HUMAN RESEARCH PROTECTION PROGRAM | NEWSLETTER

May 2022

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Human Research Protections Program

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Office Hours
M-F: 8 a.m.– 5 p.m.

Announcements

HRPP office staff will continue our Virtual Office Hours throughout the summer. The schedule is listed below:

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 p.m.–4:30 p.m.—Jennifer Engle (Zoom link here)

Thursdays from 9:00 a.m.–11:00 a.m. p.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.

Pearls from PRIM&R

Hello UT Knoxville researchers! This month I'm providing information on situations that require submission of an iMedRIS form called "Reportable New Information." At UTK, "Reportable New Information" is generally one of three types: noncompliance, participant complaints, or other. This month we are focusing on noncompliance.

Noncompliance is categorized in one of four ways: general, serious, continuing, or both serious and continuing.

General noncompliance is defined as any deviation from UTK IRB policies and procedures, federal regulations, or state law, or failure to follow IRB requirements and/or determinations. Happily, the great majority of instances here at UTK fall into the category of general noncompliance.

Serious Noncompliance is defined as noncompliance that, in the judgment of the convened IRB, increases risks to subjects, adversely affects the rights, welfare, or safety of subjects, or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious noncompliance.

Continuing Noncompliance is defined as a pattern of noncompliance that, in the judgment of the convened IRB, suggests a likelihood that instances of noncompliance will continue unless the IRB or institution intervenes.

Reporting. Investigators and study staff must report possible noncompliance to the IRB as soon as possible, but at least within 7 working days of discovery.

Additionally, anyone may report concerns of possible noncompliance either verbally or in writing. The identity of the person who reports possible noncompliance can be kept confidential. If you are uncertain whether there is cause to report noncompliance, feel free to contact the HRPP Director, IRB Chair, or Institutional Official (Sarah Pruett) directly.

Review Procedures. Reportable New Information forms are assigned to the IRB Chair or to a designated reviewer. If the report came from a source other than an iMedRIS form (verbal or email for example), the assigned reviewer will work with the investigator to create and upload a report into iMedRIS. If information suggests that subjects may be at risk without immediate intervention or that research misconduct may have occurred, the HRPP Director, Institutional Official (IO) and/or Research Integrity Officer will be notified.

Determinations. The IRB Chair or designated reviewer makes an initial determination as to whether the event represents noncompliance, and, if so, whether the noncompliance may be serious or continuing. If needed, additional information may be requested to help with this determination. If the reviewer determines the event is *not noncompliance, or is general noncompliance*, they will review corrective and preventative action plans and determine if the plans are acceptable or need modification. The reviewer may refer the matter to the convened IRB for review if necessary. The results of the review are recorded in iMedRIS and communicated to the investigator.

If the reviewer determines that the event or issue may be *serious noncompliance, continuing noncompliance or both serious and continuing noncompliance*, the report will *always* be referred for review by the convened IRB. The convened IRB determines whether the event is serious noncompliance, continuing noncompliance, or both serious and continuing noncompliance. The IRB reviews corrective and preventative action plans and determines if the plan is acceptable or if modifications to the plan or additional actions are necessary to ensure the protection of human subjects. If needed, the IRB may request additional information. The results of the review will be recorded in IRB minutes and communicated to the investigator.

When the IRB determines that an event is *serious noncompliance, continuing noncompliance, or both serious and continuing noncompliance*, the IRB may take any of the following actions:

1. Require modifications to the protocol or research plan
2. Revise the continuing review timetable such that continuing review occurs more often than once a year
3. Require modifications to the consent process or consent document
4. Require the investigator to provide additional information to current or past participants
5. Require the investigator to provide past participants an opportunity to reevaluate their participation
6. Require additional training of the investigator and/or study staff
7. Require that current subjects be re-consented
8. Monitor the research and/or the consent process

9. Report or refer the issue to additional parties as appropriate (e.g., the IO, Compliance, Risk Management, Privacy Officer)
10. Suspend or terminate IRB approval
11. Take other actions as appropriate given the specific circumstances

In cases of serious noncompliance, continuing noncompliance, or both serious and continuing noncompliance, HRPP staff will report to regulatory agencies, sponsors, and organizational officials as appropriate.

If the IRB suspends or terminates research, the letter communicating the decision describe the basis for the action and offer the investigator the opportunity to respond in person or in writing. If an investigator disagrees with an IRB requirement or decision or believes that providing the IRB with additional information may result in a different outcome, they may request that the IRB reconsider its decision by submitting a memo and other supportive materials via iMedRIS. The investigator may be invited to attend the IRB meeting to discuss the request and provide information but must leave the meeting during board deliberations and voting.

I hope this information about noncompliance is helpful to you, your coinvestigators, and your students. We are fortunate at UTK that our research community has high ethical standards, and that most noncompliance is minor in nature (for instance, enrolling a few more participants than the project was approved for, or sometimes using an outdated version of a consent form).We are grateful to each of you for your time and attention in ensuring that your research meets the highest standards. If you have questions about research noncompliance, related matters or want to discuss a project specific issue, feel free to reach out any time to utkirb@utk.edu and/or (865) 974-7697.

May all your research endeavors be successful ones! Until next time!

Lora Beebe, PhD, PMHNP-BC, FAAN

UTK IRB Chair

AAHRPP Accreditation Update

As some of you who attended our Town Hall meetings know, the Human Research Protection Program is currently undergoing accreditation from the Association for Accreditation of Human Research Protection Programs (AAHRPP). Becoming AAHRPP accredited will provide a public-facing assurance of quality and commitment to ethical research for institutions that may wish to collaborate with our researchers, as well as to potential research sponsors and research participants. In addition, the continuous quality improvement practices that will be implemented as part of accreditation will improve the overall quality of the HRPP as we work to increase consistency, quality, and efficiency in reviews.

The process of preparing and applying for accreditation began in 2019 as faculty and staff members of the Accreditation Task Force assisted with a thorough self-assessment of the HRPP. Our initial and secondary applications for accreditation have been submitted and reviewed, and the next step will be a site visit, which will be occurring virtually from July 19-21. The site visitors will meet with compliance officers from the HRPP as well as from other units, as well as IRB members and university researchers. You will be hearing more from us soon as we continue preparation for the site visit.

When a Principal Investigator Leaves UTK

As we are nearing the end of the semester, we wanted to offer some reminders on what to do with your research after you leave the University. Please see the information below for guidance and contact us if you have any questions.

Often principal investigators (PIs) leave an institution without effectively managing their research studies. PIs are responsible for managing their studies prior to departure. Likewise, faculty advisors and department administrators have a responsibility to ensure these duties are carried out before the PI leaves. Below are the procedures required for studies involving human research participants.

Study Completed:

If all study activities have been completed and no research data/specimens will be transferred to a new institution, submit a Form 7 Study Closure Form in iMedRIS. All consent documents must be deposited with the departing PI's faculty advisor or department head.

Study Active – PI No Longer Involved in Study:

If the study will remain active at UT and the departing PI will have no further involvement with the study, submit a Form 2 Change Request in iMedRIS to assign a qualified individual as the new PI. Revise any documents (consent documents, recruitment materials, etc.) to list the new PI's name and contact information. Confirm in the Form 2 that all study records and data have been deposited with the new PI.

Study Active – PI Continues Involvement in Study:

If the study will remain active at UT and the departing PI will continue as part of the research team, submit a Form 2 Change Request in iMedRIS to:

- Assign a qualified individual as the new PI
- Explain the departing PI's new role, including a description of any continued access to data
- Confirm that all study records and data have been deposited with the new PI or explain alternate arrangements
- List the departing PI's new contact information and institutional affiliation
- Submit a copy of the departing PI's IRB approval from their new institution
- Revise any documents, such as consent documents, recruitment materials, etc. to list the new PI's name and contact information.

Transferring Research to Another Institution:

Any departing investigator wanting to transfer research records, data and/or specimens to a new institution must do the following:

- Contact the IRB to determine next steps. The IRB is obligated to ensure protections promised to research participants are maintained.

- Contact Jennifer Engle (jengle@utk.edu), HRPP Director to ensure all university requirements are met.
- Other Issues: Should a departing investigator encounter an issue not covered in the above procedures, please contact the IRB.

Performance Metrics

Review Turnaround Times in Calendar Days

Submission Type	Review Type	Average	
		March	April
New Studies	Exempt	6.2	6.1
	Expedited	7.9	9.2
Amendments	Exempt	4.0	3.8
	Expedited	6.6	10.9

IRB Submissions:

Submission Type	Submissions	
	March	April
Pre-Review Changes	51	67
New Studies	89	77
Amendments	94	68
Change in Personnel	25	19
Continuing Reviews	30	34
Reportable New Information	5	5
Study Closure	2	11
Miscellaneous	1	0
TOTAL	**297**	**281**

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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