

HRPP Newsletter

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Summer 2016

Summer is in full swing. Although many have left campus for a well-deserved break, we are busy preparing for the upcoming academic year. Please see our announcements below. For those who missed our last newsletter, we are re-printing our previous article, *When a Principal Investigator Leaves UT*. As always, we want to hear your suggestions on topics to cover for future issues. We hope you all enjoy the remainder of your summer.

– HRPP Staff

Announcements

New Streamlined iMedRIS Application – We are pleased to announce that our Initial Review Application (Form 1) has been revised to eliminate unnecessary questions, streamline format and increase Help menu guidance. Available on or before July 1st.

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

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: Write Readable Informed Consent Forms

Requirements

Informed Consent Forms (ICFs) submitted with new applications are rarely approved without IRB requested changes. This is most often because, in addition to including the required elements of consent, ICFs must also communicate those elements in a language understandable to the research participant or their legally authorized representative such as a parent or caretaker. This means the document must be written in plain language, in lay terms without jargon or technical language and at a reading level they can comprehend.

Many words and concepts used in research settings are complicated and unfamiliar to the average adult. The use of technical language in consent materials is not limited to biomedical research. All disciplines of research use language that may not be understood by a person unfamiliar with that discipline regardless of their education level. Further complicating the matter, nearly half of American adults read at or below an 8th grade level. For these reasons, we recommend that all participant materials such as ICFs, recruitment materials and study instructions be written at or below an 8th grade reading level.

Plain Language

Plain language uses evidence-based standards in structuring, writing, and designing materials. When using plain language, the resulting texts are easy to read, user-friendly, and reader-focused.

Resources

Translating research or academic terminology into a comprehension level appropriate to the general public is challenging. A variety of resources are available to assist investigators in developing materials that are readable and participant centered.

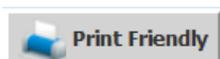
- PRISM Readability Toolkit – A free, 81-page plain language handbook illustrating why literacy is important and how to improve the readability of research consent forms and other materials for study participants. It provides a quick reference guide and plain language alternatives to complex terms.

- PRISM Online Training – A web-based plain language hour-long tutorial created for research professionals, including scientists, research staff, Institutional Review Boards (IRBs), or communications staff. It covers plain language strategies and examples, readability, health literacy and interactive editing examples and exercises. This course is free.
- Plainlanguage.gov – provides guidance, examples, suggested word usage, etc.
- MS Word can calculate readability statistics using the Flesch Reading Ease Score. The Flesch-Kincaid Grade Level score rates text on a U.S. grade-school level. Unfortunately, this scale underestimates the reading level of health-related text by one to two grade levels. If the Flesch-Kincaid is used, it is safest to add 2 grade levels.

Tips On Writing Readable ICFs

- Write in the second person (you), not third person (the participant).
- Use common, everyday words familiar to the non-academic/nonscientific reader.
- Avoid abbreviations and acronyms (if using, spell out when first used).
- Use a conversational tone.
- Use headings and subheading to group text together.
- Write short, simple, and direct sentences.
- Avoid using e.g. or etc., use instead, “for example,” “so forth”.
- Keep paragraphs short and limited to one idea.
- Use page numbers, if appropriate.
- Use at least 12-point font and consider a larger font based on your audience.
- Check the text to see if each idea is clear and logically sequential.
- Avoid repetition.
- Avoid large blocks of printed text and embrace “white space”.
- Use photos or pictures if they will help clarify procedures.
- Be consistent with use of all terminology, such as procedures, activities and abbreviations.
- Check the reading level.
- Ask someone to read the material and provide feedback. Asking someone unfamiliar with research or your area of study can be particularly 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.

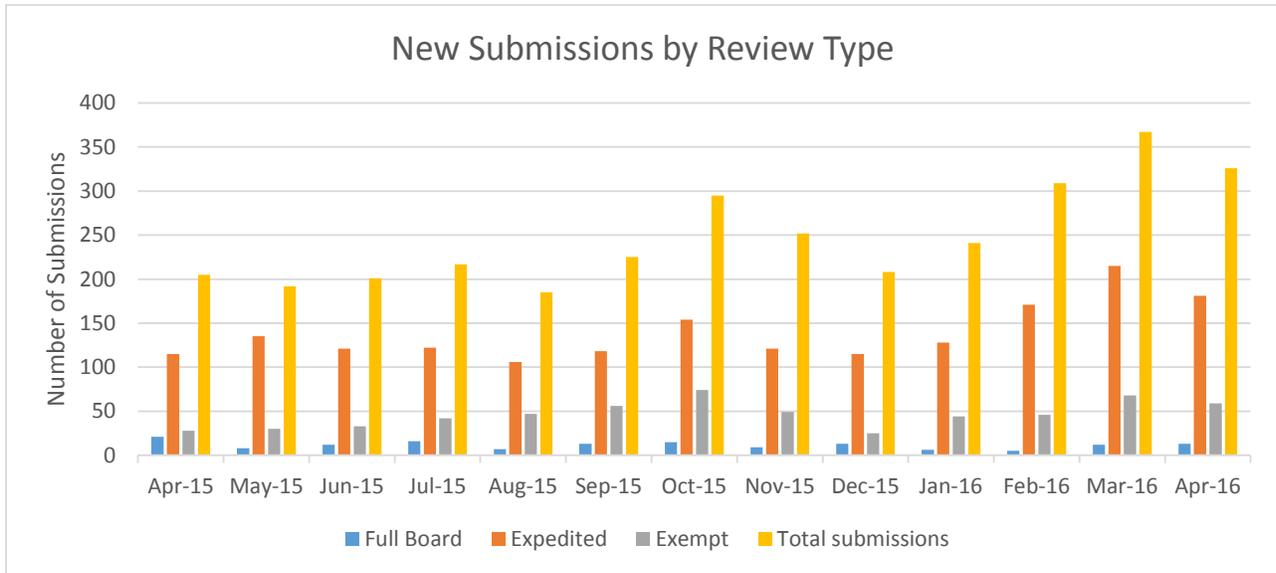
Training and Outreach Opportunities

Although no live events are currently scheduled, the HRPP is planning several workshops beginning in August. These will be posted on [ORE's Training and Workshops website](#) as details become available. In the meantime, please take advantage of our video, [Path to IRB Approval](#). Recorded at January's Responsible Conduct of Research (RCR) Lunch Series, this presentation instructs you on preparing your IRB application with several helpful tips.

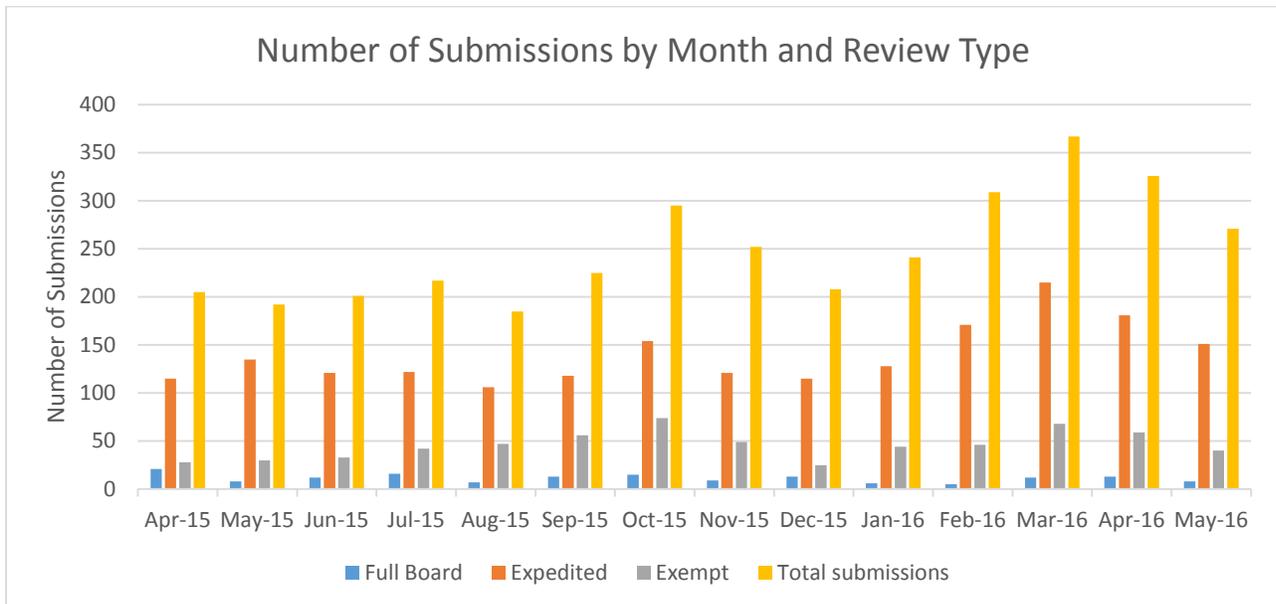
IRB Metrics Update

New Submissions by Review Type

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



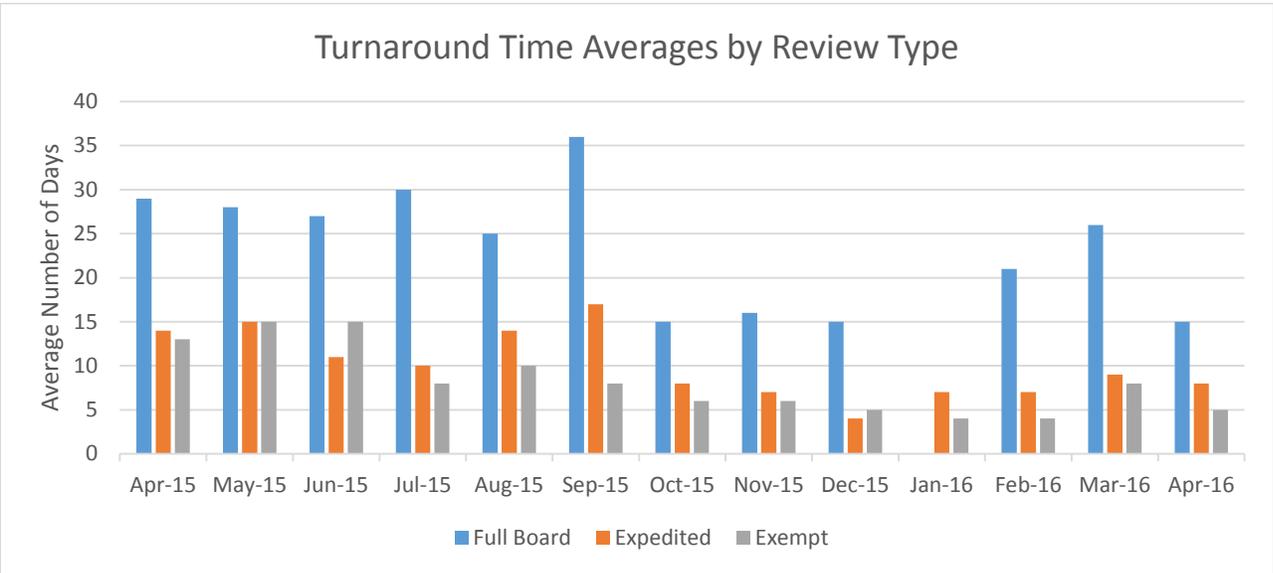
April 2016 – A total of 326 submissions were received. An average of 247 submissions were received per month for the preceding 12 months.



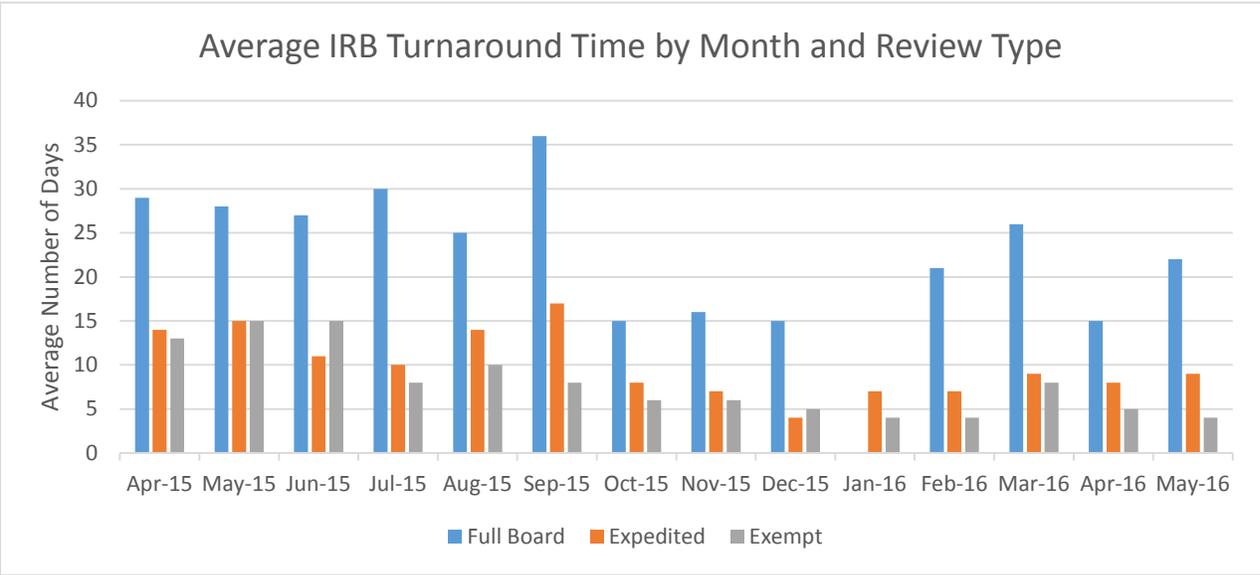
May 2016 – A total of 271 submissions were received. An average of 253 submissions were received per month for the preceding 12 months.

Turnaround Time Averages by Review Type

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



April 2016 – The average review time for all submissions in April improved more than one week – from 15 days in 2015 to 6 days in 2016 – across all review types.



May 2016 – This month continues the IRB’s trend of reducing its average review time across all review types.

Contact Information

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