

HRPP Newsletter

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The Home Stretch

The semester's end is quickly approaching and soon some investigators will bid farewell to UT for new opportunities. If you are one of them, please review the guidance, [When a Principal Investigator Leaves UT](#), for information on how to close or transfer studies before your departure. As part of our continued efforts to assist investigators, face-to-face training opportunities are available in both April and May. We have also included new guidance and tips. We want to hear your thoughts. Please contact us with your suggestions for future topics.

– HRPP Staff

When a Principal Investigator Leaves UT

Too often principal investigators (PIs) depart without effectively managing their research studies. PIs are responsible for ensuring the disposition of their studies prior to their departure. Likewise, faculty advisors and department administrators have a responsibility to ensure these responsibilities are carried out before the PI leaves.

Below are the procedures required for studies involving human research participants. Please consider the status of the study as well as the PIs future plans related to the study.

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 UTK 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, such as consent documents, recruitment materials, etc., to list the new PI's name and contact information. Affirm 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 UTK 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, and
- explain the departing PI's new role including describing any continued access to identifiable data or specimens, and
- affirm that all study records and data have been deposited with the new PI or explain any alternate arrangements.
- list the departing PI's new contact information and institutional affiliation, and
- submit a copy of the departing PI's IRB approval from his/her new institution, and

- revise any documents, such as consent documents, recruitment materials, etc., to list the new PI's name and contact information.

Transfer of Research Data/Specimens to a New Institution:

Any departing investigators 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 Robert Nobles, Associate Vice Chancellor of Research, to ensure all University requirements are met. He may be contacted at 865-974-3053 or nobles@utk.edu.

Other Issues: Should a departing investigator encounter an issue not covered in the above procedures, please contact the IRB.

Tip of the Month: CITI Training and Registration Instructions

As many of you know, UTK has selected the [Collaborative Institutional Training Institute \(CITI\)](#) operated by the University of Miami to provide web-based training on a number of research topics including human subjects research. We have added screen shots to our detailed [Registration Instructions](#) that lead investigators through the step-by-step process of registration and selecting the correct curriculum to meet IRB training requirements. We hope our research community will find these instructions helpful.

iMedRIS Tip: Print a Draft of Your IRB Application



It is easy to print a copy of your IRB application even when it is still in draft form. Open the application you want to print. Just above the Section View and Entire View tabs at the top of the page is the Print Friendly button. Depending on which of those tabs are active, the button may be near the center or by the right margin of the screen. Alternately look below the Help button.

Training Opportunities

There are two more training opportunities left this semester. [Registration](#) is recommended.

Unable to attend a live training session?

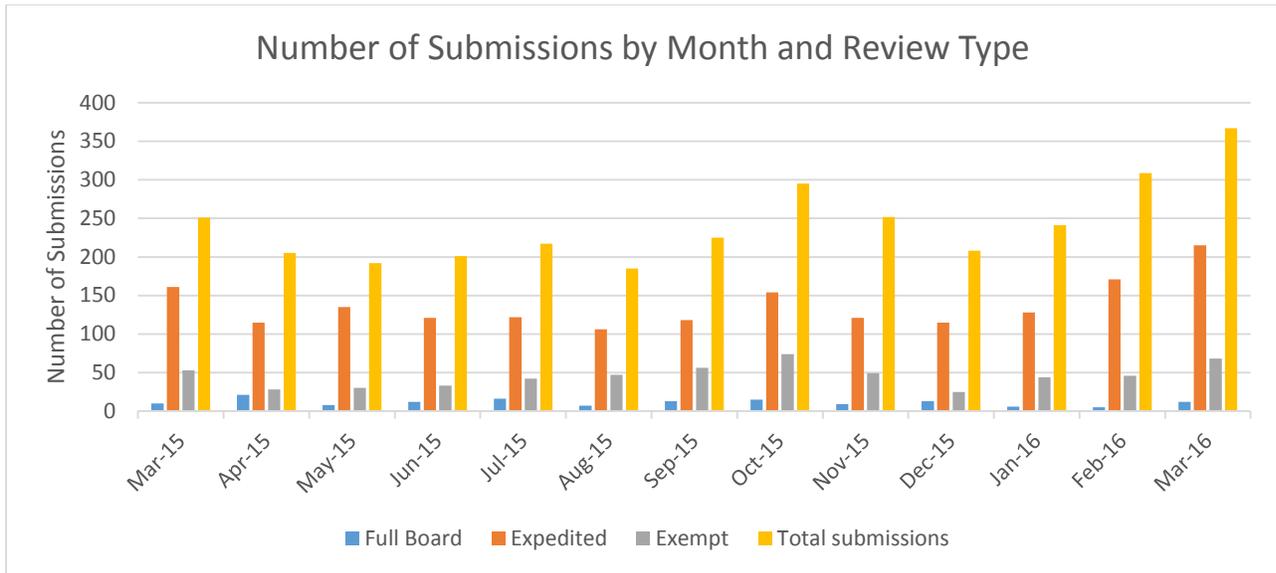
Check out our [Path to IRB Approval](#) video. Recorded at January's Responsible Conduct of Research (RCR) Lunch Series, this presentation targets how to write an application for IRB approval.

IRB 101 – An overview of IRB requirements and procedures designed for anyone interested in conducting human subjects research at the University of Tennessee, Knoxville.

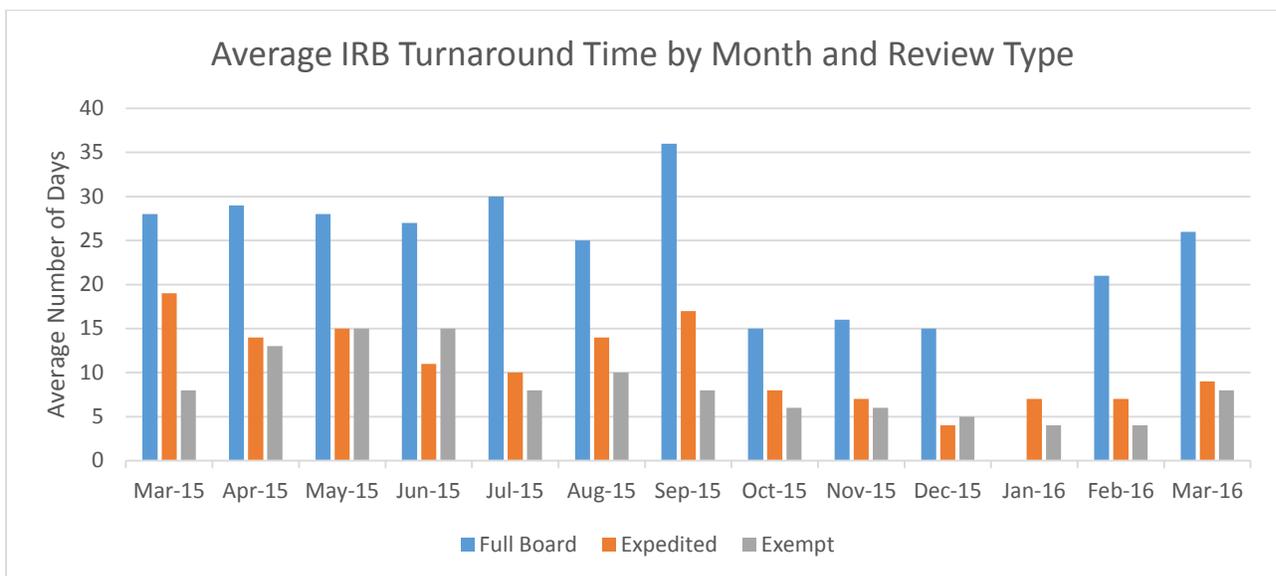
IRB: Forms 2, 3, 4 and 7 – Learn how to modify an already approved study, request renewal of a study's approval, report problems to the IRB, and request closure of a completed study.

IRB Metrics Update

This first graph highlights the number of submissions received over the last year (March 2015-March 2016). A monthly average of 242 studies and associated requests has been submitted for that period. During the month of March 2016 the IRB received a total of 367 submissions.



The second graph, below, highlights the average review time per month. The IRB continues to strive to maximize the efficiency of review for full board, exempt and expedited categories. The average review turnaround time for all submissions during the month of March improved by more than one week—from 16 days in 2015 to 8 days in 2016—continuing the trend of significant reduction across all review types.



Contact Information

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