HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

April 2022

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Contact Us

Human Research Protections Program

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Office Hours
M-F: 8 a.m.– 5 p.m.

Announcements

Virtual Office Hours:

HRPP Staff Virtual Office Hours will continue for the rest of the semester and throughout the summer. See the schedule and Zoom links below. You can also visit us in person in the office (Blount Hall Room 408) or contact us by email and phone.

Mondays from 2:00–4:00 pm—Ashley Brown (Zoom link here)

Tuesdays from 11 a.m.–1 p.m.—Jenny Dunn (Zoom link here)

Wednesdays from 2:30 p.m.–4:30 p.m.—Jennifer Engle (Zoom link here)

Thursdays from 9:00 a.m.–11:00 a.m. p.m.—Rob Withrow (Zoom link here)

Access to QuestionPro ending on May 31:

The University's license for QuestionPro will be expiring on May 31, 2022. After this date, investigators will no longer be able to use QuestionPro to collect or store data, and any data that is stored in QuestionPro will no longer be able to be accessed.

If projects that have IRB approval for QuestionPro are migrated to Qualtrics, it is not necessary to submit an amendment request to the IRB as long as all of the security protections approved for the project in QuestionPro are carried over to Qualtrics. For investigators with projects under review, who are not sure whether their projects will be hosted on Qualtrics or QuestionPro, the IRB recommends specifying a UT OIT-supported platform rather than the specific product.

For more information, please see the OIT QuestionPro webpage: https://oit.utk.edu/research/websurveys/questionpro-license/

Pearls from PRIM&R

This month, I'm reviewing the UTK HRPP Standard Operating Procedures for continuing review of approved full board research.

When is continuing review required?

Continuing review of full board studies is required at least once a year, unless the research only involves one or both of the following:

- Data analysis (includes of identifiable private information/identifiable biospecimens), or

- Accessing follow-up clinical data from procedures that subjects undergo during routine clinical care.

Even if the above criteria are met, the IRB may still choose to perform a continuing review. For example, the IRB may determine that continuing review is required when:

- Required by other applicable regulations (e.g., FDA);
- Required by the terms of a grant, contract, or other agreement (e.g., Reliance Agreement);
- The research involves topics, procedures, or data that are sensitive or controversial;
- The research involves vulnerable subjects or circumstances that increase vulnerability;
- An investigator has minimal experience in research type, topic, or procedures (e.g., student investigator); and/or
- An investigator has a history of noncompliance.

What is the Continuing review process?

iMedris sends automated reminders to 60 days, 30 days, and 25 days before study expiration. For Full Board studies, you also will receive a personal reminder from yours truly several weeks before your approval expires. Ultimately, it is your responsibility to ensure that the continuing review is approved prior to the expiration date. By federal regulation, no extensions can be granted.

Use the iMedris system to submit (as applicable) the following for your continuing review:

- Continuing Review Application (i.e. progress report);
- Clean copy of current consent document
- Copy of one recent signed consent document (identifiers blacked out);
- The most recent annual/progress report to the funding agency, if funded;
- Any previously un-submitted reports identified while completing the Continuing Review Application.

What will the IRB consider during my continuing review?

In order to re-approve research at the time of continuing review, the IRB must determine that the regulatory criteria for approval are still met. Because your research was previously found to satisfy the criteria, the IRB focuses its continuing review on whether *any new information* is available that would affect our prior determination. We pay attention to four aspects of the research:

- Risk assessment and monitoring;
- Adequacy of the informed consent process;
- Local investigator and organizational issues; and
- Research progress.

What are the possible outcomes of my continuing review?

At your Continuing Review, the convened IRB may vote to approve your study outright, send you conditional approval with provisos, or in the case of

significant concerns, to suspend or terminate the research (we will take up this topic in a later newsletter).

If you receive provisos after your continuing review, the IRB will specify whether any conditions need to be satisfied before your research can continue or requirements that must be adhered to. For example, if during the continuing review the IRB requires that you change the research protocol to include a new screening procedure, your proviso might read: "*Research activities involving currently enrolled subjects may continue, but no new subjects may be enrolled until a designated IRB member reviews a revised protocol and verifies that the protocol includes the new screening procedure.*"

What happens if my IRB approval lapses at the continuing review stage?

The regulations permit no grace period or extension after approval expires. Research that continues after the approval period has expired is research conducted without IRB approval. If re-approval does not occur within the time set by the IRB, all research activities must stop, including recruitment, enrollment, consent, interventions, interactions, and data collection - *even if you submitted the continuing review materials before the expiration date*. Please submit your continuing review materials in time to for IRB review before the actual expiration date.

While enrollment of new subjects cannot occur after the expiration of IRB approval, the IRB recognizes that temporarily continuing participation of already enrolled subjects may be necessary or appropriate, for example, when the research interventions hold out the prospect of direct benefit to the subjects, or when withholding those interventions or safety monitoring procedures would place subjects at increased risk. In these instances, contact the IRB office and submit a request to continue those research activities that are in the best interests of subjects. Be sure to specifically list the research activities that should continue, provide justification, and indicate whether the request applies to all or only certain subjects. The IRB Chair or designee will review the request and provide a determination regarding what activities, if any, may continue during the lapse. Such a determination may include a time limit or other conditions or restrictions. If the IRB decides that already enrolled subjects should continue to receive the interventions that were being administered to subjects under the research project, data collection (especially safety information) should also continue for such subjects.

What are the most common continuing review issues at UTK?

The two main issues that slow down continuing reviews are failure to attach a copy of a recently signed consent document (identifiers blacked out) and discrepancies between numbers of subjects enrolled year over year. For example, your continuing review indicates that 15 subjects were enrolled *at the time of* the last continuing review, and 15 subjects have been enrolled *since* the last continuing review, the TOTAL number of subjects enrolled thus far equals 30.

The IRB hope this information is helpful to you as you prepare your studies for continuing review! We are here to help and realize the importance of keeping your research on track. If you find yourself dealing with an unusual circumstance or situation, please reach out and we will do what we can to ensure that your project can move forward in a timely manner. Feel free to reach out anytime to utkirb@utk.edu and/or (865) 974-7697
Until next time!
Lora Humphrey Beebe, PhD, PMHNP-BC, FAAN
UTK IRB Chair

Upcoming Workshops

The HRPP is hosting three upcoming workshops. The first is a **Panel Discussion on Ethical and Affirming Research Conduct with LGBTQ+ Individuals.** Faculty and graduate students with extensive experience in this area will provide a short, educational presentation on important issues and considerations when doing research with and for LGBTQ+ individuals. They will also answer questions submitted in advance by registered attendees. The Panel Discussion will occur via Zoom on April 19th from 2-3. Register here: https://utk.co1.qualtrics.com/jfe/form/SV_4SJDGH60ftl02zQ

The second is a workshop on **Internet Research and Protection Against Bots.** The workshop will provide tips for successfully conducting research on the internet while maintaining compliance with human subjects research regulations. Topics to be discussed include using the internet to recruit participants, best practices for collecting online data, and protecting participant privacy and confidentiality online. A representative from OIT will also be present to give tips on how to prevent Bots and other bad actors from fraudulently completing online surveys. The workshop will end with a Q&A session. The workshop will occur via Zoom on April 29th from 12-1. Register here: ORIED Workshops & Tutorials

The third is a workshop on **Conducting Human Subjects Research Internationally.** The workshop will highlight some of the requirements for conducting research with human subjects internationally. Presenters will discuss how to determine whether review by an international Ethics Committee is required, when data privacy laws such as the General Data Protection Regulation (GDPR) apply, when letters of support or cultural appropriateness are needed, and best practices for using translators. The workshop will end with a Q&A session. The workshop will occur via Zoom on May 4th from 10-11. Register here: ORIED Workshops & Tutorials

When a Principal Investigator Leaves UTK

As we are nearing the end of the semester, we wanted to offer some reminders on what to do with your research after you leave the University. Please see the information below for guidance and contact us if you have any questions.

Often principal investigators (PIs) leave an institution without effectively managing their research studies. PIs are responsible for managing their studies prior to departure. Likewise, faculty advisors and department administrators have a responsibility to ensure these duties are carried out before the PI leaves. Below are the procedures required for studies involving human research participants.

Study Completed:
If all study activities have been completed and no research data/specimens will be transferred to a new institution, submit a Form 7 Study Closure Form in iMedRIS. All consent documents must be deposited with the departing PI's faculty advisor or department head.

Study Active – PI No Longer Involved in Study:
If the study will remain active at UT and the departing PI will have no further involvement with the study, submit a Form 2 Change Request in iMedRIS to assign a qualified individual as the new PI. Revise any documents (consent

documents, recruitment materials, etc.) to list the new PI's name and contact information. Confirm in the Form 2 that all study records and data have been deposited with the new PI.

Study Active – PI Continues Involvement in Study:
If the study will remain active at UT and the departing PI will continue as part of the research team, submit a Form 2 Change Request in iMedRIS to:

- Assign a qualified individual as the new PI
- Explain the departing PI's new role, including a description of any continued access to data
- Confirm that all study records and data have been deposited with the new PI or explain alternate arrangements
- List the departing PI's new contact information and institutional affiliation
- Submit a copy of the departing PI's IRB approval from their new institution
- Revise any documents, such as consent documents, recruitment materials, etc. to list the new PI's name and contact information.

Transferring Research to Another Institution:
Any departing investigator wanting to transfer research records, data and/or specimens to a new institution must do the following:
Contact the IRB to determine next steps. The IRB is obligated to ensure protections promised to research participants are maintained.

Other Issues: Should a departing investigator encounter an issue not covered in the above procedures, please contact the HRPP Office.

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		February	March
New Studies	Exempt	9.9	6.2
	Expedited	9.5	7.9
Amendments	Exempt	4.0	4.0
	Expedited	4.4	6.6

IRB Submissions

Submission Type	Submissions	
	February	March
Pre-Review Changes	45	51
New Studies	74	89
Amendments	63	94
Change in Personnel	28	25
Continuing Reviews	30	30

Reportable New Information	2	5
Study Closure	7	2
Miscellaneous	1	1
TOTAL	**250**	**297**

Contact Us

General Questions (submission procedures, application and materials development, iMedRIS, etc.) contact us at (865) 974-7697 or utkirb@utk.edu.

Submissions that are currently in review, contact your unit's ***liaison***.

Reportable New Information (unanticipated problems, adverse events, complaints, concerns about participant welfare or safety, etc.), contact Lora Beebe (lbeebe1@utk.edu) or Jennifer Engle (jengle@utk.edu)

Reliance Agreements/Single IRB and Other Collaborative Research, contact Jennifer Engle (865-974-7494, jengle@utk.edu).

Education and Training, contact Jennifer Dunn (jdunn36@utk.edu).

ClinicalTrials.gov, contact Jennifer Engle (865-974-7494, jengle@utk.edu).

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