



February 2021

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## Contact Us

### Human Research Protections Program

Blount Hall, Room 408  
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Knoxville, TN 37996-1529  
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utkirb@utk.edu  
irb.utk.edu

Office Hours  
M-F: 8 a.m. – 5 p.m.

## Announcements

### Virtual Office Hours

HRPP office staff are currently working a hybrid schedule, with some days in the office and some days working remotely. If you need assistance, you can visit us during virtual office hours, visit us in person in the office (Blount Hall Rooms 408 and 410), or contact us by email and phone. Below is our office hours schedule:

**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 – 4:30 p.m.** — Jennifer Engle ([Zoom link here](#))

**Thursdays from 9:00 – 11:00 a.m.** — Rob Withrow ([Zoom link here](#))

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.

### iMedRIS Upgrade

The IRB online submission system, iMedRIS was upgraded to version 13.01 last week. The new upgrade includes changes to icons on the home screen and a new “By the Numbers” box that gives an overview of how many forms are in process, pending submission, or pending a response. Under Featured Project Operations on your home screen, you can now easily access the currently approved versions of your study documents by clicking View the Current Approvals for one of My Studies. You can also set a priority (low, medium, or high) for a submission to help you keep track of those that need to be addressed more quickly, and you can get an overview of where your submission is in the review process by clicking to open the study from your home page and viewing the Submission Review Status progress bar.

Please have patience with us and our iMedRIS Tech Support team as they work out the bugs in the upgraded system, and let us know if you’re having any issues. We’ll work to address them as soon as possible.

## Pearls from PRIM&R

### **IRB Must Evaluate Study Design and Quality**

Lora Beebe, IRB chair here. This month, I’d like to provide some information about an issue that has been raised in several meetings recently, the IRB’s role in evaluation of study design and quality. My source document is the

"Institutional Review Board Member Handbook, 4<sup>th</sup> ed" by RJ Amdur & EA Bankert.

While the authors acknowledge that there is debate among IRB members, institutional officials, and researchers as to the role of the IRB in evaluating study design, they go on to provide evidence in support of the IRB's obligation to evaluate scientific quality in order to function in compliance with both ethical codes and federal research regulations.

Scientific quality is addressed in both the Nuremberg Code (section 12) and the Declaration of Helsinki (sections 18, 21 and 32). The assessment of scientific quality relates to the study's risk benefit ratio. The Nuremberg Code (1947) states, "The experiment should be so designed...that the anticipated results will justify the performance of the experiment." Similarly, federal law (regulation 45 CFR 46.111 (a) requires the IRB to determine that a study is designed:

- 1-so that risks to subjects are minimized and
- 2-the risks of the study are justified by potential benefits.

It is *these two points* that the IRB must evaluate in relationship to study design.

As a researcher, you can address these points by closely aligning your study purpose, hypotheses, and planned analysis. While the IRB does not intend to evaluate the nuances of your analysis plan, making explicit the relationship of your planned analysis to your study purpose will assist us in determining that risks are justified. For instance, if multiple data points (e.g. interviews and focus groups) are necessary to fulfill the study purpose, the IRB will need the details about how each data point will contribute to achieving the stated aims.

A word about very low risk studies: in the absence of risk, Amdur & Bankert suggest there is no strong ethical justification for the IRB to make revisions a condition of study approval. Especially with student investigators, the UTK IRB may make suggestions to strengthen the proposal, but *suggestions will be clearly noted in the feedback* and acceptance of suggestions is *not* required for approval.

As usual, evaluations of study design, risk minimization and justification are best made on a case-by-case basis. The IRB works hard to help investigators maintain compliance without prescribing research design decisions best left to the content experts. If you would like to discuss these or other issues relating to a specific project, don't hesitate to reach out anytime!

You can always contact the IRB for study specific discussion: [utkirb@utk.edu](mailto:utkirb@utk.edu) and/or (865) 974-7697

Happy researching until next time!

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

## Research Match

The University of Tennessee, Knoxville has joined [Research Match](#) as a [participating institution](#). Research Match is a free and secure online tool for connecting researchers with volunteer study participants.

The program facilitates the successful completion of human subjects research, which can often be delayed or not completed due to difficulties recruiting study participants. Any researcher who is conducting any type of health-related research can use Research Match to recruit participants. Researchers can also sign up for feasibility access before recruiting on Research Match to determine how many participants in their target demographic are volunteers on the site.

If you are interested, you can sign up to be a [volunteer study participant](#) as well.

If you have questions about using Research Match, please contact UT's institutional liaisons for the program:

- [Jennifer Engle](#), Director, Human Research Protection Program ([jengle@utk.edu](mailto:jengle@utk.edu) or 974-7494)
- [Ashley Brown](#), Assistant Compliance Officer, Human Research Protection Program ([abrow269@utk.edu](mailto:abrow269@utk.edu) or 974-7687)

## Performance Metrics

### Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		December	January
<i>New Studies</i>	Exempt	6.7	8.2
	Expedited	10.3	13.3
<i>Amendments</i>	Exempt	3.9	4.5
	Expedited	8.7	6.9

### IRB Submissions:

Submission Type	Submissions	
	December	January
<i>Pre-Review Changes</i>	27	51
<i>New Studies</i>	57	67
<i>Amendments</i>	33	60
<i>Change in Personnel</i>	6	23
<i>Continuing Reviews</i>	29	48
<i>Reportable New Information</i>	0	8
<i>Study Closure</i>	15	8

<i>Miscellaneous</i>	1	0
<b>TOTAL</b>	<b>168</b>	<b>265</b>

## Contact Us

**General Questions** (submission procedures, application and materials development, iMedRIS, etc.) contact us at (865) 974-7697 or [utkirb@utk.edu](mailto: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](mailto:lbeebe1@utk.edu)) or Jennifer Engle ([jengle@utk.edu](mailto:jengle@utk.edu))

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

**Education and Training**, contact Jennifer Dunn ([jdunn36@utk.edu](mailto:jdunn36@utk.edu)).

**ClinicalTrials.gov**, contact Jennifer Engle (865-974-7494, [jengle@utk.edu](mailto:jengle@utk.edu)).

### Human Research Protections Program

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