HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

August 2021

In This Issue

Contact Us

Human Research Protections Program

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Office Hours
M-F: 8 a.m.– 5 p.m.

COVID-19 Update

In keeping with the Chancellor's message regarding safety measures for the COVID-19 delta variant, the HRPP requests that all human subjects researchers and participants employ mask wearing and social distancing. These preventive measures should be reinstated based upon the expectations of our local area and are applicable to all faculty, staff, students, and visitors. For researchers whose activities occur off-campus, please continue to follow any additional requirements that may be in place at those sites.

Announcements

After careful consideration and based on the recommendation of the Assistant Vice Chancellor for the Responsible Conduct of Research and the Vice Chancellor for Research, the Human Research Protection Program at the University of Tennessee, Knoxville has applied for accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). By obtaining this accreditation, we will join an elite group of institutions internationally renowned for promoting exceptional ethical and professional standards in the conduct of human subjects research. This will help us stand out among peer institutions, since only 4 of our 11 peer institutions are accredited at this time, and move toward our aspirational counterparts, as all six of our aspirational schools are AAHRPP accredited.

Accreditation by AAHRPP is a peer-review process, which, in addition to identifying areas for improvement, will also identify areas of excellence that can make the institution more competitive in obtaining funding and recruiting researchers and research participants. In addition, AAHRPP accreditation is increasingly being required by other institutions as a condition of entering into a Reliance Agreement for cooperative research.

Preparations for accreditation began in 2018 with a Task Force of Faculty Members who helped the HRPP conduct a thorough self-assessment and provided input on selected Standard Operating Procedures. We wish to give a special thank you to all of the individuals who were part of the Task Force for all of their hard work.

In working towards accreditation, the HRPP is implementing a number of improvements including the creation of Standard Operating Procedures, updates to the HRPP website, changes to the iMedris application screens and increased education for faculty, administration, staff, and students involved in human subjects research. More improvements will be coming as we continue to work through the accreditation process.

As we move toward our accreditation site visit (expected in Summer 2022) you can expect to hear more about the accreditation process and how you can be

involved. Should you have questions in the meantime, feel free to reach out to HRPP Director, Jennifer Engle at jengle@utk.edu or (865) 974-7494.

For more information on AAHRPP visit: https://www.aahrpp.org/

For a list of AAHRPP accredited institutions visit: https://www.aahrpp.org/learn/find-an-accredited-organization

Changes to iMedRIS application and Other Procedures

In response to our self-assessment and in preparation for accreditation, we have already implemented some changes. They are summarized below:

One change is a new procedure for Exempt studies and Expedited studies that do not require continuing review. As of July 2, 2021, Exempt studies and Expedited studies that do not require continuing review will now be approved for 3 years instead of having no expiration date. If investigators wish to keep the study open longer than 3 years, a Study Update form must be submitted before the expiration date. This form will be a shortened version of the continuing review form. If a Study Update form is not submitted before the expiration date, HRPP office staff will administratively close the study. Investigators will be informed of this in their approval letter and will receive reminders from iMedRIS at 60, 30, and 25 days before the Study Update form is due. Implementing this new procedure will help the HRPP keep better track of our active studies.

We have also made some changes to the iMedRIS application. You will notice two new Exemption Categories that are available to you (Categories 1 and 6). We have also added questions that will allow us to gain more complete information from investigators who are conducting research internationally and who are applying for IDE Exemptions for FDA-regulated studies. Collecting this additional information up front will help speed up review times and reduce the number of times applications must be sent back for changes.

Lastly, we are implementing a new process for some Reliance Agreements. Investigators who request a Reliance Agreement in which the University of Tennessee, Knoxville IRB will rely on an external IRB, or who want a Reliance Agreement for an Exempt Study will now be required to complete a short submission form in iMedRIS. Previously, this information has been collected via email, but having it in iMedRIS will help us to have a more streamlined and efficient system.

Stay tuned for more information about these changes. The HRPP Office will be sharing updated guidance and educational materials soon. In the meantime, don't hesitate to Contact Us or stop by our Virtual Office Hours.

Pearls from PRIM&R

Hello UT Research Community! This month, I viewed a virtual session entitled "College students and research: Challenges and issues" that was presented at the 2019 Social, Behavioral and Educational Research conference by A McDowell and J Simpson.

Relevant laws and regulations. Besides HIPPA, there are two federal laws pertaining to research with student participants on campus. *The first* is the Family Education Rights and Privacy Act or FERPA (I wrote about FERPA in the April 2021 newsletter). As a refresher, FERPA (1974) affords students the right to:

-inspect their educational record,
-request that a school correct record they believe are inaccurate/misleading,
-privacy with respect to disclosure of their educational records, and
-to file a complaint with the US Department of Education.
With a few exceptions, schools must have written permission from the student to grant access to information in the student's educational record. Educational records include things like ID numbers, social security numbers, birthday, race, ethnicity, grades, and financial aid information among others.

The second federal law is Title IX, federally mandated reporting. UTKs Title IX Policy applies to students, faculty and staff and prohibits sexual harassment (including sexual assault, dating violence, domestic violence and stalking), sexual exploitation, and retaliation. Mandatory reporters are required to report information about known or suspected prohibited conduct to the Office of Title IX within 48-hours. Visit https://titleix.utk.edu/faculty-and-staff/mandatory-reporters/ to see who is a mandatory reporter at UTK.

Of note, mandatory reporting information must be included in informed consent forms for research if applicable. Our consent template includes a section titled "Who can see or use the information collected for this research study?" Among other things, any circumstances that would limit confidentiality (like Title IX if applicable) are discussed in this section. See the informed consent templates at: https://irb.utk.edu/forms/ for more information. If particularly sensitive data will be collected and remain identifiable, the IRB may require that a Certificate of Confidentiality be obtained. However, a Certificate of Confidentiality *does not apply* to mandatory reporting laws.

Common issues relating to students as research participants:
1-Make sure you articulate a sound research rationale for the use of students in your IRB application
2. Take care to describe how you will minimize the power differential, undue influence, and coercion during research activities (e.g., refrain from direct recruitment)
3-Make every effort to craft your methodology so that faculty and other students are unaware of who is participating (including addressing issues surrounding ease of identification in small samples if applicable)
4-Be certain there are NO negative consequences for students who choose not to participate
5- Consider using students in another section or at another institution. This allows you to "swap" so that each researcher uses the other's students for the research rather than their own, eliminating several of the above concerns

The use of student subject pools. Like most things, subject pools have pros and cons. Some criticisms are that such pools are biased, do not represent the general population, do not ensure true voluntariness, and may include minors. The rationale for requiring research as part of course credit may not be clear to students. Likewise, student alternatives to participation may not be clearly communicated and the alternative may require more time or effort than participating in the research.

Best practices-for subject pools include

- Making sure you explain how students can earn research credit without participating in research
- Making certain the alternatives are truly equivalent in length and ease of completion
- Being clear about the research activities and alternatives in recruitment announcements
- Including the right to withdraw in all communication
- Discussing the educational aspects of the experience during debriefing (if debriefing is done)
- Only allowing those 18 and over to register for the research pool

Here at UT, the Psychology Department's research experience program gives students enrolled in Introductory Psychology and a handful of other courses opportunities to learn about psychological research first-hand. Students earn a small portion of course credit by taking part in research studies conducted by department faculty and students. The range of studies reflect the range of research interests in the department. Some studies are qualitative and others are quantitative, some are online and others are in person. By taking part in the research experience program, students see the variety of questions about human behavior and mental processes that can be studied with scientific methods, learn how and why we conduct psychological research, and learn how the results are used to help understand behavior and mental processes.

More resources may be found here:
FERPA: http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
TITLE IX: https://titleix.utk.edu/
For more information about the psychology department's student pool, contact Dr Jeff Larsen at jeff.larsen@utk.edu or contact the UT IRB at: utkirb@utk.edu and/or (865) 974-7697

Happy researching until we meet again!

Lora Humphrey Beebe, PhD, PMHNP-BC, FAAN
UT IRB Chair

Human Subjects Research Determination Worksheet

We have a new tool available to you, the **Human Subjects Research (HSR) Determination worksheet**. It is intended to assist you in determining if an activity you are planning fits the definition of

- human subjects research, or
- other activity requiring review, such as
    - accessing HIPAA-covered information,
    - devices falling under FDA requirements, etc.

These definitions can be confusing, but it's important to know if they apply to your project. If your planned activity meets the definition of human subjects research or other activities requiring review, an IRB application must be submitted for review before the activity begins. If your planned activity does not fall under any of these definitions, IRB review and approval are not required.

The HSR Determination worksheet provides you with the opportunity to answer a series of questions that assess your activity against these definitions.

It is available to you on Qualtrics: https://tiny.utk.edu/hsrworksheet

If you complete the worksheet, you will receive a copy of it for your records, which you may use to communicate this determination to others such as conference organizers, journal editors, etc.

A short, captioned video is also available https://tiny.utk.edu/HSRworksheetVIDEO. The video introduces the tool (select UTK Canvas (main) to sign in).
You will also be provided with instructions for how to request a more formal determination from the Human Research Protection Program (HRPP) if needed. Please don't hesitate to contact the HRPP with any questions you have.

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		June	July
New Studies	Exempt	5.5	6.2
	Expedited	8.3	8.5
Amendments	Exempt	4.2	4.3
	Expedited	5.7	9.2

IRB Submissions

Submission Type	Submissions	
	June	July
Pre-Review Changes	19	50
New Studies	105	91
Amendments	50	35
Change in Personnel	22	16
Continuing Reviews	40	33
Reportable New Information	16	13
Study Closure	13	13
Miscellaneous	1	0
Request to Resume in-Person Research	1	1
TOTAL	**267**	**252**

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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