

- [Announcements](#)
 - [Investigator Responsibilities](#)
 - [Training & Education Opportunities](#)
 - [News](#)
 - [IRB Metrics](#)
 - [Contact Us](#)
-

Announcements

Exciting News...and a Plea for Patience



The HRPP is being restructured!

We are pleased to announce that the Human Research Protection Program reorganizing our office staff structure. Our original model included two IRB Compliance Officers (review of IRB submissions and other compliance duties) and two IRB Compliance Specialists (processing of IRB submissions). **Our new structure increases the number of positions dedicated to IRB reviews from two to three.**

These positions include the HRPP Director and two Assistant IRB Compliance Officers. Kristine Hershberger, CIP, was named Director HRPP effective July 1st and a search begun to fill the remaining two positions.

Those position have now been filled. This month our new staff members begin intensive, hands-on training. **Be prepared to experience delays** in office response times. IRB members are still assisting with IRB application reviews, so we hope those turnaround times will not be significantly impacted. However other business items may be delayed.

Due to staff structure changes and two of those in training, we now have only one staff member processing applications on a regular basis. Although we are working to automate and streamline our office operations, we are still adapting to our new organizational structure and processes. Although these next few months will be challenging, our staff's training is a necessary investment and critical to our success in meeting the research community's needs. After this transition, we expect turnaround times to return to previous levels and then to start reaping the benefits of increased consistency, better tracking of items and more flexibility in handling workload fluctuations.

Update – Revised Common Rule

Earlier this year we announced that the U.S. Department of Health and Human Services published in the Federal Register revisions to the *Federal Policy for the Protection of Human Subjects*, also known as the Common Rule. We also reported that the revised Common Rule was being reviewed by the current administration. To date, the outcome of that review is pending and the status of the revised Common Rule remains uncertain.

The UTK HRPP and IRB are working to interpret the new regulations, update business processes, applications, templates and guidance materials in preparation for the revised Common Rule's January 19, 2018 effective date. In the upcoming months we will announce any new information about the revised regulations received from the current administration and provide updates on our progress in preparing for their implementation.

Related reading -

- [What do revised U.S. rules mean for human research?](#) (Science, 8/18/2017)
- [Joint Letter Requesting an Extension to the Compliance Date for the Common Rule](#) (AAMC, AAU, APLU and COGR, 6/21/2017)

Update – NIH Single IRB (sIRB) Policy

The effective date for the [NIH single IRB](#) (sIRB) policy has been extended to January 25, 2018 from its previous effective date of September 25th. New grant applications to NIH submitted on or after this date must include a plan for use of a sIRB including identification of the sIRB, relying site agreement to utilize the sIRB, and a plan for communication between the sIRB and the relying sites.

The HRPP is assessing the impact of this policy and working to create guidance and develop procedures and processes for local implementation of sIRB review. Look for details on these upcoming changes in our October 2017 issue. In the meantime, visit the resources listed below to learn more about sIRB requirements

Related resources -

- [FAQs](#) about the Implementation of the sIRB policy
- [FAQs](#) on Costs
- [NIH Guide Notice](#) on scenarios illustrating the use of direct and indirect costs for single IRB review
- Other information as it becomes available, on the [NIH sIRB website](#)

Investigator Responsibilities

UT investigators, including all research personnel, engaged in the conduct of human subjects research are responsible for protecting the rights and welfare of those research participants and are expected to follow all federal, state and university requirements related to their research.

All Investigators

- Design and conduct research that protects the rights and welfare of human research participants, including equitable selection of research participants, minimization of risks to participants, and ensures that risks to participants are reasonable in relation to anticipated benefits.
- Complete required training.
- Follow all applicable IRB requirements, federal regulations and guidelines, state laws, institutional policies and guidelines pertaining to the research.

- File and update Outside Interests Disclosures reporting relevant potential conflicts of interest, including financial conflicts of interest, in accordance with UT Policy FI0125 – Conflicts of Interests.
- Ensure that all human subjects research receives IRB review and approval prior to initiating any human subjects research activities, including screening and/or recruitment.
- Ensure that the research is conducted in accordance with the IRB-approved application.
- Obtain and document participant prospective informed consent in accordance with the IRB-approved application, unless waived by the IRB.
- Obtain IRB review and approval *before* changes are made to the previously approved application and study materials.
- Ensure that research studies receive continuing IRB review (i.e., renewal) and approval prior to the expiration date stated on the IRB Approval Letter and the iMedRIS study record.
- Promptly respond to all requests for information or materials solicited by the IRB, including the timely submission of the research study for IRB continuing review (i.e., renewal).
- Promptly report to the IRB all actions or processes that deviate from the IRB-approved application.
- Respond promptly to participant complaints and/or concerns or requests for information and report to the IRB any complaints and concerns regarding the conduct of the research.
- Obtain and document participant written permission (i.e., authorization) for use of Protected Health Information created or used in the research, unless waived by the IRB.
- Assure that the Protected Health Information (PHI) created or used in the research study, if any, is the minimum necessary to meet the research objectives, and that PHI is not reused or disclosed to any parties other than those described in the IRB-approved application, except as required by law.
- Design and carry out the research with adequate data and safety monitoring, when appropriate.
- Ensure that there are adequate resources available to safely conduct the research and to ensure the safety of research participants.
- Comply with all IRB determinations, conditions and requirements.
- Submit a closure report to the IRB after completion of the research.
- Obtain approvals from other institutional entities (Radiation Safety Committee, Export Control, Institutional Biosafety Committee, etc.), when applicable.

Principal Investigators

The Principal Investigator (PI) named on the IRB application assumes overall responsibility for the conduct of the research, and as such, assumes responsibilities in addition to those listed above. While the PI may delegate responsibilities to other investigators and research personnel, the PI remains ultimately responsible for all aspects of the research.

General Responsibilities – Principal Investigators

- Ensures that they have sufficient time to properly conduct and/or supervise proposed research and study personnel, and that adequate resources (qualified personnel, facilities, medical/psychosocial services, etc.) are available to safely carry out the approved research.
- Reports to the IRB any changes in availability that impacts the conduct of, or supervision of, ongoing research such as going on sabbatical, taking extended leave or leaving UT. The PI is responsible for either amending the study appointing another PI or closing the research as appropriate.
- Registers the research on [ClinicalTrials.gov](https://clinicaltrials.gov), if applicable.
 - [NIH Policy and definition of a Clinical Trial](#)
 - [DHHS Final Rule \(FDA\) and definition of Applicable Clinical Trial](#)
 - [International Committee of Medical Journal Editors \(ICMJE\) Policy and definition of Clinical Trial](#)

Recordkeeping Responsibilities – Principal Investigators

- Maintains records of all IRB-approved documents and correspondence which must include, at a minimum, the IRB application, screening, recruitment and consent documents, data collection materials and instruments, documentation of participant eligibility and participation and a copy of all signed consent documents (unless waived by the IRB).
- Retains all study records for a minimum of three years after closure of the study with the IRB. For studies involving PHI, a minimum of six years is required. If there are sponsor requirements (for funded studies) retains the records for the longest applicable retention period.
- Makes all research records accessible for review by authorized representatives of the IRB and/or the department or agency supporting or conducting the research to ensure proposer performance of the study and compliance with federal regulations and institutional policies.
- Maintains confidentiality of stored records in accordance with the IRB-approved application.
- Retains records for studies involving FDA regulated test articles (devices, drugs, biologics) in accordance with applicable FDA regulations.

Supervisory Responsibilities – Principal Investigators

- Delegates responsibilities to co-investigators and research personnel that are commensurate with their training and qualifications.
- Ensures all co-investigators and research personnel file and update Outside Interests Disclosures reporting relevant potential conflicts of interest, including financial conflicts of interest, related to the research in accordance with UT Policy FI0125 – Conflicts of Interests.
- Ensures that all co-investigators and research personnel have completed the mandatory Human Subjects Protections training.
- Ensures all co-investigators and research personnel are fully informed and trained regarding,

- their obligations for following the IRB-approved study and applicable regulations, laws and policies;
 - changes made to the research while the study is ongoing including changes in status (e.g., open to enrollment, closed to enrollment, suspended, data analysis only, closed);
 - conduct of the informed consent process, including obtaining and documenting written informed consent in accordance with the IRB-approved application;
 - conduct of the study procedures and data collection in accordance with the IRB-approved application;
 - potential risks and adverse events associated with study participation and the steps to be taken to minimize potential risks;
 - reporting requirements of unexpected problems or adverse events, deviations, incidents, complaints and protocol violations to the IRB; and
 - record-keeping requirements.
 - Oversees the conduct of the research, including recruitment, informed consent and study procedures, data collection including its storage and security, and accurate analysis of data.
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Training & Education Opportunities

IRB 101

This workshop provides an overview of IRB requirements and procedures. Learn if your project requires IRB review, how to submit an application and obtain IRB approval. All are welcome. Details are posted on [ORE's Training and Workshops website](#).

News

Changes Ahead for NIH Funded Human Subjects Research

The National Institutes of Health (NIH) are rolling out several policy changes related to NIH-funded research involving human subjects. These changes began with the implementation of NIH's [revised definition of clinical trial](#) that went into effect earlier this year and includes research on both biomedical and behavioral health outcomes. Other policy changes, including the required use of an updated application forms package (FORMS-E), start with application due dates on and after January 25, 2018. NIH Deputy Director for Extramural Research Michael Lauer further clarified these upcoming changes on August 11th in both an [email to the research community](#) and in a [blog post](#) on the NIH website. Listed below are additional readings and resources on this topic including an article by the Association for Psychological Science about these changes and their impact on behavioral research and a video tour of the new NIH form.

Related reading and resources –

- [Major Changes Ahead for Funding of Human Subjects Research at NIH](#) (Association for Psychological Science, 8/15/2017)

- *NIH Issues Best Practices for Clinical Trials in Social and Behavioral Sciences* (Association for Psychological Science, 7/20/2017)
- *New Human Subjects and Clinical Trial Information Form* (7/26/2017)
- *PHS Human Subjects and Clinical Trials Information Form Walk-through* (NIH, 8/10/2017)
- *New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018* (4/27/2017)
- *Director's Voice: New NIH Clinical Trials Policies: Implications for Behavioral and Social Science Researchers* (NIH, 10/18/2016)
- *Good Clinical Practice for Social and Behavioral Research – eLearning Course* (NIH)

NIMH Releases Updated Guidance on Research with Participants at Elevated Risk for Suicide

The National Institute of Mental Health released updated [guidance](#) for researchers who conduct research involving participants who are at elevated risk for suicide. The guidance includes a discussion of safety and ethical questions as well as considerations for research design, data elements, informed consent, monitoring, reporting, withdrawal, and responding to suicidal crises and clinical worsening.

FDA Releases New Guidance on Waivers

The Food and Drug Administration has published the guidance document, *IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects*. This marks the first time that the FDA has permitted waivers or alterations to informed consent requirements in research that has not involved life-threatening situations or emergency research.

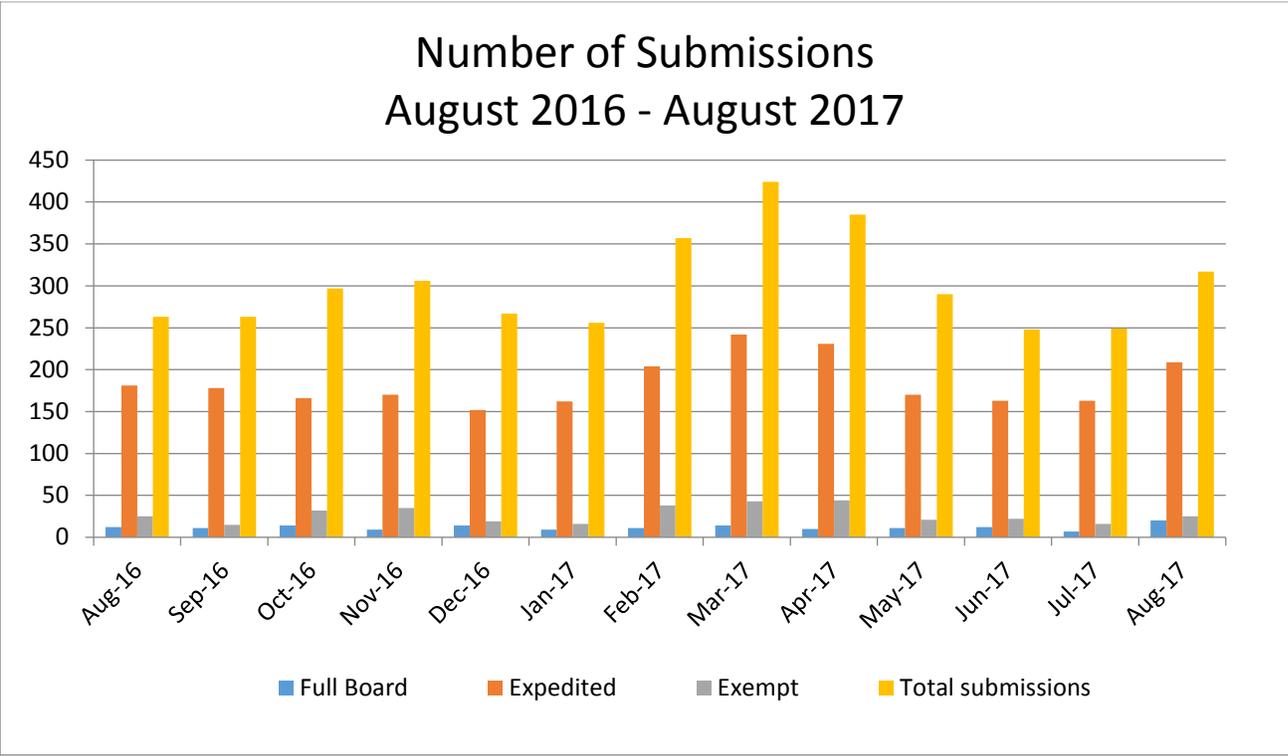
FDA Releases Draft Guidance on Electronic Records and Signatures

The Food and Drug Administration has issued draft guidance on *Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers*. This long-awaited guidance, albeit “draft”, provides 28 questions and answers detailing how clinical investigators, IRBs and others can ensure electronic systems meet the agency’s requirements. The FDA’s first and only guidance on this topic, *Part 11, Electronic Records; Electronic Signatures – Scope and Application*, was issued in 2003,

IRB Metrics

New Submissions

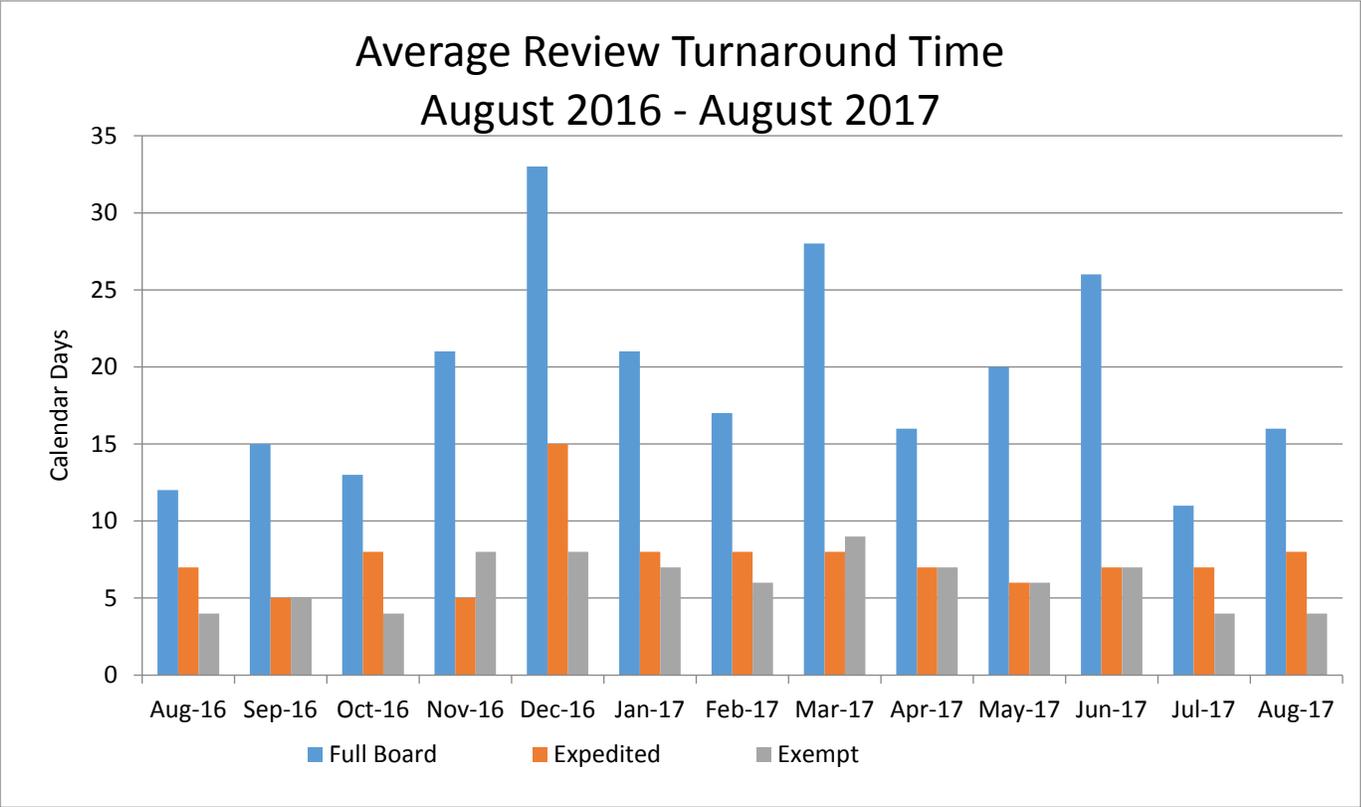
The chart below shows the number of new submissions received by the IRB during the month of August 2017 compared to the number submissions received during the preceding 12 months.



A total of 317 submissions were received during August 2017. During August 2016, a total of 292 submissions were received.

Turnaround Time Averages

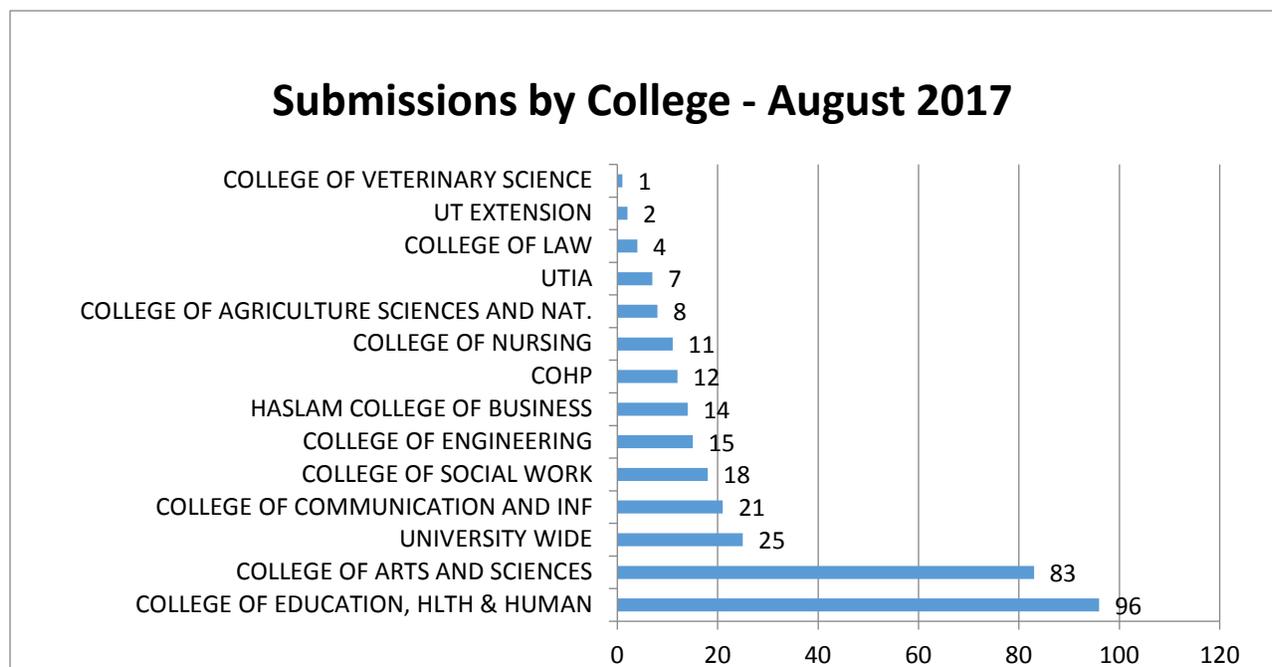
The chart below show the average review time for all submissions on a monthly basis during the past year.



The average turnaround time of reviews for all submissions during August 2017 was 7 days. This is down from the average of 9 days in 2016.

Submissions by College

The chart below show the number of submissions from each college.



Contact Information

Contact us with suggestions for future issues of our newsletter.

View past issues archived on our website.