HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

October 2021

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Contact Us

Human Research Protection 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 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 • KRSS • 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 • 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.

HRPP Task Force & Accreditation

As the HRPP began preparation for accreditation from the Association for Accreditation of Human Research Protection Programs (AAHRPP), our first action was to create a faculty task force. The task force began meeting in 2017, and members have worked on reviewing existing procedures, identifying gaps, and providing input toward new Standard Operating Procedures. Moving forward, the task force will help spread the word around campus about new procedures we have implemented and help us prepare for our accreditation site visit in Summer 2022. We want to thank our task force members and recognize them for all of their hard work.

Members are listed below:
Suzie Allard, College of Communication and Information
Lora Beebe, IRB Chair and College of Nursing
Phillip Daves, Haslam College of Business
Bill Nugent, College of Social Work
Hollie Raynor, College of Education, Health, and Human Sciences
Allison Sharp, Libraries
Elizabeth Strand, Veterinary Social Work
Jindong Tan, Mechanical, Aerospace and Biomedical Engineering
Deadric Williams, College of Arts & Sciences
Jeanine Williamson, Libraries
Tami Wyatt, College of Nursing

Pearls from PRIM&R

Hello UTK research community! This month I attended a PRIM&R webinar entitled "Real World Approaches to Informed Consent" and presented by K Blackwell, P Herbison & A Johnson.

For adult participants in research studies, the informed consent document should be written at about a 6-8th grade reading level. The regulatory requirements that must be covered in the document may be found on our website (Informed Consent) and are briefly listed below:

- A statement that the study involves research
- An explanation of the purpose(s) of the research
- The expected duration of participation
- A description of study procedures
- Identification of any procedures that are experimental
- A description of foreseeable risks
- A description of benefits to participants or to science/society
- Disclosure of alternate procedures, if any
- A description of measures to protect confidentiality
- If the study is greater than minimal risk, a statement about whether compensation is available for participants who might be injured as a result of study procedures
- Contact information for whom to contact with questions
- A statement that participation is voluntary

If applicable, the following are also required in the informed consent document:

- A statement that study procedures may involve risks that are unforeseeable

- The circumstances under which the participant may be terminated from the study by the PI
- Any additional cost participants will incur during the study
- The approximate number of participants
- An explanation of random assignment

Additional consent elements were added in January 2019 (when the revised common rule went into effect). They include: A key information summary at the beginning of the consent form for federally funded studies, information about returning research results to participants, commercial profit disclosure, and information about whole genome sequencing of biospecimens.

According to the regulations, key information consists of a concise summary of information of highest importance to participants in their decision about participation. The challenges to framing this portion of the consent are the lack of a definition of the term "concise," and scant information from participants themselves about what they consider most relevant to their decision about research involvement. The webinar presented results from a focus group of participants conducted at an academic medical center. The main take aways from this small group were that participants want the key information summary to state:

- How long it takes to complete any required pre-screening to find out if they qualify for the study
- Whether the study involves pain or lifestyle changes
- Whether it will cost them anything to participate in the study
- Whether they will be randomly assigned to study conditions
- The rationale for the study and how the study adds to what is already known. *This is particularly important if the participants do not stand to personally benefit from participation.*
- Information with figures rather than dense text.

The good news is that at UTK, the key information section is ONLY required if your project is federally sponsored.

In regard to returning research results, your consent form must include a statement addressing whether clinically relevant research results, including individual results, will be disclosed to participants, and if so, under what conditions. This scenario raises several related issues on which the regulations are silent, among them the definition of "clinically relevant," direction about who should return research results, and how to handle the results from social/behavioral/educational measures that could also have importance to participants and their caregivers. Many investigations have documented that participants are interested and desire that research results be shared with them both for possible health benefits as well as to evoke a sense of reciprocity for their participation. The ethical principles of respect for persons and beneficence also appear to be related to the decision to share results with participants. For more guidance about returning individual research results to participants, see the National Academies report located here: participants research results.

If the research includes biospecimens, an additional statement must be included describing whether the participant's biospecimens may be used for commercial profit and whether the participant will or will not share in the profit. This statement must be included *even if the biospecimens are deidentified*.

Finally, for research involving biospecimens, the consent form must disclose whether the research will or might include whole genome sequencing.

I know this seems like a lot! Remember the HRPP and IRB are here to help! We will take up the topics of parental consent and the assent of minors in a future column. In the meantime, you can find consent guidance along with various consent templates at https://irb.utk.edu/forms/

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

Here's to a successful consent process in your research!
Lora Humphrey Beebe, PhD, PMHNP-BC, FAAN
UT IRB Chair

HRPP Workshops for Fall 2021

The HRPP & IRB are hosting several workshops in the next couple months starting with New Faculty Orientation next week. If you are new faculty at UT and will be conducting human subjects research, we encourage you to join one of the workshops. Please note that the workshops on the 7th and 8th will be the same, so you will only need to attend one workshop and not both.

We will also be presenting our workshop on Diversity and Inclusion in Human Subjects Research again in November. To register please follow the links below.

- **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.
- **Diversity and Inclusion in Human Subjects Research**
  11/9/21, 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	
		August	September
New Studies	Exempt	6.4	6.3
	Expedited	9.9	8.4
Amendments	Exempt	4.0	3.6
	Expedited	8.3	4.9

IRB Submissions

Submission Type	Submissions	
	August	September
Pre-Review Changes	35	47
New Studies	85	90
Amendments	76	95
Change in Personnel	19	23
Continuing Reviews	26	35
Reportable New Information	8	11
Study Closure	2	10
Miscellaneous	3	2
Request to Resume in-Person Research	0	0
TOTAL	**254**	**313**

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
Blount Hall, Room 408
1534 White Avenue
Knoxville, TN 7697
Phone: 865-974-7697
Fax: 865-974-7400
Email: utkirb@utk.edu
Website: irb.utk.edu