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June 2017

This month's issue includes guidance on consent forms. Additionally we report continuing reductions to review turnaround times.

– *HRPP Staff*

Tip Of The Month: Writing Readable Informed Consent Forms

Requirements

Informed Consent Forms (ICFs) submitted with new applications are rarely approved without required 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/non-scientific 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.

Training and Outreach Opportunities

Upcoming Workshops

The overview of IRB requirements and procedures is open to and appropriate for anyone who wishes to learn how to receive human subjects approval for research at the University of Tennessee, Knoxville – whether you are new to the campus, new to human subjects research, or just want a refresher!

This workshop will answer questions such as...

- Do I need IRB approval? Why?
- How do I submit an IRB application?
- How does the IRB process work at UT Knoxville?
- Who can help me with my IRB application?

IRB 101:

- Thursday, June 22, 2017; 10:00 a.m. to 12:00 p.m., A 004 Blount Hall

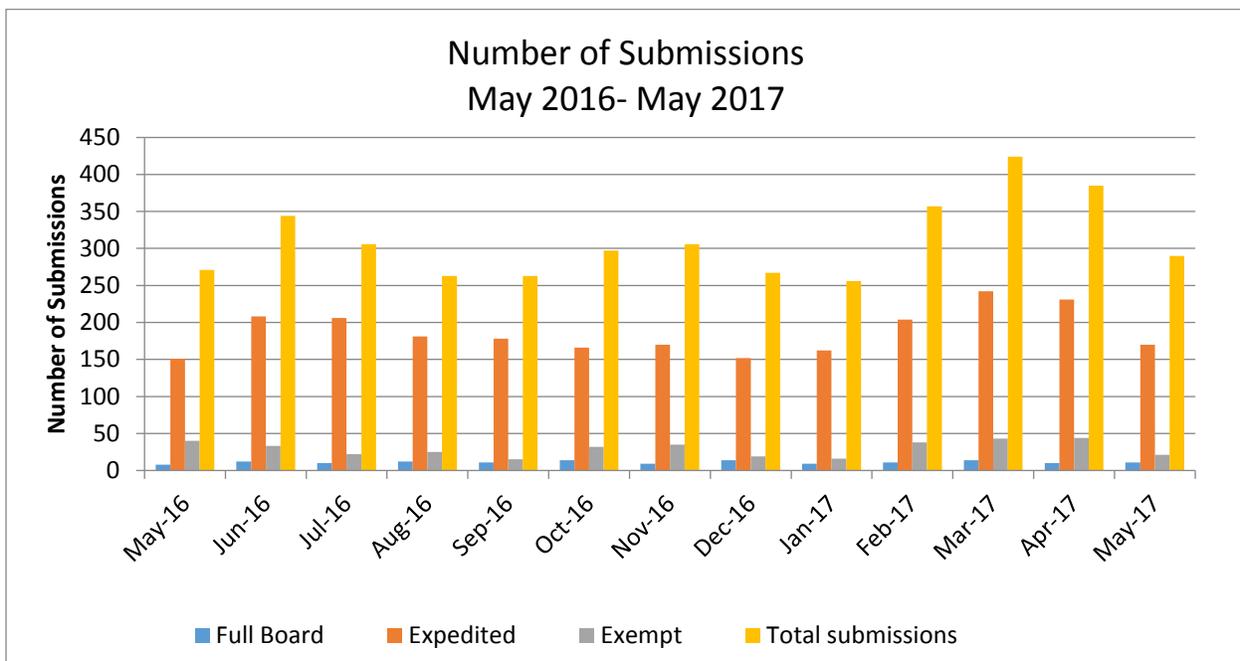
While registration is not mandatory, it is appreciated so presenters may have an estimate of how many participants to expect. Walk ins are always welcome. Please contact the IRB at utkirb@utk.edu with any questions.

Please also check out future scheduled training sessions posted on [ORE's Training and Workshops website](#).

IRB Metrics

New Submissions

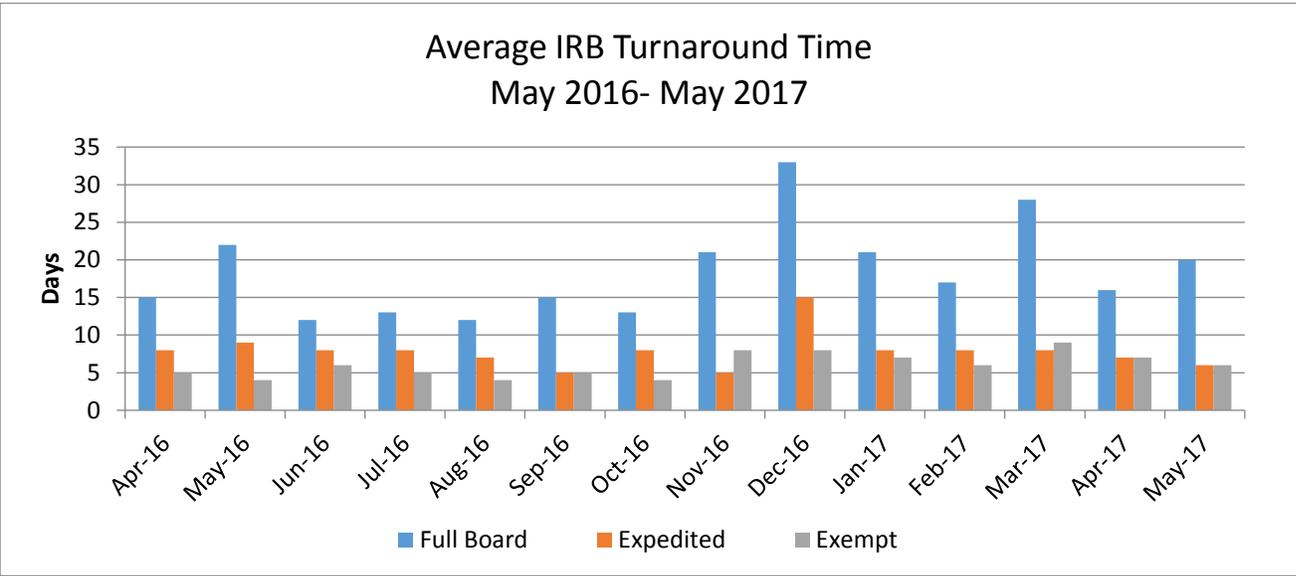
The chart below shows the number of new submissions received by the IRB during the month of May 2017 compared to the number submissions received during the preceding 12 months.



May 2017 – A total of 290 submissions were received compared to a total of 271 received in May 2016.

Turnaround Time Averages

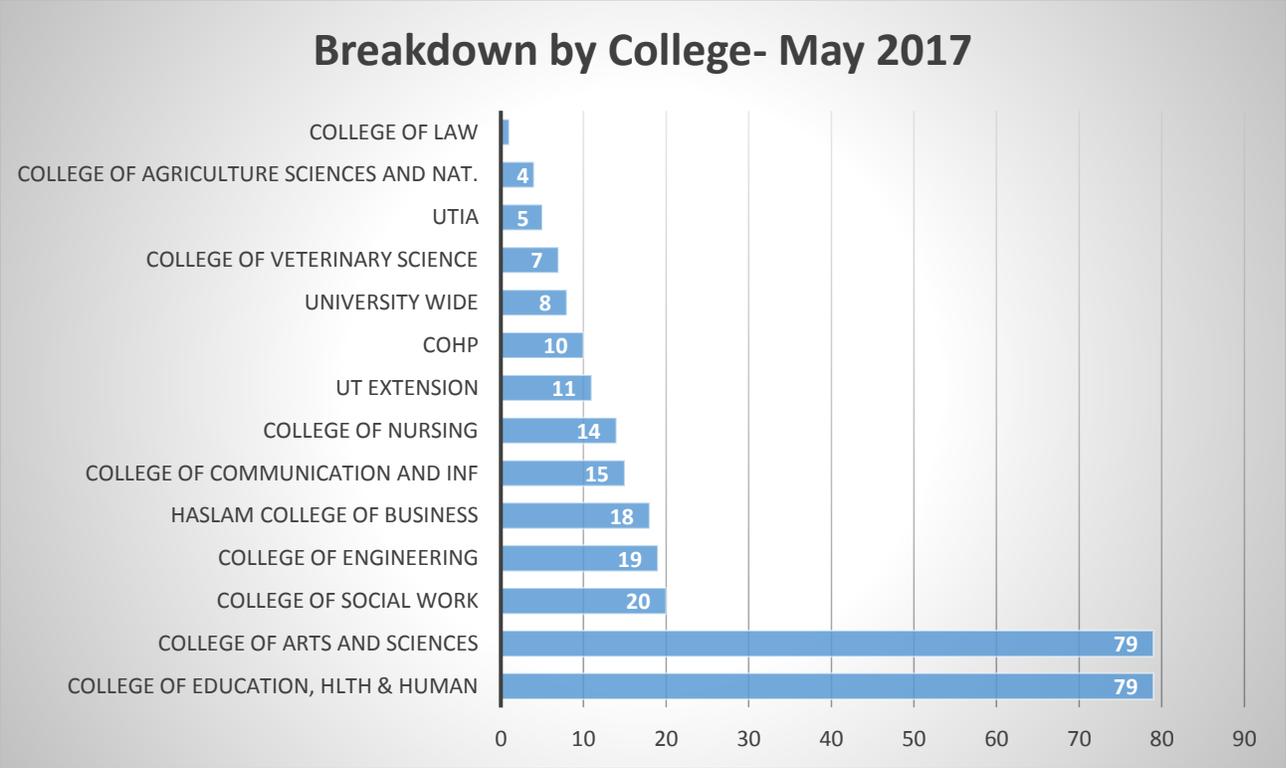
The chart below show the average review time for all submissions on a monthly basis during the past year.



May 2017 – Average review turnaround time for all submissions during the month of May improved by numerous days – from 12 days in 2016 to 5 days in 2017. May review times demonstrate – the continuing trend of reduced turnaround time.

Submissions by College

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



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](#).