HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

June 2022

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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 continuing our Virtual Office Hours throughout the summer. If you need assistance, you can visit then, visit us in person in the office (Blount Hall Room 408), or contact us by email or 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.

SOPs Available

As part of our preparations for accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The HRPP Office has developed Standard Operating Procedures. These SOPs are unchanged from our current procedures, but we are happy to have all of our SOPs available in one place for your review. They can be found on our website: https://irb.utk.edu/research-guidelines/.

Pearls from PRIM&R

Hello UTK research community! This month I thought it might be interesting to give everyone the opportunity for a brief self-assessment of our knowledge about human research protections and IRB related matters, including the Revised Common Rule and the IRB review criteria. Take a few moments to answer the following five questions (answers are located at the end of this newsletter) and let's see how we all do!

1. The criteria in the Common Rule that the IRB refers to in granting research approval are known as the 111 criteria. Which of the following is NOT one of the 111 criteria?

A. Risks to subjects are minimized
B. Selection of subjects is equitable
C. Informed consent is always documented
D. Safeguards for vulnerable subjects are included

2. The Revised Common Rule went into effect recently. It applies to expedited and full board studies that were *initially* approved AFTER which of the following dates?

A. January 21, 2017
B. January 21, 2019
C. January 21, 2019
D. January 21, 2020

3. A waiver of informed consent is NOT the same as a waiver of documentation of consent.

A. True
B. False

4. The 111 criteria are the only considerations researchers must meet to obtain research approval.

A. True
B. False

5. The ethical principles of the Belmont Report include all the following EXCEPT:

A. Respect for persons
B. Equity
C. Beneficence
D. Justice

If you have questions about the answers, or suggestions for topics you'd like to see addressed in future IRB chair columns, feel free to reach out any time at utkirb@utk.edu and/or (865) 974-7697.

Hope your summer is off to a great start!

Lora Beebe, PhD, PMHNP-BC, FAAN

UTK IRB Chair

AAHRPP Accreditation Site Visit

The site visit for the HRPP accreditation by AAHRPP will be occurring virtually on July 19-21, 2022. Those individuals who have been selected to meet with the site visitors have been contacted already and we are in the process of finalizing the site visit agenda. We are excited to be moving towards this next step in the accreditation process, and we thank our researchers for their support as we prepare for accreditation.

Workshops

The HRPP is taking a break from hosting workshops for the summer, but we have lots of workshops already planned for the fall semester. Keep an eye on our workshop registration page for the registration to open, and for other upcoming workshops.

- August 4th - Department Review Chair and Department Head Training
- August 8th - Department Review Chair and Department Head Training
- August 10th - New Faculty Workshop
- September 9th - Exempt Category 1 Workshop
- September 16th - New Graduate Student Workshop

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		April	May
New Studies	Exempt	6.1	5.8
	Expedited	9.2	7.8
Amendments	Exempt	3.8	3.8
	Expedited	10.9	4.8

IRB Submissions

Submission Type	Submissions	
	April	May
Pre-Review Changes	67	40
New Studies	77	95
Amendments	68	46
Change in Personnel	19	11
Continuing Reviews	34	30
Reportable New Information	5	7
Study Closure	11	6
Miscellaneous	0	9
TOTAL	**281**	**244**

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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Self-Assessment Answers:

1: C. Informed consent need not ALWAYS be documented. Federal regulations (45 CFR 46.116f) specify when informed consent may be waived or altered.

2: C. The revised common rule went into effect for initial submissions approved after January 21, 2019.

3: A. True. A waiver of *documentation of consent* means the researcher need not obtain the subject's signature (commonly done if the only record linking subjects to the research is the consent form, and the principal risk is a confidentiality breach). A *waiver of informed consent* means that informed consent is not required to be collected for the research (commonly done when a researcher is conducting secondary analysis of data and does not record identifying information about participants).

4: B. False. Researchers must also adhere to the ethical principles set forth in the Belmont Report and other research guidelines as applicable. For example, your research may fall under Health Insurance Portability and Accountability Act (HIPAA) or Family Educational Rights and Privacy Act (FERPA) federal regulations, or it may be subject to Food and Drug Administration guidelines. Research that is being conducted internationally may also be subject to international research guidelines or regulations such as General Data Protection Regulation (GDPR).

5: B. Equity is not one of the three principles in the Belmont report, however it is still an important consideration when conducting human subjects research. In the Belmont Report, equity is addressed under the principles of respect for persons and justice.