HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

November 2021

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Human Research Protections Program

Blount Hall, Room 408
1534 White Ave.
Knoxville, TN 37996-1529
865-974-7697
utkirb@utk.edu
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 Engle HRPP Director (865) 974-7494 Jengle@utk.edu			**X**	**X Office Hours on Zoom 2:30-4:30pm Zoom link here**	**X**	**X**
Jenny Dunn (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 Brown (865) 974-7687 abrow269@utk.edu	• CEHHS: Child and Family Studies • ELPS • EPC • KRSS • Nutrition • Public Health • TPTE	**Office Hours on Zoom 2-4pm Zoom link here**		**X**	**X**	
Rob Withrow (865) 974-2457 rwithrow@utk.edu	• Arts and Sciences • 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.

Research Match

The University of Tennessee, Knoxville has joined Research Match, which is an NIH-Funded research participant recruitment registry. Over 157,000 volunteers across the United States have signed up to participate in research through Research Match, and researchers at our university will now have access to these volunteers for their studies. Research Match is a free and secure online tool.

Volunteers who are interested in participating in research sign up and create a profile in Research Match, which includes their demographic information and information on specific health conditions they have. Researchers can search the registry based on this information to see how many individuals on Research Match fit the criteria for their project. Researchers can then use the registry to send recruitment messages to individuals who might be interested in their study.

You can visit their website for more information about signing up to be a research volunteer or a researcher.

For questions about Research Match, please contact Jennifer Engle or Ashley Brown.

Pearls from PRIM&R

This month I attended a virtual conference titled Fundamentals of Qualitative Research and conducted by JF Simpson and PB Cordon. Before we address the ethical issues pertaining to qualitative research, let's do a quick review.

Qualitative research is an approach rather than a set of techniques. The decision whether to use quantitative or qualitative approaches rests upon the nature of the phenomenon under study and the researcher's questions of interest. The qualitative paradigm encompasses the concepts of multiple realities, interdependence between researcher and participant, and situated, interpretive portrayal of phenomena. The contrast between quantitative and qualitative approaches requires that IRBs have an understanding of the differing paradigms.

Assessing scientific integrity in qualitative research. Items you can address in your application to help the IRB make a determination about scientific integrity in qualitative research include:

- An explicit statement of why the research question is appropriate for a qualitative approach
- A clear purpose and/or significance statement
- Appropriate methodology (phenomenology, ethnography, grounded theory) to answer your question with rationale
- A robust data collection plan including specific techniques (observation, interview, focus group) to answer your question
- A detailed data analysis plan, including coding procedure

Ethical Issues in Qualitative Research. There are some unique issues for qualitative research participants surrounding privacy, informed consent, and confidentiality. Field notes and recordings are often used in qualitative data collection, raising questions about data security and storage that your application needs to address. The small sample sizes and detailed description that are the hallmarks of qualitative reporting may make it more likely that a participant's identity could be ascertained. The IRB will want to verify that you have considered these potential risks and done what you could to mitigate them. As in any study, mandatory reporting should be addressed if applicable, both in your data collection plans and in participant consent. We know that part of informed consent is a discussion of potential risks and how they will be minimized, however the unfolding nature of qualitative investigations makes it difficult to anticipate risks. Demonstrating that you have thoughtfully considered likely risks and have a plan to mitigate them, will facilitate this portion of your IRB review process.

Strategies for qualitative researchers. The IRB suggests that you familiarize yourself with not only the recent literature on your topic, but also on the qualitative approach(es) you propose. Develop contingency plans to mitigate any risks you deem likely. Document how you will educate your participants about research and any existing role conflict (important if you have access to participants through your employment or other, non-research roles). Consider the use of 1:1 data collection methods for sensitive data. Remain reflective throughout your project - this is a strength of the qualitative approach and help will ensure that you remain self-aware about your effect upon participants and the data they provide. And finally, adhere to the principles set forth in the Belmont report: respect for persons, beneficence and justice.

Below is a short list of qualitative journals for further reading:

International Journal of Qualitative Methods:
https://journals.sagepub.com/home/ijq
The Qualitative Report: https://nsuworks.nova.edu/tqr/
Qualitative Health Research: https://us.sagepub.com/en-us/nam/journal/qualitative-health-research

And as always, feel free to contact the UT IRB with questions: utkirb@utk.edu and/or (865) 974-7697

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

HRPP Workshops for Fall 2021

The HRPP is presenting a workshop on Diversity and Inclusion in Human Subjects Research again in November. To register please follow the link below.

- **Diversity and Inclusion in Human Subjects Research**
  11/9/21, 12–1 p.m.

We also have several workshops planned for the Spring Semester. Stay tuned for more details!

Office Schedule for November and December

The HRPP office staff and IRB Chair will be attending the virtual Public Responsibility in Medicine and Research (PRIM&R) Conference on **November 16-19**. Please note that response times to emails and voicemails, as well as review response times may be a little longer than usual during this time.

We also want to remind everyone that the University will be closed from **Friday, December 24 through Friday, December 31**. Because the University is closed, HRPP office staff will not be working that week. Please make a note of this if you are planning to submit items for review during that time.

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		September	October
New Studies	Exempt	6.3	5.3
	Expedited	8.4	10.3
Amendments	Exempt	3.6	5.1
	Expedited	4.9	7.1

IRB Submissions

Submission Type	Submissions	
	September	October
Pre-Review Changes	47	59
New Studies	90	90
Amendments	95	60
Change in Personnel	23	20
Continuing Reviews	35	24
Reportable New Information	11	8
Study Closure	10	8
Miscellaneous	2	1
Request to Resume in-Person Research	0	0
TOTAL	**313**	**270**

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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Fax: 865-974-7400
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Website: irb.utk.edu