THE UNIVERSITY of TENNESSEE
GRADUATE SCHOOL OF MEDICINE

IRB NEWSLETTER

July 2017 Volume 1 Issue 2

THIS ISSUE

ANNOUNCEMENTS

Welcome to the second publication of the GSM IRB Newsletter! We hope you find it informative and helpful.

TIP OF THE MONTH

New Guidance Document from FDA

FDA has issued guidance for immediate implementation to allow IRBs to waive or allow an alteration of informed consent for clinical trials if the study involves no more than minimal risk to human subjects. Passing of the 21st Century Cures Act on December 13, 2016 gave FDA the authority to permit an exception from informed consent requirements.

FDA has not yet changed the regulations, but the agency does not intend to object to an IRB waiving or altering the elements of informed consent for studies that are minimal risk to subjects when the IRB finds and documents the following:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

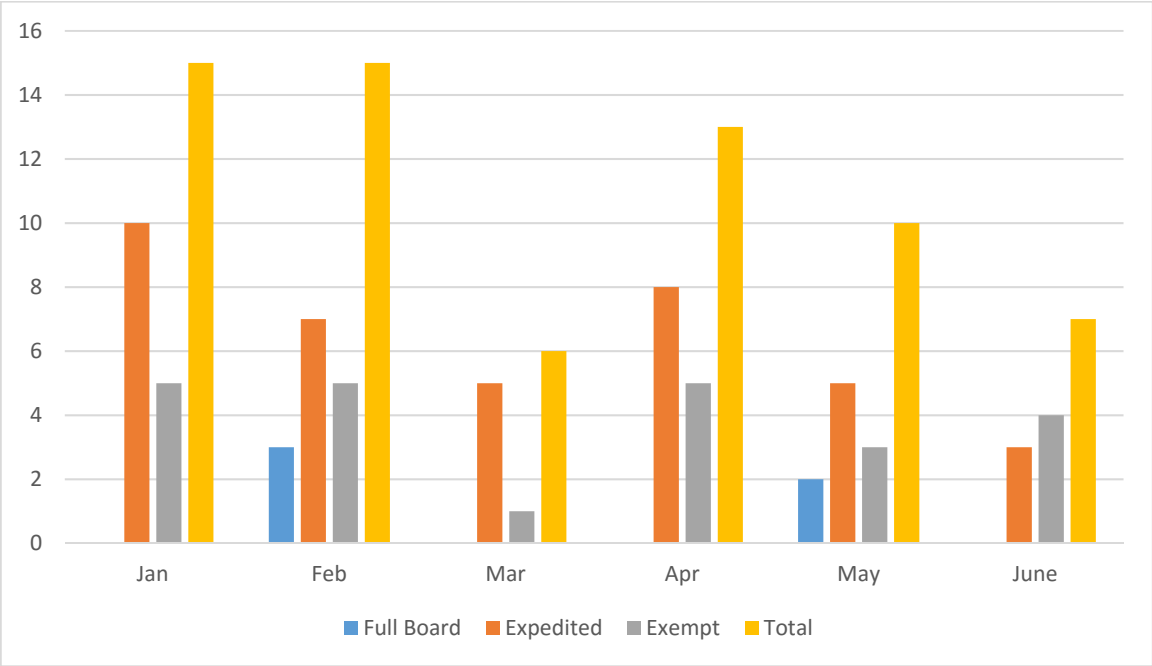
Minimal risk is defined in applicable FDA regulations as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (21 CFR 50.3(k), 56.102(i)).

The full guidance document can be found at https://www.fda.gov/regulatoryinformation/guidances/ucm566474.htm

IRB METRICS

New Submissions by Review Type = 66

The chart below shows the number of new submissions reviewed by the IRB from January 2017 – June 2017.



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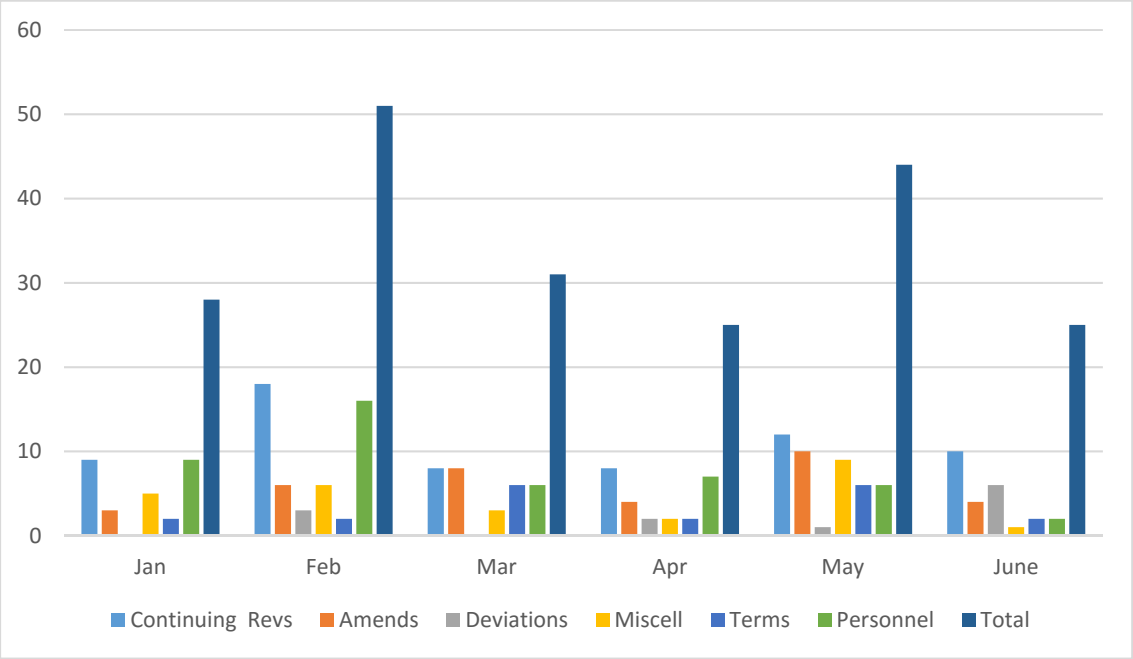
Other 2017 Reviews by Review Type = 204



Legend: Continuing Review, Amendments, Deviations, Miscellaneous Reports, Terminations, Change in Personnel, Total

Other IRB Reviews / Activities

3 IRB Audits of Active Studies

38 Case Report Submissions

10 Not Human Subjects Determinations

4 Quality Improvement / Process Improvement Reviews

2 Live Training Sessions by IRB Personnel

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HAVING TROUBLE NAVIGATING IMEDRIS?

Let us help you! Visit us in the IRB office and we will walk you through your submission. Use our laptop or bring your own. We are happy to help!

CONTACT US

If you have questions or concerns, please do not hesitate to contact the IRB office:

Phones: 305-9781 or 305-6892.

Hours: 7:30 a.m. – 5:30 p.m.

Location: 3rd floor GSM

Website: http://gsm.utmck.edu/irb/main.cfm