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Human Research Protection Program (HRPP)  
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Office of Research and Engagement  
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June 2018
Form 1 Initial Submission Instructions
Applying for Institutional Review Board (IRB) Approval
Using the UT, Knoxville Application Revised 6/1/2018

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

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### Application Screen

**Log In**

The University of Tennessee

iMedRIS

International System

User ID:
Password:

System Browser Requirements

**Initial Screens (all applications)**

#### Completion Instructions

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 a Biosafety Committee, the UT IRB cannot see it, review it, or approve it.

### 1.0 General Information

* Please enter the full title of your study; for UTHSC/GSM - the generic/trade name of the NHL; the name of the device or drug for Treatment Use; the name of the device for Companation Use; or the name of the device or drug for Emergency Use.

* Please enter a working title up to 15 characters.

#### 2.0 Add Department(s)

2.0.1 List all departments and affiliated institutions associated with this study/project, and please mark the Principal Investigator's UTHSC Department as the primary department. If any of your study/project activities are being conducted at the following sites, list those organizations as well: Methodist and/or St. Boniface, Regional One Health, UT Medical Center, University of Tennessee College of Medicine, University of Tennessee College of Nursing, University of Tennessee Health Science Center, University of Tennessee, Knoxville, Oak Ridge National Laboratory, University Family Physicians, UT Genetic Center, etc.

For UTK projects, please select the EHR's home department as the primary department for this study (also if it is not pre-validated).

**Primary Dept**

Department Name

Add

### Diagram
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.

3.6 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.
<table>
<thead>
<tr>
<th>Application Screen</th>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(300) UTK IRB Submission</strong></td>
<td><strong>(300) UTK IRB Submission</strong></td>
</tr>
<tr>
<td>* Project Classification: Provide an appropriate description (e.g., Research Project, Dissertation, Thesis, etc.)</td>
<td><strong>Classification:</strong> 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 &quot;other&quot; and specify the category in the text box.</td>
</tr>
<tr>
<td>* Please indicate the correct status of this submission:</td>
<td><strong>Submission status:</strong> Leave the default, &quot;I am requesting initial approval for research,&quot; unless you have been in conversation with the IRB and have been explicitly told to select the other option.</td>
</tr>
<tr>
<td><strong>(415) UTK Key Project Study Contact Information</strong></td>
<td><strong>(415) UTK Key Project Study Contact Information</strong></td>
</tr>
<tr>
<td>For the Principal Investigator and all Study Contacts (as listed in section 3.3 above) provide the following contact information: e-mail address; whether he/she will obtain consent from participants; and whether he/she will have access to research records of participants. All OTHER key study personnel (as listed in section 3.2A &amp; D) must be added to the chart below if they will obtain consent or have access to research records; however, you do not have to complete any other columns for those persons (except the last 2 columns).</td>
<td><strong>(417) UTK Key Study Personnel (KSP) Credentials</strong></td>
</tr>
<tr>
<td>Note: All IRB correspondence will be sent automatically to your UF email account. You may contact the HELP Desk at (813) 974-9900 to have your UF email forwarded to another account.</td>
<td>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):</td>
</tr>
<tr>
<td></td>
<td>• 3.1 Principal Investigator</td>
</tr>
<tr>
<td></td>
<td>• 3.2 Research Staff</td>
</tr>
<tr>
<td></td>
<td>• 3.3 Project Contact</td>
</tr>
<tr>
<td></td>
<td>• 3.4 Faculty Advisor</td>
</tr>
<tr>
<td>You will list collaborators at other institutions in your study design/procedures below in (925) Study/Project Synopsis.</td>
<td></td>
</tr>
<tr>
<td><strong>(420) Review Board Routing Questions</strong></td>
<td><strong>(468) Funding Source</strong></td>
</tr>
<tr>
<td>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.</td>
<td>If you respond, &quot;No,&quot; in screen 468, you will not see the rest of the funding screens.</td>
</tr>
<tr>
<td><strong>(468) Funding Source</strong></td>
<td><strong>(470) Funding Source</strong></td>
</tr>
<tr>
<td>If you respond, &quot;Yes,&quot; in screen 468, you will be asked to name your funding source here.</td>
<td></td>
</tr>
</tbody>
</table>
### (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.
<table>
<thead>
<tr>
<th>Application Screen</th>
<th>Completion Instructions</th>
</tr>
</thead>
</table>
| (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/ and if 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. |
### (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. 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/](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.

### (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—a 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.
### Application Screen

<table>
<thead>
<tr>
<th>Participant Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants:</td>
</tr>
<tr>
<td>Age range: Critical</td>
</tr>
<tr>
<td>Research involving minors requires special protections, including parent permission.</td>
</tr>
<tr>
<td>Depending on the type of study activities, other age groups might be at increased risk.</td>
</tr>
<tr>
<td>If you plan to exclude any racial or ethnic group, you must provide a rationale for doing so.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vulnerable Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>If special protections are warranted, you will explain them in your selection and recruitment procedures, and in your inclusion/exclusion criteria.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FERPA</th>
</tr>
</thead>
<tbody>
<tr>
<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) without participants' consent.</td>
</tr>
<tr>
<td>Please see <a href="http://ferpa.utk.edu/">http://ferpa.utk.edu/</a> for more information about FERPA on the UT campus.</td>
</tr>
<tr>
<td>If you select &quot;Yes&quot; you will be branched to the second screen, in which you need to:</td>
</tr>
<tr>
<td>• describe in the text box the FERPA-protected material you wish to use, and</td>
</tr>
<tr>
<td>• attach at the end of the application documentation of your permission from the University's FERPA officer to do so.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>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>If you select &quot;Yes&quot; 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conflict of Interest Management Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please contact Research Conflict of Interest Office (<a href="mailto:kate@utk.edu">kate@utk.edu</a>) to begin the process of developing a COI Management Plan.</td>
</tr>
</tbody>
</table>
### Application Screen

#### (701) Define "Expedited" and Minimal Risk

"Expedited Review" is a faster process than "Full Board Review."

Proposals that may qualify for Expedited Review include:

**Research activities that**

1. present no more than minimal risk to human participants
2. involve only procedures listed in one or more of seven Expedited Review Categories.

By answering the following questions, you will assist the IRB in determining if your proposal will be granted an Expedited Review.

Please hit "Save and continue..." in the upper right corner.

<table>
<thead>
<tr>
<th>Do the Research activities present no more than minimal risk to human participants?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes. The research activities present no more than minimal risk to human participants.</td>
</tr>
<tr>
<td>☐ No. The research activities DO present more than minimal risk to human participants.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>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, licensability, reputation, or be stigmatizing?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes. Identification of participant or participant responses COULD place the participant at risk.</td>
</tr>
<tr>
<td>☐ No. Identification of participant or participant responses WOULD NOT place participant at risk.</td>
</tr>
</tbody>
</table>

### Completion Instructions

#### (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.

#### (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.
(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.
Expedited & Full Board Application

(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 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 in the text box 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.

Use the calendar to indicate how long you expect the entire project to last, including data analysis. This is an estimate, and may be changed at any time.

(1600) Participant Recruitment
Please indicate if your research is limited solely to the secondary use of de-identified data; in this case, you will skip the rest of the recruitment section.

If you are recruiting participants, you will be asked first to indicate how you will identify potential participants for study.
In the text box, describe how the identification will be carried out, including such details as how you have obtained access to any lists or records, or how individuals might be referred to your study.

Then, check all direct and/or indirect methods that you will use to contact potential participants for your project.

Describe in the text box the procedures you will follow to carry out the recruitment methods you have checked in the list(s) above.

If you plan to contact potential participants more than once to invite them to participate, select "Yes" and you will receive the text box to describe the timing of these contacts.

If your project will involve eligibility screening, select "Yes" and then provide details in the text box, addressing the bullet points listed.

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.
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.

In the text box, describe the procedures you will use to protect the privacy of individuals during identification, recruitment, and data collection. Possible procedures include the following:

- Research procedures will be conducted in a private setting or according to the participant’s wishes
- Only authorized research study personnel will be present during research-related activities
- The collection of information about participants is limited to the amount necessary to achieve the aims of the research
- Data will be captured and reviewed in a private setting
- Participants will not be approached in a setting or location that may constitute an invasion of privacy or create unwanted attention (sensitive topics, etc.)

Then, check the box(es) that indicate the format(s) you will use for data collection. These responses will determine which additional screens you will see.
10.3 Please describe the procedures that will be used to collect/obtain electronic information for this research. Select all that apply, and then describe your detailed plan in the text box.

More information, including examples, of these procedures can be seen by clicking on the Help button below.

- Web-based survey - identify the software/survey tool to be used and its security safeguards
- Computer application (not internet-based)
- Computer application (Internet-based)
- Social media platforms - identifies the permissions to be used and its security safeguards
- Survey/Research service - identifies the vendor, services provided, confidentiality policies, etc.
- Mobile/Wireless technology - identify the technology and its security safeguards
- Access electronic records

* Provide a complete description of the platform/application/tool including product/brand name, host, security measures, encryption, and how collected data will be maintained and secured by the organization.

If you are collecting or obtaining electronic data, check the box(es) that indicate the procedures you will use, and describe those in detail in the text box. Examples of such procedures include the following:

- Web-based survey examples: QuestionPro, Qualtrics, Survey Monkey, etc. See [https://oit.utk.edu/research/websurveys/](https://oit.utk.edu/research/websurveys/)
- Computer Application (not internet-based) examples: software user-testing, virtual reality, augmented reality, some mobile device applications, some wearable technology, etc.
- Computer Application (internet-based) examples: online tools, mobile device applications, some wearable technology applications, etc.
- Social Media Platforms examples: social networking sites (Facebook, Google Plus); micro-blogging sites (Twitter, Tumblr); photo sharing (Instagram); crowd-sourcing (Amazon Mechanical Turk); collaboration tools (WikiTravel); video sharing (YouTube, Vimeo)
- Survey/Research service examples: call centers, social research institutes, etc
- Mobile/Wireless technology examples: tablets, smartphones, activity trackers, etc.

Select and describe in this screen how electronic data will be stored and secured.

Examples of secure electronic storage options include the following:

- Security Software: firewall, anti-virus, anti-intrusion/malware, etc.
- Secured Database example: REDcap
- Secured File Hosting Site examples: UT’s OneDrive, UT’s GoogleDrive

Select and describe in this screen how identifiable data will be transmitted, shipped, or moved in any way from one location to another. This includes emailing data to yourself or others.

Descriptions of some electronic transmission methods are available by clicking the Help button.

If no identifiable data will be transmitted or shipped, select "None of the above" and enter n/a in the text box.
In this screen, describe your plans for secure storage of paper/analog/hard copy research materials. Examples of appropriate safeguards include the following:

- All research information being collected or obtained will be completely anonymous
- Restricted access to authorized research personnel
- Locked cabinet or file storage
- Locked office/lab
- Locked refrigerator
- Access rights are terminated when authorized research personnel leave the study
- Other: specify

If you plan any additional protections, describe those here. Some other possible safeguards include the following:

- Destruction of source data immediately after data collection (to preserve anonymity of participants)
- Recordings (audio/video) will be transcribed and then destroyed prior to analysis
- Recordings (audio/video) will be modified so that participants cannot be identified (blurring, faced blocked, etc)
- Photos/images will be modified so that participants cannot be identified (blurring, faced blocked, etc)
- Other: specify

Enter n/a in the text box if this is not applicable to your study.

Select and describe the protections you plan to implement before you begin analysis of your data.

Select "Yes" or "No" to describe whether or not identifiable information will be included in publications or presentations about the project. This includes the possibility that individual identities might be inferred from information you present—even if direct identifiers are not used.

If you select "Yes," use the text box to describe your plans for consent and/or protections.
Describe how your data will be handled once the study is terminated (after you have completed all research activity including analysis and have submitted a study termination application to the IRB).

Examples of disposition include the following:

- Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed).
- Direct identifiers and/or the key to the codes will be retained.
- These data/biospecimens and/or research results will be shared with the source/provider.
- These data/biospecimens and/or research results will be shared with holder of the code key.
- These data/biospecimens and/or research results will be shared with collaborators external to UTK.
- Retained by the investigator for future research use.
- Retained by the investigator for future uses UNRELATED to research.
- Will be submitted to an existing repository or investigator will create a repository.
- Shared according to a data sharing agreement.
- Restricted use data will be destroyed or returned to the source.
- If applicable, Protected Health Information (PHI) will be destroyed or returned to the source and research records retained for 6 years after closure of the study.
- No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained.
- This research will be retained in accordance with the sponsor's requirements.
- Other (specify)
If you are offering participants any sort of compensation for their participation in your study, you must select "Yes" in (3045) and 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.
**Expedited & Full Board Application**

**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 mailing 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?

**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: 

**Practicality Without Waiver of 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 analysis of the results of the study.
- Other reason.

**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.

**Consent Outside Research**

* Does the research involve any procedures for which separate, written consent is normally required outside the research setting?

- Yes, the research involves 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.

**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.

**Consent Process**

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

---

**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.

---

**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).
<table>
<thead>
<tr>
<th>Application Screen</th>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(3300) Conflict of Interest</strong></td>
<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>If you select &quot;Yes&quot; 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.</td>
<td></td>
</tr>
<tr>
<td><strong>(3450) HIPAA</strong></td>
<td>In this screen, please select &quot;Yes&quot; or &quot;No&quot; 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.</td>
</tr>
<tr>
<td>If you select &quot;Yes&quot; 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)</td>
<td></td>
</tr>
<tr>
<td>For the second item, indicate whether or not you plan to collect PHI yourself.</td>
<td></td>
</tr>
<tr>
<td><strong>(10000) Routing for Signatures and Attaching Documents</strong></td>
<td>In the event that there is more you wish to tell the IRB about your submission, this is the place to do it.</td>
</tr>
<tr>
<td>Click on &quot;Save and continue&quot; to advance to the screens for adding attachments, and routing for necessary review and approval.</td>
<td></td>
</tr>
<tr>
<td><strong>1.0 Routing Form</strong></td>
<td>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. &quot;Save and Continue&quot; unless you wish to attach a different version of the application.</td>
</tr>
<tr>
<td>**2.0 <strong>(555) Consent Form(s)</strong></td>
<td>Please upload your consent documents here, and not as &quot;other study documents.&quot; Use the drop down menu (in the dialog window in which you upload) to select the appropriate category of consent form:</td>
</tr>
<tr>
<td>• <strong>Main Consent Form</strong></td>
<td></td>
</tr>
<tr>
<td>• <strong>Consent Statement/Elements</strong> (this is the cover sheet used for surveys)</td>
<td></td>
</tr>
</tbody>
</table>
### Application Screen

#### 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)

---

### 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/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.**

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><strong>(3455) ff. HIPAA</strong></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>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.</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) is 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 all of the 18 HIPAA-specified identifiers. (The 18 identifiers can be found by clicking on the question mark to the right of this section.)</td>
<td></td>
</tr>
<tr>
<td>- 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.)</td>
<td></td>
</tr>
</tbody>
</table>

| **(3460) Section A: Use of PHI** | |
| * Briefly explain who will receive and use the Protected Health Information (PHI) and where it will be stored. | |

| **(3462) 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. | |

| **(3464) 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." | |

| **(3466) HIPAA Waiver or Alteration** | |
| * Briefly describe the plan to protect the Protected Health Information (PHI) identifiers. | |
| * Briefly describe 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

#### (3467) HIPAA Alteration Practicability

* Briefly explain why the research activity could not practically be conducted without alteration of the authorization requirement.

#### (3468) HIPAA Waiver Practicability

* Why can this research not be practically carried out without the waiver of the authorization requirement?

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

* If you selected "Other reason," please explain. Otherwise, type "N/A."

#### (3470) 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.

#### (3475) 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 on 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 final IRB approval of this proposal.

#### (3480) 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 16 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 derivable 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.
### (3485) 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.

### (3600) 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.

- No, 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.

### (3610) 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 485 and answer the subsequent questions that are prompted.