HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

December 2021

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Human Research Protections Program

Blount Hall, Room 408
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Knoxville, TN 37996-1529
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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. If you need assistance you can visit us during virtual office hours, visit us in person (Blount Hall Room 408), or contact us by email and phone. Below is our office hours schedule:

Mondays from 2:00 – 4:00 p.m. — 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.

Holiday Hours

HRPP staff will be out of the office on the following days as the University of Tennessee, Knoxville is closed:

- Dec. 24, 2021
- Dec. 27- 31

If you have an emergency during this time, please call our office phone number at (865) 974-7697 and leave a voicemail. We will monitor voicemails for emergencies. All other emails and voicemails will be returned after the administrative break. Happy Holidays!

Pearls from PRIM&R

This month I viewed a webinar entitled, "Assessing plans to maintain confidentiality: How IRBs determine whether data security and management plans are sufficient" and presented by G.L.J. Angding and Dr E.A. Buchanan at the 2019 Social, Behavioral and Educational Research Conference.

Under the Revised Common rule 45 CFR 46.111, the IRB must review provisions for privacy and confidentiality of all studies (similar rules apply to FDA funded studies under FDA 21.CR 56.111). During this review, the IRB will assess:

- Privacy of the processes and protection of collected data during both recruitment and follow up

- Provisions to protect data and samples during use and storage
- Identification of individuals or organizations who may access identifiable information
- Plans for deidentification and/or destruction of data or specimens when appropriate

As a review, privacy refers to *people;* that is, the right of an individual to have control over how their personal information is collected, used and/or disclosed. Confidentiality encompasses the processes and protocols the PI will use to protect the *information* participants provide. The participants' understanding of and agreement to ways their identifiable information will be stored and shared are addressed during the informed consent process. For example language, see the UT standard informed consent template: https://irb.utk.edu/forms/

Among other things, the IRB review considers:

- The nature of (both direct and indirect) identifiers associated with the data
- Whether collection of identifiers is necessary to conduct the research
- Characteristics of the study population-for instance, are they vulnerable? Are they somehow unique and therefore easily identifiable? Does the (small) sample size lend itself easily to identification of individuals?
- The overall sensitivity of the data- is information being collected about illegal activity, mental health, or sexual matters?
- What persons or groups will access the data
- What procedures and processes will be used to share the data
- The likely retention period of identifiable data and specifics of the data deletion procedure
- Other data security controls including physical safeguards for paper records, technical safeguards for electronic records and secure data sharing/transfer if applicable

The most important thing the IRB considers is the level of potential risk for harm if security of data is compromised. For example, would knowing someone was a participant in your study expose them to risk for physical, reputational, economic or other harm?

Practical solutions for PIs:

To ensure your project addresses all of the above, be sure you describe measures to demonstrate that data will be securely stored. OIT has great resources including statistical analysis, data acquisition and management, installation and use of software and more located at: https://oit.utk.edu/services/.

For research in the field, the IRB recommends that you use only approved portable devices for temporary storage, and transfer data to an encrypted, secure device or location (deleting data from your temporary device) as soon as possible. Always store sensitive or identifiable data separately from other data.

Remember, the *level of sensitivity of the information* you are collecting should guide your level of security. For instance, if you are collecting protected health information (PHI), your data storage must be HIPAA compliant.
Finally, consider a certificate of confidentiality (COC) for your project. This certificate permits PIs to protect participant privacy by refusing to disclose

participant names and other identifying characteristics, even if asked to do so by courts or governmental agencies. COCs issue automatically for NIH funded projects that use identifiable sensitive information, but you can request one for any study that addresses the NIH mission using the procedure here: https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm.

And as always, you can contact the IRB anytime for study specific options or questions: utkirb@utk.edu and/or (865) 974-7697

Happy researching!
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, 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.

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		October	November
New Studies	Exempt	5.3	5.3
	Expedited	10.3	8.4
Amendments	Exempt	5.1	3.5
	Expedited	7.1	5.2

IRB Submissions:

Submission Type	Submissions	
	October	November
Pre-Review Changes	59	48
New Studies	90	97
Amendments	60	70
Change in Personnel	20	12
Continuing Reviews	24	37
Reportable New Information	8	0
Study Closure	8	6
Miscellaneous	1	0
Request to Resume in-Person Research	0	0
TOTAL	**270**	**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).

Human Research Protections Program
Office of Research & Engagement

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