

# HRPP Newsletter

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## August 2016

The IRB and HRPP staff welcome all of you who are new to UTK's research community as well as those of you returning from the summer break. We recommend that those of you who are new to UTK or new to human subjects research read our Tip of the Month. This month's tip provides a primer on UTK's IRB application and review process as well as transferring ongoing studies. We also have several workshops scheduled. We hope your semester is off to a great start.

– *HRPP Staff*

## Announcements

### iMedRIS Updates

Streamlined IRB Application – This past July we posted a revised version of our Initial Review Application (Form 1). This new form eliminates unnecessary questions, streamlines the format and includes more in-application guidance. We hope you will find it an improvement over the previous version.

**Newsletter Archives** – View past issues of our newsletter archived on our [website](#).

## Tip of the Month: Are You New to UTK? How to Get Started.

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.

### ➤ **Training**

The UTK 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 UTK. You can find additional information on the IRB [Training webpage](#).

In addition to CITI training, a number of workshops which cover a range of topics from introducing investigators to UTK's IRB review process and training for our electronic application system, [iMedRIS](#). See the [Training and Outreach Opportunities](#) section of this newsletter.

## ➤ IRB Application and Submission Process

**iMedRIS** – UTK’s IRB uses iMedRIS, electronic application system, for its submission and review process. Below are some steps to get you started.

1. 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.
2. 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:
  - *Form 1 – IRB Application Instructions (UTK)* which provides question-by-question guidance for completing your application.
  - *Routing and Workflow Tracking Guide (UTK)* and *How to Route for Sign-off - video (UTK)* 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.
  - *PI Response Form Instructions (UTK)* instructs you how to respond to comments and revise study materials if the IRB requests any changes or additional information.

**Resources for Developing Your IRB Application and Study Materials** – We have a number of conveniently accessible resources to assist you.

1. **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.
2. **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*.
3. **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.
4. **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](#).

## ➤ New Investigators with Ongoing Research

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 UTK’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](mailto:kh@utk.edu)) to determine if the research is eligible for an agreement deferring IRB review.

The above guidance does not cover all the possible ongoing research scenarios, but we hope it will help to start the process. Please contact our office (865-974-7697 or [utkirb@utk.edu](mailto:utkirb@utk.edu)) with any questions. Additionally, if you think a collaborative agreement is appropriate for your ongoing research, contact Kristine Hershberger (865-974-7687 or [kh@utk.edu](mailto:kh@utk.edu)).

## iMedRIS Tips:

### ➤ How to Determine the Status of Your IRB Application

The question most frequently asked in our office is “What is the status of my IRB application?” Fortunately, iMedRIS makes answering this question easy, and you don’t even need to contact our office to get the answer. See our guidance [How to Determine Submission Status in iMedRIS](#).

### ➤ How to Respond to Requested Changes from Departmental Reviewers

When a new application (Form 1) is submitted to the IRB, it must first be routed to multiple individuals for review and approval before it even reaches the IRB’s inbox. These individuals include the PI, all Investigators listed under application item 3.2A, Faculty Advisor if the PI is a student, Department Review Chair, and Department Head/Chair. Each of these individuals are expected to review the application package and then, if they have no concerns, signoff their approval allowing the application to continue through the routing process to the IRB.

However, should any of those same individuals deny approval, the application package is returned to the principal investigator with that reviewer’s comments. In response to investigator requests, we created the guidance [How to Respond to Requested Changes from Departmental Reviewers](#). We hope you find this guidance helpful.

## Training and Outreach Opportunities

Several IRB 101 workshops have been scheduled, see available sessions below. These workshops provide an overview of IRB requirements and procedures. Ideal for those who are new to UTK, new to human subjects research or just want a refresher. No registration is necessary.

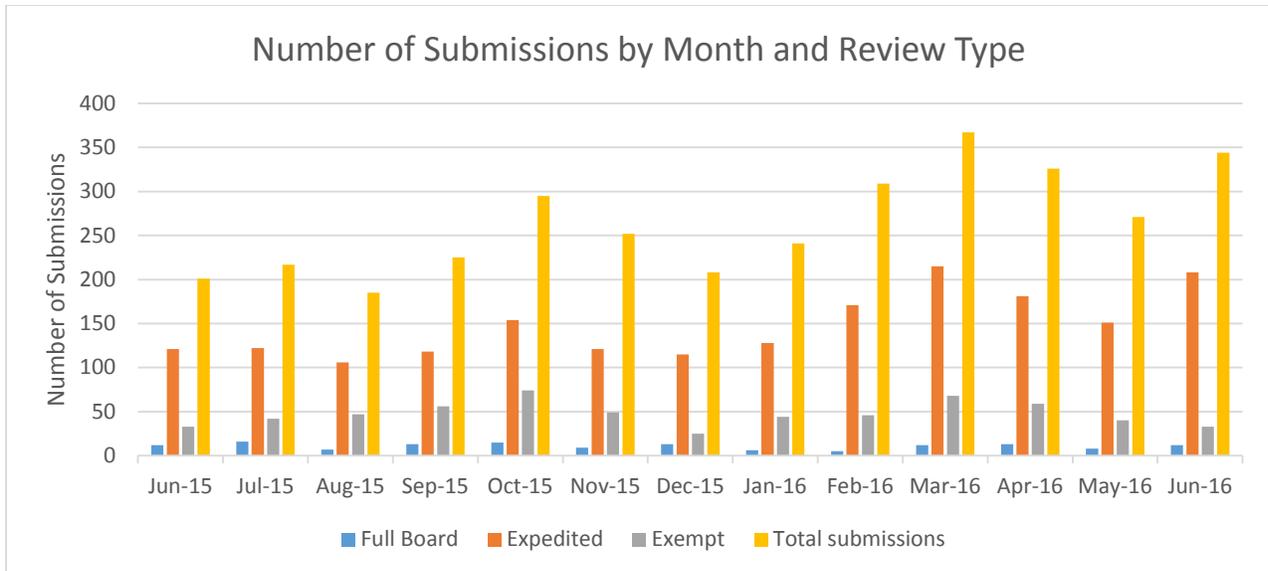
Additional trainings will be scheduled as the semester progresses and will be posted on [ORE’s Training and Workshops website](#) as details become available. If you cannot attend one of the sessions listed below, take advantage of our video, [Path to IRB Approval](#). Recorded at last January’s Responsible Conduct of Research (RCR) Lunch Series. This presentation instructs you on preparing your IRB application and contains several helpful tips.

Date	Time	Location	Room Capacity
Mon Aug 22	1:00 - 3:00 p.m.	321 Communications (COM)	98
Wed Aug 24	10:00 a.m. to 12:00	206 Claxton Education Building (C)	55
Thurs Aug 25	10:00 a.m. to 12:00	A004 Blount Hall (BLNT)	50
Tues Aug 30	1:00 to 3:00 p.m.	132 Taylor Law Center (LAW)	120
Tues Sept 6	10:00 a.m. to 12:00	A004 Blount Hall (BLNT)	50
Wed Sept 7	9:00 to 11:00 a.m.	132 Taylor Law Center (LAW)	120
Mon Sept 12	10:00 a.m. to 12:00	321 Communications (COM)	98
Tues Sept 13	2:00 to 4:00 p.m.	160 Plant Biotechnology Building (PBB)	60
Wed Sept 14	1:00 to 3:00 p.m.	206 Claxton Education Building (C)	55

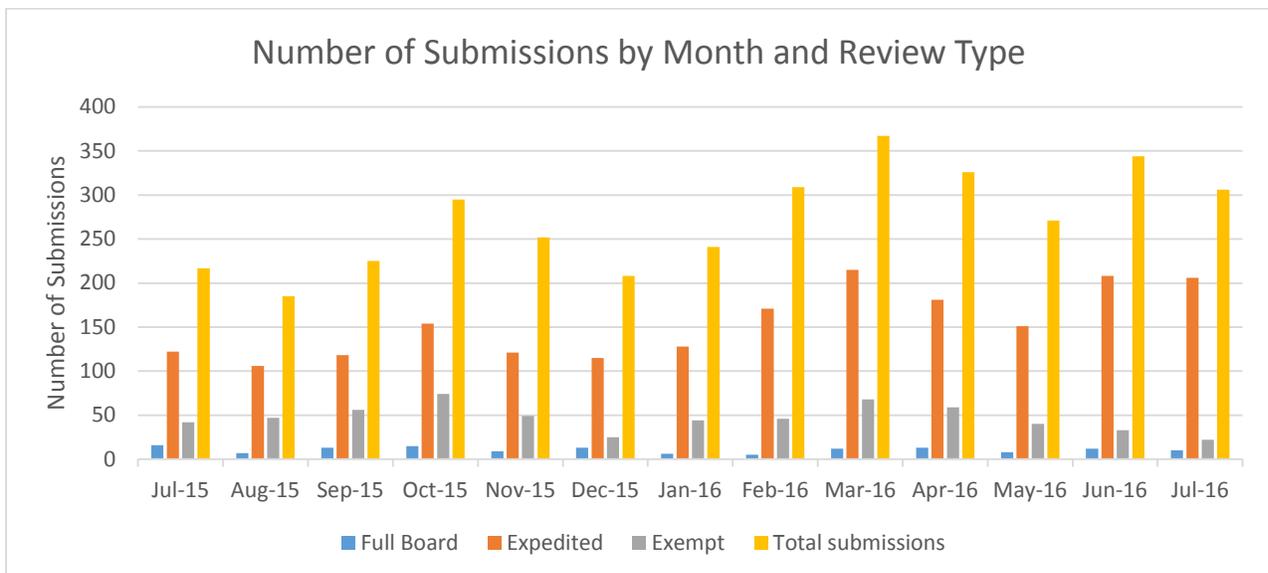
# IRB Metrics Update

## New Submissions by Review Type

The following two charts show the number of new submissions for June and July 2016, respectively, compared to those received during the preceding 12 months.



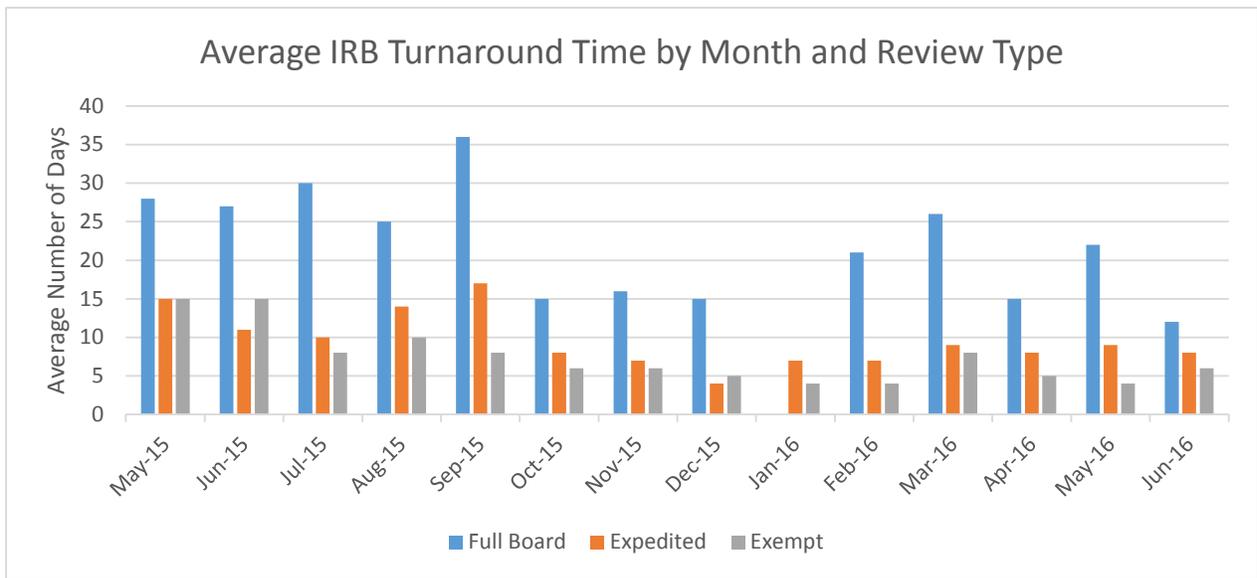
**June 2016** – A total of 344 submissions were received in June 2016 compared to a total of 201 submissions in June 2015.



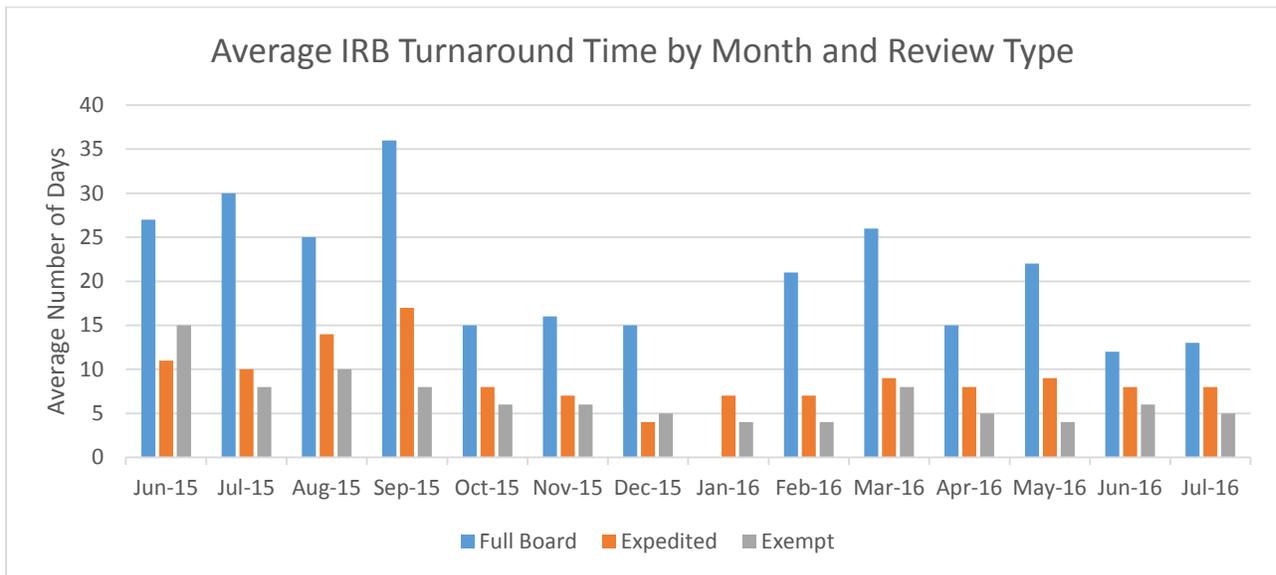
**July 2016** – A total of 306 submissions were received compared to a total of 226 submissions in June 2015.

## Turnaround Time Averages by Review Type

The IRB is always striving to improve our services to the UTK research community. The charts below highlight how the IRB has significantly reduced its average review time across all review types.



**June 2016** – The average review time for all submissions in June improved by more than one week—from 13 days in 2015 to 6 days in 2016 – across all review types.



**July 2016** – The average review turnaround time for all submissions during the month of July improved from 10 days in 2015 to 6 days in 2016, continuing the trend of reduction across all review types.

## Contact Information

If you have questions or concerns, please don't hesitate to contact any of [our team members](#).