HRPP Newsletter

In this issue:

April 2017

This month's issue includes updates in regulatory requirements and guidance on recruitment methods. Additionally we report continuing reductions to review turnaround times.

– HRPP Staff

Revised Human Subjects Regulations

On January 19, 2017, the U.S. Department of Health and Human Services published the first revision of the federal regulations that govern human subjects (45 CFR 46) since their original publication in 1981. These regulations, also known as the Common Rule, have been adopted by sixteen federal agencies including NSF, DOE, DoD and several others.

Although slated to go into effect in January 2018, the future of the revised regulations is uncertain. Due to the new administration's moratorium on new regulations and the Congressional Review Act, these regulations could still be overturned or repealed. We will continue to update the research community as information becomes available.

What is the HRPP and IRB doing to prepare for these changes? Currently our preparations are limited to the following activities until it is certain the revised regulations will be implemented.

- Studying the revisions and the extensive commentary that accompanies them.
- Informal preliminary planning to identify necessary resources, timelines and what will be required to implement the changes.

Expansion of ClinicalTrials.gov Registration Requirements

As we reported in our February issue, the U.S. Department of Health and Human Services (HHS) released the Final Rule expanding the scope of research that must be registered at ClinicalTrials.gov. Concurrently, NIH issued its Policy on the Dissemination of NIH-Funded Clinical Trial Information.

Both the Final Rule and NIH policy went into effect on January 18, 2017. It is important to be aware that the NIH policy requires registration of research *not regulated by the FDA* such as **studies evaluating health-related behavioral health outcomes**. The HRPP is currently developing additional guidance to assist researchers in understanding their responsibilities related to these new requirements and will provide further information in the near future.

Recruitment Methods

Recruitment activities take many forms and may involve multiple stages such as the identification, initial contact and screening of potential participants. As these activities mark the beginning of the informed consent process, the IRB must review and approve all methods used for these activities including the mode of their communication and the information communicated to ensure appropriate subject protections.

All stages of the recruitment process should demonstrate respect for potential participants by avoiding the potential for undue influence and protecting both the privacy of the individual and the confidentiality of any information obtained/used for recruitment and screening purposes. Below we identify both acceptable and unacceptable recruitment methods. In identifying acceptable recruitment methods we include guidance on the associated information required by the IRB.

Acceptable Recruitment Methods

The methods identified below have been used in studies conducted at UT and are generally acceptable. However, there may be circumstances in which certain methods are not appropriate for a particular study. All recruitment methods to be used for a study must be thoroughly described in the IRB application's Participant Recruitment (1600) section. This list is not exhaustive. Researchers should feel free to propose all recruitment methods they hope to use, but understand that the IRB must approve those methods prior to their use.

Participant Identification Methods	
Method	**Include in IRB Application**
Review of Public Records, such as UT directory, phone directories, voter lists, etc.	Identify source(s).
Review of Private Records, such as education records, medical records, employment records, etc.	Identify the specific records to be reviewed, the information (data points) to be abstracted, obtained or otherwise used, the research team member who will access the records and how they will obtain permission to do so.
Purchased Mailing Lists	Identify list sources.
Personal Contacts/ Knowledge	Describe how potential participants are known to the researcher.
Recruiting Lists/Registries	Such a protocol describes how potential research participants will be asked for and will provide consent for future contact. Researchers contact these potential participants about particular studies according to their approved IRB applications and the consent of the prospective participant. In some cases prospective participants will have consented to be contacted for future studies by means of a check-off box in a consent form for a previous study.
Referrals/Third Party (e.g., from colleagues, teachers, *snowball sampling, etc.)	Describe the process used to obtain referrals and how any privacy/confidentiality concerns will be addressed. *Use of currently enrolled participants to identify potential participants may be approved by the IRB under certain conditions for research involving non-sensitive topics which do not adversely impact confidentiality and privacy.

Participant Contact Methods	
Method	**Include in IRB Application & Materials to Submit**
Written Communication, such as letter or email	Describe the specific plans including the frequency, timing, how any privacy concerns will be addressed, etc. **Submit** – Final text of letter(s), email(s) or other written communication.
Verbal communications, such as phone call, personal announcements, word-of-mouth	Describe the specific plans including the frequency, timing, how any privacy concerns will be addressed, how undue influence will be minimized (if applicable), etc. **Submit** – Phone script(s), announcement script(s)/list(s) of talking points to be covered.
Flyers	Describe locations where they will be placed. **Submit** – Final copy of all flyers.
Website announcements, such as online bulletin boards, SONA, listserve distribution, etc.	• Describe where announcements will be placed, such as specific websites or types or website, specific listserve or types of listserves, etc. • Indicate if the general public has direct access to post or send out information. If not, describe how the researcher has permitted access or the procedures used (moderator permission, etc.). **Submit** – Final text to be posted or distributed.
Personal or verbal announcements	• Indicate where announcements will be made, such as meetings, classes, public venue, etc. • Identify the intended audience. • If announcements will occur where individuals may have an expectation of privacy, such as AA meetings. **Submit** – Announcement script(s) or list of talking points.
Social media postings	• Identify the social media platform and specific site (social networking - Facebook; micro-blogging - Twitter; etc.) • Describe whose account will be used, such as personal, professional, departmental, research study-specific. **Submit** – Final text of posting(s).
Third party (researcher asks another to distribute study information to potential participants)	• Describe these plans, including the relationship between the individual distributing study information and the potential participants. • Describe how any concerns related to privacy and undue influence will be addressed. **Submit** – Final text of information to be shared with potential participants.
Television or radio advertisements	Indicate which medium used and where they will be placed. **Submit** – Final content of the advertisement.

Unacceptable Recruitment Methods

- **Cold Calling** – A method in which a party, having no previous relationship with the participant, phones potential participants based on confidential information.

- **Use of Incentives, Finder's Fees or Bonuses** – Payments in exchange for referrals of potential participant or designed to accelerate recruitment.

- **Sharing Participant Names and Contact Information** – Researchers may not share names and/or contact information of previous research participants without those participant permission/consent to be contacted for future research.

- **Student Education Records** – Use of identifiable student information, other than directory information, for research purposes without either the student's consent (or parent's permission if student is under age 18) or receipt of an exception to FERPA granted by the Records Custodian of the institution holding the records. At UTK the records custodian is the Registrar.

- **Medical Records** – Unless the researcher is a potential participant's health care provider, researchers may not directly contact individuals by using confidential information. Patients must initiate contact unless there is documented permission from the patient that they agreed to be contacted for this purpose.

Training and Outreach Opportunities

Check out scheduled training sessions posted on ORE's Training and Workshops website as details become available.

IRB Metrics

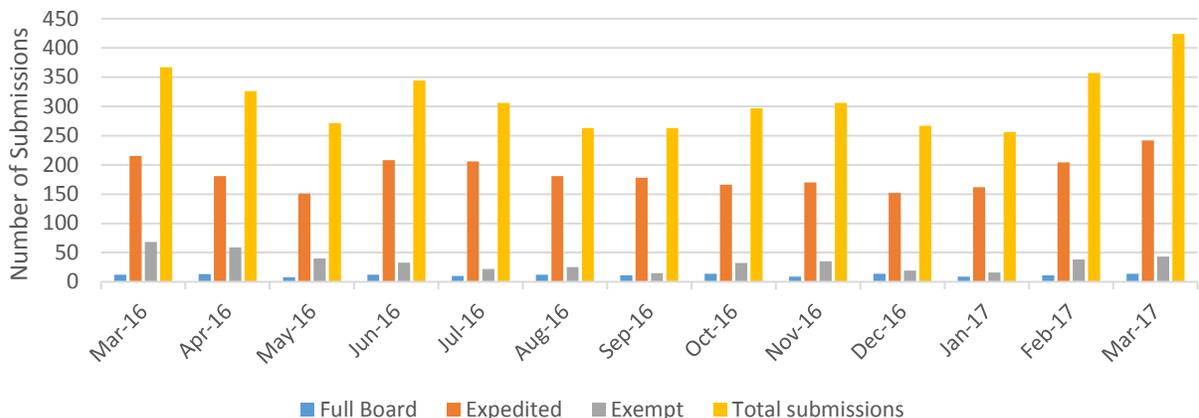## New Submissions

The charts below show the number of new submissions received by the IRB during the months of February and March 2017 compared to the number submissions received during the preceding 12 months.

Number of Submissions
February 2016 - February 2017
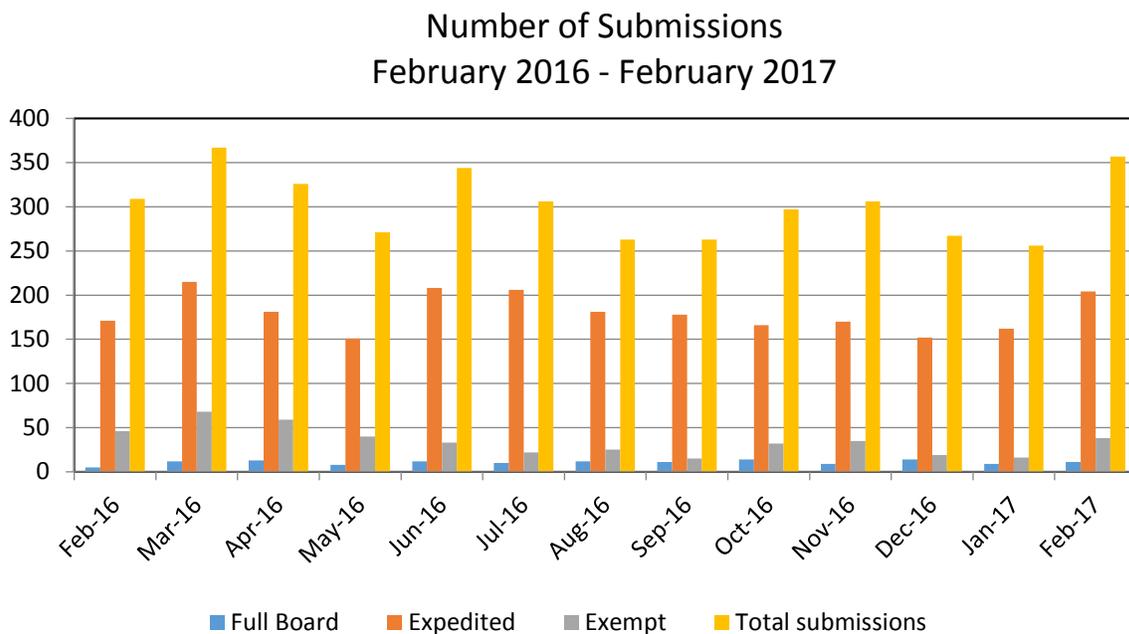
February 2017 – A total of 302 submissions were received compared to a total of 236 submission received in February 2016.
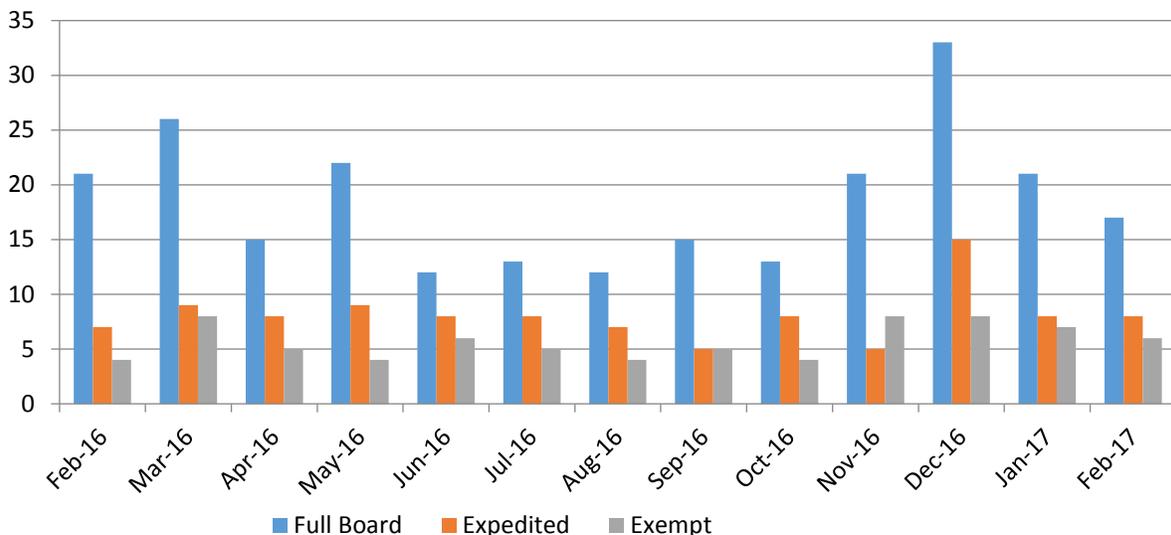
Number of Submissions
March 2016 - March 2017

March 2017 – A total of 424 submissions were received compared to a total of 367 received in March 2016.
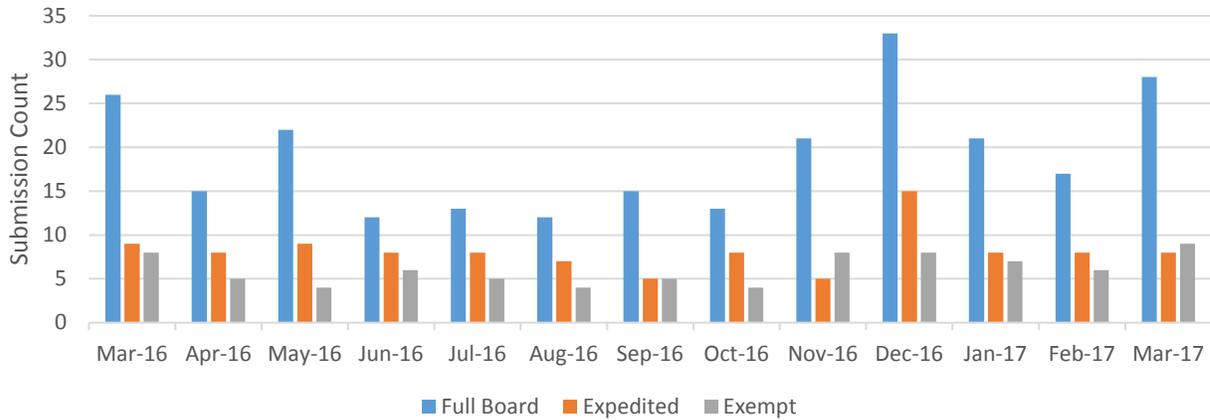
Turnaround Time Averages

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

Average IRB Turnaround Time
February 2016 - February 2017

February 2017 – Average review time reduced by nearly a week – from 10 days in February 2016 to 6 days in February 2017.
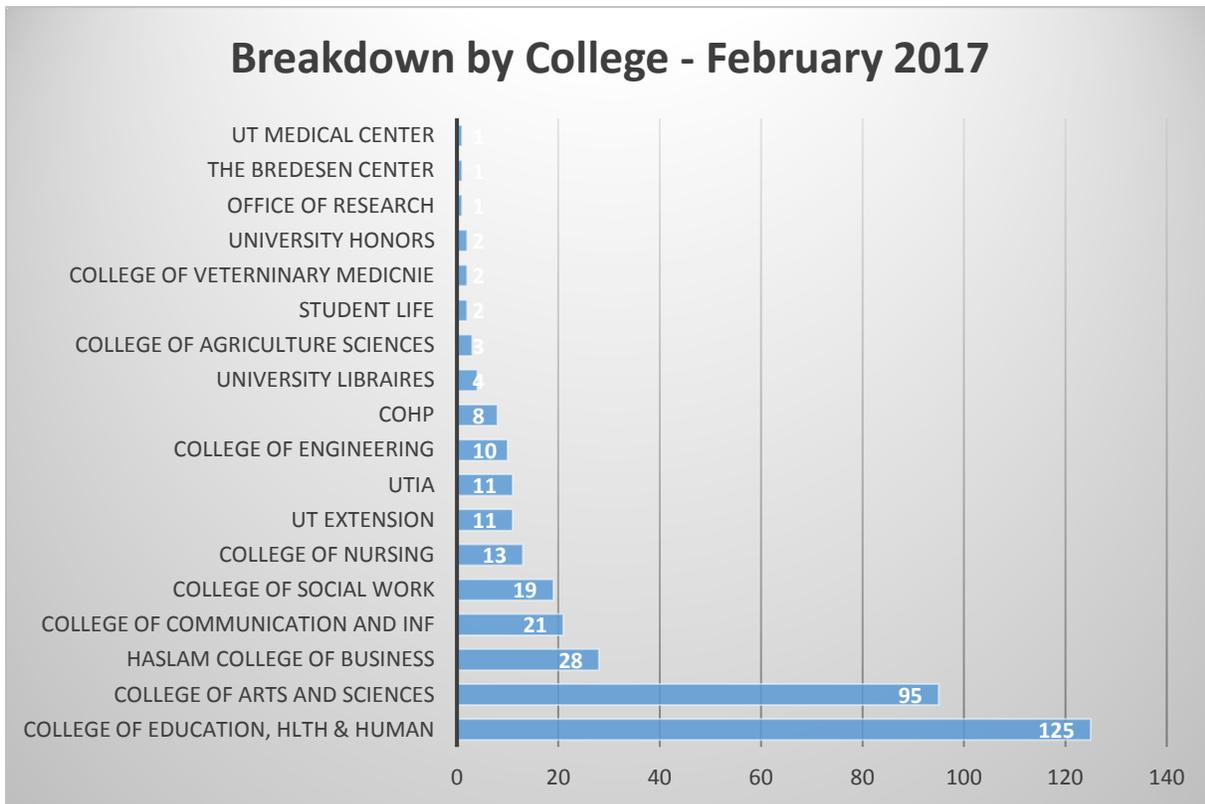
Average IRB Turnaround Time
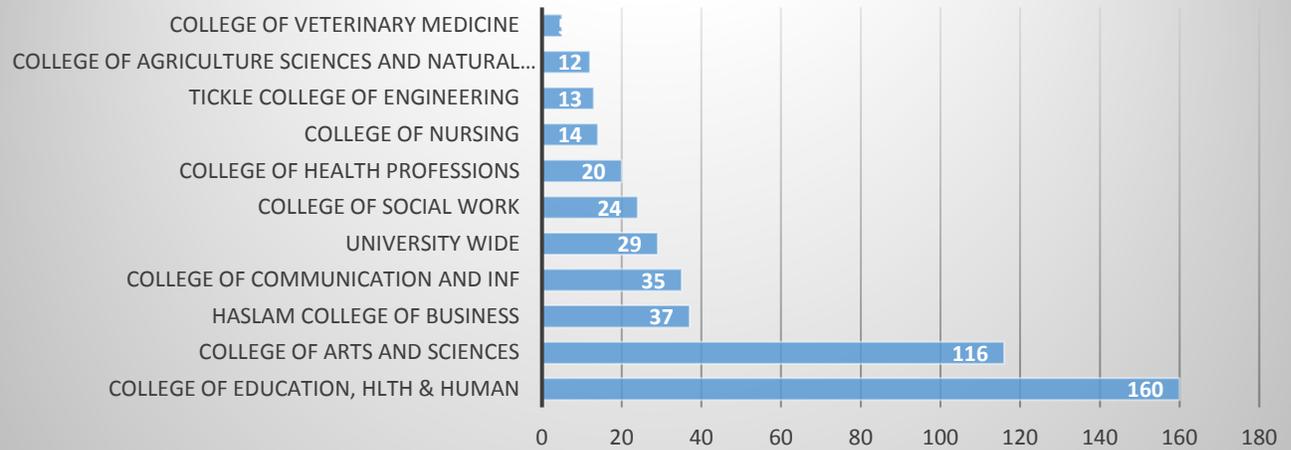**March 2016 - March 2017**

March 2017 – Average review turnaround time for all submissions during the month of March improved by numerous days – from 13 days in 2016 to 7 days in 2017. Both February and March review times demonstrate – the continuing trend of reduced turnaround time.

Submissions by College

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

Breakdown by College - February 2017

College	Count
UT MEDICAL CENTER	1
THE BREDESEN CENTER	1
OFFICE OF RESEARCH	1
UNIVERSITY HONORS	2
COLLEGE OF VETERNINARY MEDICNIE	2
STUDENT LIFE	2
COLLEGE OF AGRICULTURE SCIENCES	3
UNIVERSITY LIBRAIRES	4
COHP	8
COLLEGE OF ENGINEERING	10
UTIA	11
UT EXTENSION	11
COLLEGE OF NURSING	13
COLLEGE OF SOCIAL WORK	19
COLLEGE OF COMMUNICATION AND INF	21
HASLAM COLLEGE OF BUSINESS	28
COLLEGE OF ARTS AND SCIENCES	95
COLLEGE OF EDUCATION, HLTH & HUMAN	125

Breakdown by College - March 2017

College	Value
COLLEGE OF VETERINARY MEDICINE	5
COLLEGE OF AGRICULTURE SCIENCES AND NATURAL...	12
TICKLE COLLEGE OF ENGINEERING	13
COLLEGE OF NURSING	14
COLLEGE OF HEALTH PROFESSIONS	20
COLLEGE OF SOCIAL WORK	24
UNIVERSITY WIDE	29
COLLEGE OF COMMUNICATION AND INF	35
HASLAM COLLEGE OF BUSINESS	37
COLLEGE OF ARTS AND SCIENCES	116
COLLEGE OF EDUCATION, HLTH & HUMAN	160

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.