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NEWS

New IRB Vice Chair Named

Earlier this month Gina Owens, professor in the Department of Psychology, was named Vice Chair of the Institutional Review Board. Owens joins Collen Gilrane, IRB chair, and Tami Wyatt, IRB vice chair.

In addition to continuing as an active Board member, Owens will be an expedited (in-office) reviewer, serve on the IRB leadership team and will serve as acting chair when required. She has served on the UT IRB since 2015. She also conducts research requiring IRB approval providing her with both an understanding of the researcher perspective and an in-depth understanding of human research protection procedures.

Owens succeeds Marlys Staudt, associate professor of social work, who went on sabbatical earlier this summer after serving as IRB vice chair since 2015. Please join us in welcoming Dr. Owens to our IRB leadership team.

The GDPR is Here and May Affect Your Research

On May 25, 2018, the European Union (EU) [General Data Protection Regulation](#) (GDPR) became effective in the EU's 28 member states as well as Iceland, Liechtenstein, and Norway (members of the European Economic Area (EEA)). These new regulations provide privacy and security protections for personal data collected in these countries and may impact research involving human participants.

Currently, research that may be impacted by the EU GDPR will be reviewed on a case-by-case basis. In the near future, we will provide guidance on this topic. For now, some recommended resources on both the GDPR and the impact of the GDPR on human subjects research are listed below.

- UT Knoxville [Data Privacy Notice](#)
- UT System [European Union General Data Protection Regulation](#) resources webpage
- University of Pittsburgh [Human Research Protection Office](#)

“Who is my IRB Liaison?”

For study-specific or research-specific questions, contact your college/unit's IRB Liaison. Each college or unit has an assigned HRPP staff member. Find your assigned liaison by visiting the Contact Us page on our IRB website and scroll down to [Study or Research-Specific Questions](#).

Are You Developing a Mobile Health Application?

If you are creating or testing a health app for mobile devices, or just thinking about it, go to the [Mobile Health Apps Interactive Tool](#) to learn which federal laws may apply. If your mobile app will collect, create or share consumer information, there may be one or more federal laws that apply. The free resource is available at Federal Trade Commission's website ([ftc.gov](#)).

Requirement to Post Clinical Trial Consent Forms

The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form be posted on a publicly available federal website within a specific time frame. The consent form must have been used in enrolling participants in order to satisfy this new provision.

Currently, only two publicly available federal websites have been identified that satisfy this consent form posting requirement: [ClinicalTrials.gov](#) and a docket folder on [Regulations.gov](#) (Docket ID: HHS-OPHS-2018-0021). In the future, other federal websites may be identified that satisfy this clinical trial consent form posting requirement. HHS and other Common Rule departments and agencies are developing instructions and other materials providing more information to the regulated community about this posting requirement.

Researchers Planning to Conduct Social Behavioral Clinical Trials

NIH [announced](#) the availability of a new template for behavioral and social science interventions has been created to help investigators through the systematic development of a comprehensive clinical protocol. NIH also [released a request for public comments](#) on this template. Comments will be accepted until October 11, 2018.

AAHRPP Accreditation

The Office of Research and Engagement is seeking accreditation of UT's Human Research Protection Program (HRPP) by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) as part of its continuing efforts to advance program improvements, best practices and strengthen the university's research infrastructure.

Protecting research participants is the responsibility of everyone within an organization. To earn accreditation, HRPPs must meet rigorous standards for quality and protection. Organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement. As the "gold seal," AAHRPP accreditation offers assurances to research participants, researchers, sponsors, government regulators, and the general public that an HRPP is focused first and foremost on excellence.

To meet this goal, Robert Nobles, interim vice chancellor for research, formed the HRPP working group in October 2017. The working group was constituted to reflect UT's human subjects research community and is made up of representatives from each college, university-wide units (e.g., UT Libraries, Division of Student Life), the UT Institute of Agriculture, the

Research Council and is led by co-chairs Tami Wyatt, IRB vice chair, and Kristine Hershberger, director of the HRPP.

The group's diverse representation and researcher perspective is paramount to achieving our accreditation goals. Since its formation, the HRPP working group has met monthly, focusing on the first step of the accreditation process, an intensive self-assessment. This step involves a comprehensive examination of all UT policies, practices and procedures relating to its human subjects research enterprise, including the IRB and its infrastructure. This process helps us to identify gaps and opportunities for improvement for a more effective and efficient program.

We would like to take this opportunity to extend our gratitude to those contributing to this process and the improvement of our program. More information on accreditation and our progress towards it will be included in upcoming issues of our newsletter. To learn more about accreditation, please visit the [AAHRPP](#) website.

Regulatory Changes

Delayed until January 21, 2019

Previously expected to go into effect on July 19, 2018, a [recent final rule](#) from DHHS has delayed the general compliance date for the revised Common Rule to January 21, 2019. During these next few months leading up to this new implementation date, the HRPP and IRB will be issuing guidance on the overall transition plan, new procedures, new forms including new informed consent templates and education to prepare the UT research community.

Metrics

As part of our continued commitment to transparency and quality improvement, we offer the information below on a variety of IRB/HRPP activities.

Charts begin on page 5. For accessibility, tables containing the same data are included beginning on page 8.

Submissions

This metric measures the volume of activity associated with a study. Each submission is counted only once, even if it undergoes multiple rounds of review (returned for corrections, additional information, etc.). The chart below does not display the number of a submission type if <10. Total submission number is displayed above each column.

Submission: Researcher initiated activity associated with a study that includes the following types:

- New Study (NEW STUDY)
- Continuing Review (CR)
- Amendment (AMEND)
- Reportable New Information (RNI)
- Closure Report (CLOSURE REPORT)
- Miscellaneous (category not shown in chart, but included in total submission number)

Review Actions

This metric provides a more accurate look at the review workload (i.e., volume of reviews conducted).

Review Action: This metric measures the number of times that a submission is reviewed by the IRB and HRPP displayed by submission type. This metric does not include pre-reviews resulting in requests for corrections such as those related to routing issues.

Turn-around Time

Typically of greatest interest to the research community, this metric measures the time it takes for a round of review (i.e., review cycle) to be completed.

Round of Review (i.e., review cycle): measurement in **calendar days** from when the submission is received by the IRB until the time the IRB takes one of the following actions:

- Returned for corrections (typically routing problems/lack of departmental sign-off)
- Request for additional information/changes.
- Approval or determination (determination of exemption, etc.)

Ways to Reduce Turn-around Time

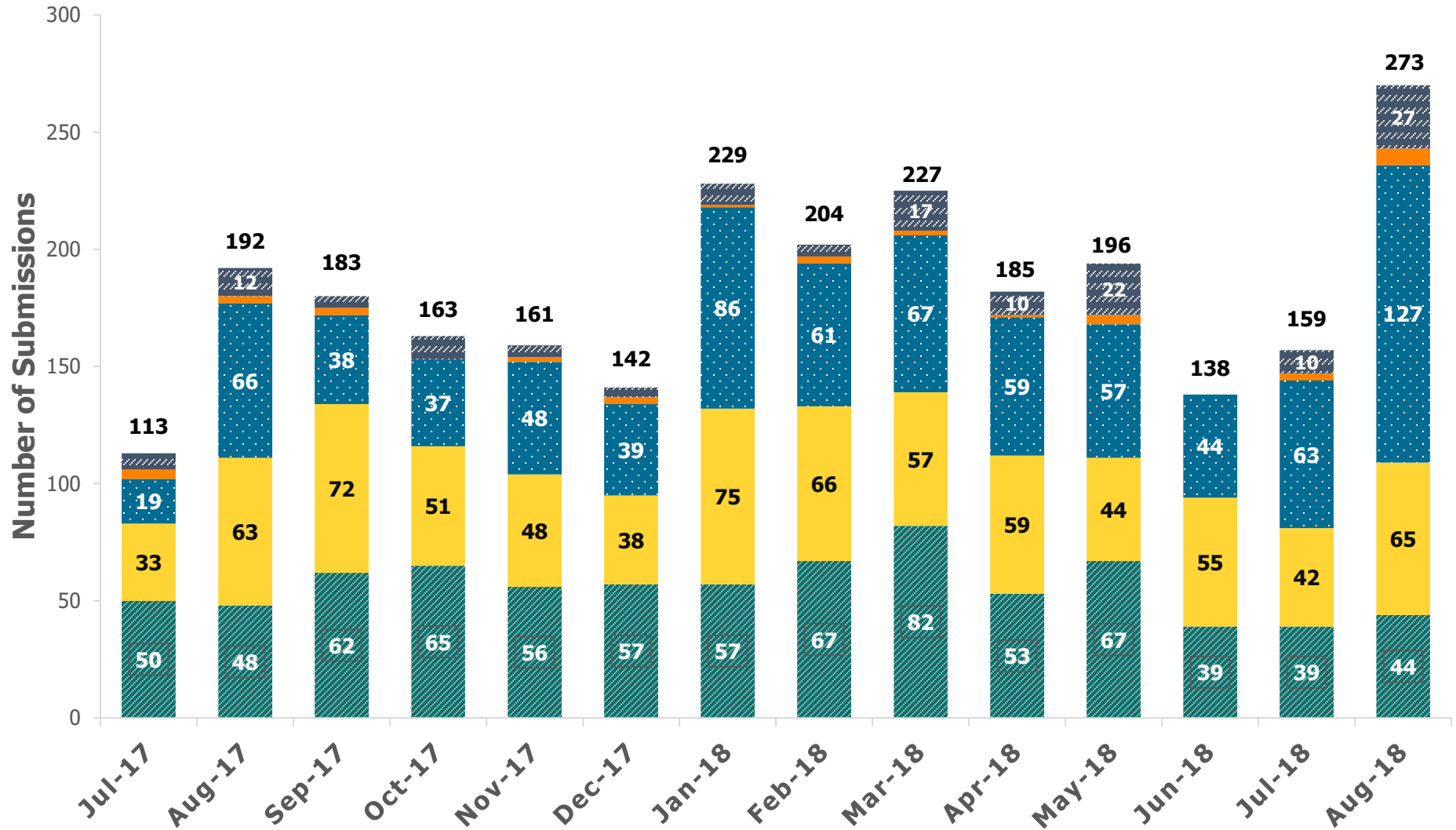
Turn-around time can depend on a variety of factors. Researchers can avoid some of the most common reasons for delays by ensuring applications are complete, including all materials, and contain consistent information both within the application itself and between the application and supporting materials (consent documents, etc.).

Total Submissions

by Month and Submission Type

July 2017 - August 2018

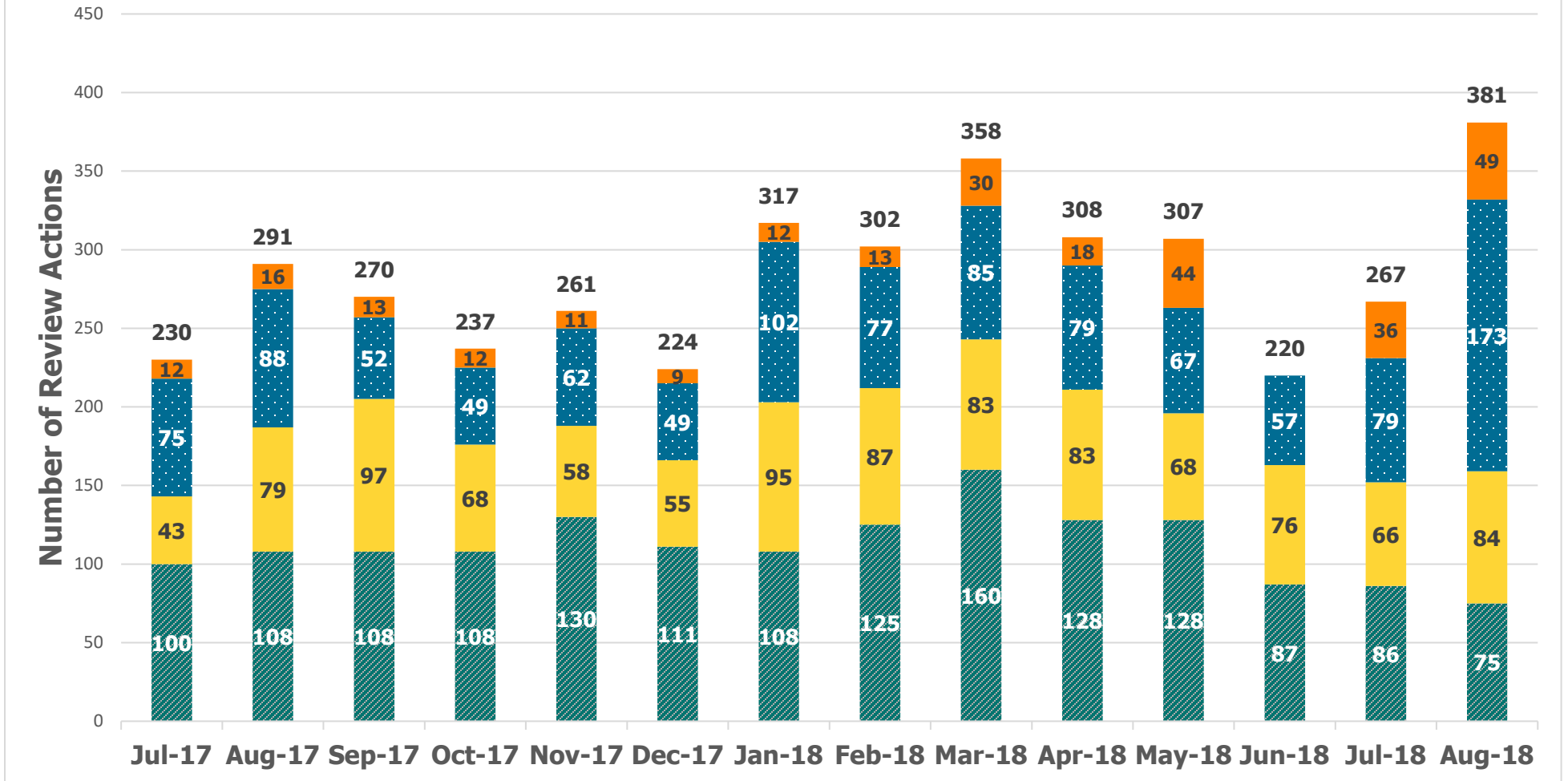
NEW STUDY AMEND CR RNI CLOSURE REPORT



Total Review Actions by Month and Submission Type

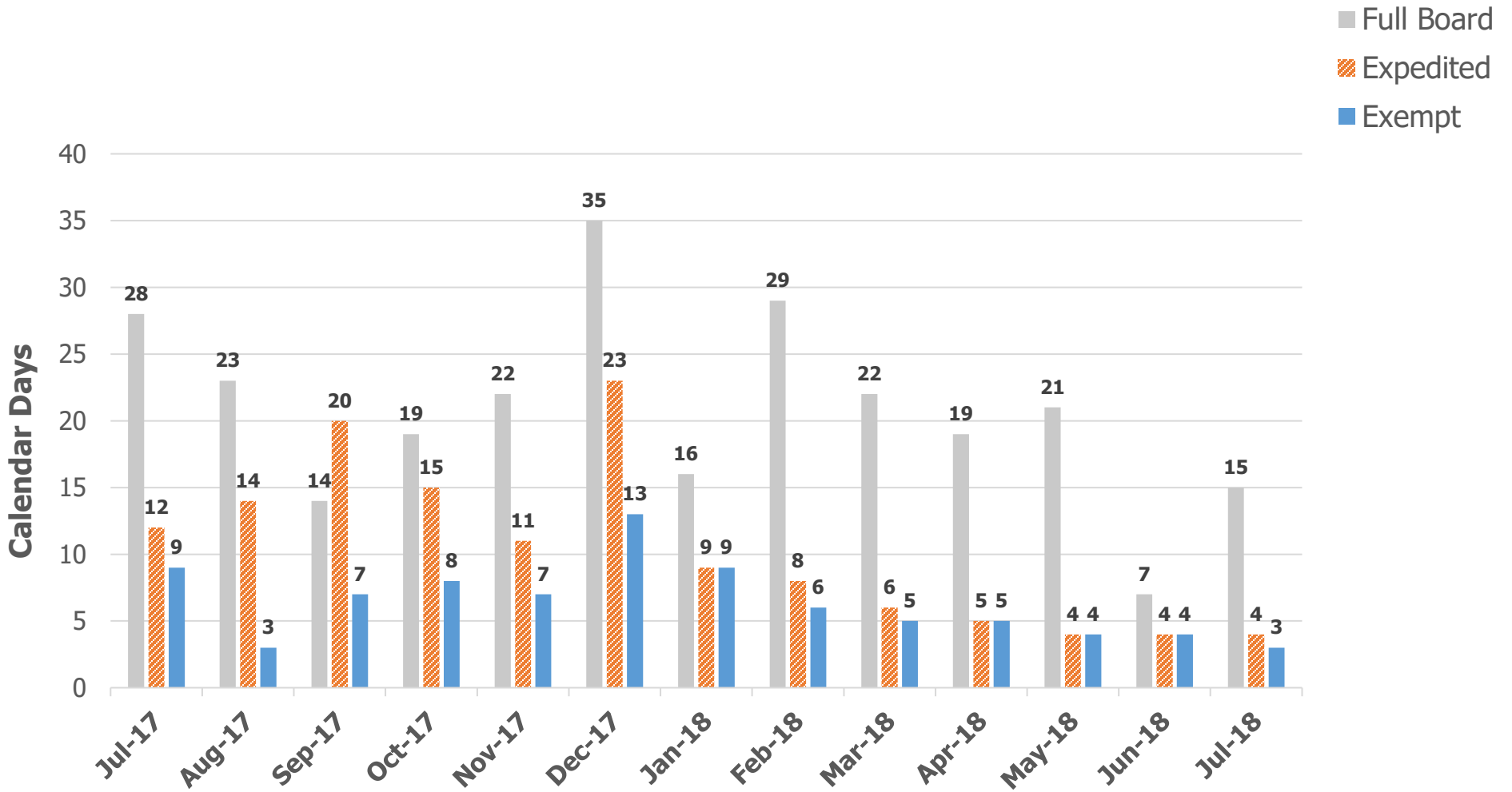
July 2017 - August 2018

NEW STUDY AMEND CR OTHER*



* Other includes the following submissions: reportable new information, closure reports, and miscellaneous

Turnaround Time Averages for New Applications in Calendar Days July 2017 - July 2018



Total Submissions by Month and Submission Type

July 2017 - August 2018

New Submissions	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18
NEW STUDY	50	48	62	65	56	57	57	67	82	53	67	39	39	44
AMEND	33	63	72	51	48	38	75	66	57	59	44	55	42	65
CR	19	66	38	37	48	39	86	61	67	59	57	44	63	127
RNI	4	3	3	0	2	3	1	3	2	1	4	0	3	7
CLOSURE REPORT	7	12	5	10	5	4	9	5	17	10	22	0	10	27
Total	113	192	183	163	161	142	229	204	227	185	196	138	159	273

Total Review Actions by Month and Submission Type

July 2017 - August 2018

Review Actions	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18
NEW STUDY	100	108	108	108	130	111	108	125	160	128	128	87	86	75
AMEND	43	79	97	68	58	55	95	87	83	83	68	76	66	84
CR	75	88	52	49	62	49	102	77	85	79	67	57	79	173
OTHER*	12	16	13	12	11	9	12	13	30	18	44	0	36	49
Total	230	291	270	237	261	224	317	302	358	308	307	220	267	381

* **Other** includes the following submissions: reportable new information, closure reports, and miscellaneous

Turnaround Time Averages for New Applications in Calendar Days

July 2017 - August 2018

Average TAT in Calendar Days	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18
Exempt	9	3	7	8	7	13	9	6	5	5	4	4	3
Expedited	12	14	20	15	11	23	9	8	6	5	4	4	4
Full Board	28	23	14	19	22	35	16	29	22	19	21	7	15