describe your research plans using the four subheadings provided. (Many investigators prefer to write this section in a word processor document, and then copy and paste the text into iMedRIS.)

Item #3 is where you should name any non-UT Knoxville collaborators and their institutions, and describe their roles in your study.

(1075) Background & 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.

(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.
Exempt Application

Application Screen

Completion Instructions

(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.**

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. **Do not assume your participants are not vulnerable before reading the list of categories.**

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.

(1490) (1492) FERPA
In the first 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.**

Please see [http://ferpa.utk.edu/](http://ferpa.utk.edu/) for more information about FERPA on the UT campus.

If you select "Yes" you will be branched to the second screen, in which you 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.

(1494) Study/Project Duration
Please describe here how long you expect any individual participant to be involved in study activities. Be sure that what you write here matches what you tell participants about time estimates in your consent form.
### (1600) Participant Recruitment

Please explain in detail all procedures to be used for recruitment of participants into your study. The explanation should:

- identify who will approach/contact potential participants,
- identify any data/information sources used to identify potential participants and, if not public, how access is permitted,
- explain how participants will be contacted,
- explain if follow-up attempts will be made, and
- identify how many attempts will be made.

**Recruitment Materials:**

The IRB must review all recruitment materials, such as flyers, emails, invitation letters, verbal scripts, or social media posts. **Please attach these at the end of the application, as "Other Study Documents" in the Recruitment/Advertising Materials category.**

### (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 research, and there must be a possible societal or 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(s) 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.
**Application Screen**

<table>
<thead>
<tr>
<th>(2800) Confidentiality 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please note that there are four categories asked about here; please type &quot;n/a&quot; if any particular one is not relevant to your study:</td>
</tr>
<tr>
<td>1. storage of <strong>paper</strong> records</td>
</tr>
<tr>
<td>2. storage of <strong>electronic</strong> records</td>
</tr>
<tr>
<td>3. storage of biological <strong>specimens</strong></td>
</tr>
<tr>
<td>4. <strong>transmission</strong> of any records (electronic or paper) or specimens</td>
</tr>
<tr>
<td>5. For each that is relevant, the IRB must know the security and/or coding procedures to be used and who will have access.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(3045) Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(3050) Describe Payment</td>
</tr>
<tr>
<td>If you are offering participants any sort of compensation for their participation in your study, you must select &quot;Yes&quot; in (3045) and the describe the payment in (3050).</td>
</tr>
<tr>
<td><strong>The IRB—and the participants (via your Consent Form)—must understand</strong></td>
</tr>
<tr>
<td>• the amount of compensation,</td>
</tr>
<tr>
<td>• how it will be prorated (for example, will participants receive partial payment if they begin but do not complete the study?),</td>
</tr>
<tr>
<td>• to whom it will be given, and</td>
</tr>
<tr>
<td>• in what form.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>Please note that course credit is considered payment!</strong></td>
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</tbody>
</table>

<table>
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<th>(3300) Conflict of Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>If you select &quot;Yes&quot; for any of these questions</strong>, you will need to have a Conflict of Interest Management Plan in place that includes disclosure to participants in the Informed Consent form.</td>
</tr>
</tbody>
</table>
**Expedited Screening Questions**

**Application Screen**

(701) Define "Expedited" and Minimal Risk

If you selected "Expedited" in (485) above, you will receive this screen.

Please respond to the second question carefully: if confidentiality were breached, would your participants be at risk?

If your responses to the first two questions indicate you may be eligible for Expedited review, you will be asked to indicate the categories that apply to your study; please read carefully and select all categories that apply.

**Completion Instructions**

(780) Not Expedited

If your responses above indicate that your study is not eligible for Expedited review, you will be directed to submit using the Full Board application.
**Application Screen**

**Completion Instructions**

**(925) Study/Project Synopsis**

Use the text box (by clicking on the text editor) to describe your research plans using the four subheadings provided. Please provide enough detail that the IRB understands clearly what you propose to do, with whom, and why. (Many investigators prefer to write this section in a word processor document, and then copy and paste the text into iMedRIS.)

Item #3 is where you should name any non-UT Knoxville collaborators and their institutions, and describe their roles in your study.

**(1075) Background & Current Status of Work in the Field**

Please provide a summary description of work in your field that should provide—a lay audience—a scientific rationale for your study.

**(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.

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.
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<td>Please read and complete this section very carefully; many applications are returned for correction in this area. <strong>Do not assume your participants are not vulnerable before reading the list of categories.</strong> 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 special protections are warranted, you will explain them in your selection and recruitment procedures, and in your inclusion/exclusion criteria.</td>
</tr>
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<td><strong>(1490) (1492) FERPA</strong></td>
<td>In the first screen, please select &quot;Yes&quot; or &quot;No&quot; to indicate whether or not you are seeking to use information protected under the Family Educational Rights &amp; Privacy Act (FERPA) <strong>without participants' consent.</strong> Please see <a href="http://ferpa.utk.edu/">http://ferpa.utk.edu/</a> for more information about FERPA on the UT campus. If you select &quot;Yes&quot; you will be branched to the second screen, in which you 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.</td>
</tr>
<tr>
<td><strong>(1494) Study/Project Duration</strong></td>
<td>Please describe here how long you expect any individual participant to be involved in study activities. Be sure that what you write here matches what you tell participants about time estimates in your consent form.</td>
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<td><strong>(1600) Participant Recruitment</strong></td>
<td>Please explain in detail all procedures to be used for recruitment of participants into your study. The explanation should • identify who will approach/contact potential participants, • identify any data/information sources used to identify potential participants and, if not public, how access is permitted, • explain how participants will be contacted, • explain if follow-up attempts will be made, and • identify how many attempts will be made. <strong>Recruitment Materials:</strong> The IRB must review all recruitment materials, such as flyers, emails, invitation letters, verbal scripts, or social media posts. <strong>Please attach these at the end of the application, as &quot;Other Study Documents&quot; in the Recruitment/Advertising Materials category.</strong></td>
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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 research, and there must be a possible societal or 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(s) 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.

(2800) Confidentiality 1
Please note that there are four categories asked about here; please type “n/a” if any particular one is not relevant to your study:

6. storage of paper records
7. storage of electronic records
8. storage of biological specimens
9. transmission of any records (electronic or paper) or specimens
10. For each that is relevant, the IRB must know the security and/or coding procedures to be used and who will have access.
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!

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.

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.
## Application Screen

### (3360) Describe Alteration of Consent

* Describe the nature of the alteration in consent being requested. For example, will you be using the survey consent elements instead of a full consent form for a survey study, or will you be altering a consent form and conducting the informed consent interview over the phone and asking the participant to mail the signed consent form back to you?

### (3365) Practicality Without Alteration of Consent

* Why can the research not be practically carried out without the alteration of consent?
  - Prospective participants cannot be contacted in person to secure their consent, but can be contacted by other means, such as telephone.
  - Achieving the objectives of the research requires that the consent disclosure not include some key elements of information about the study.
  - The research is minimal risk, the number of participants is large, and funds and personnel do not exist to conduct the consent interview utilizing a full consent form.
  - Other reason.

* If you answered "Other," please explain. Otherwise, type "NA."

### (3370) Practicality Without Waiver of Consent?

* Why can the research not be practically carried out without the waiver of consent?

### (3385) Risk/Consent

* Does the research involve more than minimal risk?
  - Yes. The research involves more than minimal risk.
  - No. The research does NOT involve more than minimal risk.

### (3390) Consent Outside Research

* Does the research involve any procedure for which separate, written consent is normally required outside the research setting?
  - Yes. The research does involve procedures for which separate, written consent is normally required outside the research setting.
  - No. The research does NOT involve procedures for which separate, written consent is normally required outside the research setting.

### (3393) Consent Summary

* Will the participant be provided with a written consent summary about the research study?
  - Yes. The participant will be provided with a written consent summary about the research study.
  - No. The participant will NOT be provided with a written consent summary about the research study.

### (3440) Consent Process

* Briefly explain when and where informed consent, permission and/or assent will be sought.

---

## Completion Instructions

### (3360) and (3365) 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.**

### (3370) ff. 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).**
Application Screen

(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, either to conduct the study, or to identify/recruit participants.

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 waiver. (see appendix)

For the second item, indicate whether or not you plan to collect PHI yourself.

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

(10000) Routing for Signatures and Attaching Documents
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)
### Application Screen

**Closing Screens (all applications)**

#### 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)

It facilitates review if you upload these documents in the correct categories, so that reviewers can find them. Use the drop down menu (in the dialog window in which you upload) to select the appropriate categories, as listed to the right.

<table>
<thead>
<tr>
<th>Document</th>
<th>Title</th>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>

### Completion Instructions

#### 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."

**You are not finished yet!! Do not stop here.**
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/a05002db21df4a5883d842f84f24cfa81d

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.**

Submission Routing Signoff Sheet

Once you have indicated everyone who needs to sign off, all of those individuals (including you) will have to do so. In this screen, scroll to the bottom and

1. Review the UTK PI Responsibilities (you are agreeing to these when you sign), and then
2. Approve using your netID and Password, and finally,
3. Save Signoff
Appendix: HIPAA Screens Specific to Studies Using PHI

<table>
<thead>
<tr>
<th>Application Screen</th>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(3455) HIPAA Type of Waiver Requested</strong></td>
<td></td>
</tr>
<tr>
<td>* Please identify the regulatory category under which the request is being made to use Protected Health Information (PHI) without participant authorization.</td>
<td></td>
</tr>
<tr>
<td>- Waiver of participant authorization is being requested.</td>
<td></td>
</tr>
<tr>
<td>- 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 this research proposal was initiated.</td>
<td></td>
</tr>
<tr>
<td>- 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-specification identifiers. (The 16 identifiers can be found by clicking on the question mark to the right of this section.)</td>
<td></td>
</tr>
<tr>
<td>- The 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-specification identifiers. (The 18 identifiers can be found by clicking on the question mark to the right of this section.)</td>
<td></td>
</tr>
</tbody>
</table>

(3450) 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.
## Appendix: HIPAA Screens Specific to Studies Using PHI

### Section A: HIPAA Alteration Practicality

* Briefly explain why the research activity could not practicably 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?

- Needs and personnel do not exist to contact all potential participants to secure their authorization.
- Failing to include all potential participants might result in skewed analysis of the results of the study.
- Other reason.

  * If you answered "other reason," please explain: [ ] Otherwise, type "NA."

### 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?

- Yes. Please describe documentation below.
- 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?

  To view a list of the 16 categories of direct identifiers that must be eliminated in a "limited data set," mouse-over the question mark icon in the right margin and click on "limited data set: 16 categories of direct identifiers."

- Yes. The 16 categories of direct identifiers will be excluded.
- 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?

- Yes. A data use agreement has been reached.
- No. If no, then 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:

- An appropriate expert has made the determination and a copy of this determination is attached to this proposal.
- The health information excludes all 18 categories of direct identifiers.

* Will the entity that maintains the health information utilize a code or other means to re-identify the records?

- Yes. Records will be re-identified.
- 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?

- True. Participants will not be able to be identified.
- 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?

- True. The maintaining entity will not disclose the means for re-identifying the records.
- 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/source from which they will be received.**

- **Yes,** 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 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 483 and answer the subsequent questions that are prompted.