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March 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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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 **Project Assistant** workspace, select **Create 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 **View 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 Knoxville Main Campus 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 or Animal Care and Use Committee, the UT IRB cannot see it, review it, or approve it.

### 1.0 General Information

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

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

**2.0 Add Department(s)**

Your default department is already listed and selected. Please "add" other departments as appropriate, both for yourself and for others affiliated with your project, and then indicate which is the Primary Department i.e., the one that will review and approve, and will have oversight responsibility.

**3.0 Assign key study personnel**

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

**3.2 Research Staff** (NB: Collaborators from outside UTK should not be listed here, but in (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.

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### Completion Instructions

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### (300) UTK IRB Submission

**1 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.

**2 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

#### 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.
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<tr>
<td><strong>(470) Funding Source</strong>&lt;br&gt;![Image](43x289 to 307x288)</td>
<td><strong>If you respond, “Yes,” in screen 468, you will be asked to name your funding source here.</strong>&lt;br&gt;&lt;br&gt;<strong>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.</strong>&lt;br&gt;&lt;br&gt;<strong>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.</strong>&lt;br&gt;&lt;br&gt;<strong>When you are prompted to attach additional study documents, upload your proposal.</strong>&lt;br&gt;&lt;br&gt;In the text box, provide details about how the sponsors are providing support. Examples are listed.</td>
</tr>
<tr>
<td><strong>(475) Contract Information</strong>&lt;br&gt;![Image](43x44 to 307x219)</td>
<td><strong>Select from the drop-down menu the office or institution that is processing your grant or contract (or specify &quot;other&quot;); and indicate where you are in the submission/funding process.</strong>&lt;br&gt;&lt;br&gt;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.</td>
</tr>
<tr>
<td><strong>(485) Study/Project Information</strong>&lt;br&gt;![Image](43x436 to 307x722)</td>
<td><strong>Please indicate the level of review you believe is required for your study.</strong>&lt;br&gt;&lt;br&gt;Your responses here will branch you to the next appropriate screens.</td>
</tr>
<tr>
<td><strong>(490) Drug, Biologics, and Device Information and Administration</strong>&lt;br&gt;![Image](43x436 to 307x722)</td>
<td><strong>You will receive this screen only if you selected “Yes” in (420) above that your study involves a drug, biologic or device.</strong>&lt;br&gt;&lt;br&gt;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.</td>
</tr>
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</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 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 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 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.
(655) Secondary research use of identifiable data—Recorded Without Identifiers (Category 4ii)

.1: Secondary use 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? or
- a non-research purpose?

.2 and .3: 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.

.4: 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.

.5: 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.

.6: 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.

(660) Informed Consent

Consent Templates and more instructions are available in the iMedRIS Help menu.
(925) Study/Project Synopsis

Use the text box (by clicking on the text editor) to describe your research plans using the four subheadings provided.

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

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

Please provide a summary description of work in your field that should provide—to a lay audience—a scientific rationale for your study. Do not simply copy and paste a review of literature from a proposal.

(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. 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.

If your research is secondary use of records, enter here the number of individuals whose records you will have access to.

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

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

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' authorization. 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 (or other institution, if not UTK students)

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.

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.
### Application Screen

#### Exempt Application

- **.2:** If you are recruiting participants, you will be asked first to indicate how you will identify potential participants for study.

- **.3:** 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.

- **.4:** 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.**

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

- **.6:** 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.

- **.7:** If your project will involve eligibility screening, select "Yes,"

- **.8:** and then provide details in the text box, addressing the bullet points listed.

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#### Completion Instructions

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- **.7:** If your project will involve eligibility screening, select "Yes,"

- **.8:** and then provide details in the text box, addressing the bullet points listed.
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., collection of their biological specimens). Privacy is an individual's right to control how others 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.

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

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

#### .5: 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/)

Please note that any non-electronic shipment or movement should also be addressed in this item.

If no identifiable data will be transmitted or shipped, select "None of the above" and enter n/a in the text box.

#### .6: 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.

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

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

#### .8: Select and describe conditions(s) of the study data at all points in the study:
- when collected/received,
- stored prior to analysis,
- during analysis, and
- following analysis.

#### .9: 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.

#### .10: If you select "Yes," use the text box to describe your plans for consent and/or protections.

#### .11: 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.
Exempt Application

Application Screen

(3045) Payment

* Will any type of payment (wages, gift card, course credit or other form) be provided to the participant for participation?

- Yes
- No

(3050) Describe Payment

* Please specify the total amount of compensation received by participants will be determined. For example, will participants receive partial payment if they begin but do not complete the study?

The amount of compensation to be paid per visit and if more than one payment (course credit, check, cash, gift card, etc.) will be the total value of all compensation less any other compensation paid to students for study participation.

Please specify how the total amount of compensation received by participants will be determined. For example, will participants receive partial payment if they begin but do not complete the study?

Completion Instructions

(3045) Payment

(3050) Describe Payment

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

The IRB—and the participants (via your Consent Form)—must understand

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

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

Please note that course credit is considered payment!

(3300) Conflict of Interest

Please read very carefully and indicate whether you or any of your key study personnel (or their families) have a conflict of interest

.1: with respect to any sponsor of your research or
.2: any entity being studied in your research.

.3: 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.

.4: Contact the University's Research Conflict of Interest Officer Dairin Malkemus for assistance at dmalkem@utk.edu.

(3300) Conflict of Interest

• 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 you are participating in a departmental participant pool, such as the Psychology Dept SONA system, please be sure your compensation aligns with the departmental policies.

• If any individual among the key research personnel (including their spouses, parents, and children) has intellectual property rights (patents, trademarks, or copyright) in the entity being evaluated or the entity is controlled by such rights and interests.

.2: No, all study personnel (or their spouses, parents, or children) do not have intellectual property rights related to the entity being evaluated or to whom the study personnel (or their spouses, parents, or children) do not have intellectual property rights related to the entity being evaluated.

.4: Yes, the research conflict of interest management plan is filed with the Research Conflict of Interest Committee.

.5: Yes

• Please contact Research Conflict of Interest Officer Dairin Malkemus (dmalkem@utk.edu) to begin the process of developing a ROIS Management Plan.
**(701) Define "Expedited" and Minimal Risk**

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

.2: Do your research activities present no more than minimal risk?

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

.4: 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

#### (303) Study/Project Synopsis
- Click on the box below and provide a synopsis of the research study addressing the following items (please use numbered subheadings):
  1. Purpose/Goals of the Study
  2. Study Procedures
    - detailed all interventions/interactions occurring after the participant consent, including sequence of events, data collection methods, time required and setting/location in which they will occur, and reasons
    - ensure that this information is shared with the secondary use of identifiable information and/or identifiable biospecimen.
  3. Planned Analyses

#### (1075) Background & Current Status of Work in the Field
- Please provide a summary description of work in your field that should provide—to a lay audience—a scientific rationale for your study. Do not simply copy and paste a review of literature from a proposal.

#### (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. **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.

If your research is secondary use of records, enter here the number of individuals whose records you will have access to.

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

### Completion Instructions

#### (925) Study/Project Synopsis
Use the text box (by clicking on the text editor) to describe your research plans using the four subheadings provided.

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

#### (1075) Background & Current Status of Work in the Field
Please provide a summary description of work in your field that should provide—to a lay audience—a scientific rationale for your study. Do not simply copy and paste a review of literature from a proposal.
(1488) Vulnerable Participants
Please read and complete this section very carefully; many applications are returned for correction in this area. Do not assume your participants are not vulnerable before reading the list of categories.

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

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' authorization.

Please see 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 (or other institution, if not UTK students)

(1494) Study/Project Duration
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.

(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.
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<tr>
<td>8. and then provide details in the text box, addressing the bullet points listed.</td>
<td></td>
</tr>
</tbody>
</table>
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.

1. List the 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)

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

2. Describe the procedures that you have built in to your study to minimize each of the risks you identified in the first box. For breach of confidentiality, you may write, "see section 2800 below" if appropriate.

3. Indicate whether or not there will be direct benefit to participants. **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.

4. 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.

You will only be asked to complete this section in an Exempt application if you have indicated that you are applying in Category 2 or 3 and will be collecting data with identifiers.
The rest of this section deals with **Confidentiality** of data—how private information will be protected by investigators from disclosure.

2: 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.

3: 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 **name** the application/platform and 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.

4: 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/)

5: 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/)

Please note that any non-electronic shipment or movement should also be addressed in this item.

If no identifiable data will be transmitted or shipped, select "None of the above" and enter n/a in the text box.

6: 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

#### .7: 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.

#### .8: Select and describe conditions(s) of the study data at all points in the study:
- when collected/received,
- stored prior to analysis,
- during analysis, and following analysis.

#### .9: 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.

#### .10: If you select "Yes," use the text box to describe your plans for consent and/or protections.

#### .11: 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 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!

1: with respect to any sponsor of your research or
.2: any entity being studied in your research.
.3: 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.
.4: Contact the University's Research Conflict of Interest Officer Dairin Malkemus for assistance at dmalkemu@utk.edu.

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.

When appropriate, the regulations provide a mechanism for waiving or altering consent requirements if the research meets specific criteria.

Select all statements that are true for your study and you will be branched to additional screens as necessary if you request modifications to the process and/or indicate the inclusion of certain populations.
(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/)

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(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

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

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(3372) Non-English Language

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

1. identify the language(s) to be used,
2. describe how recruitment, consent, and research procedures will be made understandable to participants,
3. indicate whether or not non-English consent and other documents will be used, and
4. identify and describe the qualifications of the individual(s) translating the consent documents or other study materials.
<table>
<thead>
<tr>
<th>Application Screen</th>
<th>Completion Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(3375) Waiver of Documentation of (Signed) Informed Consent</strong></td>
<td>If you indicate in <strong>(3329)</strong> 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 &quot;none of the above,&quot; your study does not qualify, and you must revise your research plans to obtain signed informed consent from all participants.</td>
</tr>
<tr>
<td>1. Describe the procedures and/or participant population for which this waiver is being requested.</td>
<td>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:</td>
</tr>
<tr>
<td>2. Explain how the research involves no more than minimal risk to the participants.</td>
<td>.2 describe the procedures and/or population for which you wish to waive documentation,</td>
</tr>
<tr>
<td>3. Explain how the research meets the requirement for involving no procedures for which written consent is normally required outside of the research.</td>
<td>.4 explain how the research presents no more than minimal risk,</td>
</tr>
<tr>
<td>5. Describe the mechanism used to ensure the informed consent process took place.</td>
<td>.5 explain how the research involves no procedures that require written consent outside of a research context,</td>
</tr>
<tr>
<td>6. Explain if participants will be provided with a written statement about the research.</td>
<td>.7 describe how you will ensure that the consent process takes place, and</td>
</tr>
<tr>
<td>7. Explain if participants will be provided with a written statement about the research.</td>
<td>.8 explain whether or not participants will be provided with a written statement regarding the research.</td>
</tr>
<tr>
<td>8. Describe the procedures and/or participant population for which this waiver is being requested.</td>
<td>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:</td>
</tr>
<tr>
<td>9. Explain how the research involves no more than minimal risk to the participants.</td>
<td>.2 describe the procedures and/or population for which you wish to waive documentation,</td>
</tr>
<tr>
<td>10. Identify the distinct cultural group or community and explain why signing form is not the norm.</td>
<td>.4 explain how the research presents no more than minimal risk,</td>
</tr>
<tr>
<td>11. Describe the mechanism used to ensure the informed consent process took place.</td>
<td>.6 identify the distinct cultural group and why signing forms is not the norm</td>
</tr>
<tr>
<td>12. Explain if participants will be provided with a written statement about the research.</td>
<td>.7 describe the alternative mechanism you will use to document that the consent process took place, and</td>
</tr>
<tr>
<td>13. Explain if participants will be provided with a written statement about the research.</td>
<td>.8 explain whether or not participants will be provided with a written statement regarding the research.</td>
</tr>
</tbody>
</table>

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

| 1. | Describe the procedures and/or participant population for which this waiver is being requested. |
| 2. | Describe the process for obtaining such participant's written documentation linking him or her to the research and how a request for such documentation will beaccommodated. |
| 3. | Describe the mechanisms used to ensure the informed consent process takes place. Examples include returns of completed study materials to the investigator, documentation in the research files that the consent discussion took place and if there were any issues, and one of the social/cultural specifics to the study population. |

### Completion Instructions

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:

1. the procedures and/or population for which you wish to waive documentation,
2. how you will accommodate participants who wish to be linked to the study (as they must be given that option), and
3. how you will ensure that the consent process takes place.

### (3380) Waiver of Informed Consent

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 waiver.

Please:

1. describe the procedures and/or population for which you wish to waive informed consent,
2. explain how the research involves no more than minimal risk,
3. explain how the waiver will not adversely affect the rights and welfare of the participants,
4. explain how it is not practicable to conduct the research if informed consent is required, and
5. indicate whether or not information will be provided to participants at a later time.

### (3440) Consent Process

Provide here a detailed explanation 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.
(3450) Protected Health Information (PHI)

.1: Please select "Yes" or "No" to indicate whether or not you are seeking to use Protected Health Information (PHI) without participants' consent, either to conduct the study, or to identify/recruit participants.

If you select "Yes" you will branch to follow-up screens to provide information that will help the IRB determine if you qualify for a HIPAA waiver. (see appendix)

.2: Indicate whether or not you plan to collect PHI for research purposes.

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

(10000) Routing for Signatures and Attaching Documents

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

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

1.0 Routing Form (100) Application

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

2.0 (555) Consent Form(s)

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

- **Main Consent Form** (includes parent permission and child assent forms)
- **Consent Statement/Elements** (this is the cover sheet used for surveys)
- **Other Consent Form** (for debriefing/reconsent forms)

Then Save and Continue.
### 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)

Then [Save and Continue](#)

### 4.0 (800) UTK Additional Information

If there is anything else you wish to share with the IRB, use this text box.

[Save and Continue](#)

When you are sure you have completed your application and all of its attachments, you will click [Signoff 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, then Save and Continue.**

All of the following persons **must** sign off before the IRB can begin its review of a new application:

- 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 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).

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 Screen**

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

After you have approved and signed off on your application, it will then be sent to each person on your routing list, in order.
### Application Screen

#### 3460 Appendix: HIPAA Screens Specific to Studies Using PHI

**Completion Instructions**

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.