HRPP Newsletter

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This month's issue includes information about upcoming changes to federal regulations. Additionally we report continuing reductions to review turnaround times.

– HRPP Staff

New to UT? How to Get Started with IRB

Whether you have ongoing research studies from your previous institution or are just getting started in human subjects research, this article will provide the information you need to hit the ground running. Of course this article does not cover all the possible research scenarios, but we hope it will help to start the process. Please contact our office with any questions (865-974-7697 or utkirb@utk.edu). If you think a collaborative agreement may be appropriate for your ongoing research, contact Kristine Hershberger (865-974-7687 or kh@utk.edu).

1. <u>Training</u>

The UT IRB requires that all individuals involved in human subjects research activities must complete the CITI Human Research Protections Training Course. Please consult our guidance on registration and, if you have taken this CITI training at your previous institution, how to transfer CITI credits to UT. You can find additional information on the IRB Training page.

2. <u>iMedRIS and Submission Process</u>

UT's IRB uses iMedRIS, electronic application system, for its submission and review process. Below you will find some steps on how to get started with the process.

- Go to iMedRIS and log in using your NetID. Once you log in, it can take up to 24 hours for the system to authenticate your user information and display the Study Assistant menu/screen from which you will create your application.

- While you are waiting to begin your application, click on the Help button which is at the top right-hand corner of the iMedRIS home page. The Help menu window will open. Under UT Knoxville iMedRIS Instructions you will find:

    a. *Form 1 – IRB Application Instructions (UT)* which provides question-by-question guidance for completing your application.

b. *Routing and Workflow Tracking Guide (UT)* and *How to Route for Sign-off – video (UT)* explain how to find, select and assign the individuals within your department who must review and sign-off on your application before the IRB can review it.

c. *PI Response Form Instructions (UT)* instructs you how to respond to comments and revise study materials if the IRB requests any changes or additional information.

3. <u>Resources</u>

We have a number of conveniently accessible resources to assist you.

- **Path to IRB Approval video** – You may want to view our Path to IRB Approval video. Recorded at January's Responsible Conduct of Research (RCR) Lunch Series, this presentation targets how to write an application for IRB approval. This link can also be found in the iMedRIS Help menu.

- **Develop Your IRB Application** – The February 2016 issue of our newsletter contains two articles to help researchers expedite the review of their IRB application, Top 10 Obstacles to IRB Approval and How You Can Speed Up Your Study's IRB Review.

- **Develop Consent Documents** – The article Writing Readable Informed Consent Forms featured in the January 2016 issue of our newsletter provides tips on how to avoid common problems with consent documents that can delay obtaining IRB approval.

- **Tips** – Our HRPP newsletters contain tips and articles on timely topics that can assist you as you navigate the IRB review process. To view past issues of our newsletter, check out our Newsletter archives on our website.

4. <u>New Investigators with Ongoing Research</u>

Different requirements may apply depending on the type of research conducted and the stage of the research, but here are a couple guidelines to get you started.

- If recruitment and/or data collection or analysis is ongoing, an IRB application should be submitted to UT's IRB.

- If the research is a collaborative study with another institution (that serves as the study lead), is closed to recruitment and data collection, and the only ongoing activity is data analysis, please contact Kristine Hershberger (865-974-7687 or kh@utk.edu) to determine if the research is eligible for an agreement deferring IRB review.

Training Opportunities

<u>Workshop for Department Review Chairs (DRCs) and Committees:</u>

Department Review Chairs and committee members, please come for breakfast and stay for a refresher workshop on conducting departmental reviews. The workshop will discuss specifics of and updates to the review process itself, and available resources, as well as technical aspects of conducting reviews in iMedRIS.

Breakfast will be at 8:30, followed by the workshop from 9 a.m. to 11 a.m.

- Friday, August 18, 2017; 8:30 a.m. to 11:00 a.m., A 004 Blount Hall
- Friday, August 25, 2017; 8:30 a.m. to 11:00 a.m., A 004 Blount Hall

While registration is not mandatory, it is appreciated so presenters may have an estimate of how many participants to expect. Walk ins are always welcome. Please contact Colleen Gilrane (irbchair@utk.edu) or the IRB (utkirb@utk.edu) with any questions.

Please also check ORE's Training and Workshops website for future scheduled training sessions.

# IRB Metrics

New Submissions

The chart below shows the number of new submissions received by the IRB during the month of July 2017 compared to the number submissions received during the preceding 12 months. Last month a total of 249 submissions were received compared to a total of 292 received in July 2016.
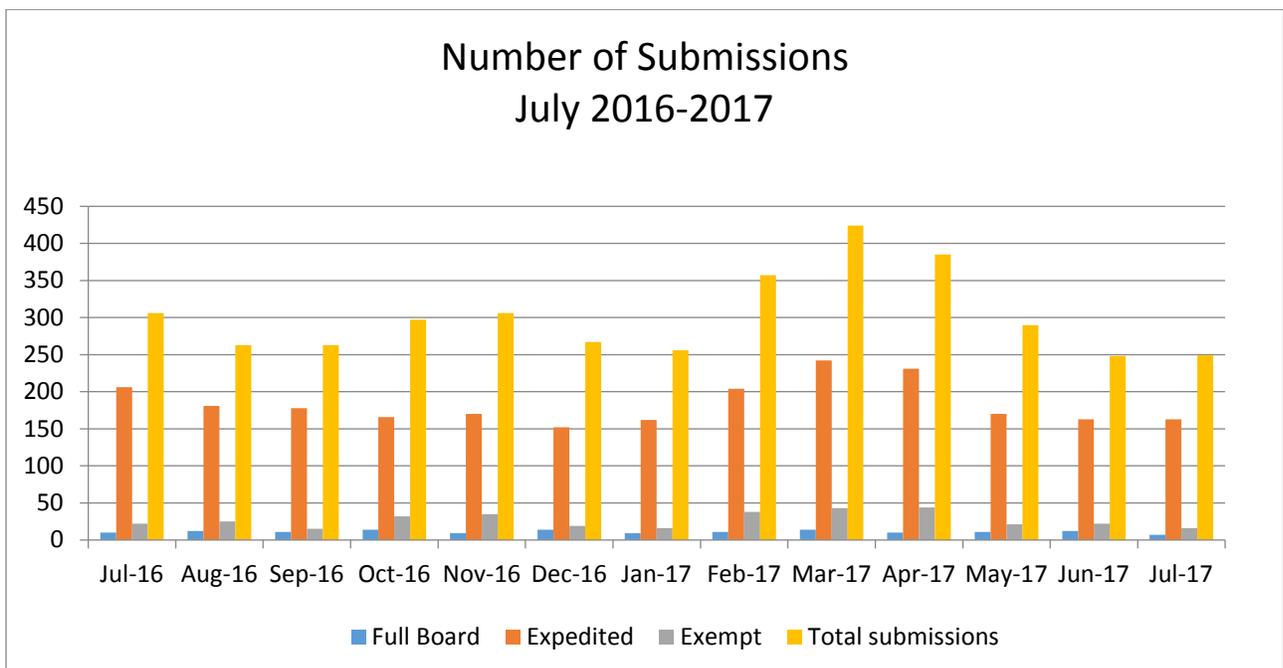
Turnaround Time Averages

The chart below shows the average review time for all submissions on a monthly basis during the past year. The turnaround time for all submissions during the month of July improved from 10 days in 2016 to 6 days in 2017.
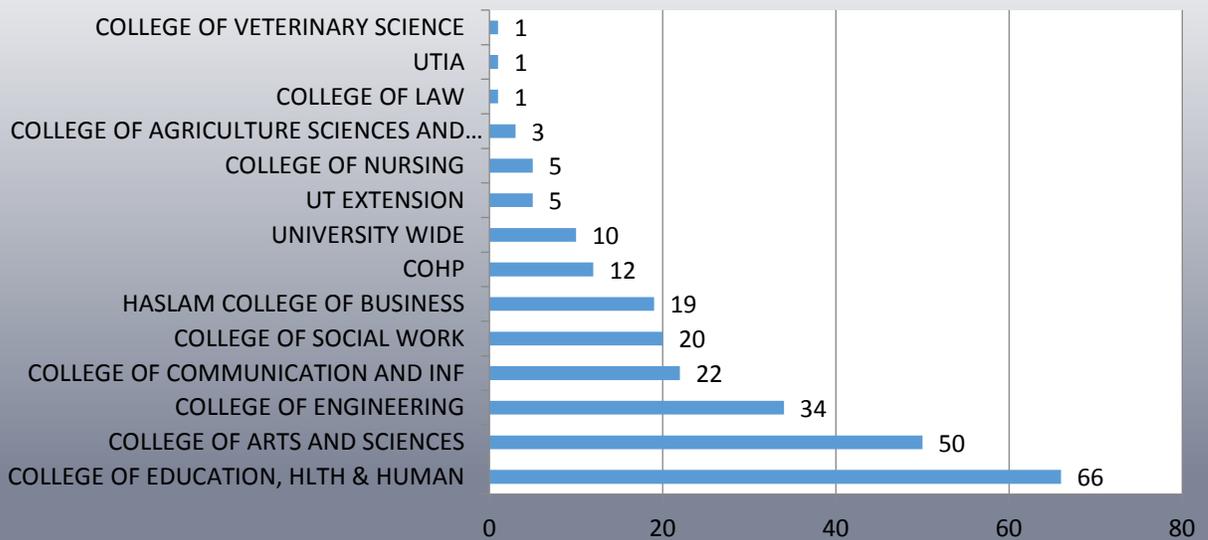
Average Review Turnaround Time July 2016-July 2017
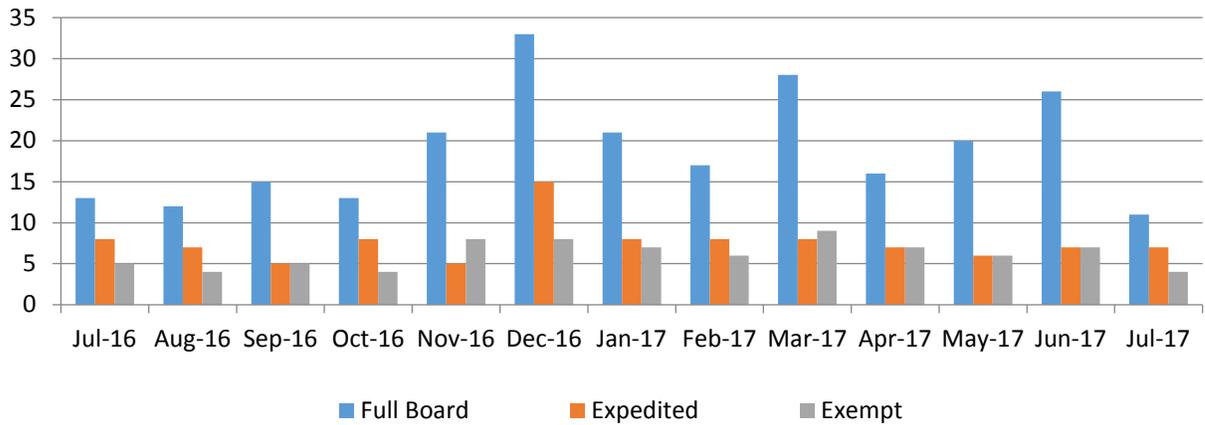
Submissions by College

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

Breakdown by College- July 2017

Contact Information

Newsletter Archives – View past issues of our newsletter archived on our website.

If you have questions or concerns, please do not hesitate to contact any of our team members.