

# HRPP Newsletter

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## January 2017

Welcome back and happy New Year! We begin 2017 with updates on new iMedRIS features, tips on avoiding multiple rounds of review, a reminder about faculty advisor responsibilities, plus the most recent IRB submission and review metrics. We look forward to continue bringing you news and tips to support your research endeavors.

As always, please contact us with your questions, concerns or suggestions for future topics to be covered in our newsletter.

– *HRPP Staff*

## Announcements

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

## Tip of the Month: Faculty Advisor Responsibilities

All students involved in the conduct of human subjects research, whether graduate or undergraduate, must have a faculty advisor. Faculty advisors serve a critical role in human research protections. Not just a mentor, the faculty advisor is considered part of the research team.

Faculty advisors are expected to be experienced researchers who are ultimately responsible for how the research is conducted. As required with all members of the research team, faculty advisors must have completed UTK's required CITI training for Human Subjects Research and maintain it in accordance with UTK IRB's education requirement.

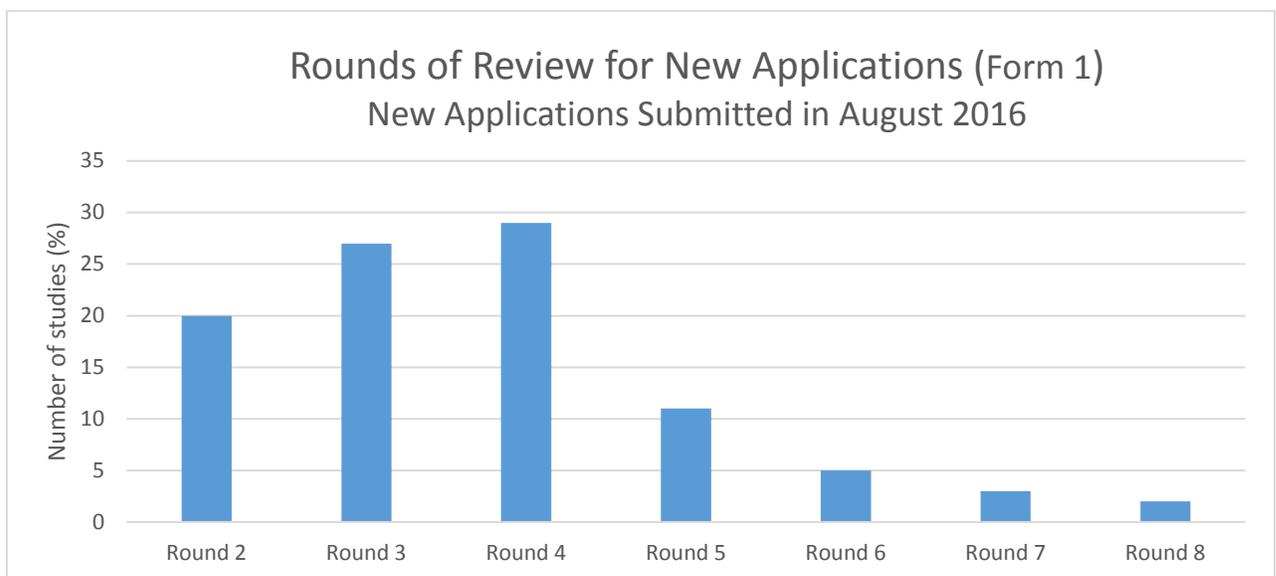
The faculty advisor is expected to fulfill the following responsibilities.

- Be an available resource to students;
- Assist students with the development of their IRB application including:
  - be added as a Project Contact along with the student PI (iMedRIS application item 3.3) to ensure receipt of all IRB communications;
  - thoroughly review the IRB application and supporting materials prior to their submission to the IRB;
  - review IRB determination letters; and
  - work with students to complete needed modifications and ensure responses are complete and accurate.
- Guide and oversee the research throughout its lifecycle including ensuring access to research records.

- Meet with the student on a regular basis to monitor study progress.
- Oversee the storage of participant consent documents on campus and the storage of any identifiable information.
- Retain copies of research records for 3 years after completion and closure of the study with the IRB (6 years if the research includes the review or receipt of HIPAA regulated information).

## iMedRIS Tip: Avoid Multiple Rounds of Review

The following graph shows how many rounds of review were required before applications could be approved (shown for studies submitted in August 2016). To help investigators reduce these rounds of review and speed up review time, we have identified key areas where delays occur. Below we highlight these pitfalls and provide useful tips to avoid them. Please note **these delays also occur within investigators' respective departments during the departmental review before the IRB even receives the application.** The tips provided address these scenarios as well.



1. **Departmental Approval:** New applications must be approved by the principal investigator's department before the IRB can review it. Be sure that you include your faculty advisor (if you are a student), your Department Review Chair (DRC), and your Department Head in the application (Section 3). If you are a member of the research team as well as the DRC or Department Head, you must designate someone else to serve in these roles for your study. Approving your own study would present a Conflict of Interest will result in the application's being returned to the principal investigator for correction.

A significant number of studies are returned to the PI due to incorrect routing. Complete the following steps when routing a new IRB application.

- Step 1 – Click “Yes” to select additional personnel for routing as shown below.

Does this submission require additional routing for approval?

YES - Click YES to select additional personnel for routing.

NO - Click NO to bypass selecting additional personnel for routing.

- Step 2 – Check each Co/Sub-Investigator, along with the PI, to include in the routing and signoff on the study. Other research personnel are not required to sign off on the application.

Select the Key Personnel required for routing and signoff

Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Approved Name	Role
<input checked="" type="checkbox"/>	 Kristine Hershberger	Principal Investigator
<input checked="" type="checkbox"/>	 Sara Mulville	Co-Investigator
<input checked="" type="checkbox"/>	 Tammy Loy	Co-Investigator
<input type="checkbox"/>	 Laura Moll	Research Assistant

- Step 3 – Check both the Department Chair and Department Review Chair required to sign off. Then assign the order in which those individuals must review it [see Instructions in the iMedRIS Help menu].

Select the additional personnel required for routing and signoff

Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Order	Approved Name/Role
<input checked="" type="checkbox"/>	2	 Colleen P Gilrane Department Chair
<input checked="" type="checkbox"/>	1	 Ms. Kristine Hershberger Department Review Chair

- 2. Departmental Rejection:** When a submission is rejected during the routing, the investigator should make changes to the submission according to the departmental reviewer's comments, then route to all departmental reviewers for signatures [see Instructions in the iMedRIS Help menu]. The IRB cannot review the study unless all departmental signatures are obtained.
- 3. IRB Requested Changes:** Some provisos may require additional information or changes to the IRB application or supplemental materials. Be sure all provisos are addressed and any new versions of the IRB application and supplemental materials are attached to your re-submission.

In making the requested changes to the submission, a PI may include additional information that results in a request for further revisions. For example, a study may be submitted for Exempt review but in reviewing the PI's responses provisos, the reviewer may find that the risk level has changed or the research no longer qualifies for exemption and ask the investigator to re-submit for Expedited review. Please be sure to provide detailed information with your first submission to accelerate the process.

# Training and Outreach Opportunities

IRB 101 workshops are scheduled for February, March and April 2017. 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. Details are posted on [ORE's Training and Workshops website](#).

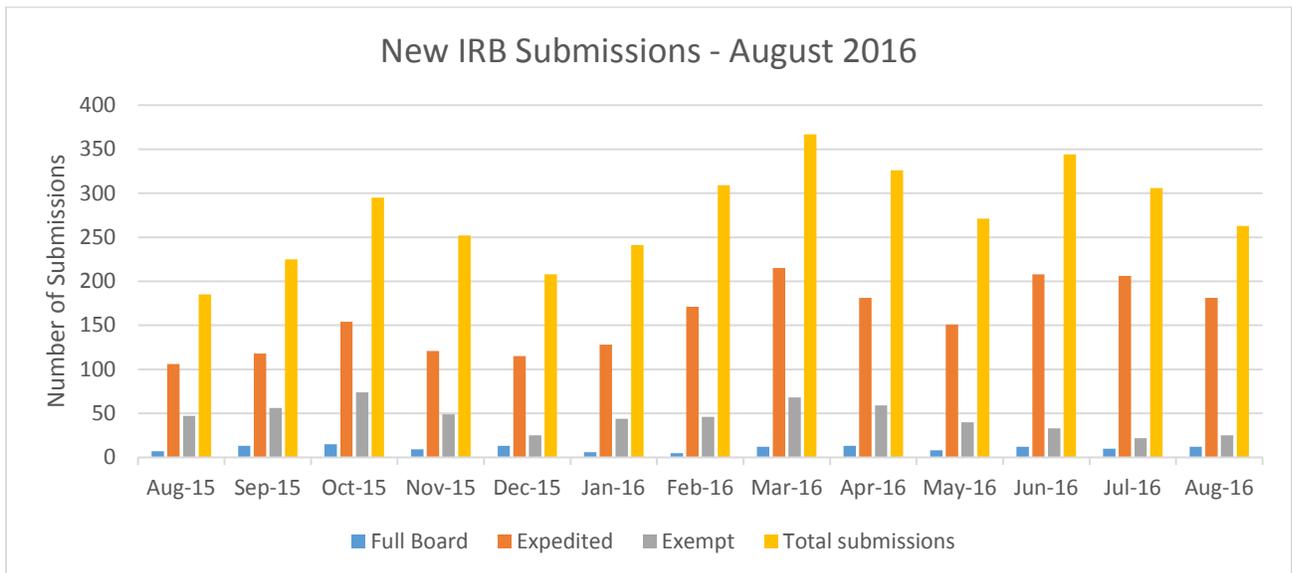
As the semester progresses, additional trainings may be scheduled and posted on [ORE's Training and Workshops website](#) as details become available.

Take advantage of our video, [Path to IRB Approval](#). Recorded at the Responsible Conduct of Research (RCR) Lunch Series held in January 2016. This presentation instructs you on preparing your IRB application and contains several helpful tips.

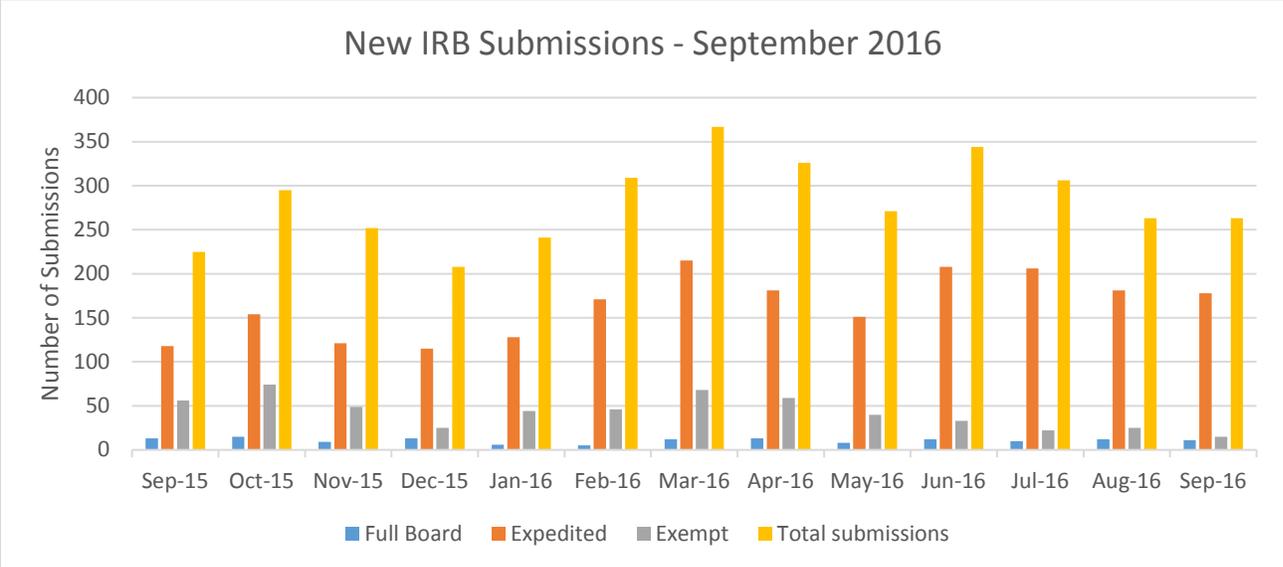
## IRB Metrics Update

### New Submissions by Review Type

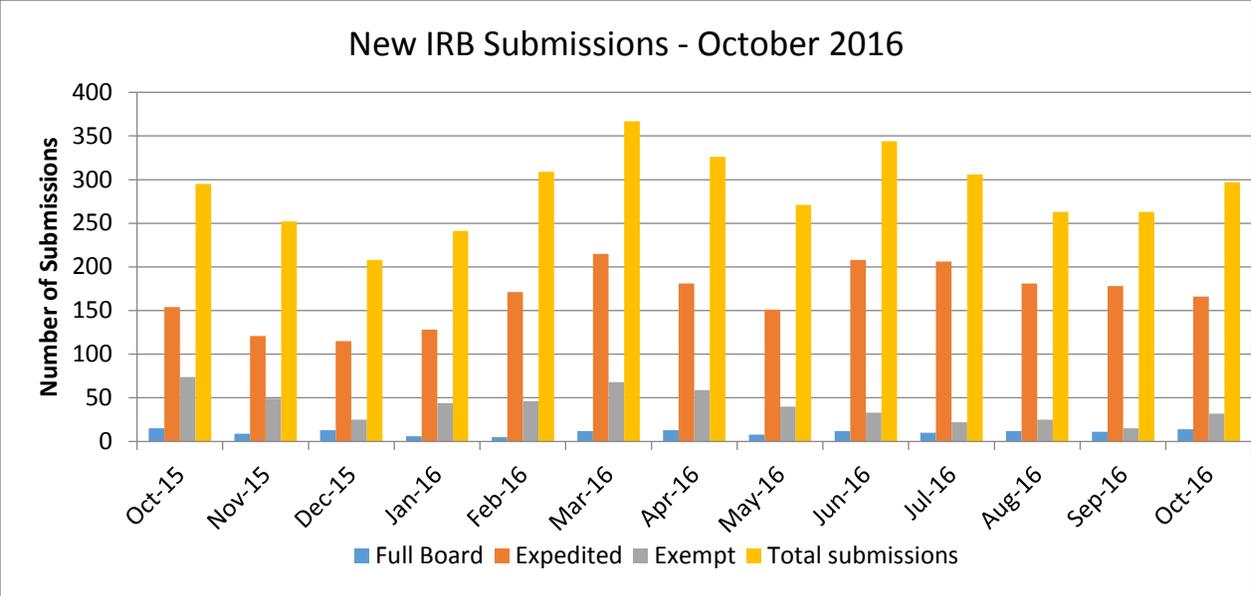
The charts below show the number of new submissions received by the IRB during the months of August through November 2016 compared to the number received during those same months in 2015.



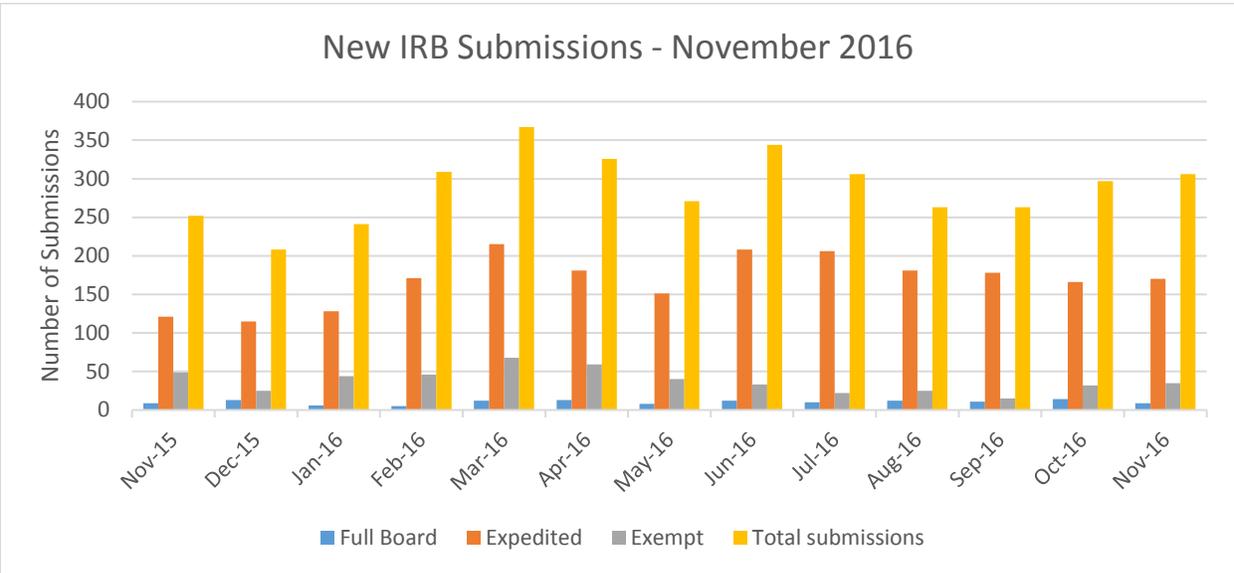
August 2016 – A total of 263 submissions were received in August 2016 compared to a total of 276 submissions in August 2015.



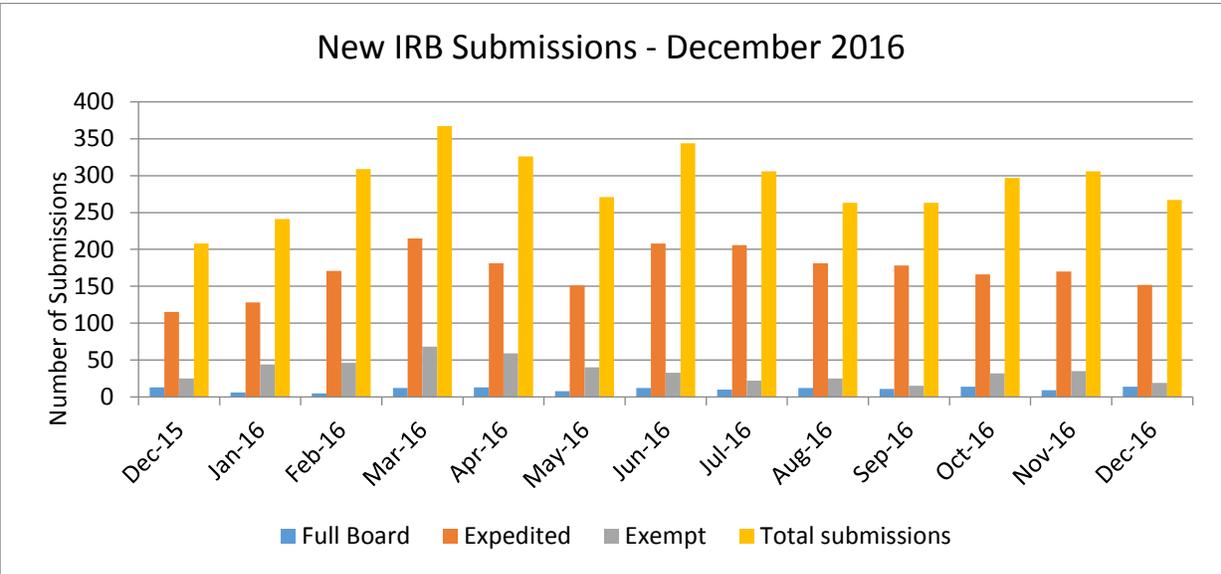
September 2016 – A total of 263 submissions were received in September 2016 compared to a total of 282 submissions in September 2015.



October 2016 – A total of 295 submissions were received in October 2016 compared to the 287 submissions received in October 2015.



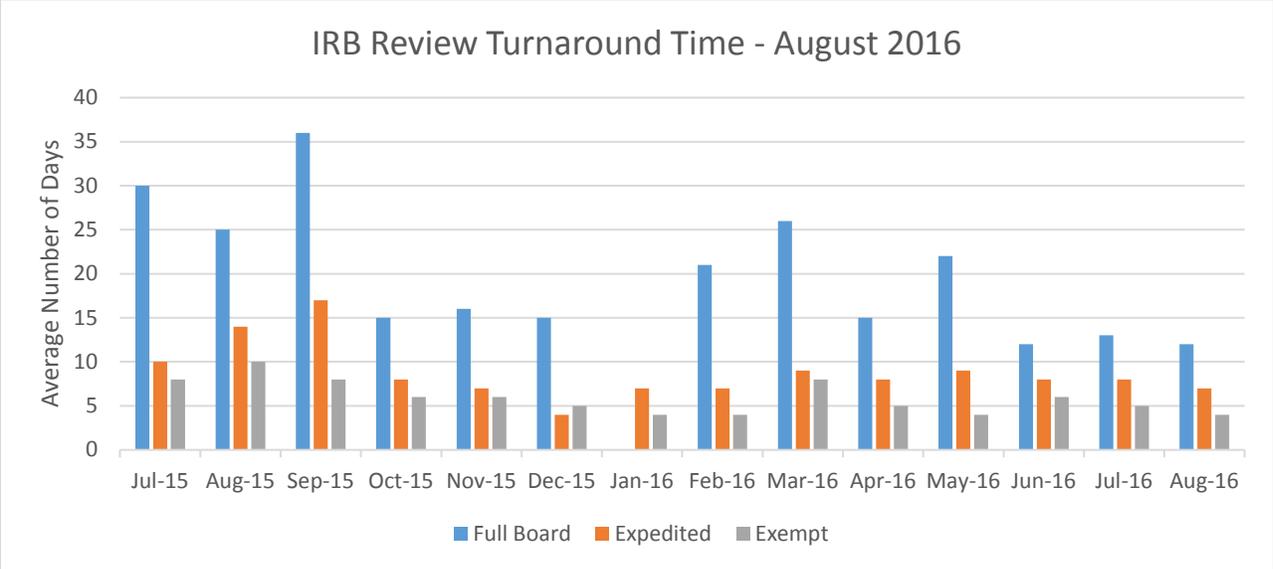
November 2016 – A total of 306 submissions were received in November 2016 compared to the 288 submissions received in November 2015.



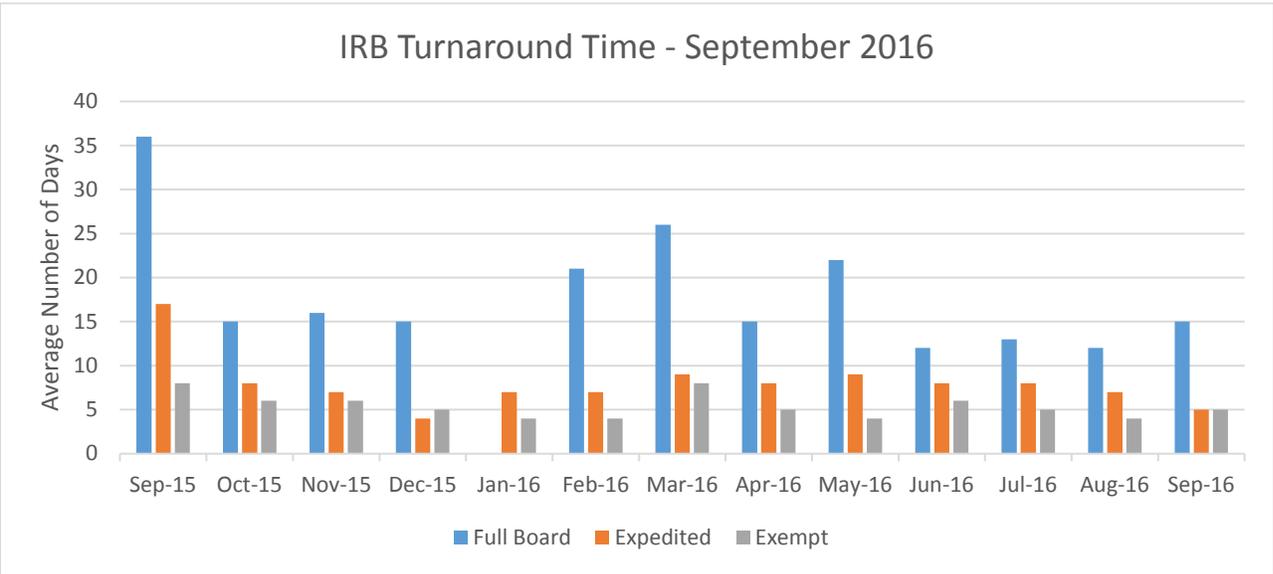
December 2016 – A total of 267 were received in December 2016 compared to 289 new submissions received in December 2015.

**Turnaround Time Averages by Review Type**

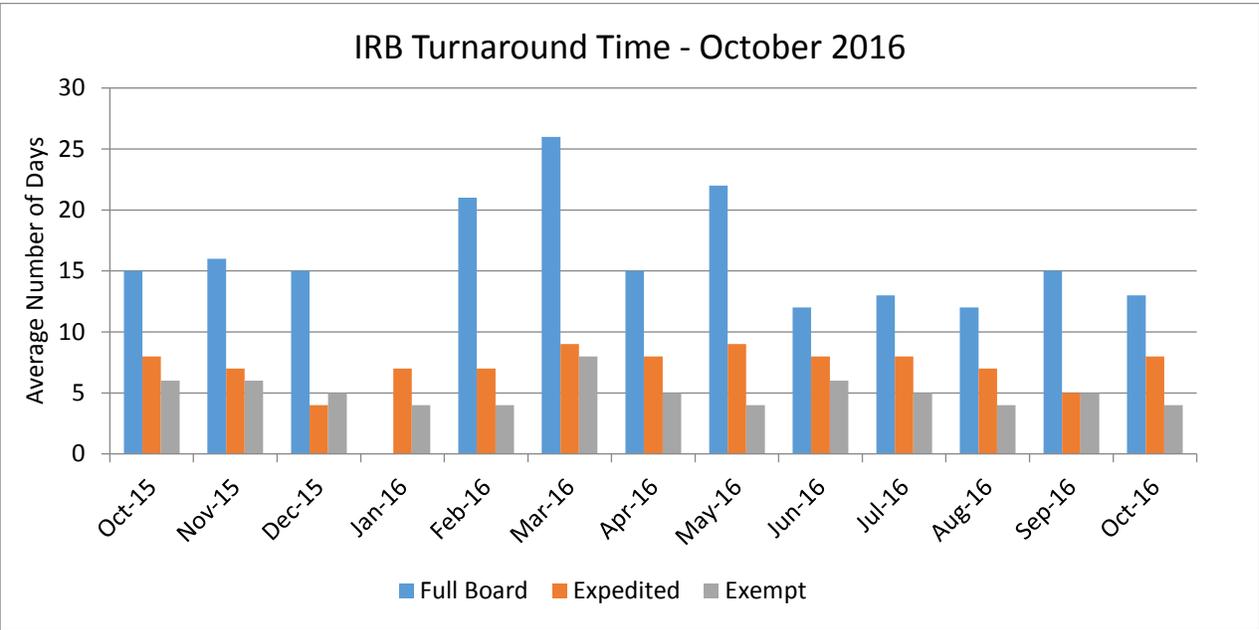
The IRB is always striving to improve our services to the UTK research community. The charts below highlight how the IRB has significantly reduced its average review time across all review types.



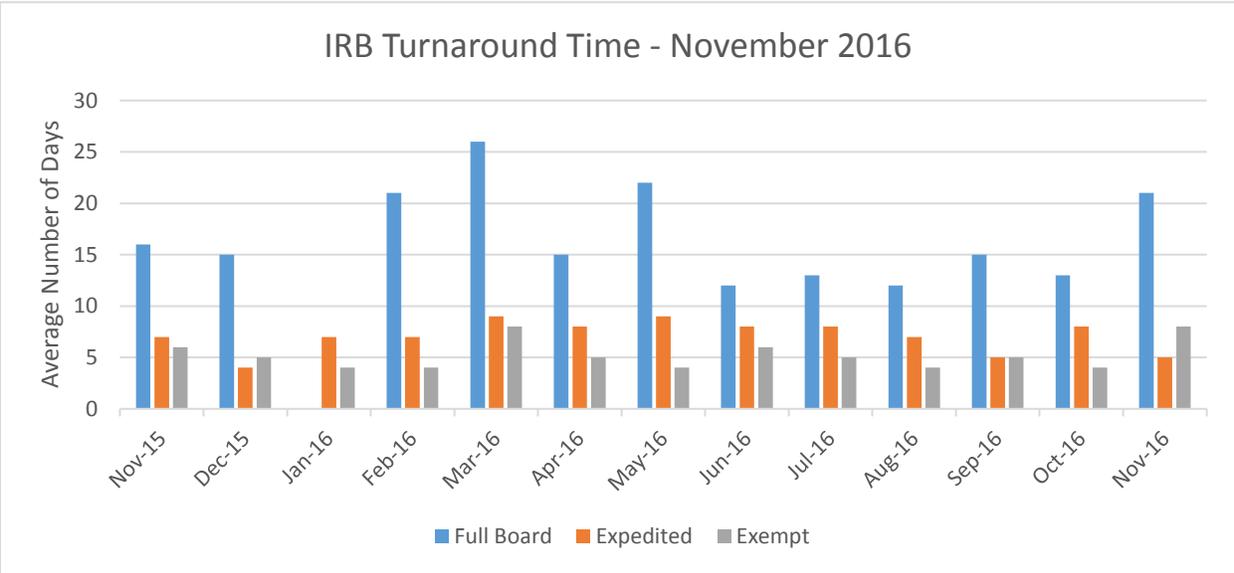
August 2016 – The average review time for all submissions in August decreased by a week – from 13 days in 2015 to 6 days in 2016.



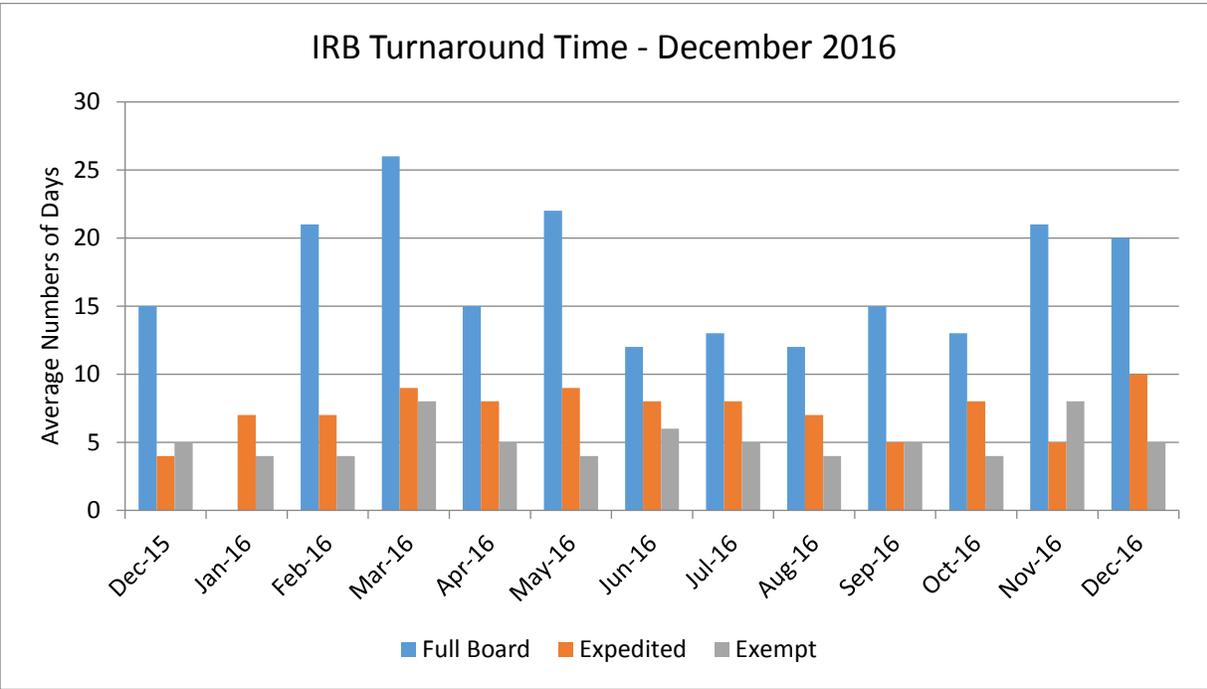
September 2016 – The average review time for all submissions in September **decreased by three weeks** – from 27 days in 2015 to 4 days in 2016.



October 2016 – The average review time for all submissions in October decreased from 10 days in 2015 to 6 days in 2016 continuing our trend of reducing review times.



November 2016 – The average review time for all submissions in November decreased from 11 days in 2015 to 7 days in 2016.



December 2016 – The average review time for submissions in December **decreased by two weeks** – from 19 days in 2015 to 7 days in 2016.

### Contact Information

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