

HRPP Newsletter

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July 2017

This month's issue includes new FDA guidance and instructions on newly added form to submit changes in study personnel. Additionally we report continuing reductions to review turnaround times.

– *HRPP Staff*

From U.S. Food & Drug Administration (FDA) Weekly Digest Bulletin.

FDA Announces Availability of Draft Guidance on Electronic Records and Electronic Signatures in Clinical Investigations

06/20/2017

FDA is announcing the availability of a draft guidance for industry entitled, "[Use of Electronic Records and Electronic Signatures in Clinical Investigations under 21 CFR Part 11-- Questions and Answers](#)." The draft guidance provides recommendations to sponsors, clinical investigators, IRBs, CROs, and other interested parties on the use of electronic records and electronic signatures under part 11 in clinical investigations of medical products. The draft guidance clarifies, updates, and expands upon recommendations in the 2003 part 11 guidance for recommendations that pertain to FDA-regulated clinical investigations conducted under parts 312 and 812. Thus, the guidance is limited to the scope and application of part 11 requirements to such clinical investigations.

The goals of the draft guidance are to clarify and update recommendations for applying and implementing part 11 requirements in the current environment of electronic systems used in clinical investigations and to encourage and facilitates the use of electronic records and systems to improve the quality and efficiency of clinical investigations.

The guidance discusses the procedures that may be followed to help ensure that electronic records and electronic signatures meet FDA requirements and are considered to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. The guidance also discusses the use of a risk-based approach when deciding to validate electronic systems, implement audit trails for electronic records, and archive records that are pertinent to clinical investigations conducted under parts 312 and 812.

More information on how to comment on this draft guidance can be found in the [Federal Register Notice](#).

Tip of the month

Our new form, **UTK Change in Personnel Form (UTK Personnel ONLY)** is designed to facilitate a quicker submission and review process for modifications when the only changes being requested are changes in UTK personnel.

To find this form, open your study in iMedRIS. It is posted on the Submission Tab of your Submissions screen.

The screenshot shows the iMedRIS interface. At the top, there are two tabs: 'Submissions' (highlighted in blue) and 'Project Management'. Below the tabs is a 'Current Approval Packet' button with a PDF icon. Underneath is a 'Protocol Items' section with a table-like structure. The items listed are: 'Project Application', 'Informed Consent', 'Other Project Documents', 'Form 2: Change Request and Amendments', 'UTK Change in Personnel Form (UTK Personnel ONLY)', and 'UTK Reportable Unanticipated Problems/Events'. The 'UTK Change in Personnel Form (UTK Personnel ONLY)' item is circled in red.

DO NOT use this form if:

- other changes are being requested at the same time, or
- the personnel changes are for non-UTK personnel.

Please contact the IRB at 865-974-7697 or utkirb@utk.edu if you have any questions.

There are three steps to this process:

1. Revise the project application to reflect the personnel changes (pages 1-2 of these instructions)
2. Complete the UTK: Change in Personnel Form (UTK Personnel ONLY) and attach the revised project application (pages 3-4 of instructions)
3. Route for sign off to the appropriate individuals (pages 5-6 of these instructions):
 - An already-approved PI, Co/Sub-Investigator, or Advisor **must sign to approve the changes**
 - Anyone being added in an Investigator or Advisor role **must sign to accept the responsibility of that role**

Detailed instructions can be found under the iMedRIS help menu.

Training and Outreach Opportunities

Upcoming Workshops

IRB 101 for New Faculty:

This workshop is aimed at faculty who are new to the University of Tennessee, Knoxville, campus. In addition to basics such as how the IRB process works here, and how to submit an application using our iMedRIS submission system, we will share specifics about how to move your data and/or projects from other institutions, so that you may continue to analyze and/or collect data. (irbchair@utk.edu).

- Wednesday, August 9, 2017; 9:00 a.m. to 11:00 a.m., 321 Communications Blount Hall

Workshop for Department Review Chairs (DRCs) and Committees:

Department Review Chairs and committee members, please come for breakfast and stay for a refresher workshop on conducting departmental reviews. The workshop will discuss specifics of and updates to the review process itself, and available resources, as well as technical aspects of conducting reviews in iMedRIS.

Breakfast will be at 8:30, followed by the workshop from 9 a.m. to 11 a.m.

- Friday, August 18, 2017; 8:30 a.m. to 11:00 a.m., A 004 Blount Hall
- Friday, August 25, 2017; 8:30 a.m. to 11:00 a.m., A 004 Blount Hall

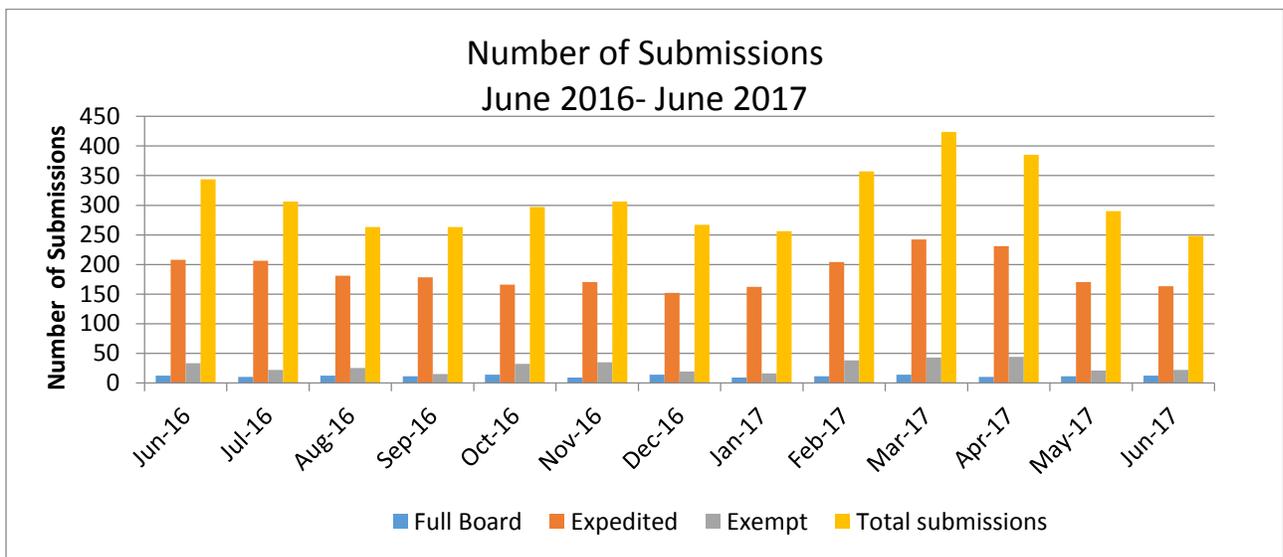
While registration is not mandatory, it is appreciated so presenters may have an estimate of how many participants to expect. Walk ins are always welcome. Please contact Colleen Gilrane (irbchari@utk.edu) or the IRB at utkirb@utk.edu with any questions.

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

IRB Metrics

New Submissions

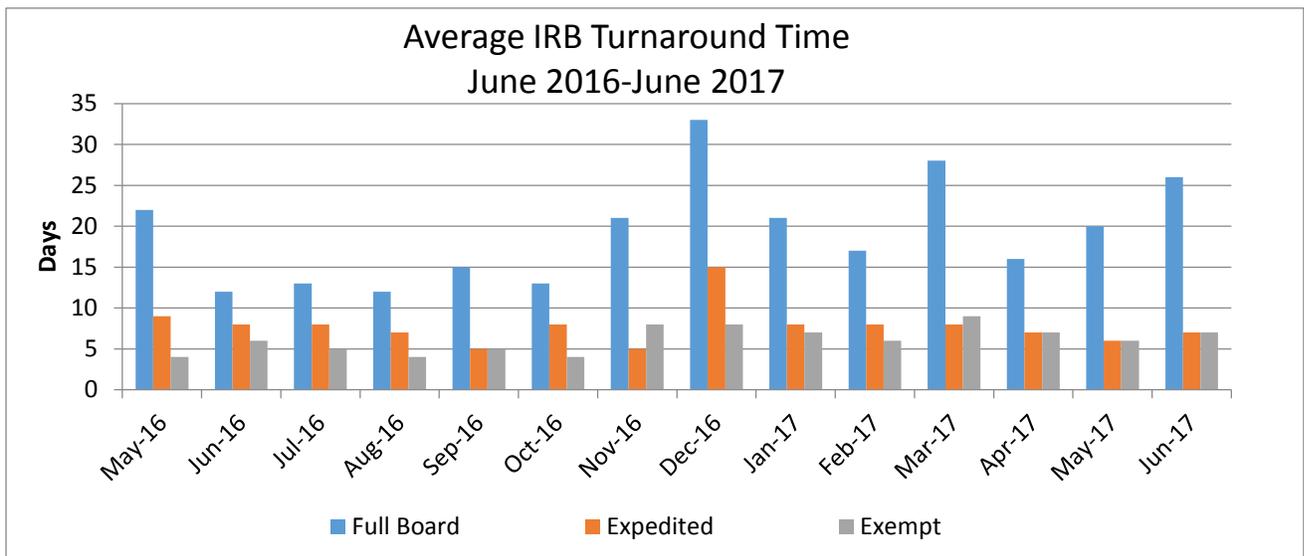
The chart below shows the number of new submissions received by the IRB during the month of May 2017 compared to the number submissions received during the preceding 12 months.



June 2017 – A total of 248 submissions were received compared to a total of 344 received in June 2016.

Turnaround Time Averages

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

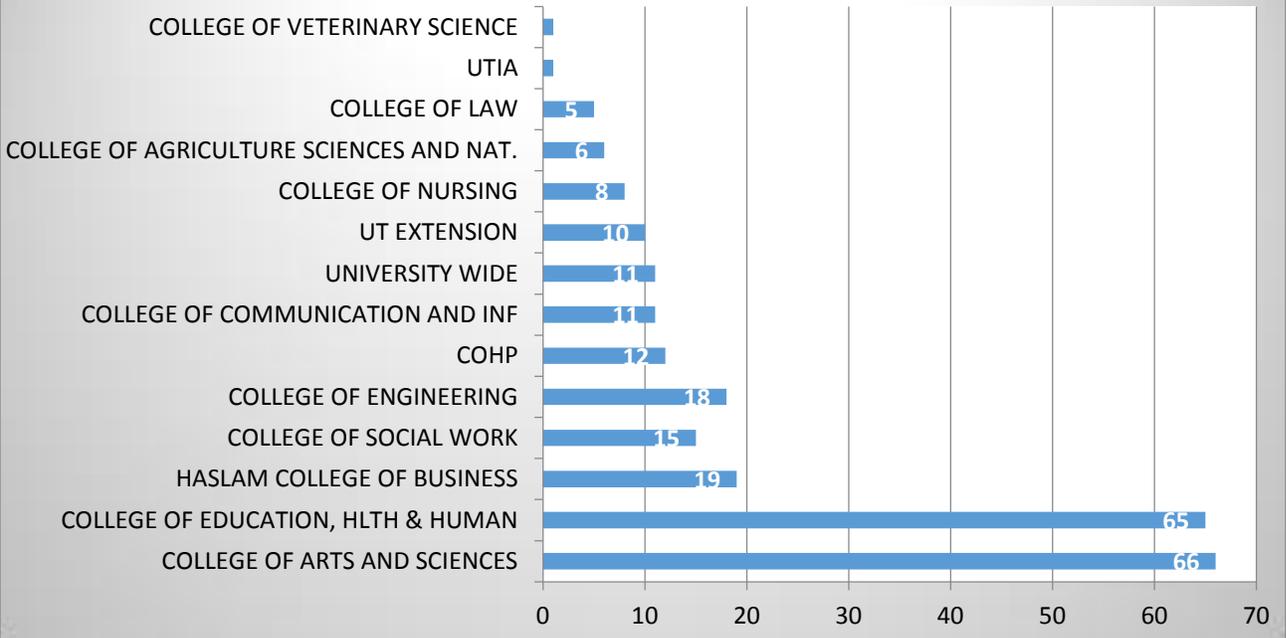


June 2017 – Average review turnaround time for all submissions during the month of June improved by numerous days – from 10 days in 2016 to 6 days in 2017. June review times demonstrate – the continuing trend of reduced turnaround time.

Submissions by College

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

Breakdown by College- June 2017



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](#).