HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

September 2021

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Contact Us

Human Research Protections Program

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irb.utk.edu

Office Hours
M-F: 8 a.m.– 5 p.m.

Announcements

HRPP office staff are currently working a hybrid schedule, with some days in the office and some days working remotely. See the table below for when we will be in the office, when we will be working remotely, and when we will be holding Virtual Office Hours on Zoom. An X in the table below indicates days that we will be in the office.

	College Liaison	Monday	Tuesday	Wednesday	Thursday	Friday
Jennifer HRPP Director (865) 974-7494 Jengle@utk.edu			X	X **Office Hours on Zoom 2:30-4:30pm** Zoom link here	X	X
Jenny (865) 974-2314 Jdunn36@utk.edu	• Agriculture/ UTIA • Business • CCI • CEHHS: RHTM • Vet Med. • University-wide Units	X	X **Office Hours on Zoom 11-1pm** Zoom link here			
Ashley (865) 974-7687 abrow269@utk.edu	• CEHHS: • Child and Family Studies • ELPS • EPC • Nutrition • Public Health • TPTE	**Office Hours on Zoom 2-4pm** Zoom link here		X	X	
Rob (865) 974-2457 rwithrow@utk.edu	• Arts and Sciences • CEHHS: Kinesiology • Engineering • Law • Nursing • Social Work				**Office Hours on Zoom 9-11am** Zoom link here	X

If these times do not work for you, we are happy to schedule an individual meeting. Please email your College Liaison to schedule a time to meet.

NEW: Expiration Dates for Exempt and Expedited Studies

In preparation for AAHRPP accreditation, the HRPP has implemented a new procedure for Exempt studies and Expedited studies that do not require annual continuing review. As of July 2, 2021, these studies will only 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 will need to be submitted via iMedRIS and approved by the HRPP before the expiration date. This form is 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 the study expiration date in their approval letter and will receive reminders from iMedRIS before the Study Update form is due.

Implementing this new procedure will help the HRPP keep better track of our active studies.
We will also be contacting investigators soon to get status updates on older Exempt studies to ask if these studies are still ongoing.

Pearls from PRIM&R

Hello UTK research community! This month I attended a PRIM&R webinar entitled "Responsible Conduct of Research" and presented by F Houman, PhD and J Simpson, PhD.

The Responsible Conduct of Research (RCR) is critically important to our research endeavor and builds upon the fundamental values of science: objectivity, honesty, openness, accountability, fairness and stewardship. RCR is the norm for research at all levels and fundamental to high quality science. The National Academies of Science Engineering and Medicine addresses RCR training by recommending the ongoing development and assessment of RCR training programs to ensure currency, and several federal agencies have enumerated RCR requirements with varying levels of detail.

The National Institutes of Health (NIH) was the first agency to require research training for individuals named in awards in 1990, although the requirement was not known as RCR at the time. In a 2009 update, NIH defined RCR as "the practice of scientific investigation with integrity" including the "awareness of application of established professional norms and ethical principles." RCR training is described as an ongoing process, and among the topics listed are conflict of interest, research misconduct, the use of human subjects, data monitoring and ethical issues. The National Science Foundation (NSF) provides no specific guidance about content, leaving that to the individual institution. Interestingly, the NSF did recommend in 2017 that RCR training be integrated into student coursework and laboratory experiences. Every NSF grantee must describe a plan for training and oversight in the responsible and ethical conduct of research for participating undergraduate students, graduate students, and postdoctoral researchers. Finally, the US Department of Agriculture (USDA) recommends RCR content on authorship, data integration, misconduct, conflict of interest and human subjects including a mention of CITI, the program we use at UTK!

Other organizations may impose their own research training requirements in addition to federal guidelines, for instance international codes such as the European code of conduct for research integrity (2017) and the Montreal statement on research integrity provide guidance on cross boundary research collaborations (2013). Professional societies such as the American anthropological association (2009) and the American chemical society (2020) have their own research requirements, as do individual publishers, journals, foundations (e.g., Gates Foundation, Howard Hughes Medical Institute) and institutions like the University of Tennessee.

The UTK RCR policy may be found at https://pubs.acs.org/page/policy/ethics/index.html.

The UTK student code of conduct addresses research ethics in section 4.27: https://studentconduct.utk.edu/wp-content/uploads/sites/53/2018/07/Fall-2020-StudentCodeOfConductBook-FINAL.pdf

Finally, RCR is a necessary but not sufficient condition for research integrity. RCR is focused on training, oversight and specific topical areas, while research integrity is a broader construct and includes such issues as rigor of design, reproducibility, institutional research climate and social responsibility. In order to enhance research integrity at the University of Tennessee, the HRPP has applied for accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP accreditation affirms the University's commitment to protecting research participants - a commitment that resonates not only with participants but also with researchers, sponsors, government agencies, and the general public. AAHRPP accreditation will document that the University of Tennessee, Knoxville follows rigorous standards for ethics, quality, and protections for human research, bring us nearer to our aspirational institutions and positioning us as a quality partner for research collaboration. Rest assured, you will be hearing a lot more about AAHRPP and the accreditation process in the months to come!

As always, contact the UT IRB with questions: utkirb@utk.edu and/or (865) 974-7697
And happy researching until next time!

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

Links for additional reading:
NIH RCR training requirements: https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training

NSF requirements: https://www.nsf.gov/bfa/dias/policy/rcr.jsp

USDA recommendations: https://nifa.usda.gov/responsible-and-ethical-conduct-research

European code of conduct for research integrity: https://allea.org/code-of-conduct/

Montreal statement on research integrity in cross boundary research collaborations: https://wcrif.org/montreal-statement/file

American anthropological association ethics statement: https://www.americananthro.org/ParticipateAndAdvocate/Content.aspx?ItemNumber=1656

American chemical society ethical guidelines: https://pubs.acs.org/page/policy/ethics/index.html

HRPP Workshops for Fall 2021

The HRPP & IRB are hosting several workshops in the next couple months starting with the Department Review Chair (DRC) & Department Head Workshop next week. If you are new to the role of DRC, we encourage you to join one of the workshops. To register please follow the links below.

- **Diversity and Inclusion in Human Subjects Research**
  9/14/21, 12–1 p.m.
  11/9/21, 12–1 p.m.
- **IRB Virtual Workshop: Department Heads and Department Review Chairs**
  9/8/21, 12–1 p.m.
  9/9/21, 10–11 a.m.
- **Human Research Protection Program and Institutional Review Board: New Faculty Orientation**
  10/7/21, 10–11 a.m.
  10/8/21, 12–1 p.m.

If you have questions about this series, please contact Jennifer Engle, Human Research Protection Program director (jengle@utk.edu).

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, or
  - 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 activity 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 or journal editors.

A short, captioned video is available here:
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 formal determination from the HRPP if needed. Please don't hesitate to contact us with any questions you have.

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		July	August
New Studies	Exempt	6.2	6.4
	Expedited	8.5	9.9
Amendments	Exempt	4.3	4.0
	Expedited	9.2	8.3

IRB Submissions

Submission Type	Submissions	
	July	August
Pre-Review Changes	50	35
New Studies	91	85
Amendments	35	76
Change in Personnel	16	19
Continuing Reviews	33	26
Reportable New Information	13	8
Study Closure	13	2
Miscellaneous	0	3
Request to Resume in-Person Research	1	0
TOTAL	**252**	**254**

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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