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Human Research Protection Program (HRPP)
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January 2019
Form 1 Initial Submission Instructions

Applying for Institutional Review Board (IRB) Approval
Using the UT, Knoxville Application Revised January 2019

*All studies approved under the Revised Common Rule (effective January 21, 2019)*
*must use this version of the application*

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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<tbody>
<tr>
<td><strong>Log In</strong>&lt;br&gt; [Image of iMedRIS login screen]&lt;br&gt;User ID:&lt;br&gt;Password:&lt;br&gt;Log In&lt;br&gt;System Browser Requirements&lt;br&gt;Terms of Use: Privacy Statement&lt;br&gt;Copyright © 2013 UT Health Science Center. All rights reserved.&lt;br&gt;Version 3.0 May 1, 2017 Updated 2017/03/09 17:20</td>
<td>Begin by logging in to the iMedRIS online submission system at <a href="https://ris01.uthsc.edu">https://ris01.uthsc.edu</a> using your UTK netID and password.</td>
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<td><strong>Initial Screens (all applications)</strong>&lt;br&gt;Begin by logging in to the iMedRIS online submission system at <a href="https://ris01.uthsc.edu">https://ris01.uthsc.edu</a> using your UTK netID and password.</td>
<td>If this is your first time in iMedRIS, it may take 24 hours after your initial login 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.)</td>
</tr>
<tr>
<td><strong>Contact the IRB if you have questions or encounter difficulties logging in.</strong>&lt;br&gt;In your <strong>Study Assistant</strong> menu, select <strong>Add a New Project.</strong></td>
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<td><strong>In your Study Assistant menu, select Add a New Project.</strong></td>
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<td><strong>When you come back to work on the project once it’s been created, you will find it as a &quot;Draft&quot; in My Projects.</strong></td>
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<td><strong>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.</strong>&lt;br&gt;<strong>Be sure to select UTK Knoxville Main Campus IRB Application!!</strong>&lt;br&gt;<strong>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.</strong></td>
<td>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.</td>
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<td><strong>1.0 General Information</strong></td>
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<td><strong>Enter the complete title of your study</strong>&lt;br&gt;(same as any funding proposals, if applicable) in the first text box.</td>
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<td><strong>&quot;Working Title&quot; is an abbreviated version (and is what you will see in your &quot;My Projects&quot; listing).</strong>&lt;br&gt;<strong>2.0 Add Department(s)</strong>&lt;br&gt;Your default department (from the UT LDAP directory) is already listed and selected. Please &quot;add&quot; 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.</td>
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<td>3.0 Assign key study/project personnel (KSP) access to the project</td>
<td>3.0 Assign key study personnel 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.</td>
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<tr>
<td>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.</td>
<td></td>
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| 3.2 Research Staff (NB: Collaborators from outside UTK should not be listed here, but in (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 recruit, enroll or consent participants, or collect or analyze data, or access study records—they may be listed here and do not need CITI training. |

Please check with your Department/College for specific instructions regarding how Departmental Approvals are handled—some units have specific arrangements with the IRB that you need to know before you complete screen 3 and route for signatures (at the end of the application below).
(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

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 & B) 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 these persons (except the last 2 columns).

Note: All InFORMED consent will be sent automatically to your UI email account. You may contact the UTEP help desk at (945) 974-9900 to have your UI email forwarded to another account.

(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

Do not include DRC and Dept Head here.

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.
### Application Screen

#### (470) Funding Source

**Completion Instructions**

If you respond, “Yes,” in screen 468, you will be asked to name your funding source here.

Click “add” in the appropriate category(ies) for each sponsor you need to include, and you will be directed to a popup window that allows you either to select your sponsor from a list or to type it in.

If your research is funded, your grant proposal must be submitted with this IRB application. **An incomplete application may delay approval of your IRB application.** When you are prompted to attach additional study documents, upload your proposal.

In the text box, provide details about how the sponsors are providing support. Examples are listed.

![Image of a spreadsheet with columns for Sponsor, Agency, Funding Source, Date Submitted, Sponsor Award Number, Sponsor Award Title, Proposal Title, OSP Award Number, OSP Title, and OSP Award Title.](Image)

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

#### (475) Contract Information

Select from the drop-down menu the office or institution that is processing your grant or contract (or specify “other”), and indicate where you are in the submission/funding process.

Proposal titles that are the same help the IRB coordinate with the Office of Sponsored Projects, which facilitates setting up your accounts. If your OSP title and IRB title are different, please provide the OSP title here.

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

#### (480) Study/Project Information

Please indicate the level of review you believe is required for your study.

**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” in (420) 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.
### Application Screen

#### (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 the category(ies) in which you believe your study is eligible for Exempt review.

#### (600) Criteria for Exempt Benign Behavioral Interventions (Category 3)

Complete this screen in order to determine whether or not your study fits the criteria for this category.

If your responses indicate that your project is eligible for Exempt Category 3, you will be directed to select whether or not you are collecting data with or without identifiers; that is, can participants be linked to their data or not? Even indirect links such as a code key count as identifiers.

#### (610) Not Exempt

If your responses indicate that your project is not eligible, you will be directed to go back to (485), change your selection to "Expedited," and complete the Expedited application.

#### (653) Secondary research use of identifiable private information or identifiable biospecimens

Publicly available means "shared without conditions on use." The IRB must be able to confirm that the data are publicly available. Please provide either a link (if data are online) or documentation of this.

#### (653) Secondary research use of identifiable data—HIPAA-covered entities (Category 4iii)

Please describe the records to be used, and in the second text box specify the data field/points to be obtained from the records.
**Exempt Application**

**Application Screen**

(655) Secondary research use of identifiable data—Recorded Without Identifiers (Category 4ii)

Secondary research means the data to be analyzed were initially collected for a purpose other than your research study. Select the correct category(ies) and then describe this purpose in the text box: is it

- a research study other than this one?
- a non-research purpose?

If the data are from a research activity other than this study, provide the information requested about the original study title, PI, and IRB/institution that approved it. Be sure to submit for review

- the original IRB approval,
- a copy of the approved consent form, and
- documentation that the original PI is giving you permission to use the data.

If the data are initially collected for a non-research purpose, please select the category(ies) of records, identify the owner of the records, and describe the process by which you will obtain access to the information.

Be sure to submit for review letter(s) of support from the owner(s) of the records, explicitly giving you permission to use them for research purposes.

Be very specific about the data points/elements/fields you will obtain from the records for your research. You may only use those data points/elements/fields that have been reviewed and approved by the IRB, so be sure to list them all.

(658) Survey or Interview

Indicate here whether you are collecting data with or without identifiers; that is, can participants be linked to their data or not? Even indirect links such as a code key count as identifiers.

**Consent Templates and more instructions are available in the iMedRIS Help menu.**

(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 Categories 2 and 3 studies, and use a Consent Statement. For surveys, this should be the first page/screen of the survey.

Please attach at the end of the application a clean copy of your consent form to be reviewed, uploading it as an [Informed Consent Document], and selecting the "Consent Statement/Elements" category.
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<td><strong>Item #3 is where you should name any non-UT Knoxville collaborators and their institutions, and describe their roles in your study.</strong></td>
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<td><strong>(1075) Background &amp; Current Status of Work in the Field</strong></td>
<td>Please provide a summary description of work in your field that should provide—to a lay audience—a scientific rationale for your study. Do not simply copy and paste a review of literature from a proposal.</td>
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<tr>
<td><strong>(1200) Site Information</strong></td>
<td>Please list in the text box all locations where your study will take place, and information about which procedures will take place at which sites, if more than one.</td>
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<td>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 &quot;Other Study Documents&quot; in the Letter of Support category.</td>
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<td><strong>(1400) Participant Population</strong></td>
<td>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. <strong>Enroll</strong> means <strong>obtain consent from</strong>, so even if participants drop out or do not provide complete data, they must be counted as part of the approved number.</td>
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<td>If your research is secondary use of records, enter here the number of individuals whose records you will have access to. <strong>If you plan to exclude</strong> any racial or ethnic group, you must provide a rationale for doing so.</td>
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<td>(1488) Vulnerable Participants</td>
<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. 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.</td>
</tr>
<tr>
<td>(1490) (1492) FERPA</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) without participants' authorization. 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 (or other institution, if not UTK students)</td>
</tr>
<tr>
<td>(1494) Study/Project Duration</td>
<td>In the text box, please describe how long any one individual participant will be engaged in research activity. The information you provide here should match what you tell participants in the consent form. (For Exempt Category 4, indicate n/a) Use the calendar to indicate when you believe the entire study will be complete, including data analysis, and you will close the study. You may revise this date at any time; it is an estimate only.</td>
</tr>
<tr>
<td>(1600) Participant Recruitment</td>
<td>Please indicate if you will be recruiting individuals to participate and/or to provide consent for use of their identifiable information. If not, you will skip the rest of the recruitment section.</td>
</tr>
</tbody>
</table>
### Application Screen

**Exempt Application**

#### Completion Instructions

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.

**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.**

Neglecting to submit these materials will cause a delay in the review and approval of your study.

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.

---

#### Direct Contact Methods

- Email
- Mail
- Telephone calls
- Face to face contact announcements
- Other
- SMS
- Online contact methods not to be used

#### Indirect Contact Methods

- Notices in local newspapers, radio, television, public bulletin boards, community bulletin boards, community centers, etc.
- Flyers, mailers, or public service announcements
- Social media
- National Turf, Quizzes, games, or similar service population
- Flyers, TV, radio, etc.
- Other
- Other online contact methods not to be used

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#### Recruitment/Advertising Materials

- 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.**

Neglecting to submit these materials will cause a delay in the review and approval of your study.
Exempt Application

Application Screen

(2800) Privacy and Confidentiality

Privacy in the context of research refers to an individual's right to control access to their personal information; it is an individual's right to control how other people see, touch or obtain information about them.

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

The rest of this section deals with Confidentiality of data—how private information will be protected by investigators from disclosure.

In this screen, 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.

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.

Do not write n/a in the text box because you have selected items in the list; use the text box to explain how you will carry out your use of the items you selected.

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

Examples of secure electronic storage can be viewed by clicking on the orange Help button. The IRB recommends consulting the Office of Information Technology's (OIT's) advice about secure storage at https://oit.utk.edu/news/google-office365/
### Application Screen

Indicate what safeguards will be used for transmitting identifiable information (data, research records, etc.) or identifiable biospecimens among the research team or with others. This refers to any time that will be shared, transferred, transmitted, shipped, or otherwise moved from one location to another (including sending data is printed or stored). Select all that apply and then describe your selected plan in the text box.

More information about some of these options can be seen by clicking on the Help button to the right.  

**Completion Instructions**

Select and describe in this screen how identifiable data will be **transmitted, shipped, or moved** in any way from one location to another. For sensitive electronic data, please select methods more secure than email, such as UT Vault at [https://vault.utk.edu/](https://vault.utk.edu/).

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 can be viewed by clicking on the orange Help button.

If you plan any additional protections, describe those here. Some other possible safeguards can be viewed by clicking on the orange Help button.

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 appropriate disposition can be viewed by clicking on the orange Help button.

This question is not asking about research records such as consent documentation and payment logs that investigators are responsible for maintaining after completion of the research.
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 course credit is to be offered as payment for research participation, be sure to describe in your application how else students may earn this credit. There must be alternatives, requiring equivalent amounts of time and effort, as students may not be pressured into research participation as a course requirement.

If course credit is to be offered as payment for research participation, be sure to describe in your application how else students may earn this credit. There must be alternatives, requiring equivalent amounts of time and effort, as students may not be pressured into research participation as a course requirement.
(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.
### Application Screen

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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. **Enroll means obtain consent from**, so even if participants drop out or do not provide complete data, they must be counted as part of the approved number.

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<tr>
<td></td>
<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></td>
<td>If you select &quot;Yes&quot; you will be branched to the second screen, in which you need to</td>
</tr>
<tr>
<td></td>
<td>• describe in the text box the FERPA-protected material you wish to use, and</td>
</tr>
<tr>
<td></td>
<td>• attach at the end of the application documentation of your permission from the University's FERPA officer to do so (or other institution, if not UTK students)</td>
</tr>
<tr>
<td>(1494) Study/Project Duration</td>
<td>In the text box, please describe how long any one individual participant will be engaged in research activity. The information you provide here should match what you tell participants in the consent form. (For Exempt Category 4, indicate n/a)</td>
</tr>
<tr>
<td></td>
<td>Use the calendar to indicate when you believe the entire study will be complete, including data analysis, and you will close the study. You may revise this date at any time; it is an estimate only.</td>
</tr>
</tbody>
</table>
### Application Screen

<table>
<thead>
<tr>
<th>1600) Participant Recruitment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Are individuals be recruited to either participate in the research study or provide consent for use of their information and/or biospecimen?</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

### Completion Instructions

**1600) Participant Recruitment**  
Please indicate if you will be recruiting individuals to participate and/or to provide consent for use of their identifiable information. If not, 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.

#### 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.** 

Neglecting to submit these materials will cause a delay in the review and approval of your study.

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.
### (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
- mental/emotional, reputational, social, legal, financial or physical harm
- vulnerability to undue influence (coercion)
- inability to understand the research

Do not simply state "minimal" risk, **identify the specific risks.**

In the second text box, describe the procedures that you have built in to your study to minimize each of the risks you identified in the first box.

Most research does not offer direct benefits to participants. Please remember that incentives or compensation (including course credit) are not benefits, and should be described in (3045) and (3050) below rather than here.

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.

Describe the potential benefit(s) to science or society in this text box.

If you indicated above that there are potential benefits to your participants, describe those here as well.

### (2800) Privacy and Confidentiality

Privacy in the context of research refers to an individual’s right to control access to their personal information including access to their body (e.g., regulations of their stomato/gastrointestinal). Privacy is an individual’s right to control how other people see, touch or obtain information about them.

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

Possible procedures can be viewed by clicking on the orange Help button.
### Application Screen

#### Completion Instructions

The rest of this section deals with **Confidentiality** of data—how private information will be protected by investigators from disclosure.

In this screen, 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.

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.

**Do not write n/a in the text box** because you have selected items in the list; use the text box to explain how you will carry out your use of the items you selected.

Examples of such procedures can be viewed by clicking on the orange Help button.

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

Examples of secure electronic storage can be viewed by clicking on the orange Help button. The IRB recommends consulting the Office of Information Technology’s (OIT’s) advice about secure storage at [https://oit.utk.edu/news/google-office365/](https://oit.utk.edu/news/google-office365/)

Select and describe in this screen how identifiable data will be **transmitted, shipped, or moved** in any way from one location to another. For sensitive electronic data, please select methods more secure than email, such as UT Vault at [https://vault.utk.edu/](https://vault.utk.edu/)

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 can be viewed by clicking on the orange Help button.
### Application Screen

Describe any other protections to be used. A list of appropriate other protections can be seen by clicking on the orange Help button in the text box.

<table>
<thead>
<tr>
<th><strong>Select and describe the protections you plan to implement before you begin analysis of your data.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>If you plan any additional protections, describe those here. Some other possible safeguards can be viewed by clicking on the orange Help button.</td>
</tr>
<tr>
<td>Enter n/a in the text box if this is not applicable to your study.</td>
</tr>
</tbody>
</table>

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 appropriate disposition can be viewed by clicking on the orange Help button.

This question is not asking about research records such as consent documentation and payment logs that investigators are responsible for maintaining after completion of the research.

### Completion Instructions

Describe the planned protections (if any) to be implemented prior to conducting analysis with identifiable information or identifiers/exception. Select all that apply and then describe your stated plan in the text box.

- 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.

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 appropriate disposition can be viewed by clicking on the orange Help button.

This question is not asking about research records such as consent documentation and payment logs that investigators are responsible for maintaining after completion of the research.
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 course credit is to be offered as payment for research participation, be sure to describe in your application how else students may earn this credit. There must be alternatives, requiring equivalent amounts of time and effort, as students may not be pressured into research participation as a course requirement.
### Application Screen

#### (3355) Alteration of Informed Consent

1. Identify which element(s) of informed consent will be altered or omitted. Click the help button to view a list of these elements.

2. Describe the procedures and/or participant populations for which this alteration is being requested.

3. Explain how the research involves no more than minimal risk to participants.

4. Explain how the alteration will not adversely affect the rights and welfare of participants. Describe whether the subject population, in general, would consider the rights and welfare affected if they knew of this alteration, or that the alteration has the potential to cause severe consequences for the subject population's rights and welfare or general well-being. Explain whether subjects will be informed that some information is being withheld until the research is completed.

5. Explain how the alteration is not practicable to conduct the research if all the elements of informed consent are required. Describe any special circumstances, such as study design, that would make it impossible to conduct the research if all elements of consent were required. For example, if deception regarding the purpose of the study is necessary in order to secure valid results, explain why.

6. Will information about the research be provided to participants after their participation?
   - If yes, explain what information will be provided, when it will be provided, and the procedure used to provide it.
   - If no, participants will not receive further information about the research, provide a justification for not doing so.

#### (3367) Individuals with Impaired Decision-Making Capacity

1. Describe the plan for assessing potential participants' capacity to consent to determine whether they are capable of consenting on their own behalf, including:
   - which participants will be assessed,
   - timing of assessments,
   - any assessment tools to be used, and
   - plans for notifying participants who fail to meet their capacity to consent during the course of the study.

2. Explain how you will identify persons authorized to give legally valid consent on behalf of individuals who cannot consent for themselves, and how they will be adequately informed of their roles and responsibilities for protecting the participants.

3. Explain how you will obtain and document consent to participate from individuals who cannot consent for themselves. If neither documentation of consent nor the consent process will occur, explain why.

#### (3372) Non-English Languages

1. Identify the language(s) to be used. If more than one language will be used (including English), describe which language will be used with which participants for which activities.

2. Describe how the consent process will be evaluated. Address the following:
   - the process and/or outcome measures
   - the process and/or outcome measures for the participants (e.g., Do they find the qualifications and expectations, if any, required prior to providing consent; do they understand the informed consent, and do they feel that the investigator will ensure that no adverse consequences will occur to the participant?

3. Will non-English consent documents and/or other study materials be used?
   - Yes
   - No

4. Who provided or will provide the translation of the informed consent document(s) and/or other study materials. Describe their qualifications or experience.

### Completion Instructions

#### (3355) Alteration of Informed Consent

If you indicate in (3329) that you wish to omit or alter one of the required elements of informed consent—such as not disclosing the true purpose of the study (deception) during the consent process—your responses in this screen will allow the IRB to determine if your study meets the criteria to grant the alteration.

The omission/alteration must not adversely affect the rights and welfare of participants or present more than minimal risk. You must describe which element(s) you wish to alter/omit, for which populations, and which procedures, and why you cannot conduct your research without the alteration. Please also describe how you will debrief participants afterward.

A list of the Required Elements of Informed Consent can be found at [https://irb.utk.edu/forms/](https://irb.utk.edu/forms/)

#### (3367) Individuals with Impaired Decision Making Capacity

If you indicate in (3329) that you will be enrolling individuals who are not able to consent for themselves, please describe in this screen

- how and when you will assess their capacity to consent,
- how you will identify who is authorized to provide consent for them, and
- how you will document the assent of these individuals who cannot provide consent for themselves.

#### (3372) Non-English Language

If you indicate in (3329) that non-English consent materials will be used in the research, please

- identify the language(s) to be used,
- describe how recruitment, consent, and research procedures will be made understandable to participants, and
- identify and describe the qualifications of the individual(s) translating the consent documents or other study materials.
### Application Screen

**3375 Waiver of Documentation of (Signed) Informed Consent**

*1. Describe the procedures and/or participant population for which the waiver is being requested.*

*2. Explain how the research involves no more than minimal risk to the participants.*

*3. Explain how the research meets the requirement for involving no procedures for which written consent is normally required outside of the research.*

*4. Describe the mechanism used to ensure the consent process takes place. Examples include return of completed study materials to the investigator or documentation in the research file that the consent process took place and if there were any issues, and use of a cultural mediator specific to the study population.*

*5. Explain if participants will be provided with a written statement regarding the research.*

---

### Completion Instructions

**3375 Waiver of Documentation of (Signed) Informed Consent**

If you indicate in (3329) that you wish to waive documentation of the consent process—that is, you will have a consent process but not collect signed forms—please select here which of the three regulatory provisions for this applies to your study. If you select "none of the above," your study does not qualify, and you must revise your research plans to obtain signed informed consent from all participants.

If you select that your research (1) involves no more than minimal risk and (2) involves no procedures for which written consent is normally required outside of research, please:

- explain here how your study addresses those two requirements,
- describe the procedures and/or population for which you wish to waive documentation,
- describe how you will ensure that the consent process takes place, and
- explain whether or not participants will be provided with a written statement regarding the research.

If you select that (1) your participants are members of a distinct cultural group for which signing form is not the norm, (2) the research involves no more than minimal risk and (3) there is an appropriate alternative mechanism for documenting that informed consent was obtained, please:

- explain here how your study addresses those three requirements,
- describe the procedures and/or population for which you wish to waive documentation, and
- explain whether or not participants will be provided with a written statement regarding the research.

Be sure that your alternative mechanism for documenting consent is culturally appropriate.
**Application Screen**

<table>
<thead>
<tr>
<th>Completion Instructions</th>
</tr>
</thead>
</table>
| If you select that (1) a signed consent form would be the only link between the participant and the study, and (2) the principal risk of the study is harm resulting from a breach of confidentiality, please describe:  
- how you will accommodate participants who wish to be linked to the study (as they must be given that option), and  
- how you will ensure that the consent process takes place. |

<table>
<thead>
<tr>
<th>(3380) Waiver of Informed Consent</th>
</tr>
</thead>
</table>
| If you indicate in (3329) that you wish to waive the consent process entirely, your responses in this screen will allow the IRB to determine if your study meets the criteria to grant the alteration.  
The omission/alteration must not adversely affect the rights and welfare of participants or present more than minimal risk. Please describe:  
- how your study meets these two requirements,  
- your rationale for requesting the waiver,  
- the procedures/participants to which it will apply, and  
- whether or not information will be provided to participants at a later time. |

<table>
<thead>
<tr>
<th>(3440) Consent Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide a detailed description of the procedures you will use to obtain informed consent, parent permission, and/or child assent. It must be clear who will obtain consent, where and when, and how you will ensure that participants are able to consider, discuss, ask questions about and understand the information presented to them before making a decision whether or not to participate.</td>
</tr>
</tbody>
</table>
### Application Screen

<table>
<thead>
<tr>
<th>(3450) Protected Health Information (PHI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In order to conduct this research, to identify or recruit potential participants, you are responding to use SUBJECT DOCUMENTS or SOURCE MATERIALS that contain Protected Health Information (PHI) of persons without their authorization (or with their limited authorization), such as through telephone screenings.</td>
</tr>
<tr>
<td>2. Are you preparing to collect Protected Health Information for research purposes?</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
</tbody>
</table>

### Completion Instructions

<table>
<thead>
<tr>
<th>(3450) Protected Health Information (PHI)</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tr>
<tr>
<td>For the second item, indicate whether or not you plan to collect PHI for research purposes.</td>
</tr>
<tr>
<td>If you are not using PHI at all, simply select &quot;No&quot; for both items.</td>
</tr>
</tbody>
</table>

### 27.0 (10000) Routing for Signatures and Attaching Documents

#### 27.1 The following text box is provided in the event that you need to share additional information with the Review Board.

#### 27.2 After clicking the "Save and Continue" button, you will advance to the routing form in order to attach any supporting documents (such as consent forms) and to mark the submission as the necessary signatures for the approval.

#### Please click here to save and continue...

### 1.0 Routing Form

**1.0 (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.

### 2.0 (555) Consent Form(s)

**2.0 (555) Consent Form(s)**

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

- **Main Consent Form**
- **Consent Statement/Elements** (This is the cover sheet used for surveys)
3.0 (575) Additional Study/Project Documents

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

4.0 (800) UTK Form Completion

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

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
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.

Your responses in (3455) will branch you to other required screens that must be completed.
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix: HIPAA Screens Specific to Studies Using PHI</td>
<td></td>
</tr>
<tr>
<td>(3467)</td>
<td>HIPAA Alteration Practicality</td>
</tr>
<tr>
<td>* Briefly explain why the research activity could not practicably be conducted without alteration of the authorization requirement.</td>
<td></td>
</tr>
<tr>
<td>(3468)</td>
<td>HIPAA Waiver Practicality</td>
</tr>
<tr>
<td>* Why can the research not be practically carried out without the waiver of the authorization requirement?</td>
<td></td>
</tr>
<tr>
<td>- Fees and personnel do not want to contact all potential participants to secure their authorization.</td>
<td></td>
</tr>
<tr>
<td>- Failure to include all potential participants might result in skewed analysis of the results of the study.</td>
<td></td>
</tr>
<tr>
<td>- Other reason.</td>
<td></td>
</tr>
<tr>
<td>* If you answered &quot;Other reason,&quot; please explain. Otherwise, type &quot;N/A.&quot;</td>
<td></td>
</tr>
<tr>
<td>(3470)</td>
<td>Section C: PHI from Deceased</td>
</tr>
<tr>
<td>* Does adequate documentation exist that all participants whose Protected Health Information (PHI) will be used in this study are deceased?</td>
<td></td>
</tr>
<tr>
<td>- Yes. Please describe documentation below.</td>
<td></td>
</tr>
<tr>
<td>- No. Please explain why in the following space.</td>
<td></td>
</tr>
<tr>
<td>* Explain why the Protected Health Information (PHI) being sought is necessary for the research study.</td>
<td></td>
</tr>
<tr>
<td>(3475)</td>
<td>Section D: Limited Data Set</td>
</tr>
<tr>
<td>* 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?</td>
<td></td>
</tr>
<tr>
<td>- Yes. The 16 categories of direct identifiers will be excluded.</td>
<td></td>
</tr>
<tr>
<td>- No. Please explain below.</td>
<td></td>
</tr>
<tr>
<td>* Has a data use agreement been reached with the covered entity for the use of the Protected Health Information (PHI) in the research study?</td>
<td></td>
</tr>
<tr>
<td>- Yes. A data use agreement has been reached.</td>
<td></td>
</tr>
<tr>
<td>- No. If no, then a data use agreement must be submitted prior to final IRB approval of this proposal.</td>
<td></td>
</tr>
<tr>
<td>(3480)</td>
<td>Section E: De-identified Data</td>
</tr>
<tr>
<td>* The health information to be used in this research has been determined to be de-identified by:</td>
<td></td>
</tr>
<tr>
<td>- An appropriate expert has made the determination and a copy of this determination is attached to the proposal.</td>
<td></td>
</tr>
<tr>
<td>- The health information excludes all 18 categories of direct identifiers.</td>
<td></td>
</tr>
<tr>
<td>* Will the entity that maintains the health information utilize a code or other means to re-identify the records?</td>
<td></td>
</tr>
<tr>
<td>- Yes. Records will be re-identified.</td>
<td></td>
</tr>
<tr>
<td>- No. Records will not be re-identified.</td>
<td></td>
</tr>
<tr>
<td>* 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?</td>
<td></td>
</tr>
<tr>
<td>- True. Participants will not be able to be identified.</td>
<td></td>
</tr>
<tr>
<td>- Not True. Participants may be able to be identified.</td>
<td></td>
</tr>
<tr>
<td>* Is it true that the entity maintaining the records will not disclose the means for re-identifying the records?</td>
<td></td>
</tr>
<tr>
<td>- True. The maintaining entity will not disclose the means for re-identifying the records.</td>
<td></td>
</tr>
<tr>
<td>- Not true. The maintaining entity may disclose the means for re-identifying the records.</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix: HIPAA Screens Specific to Studies Using PHI

#### Section F: Preparatory to Research

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, disclosure is solely preparatory to research.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No, disclosure may be used for more than research preparation.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, the PI will not copy or remove PHI from the entity maintaining the PHI.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No, the PI may copy or remove PHI from the entity maintaining the PHI.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Briefly explain why the use of the Protected Health Information (PHI) is necessary for purposes preparatory to research.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Section G: De-identified Human Cell Lines

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Briefly describe the purpose of the study.</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Briefly describe any cell lines that will be used in this study and the vendor/source from which they will be received.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No, the investigator will not have or receive any information that would allow cells used in this study to be linked to specific individuals.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, the investigator will have or receive information that would allow cells used in this study to be linked to specific individuals.</td>
<td></td>
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</tr>
</tbody>
</table>

#### Section H: 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 405 and answer the subsequent questions that are prompted.