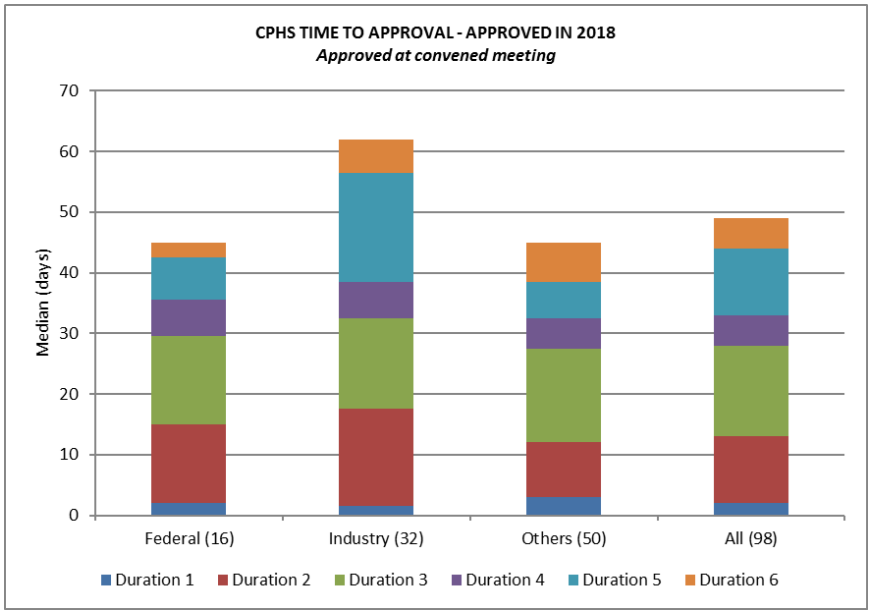
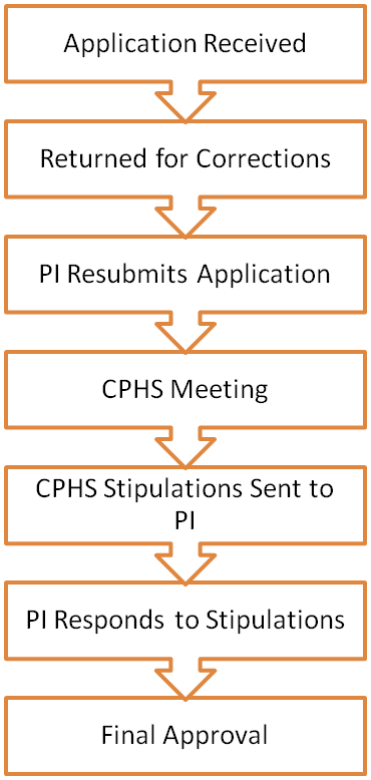
TIME TO APPROVAL—FULL BOARD ONLY





Duration 1 – Median time in days between the date the IRB office receives the application and the date the IRB office sends notification to the PI requesting changes.

***Duration 2 -** Median time in days between the date the IRB office returns the application for corrections to the PI and the date the PI re-submits a corrected application.

Duration 3 - Median time in days between the date the PI re-submits the application and the date the protocol is reviewed by the fully convened IRB.

Duration 4 - Median time in days between the IRB meeting date and the date the IRB sends stipulations to the PI.

***Duration 5 -** Median time in days between the date the IRB sends stipulations to the PI and the date that the PI submits responses to the stipulations.

Duration 6 - Median time in days between the date that a response to the stipulations is received by the IRB office and the date final approval is granted by the IRB with no contingencies remaining.

* Time with PI and study team

Acknowledgements: Thanks to Chunyan Cai, PhD, Assistant Professor, Internal Medicine—CCTS for data analysis.

UTHealth
The University of Texas
Health Science Center at Houston

REPORT TO FACULTY AND STAFF ON CPHS ACTIVITIES

-2018-

from

Anne Dougherty, MD
Vice President, Human Research Protection Program

Panel 1
Chair: Rebecca Lunstroth, JD
Vice Chair: Rita Swinford, MD
Coordinator: Stephanie Francisco, BA

Panel 2
Chair: Ben Barnett, MD
Vice Chair: George Delclos, MD, PhD
Sr. Coordinator: Stephanie Francisco, BA

Panel 3
Chair: Charles Miller, PhD
Vice Chair: Cathy Thompson, BSN, MPH
Coordinator: Vanessa Fuller, BS

Panel 4
Chair: Max Buja, MD
Vice Chair: Ralph Frankowski, PhD
Coordinator: Laura Lincoln, BS

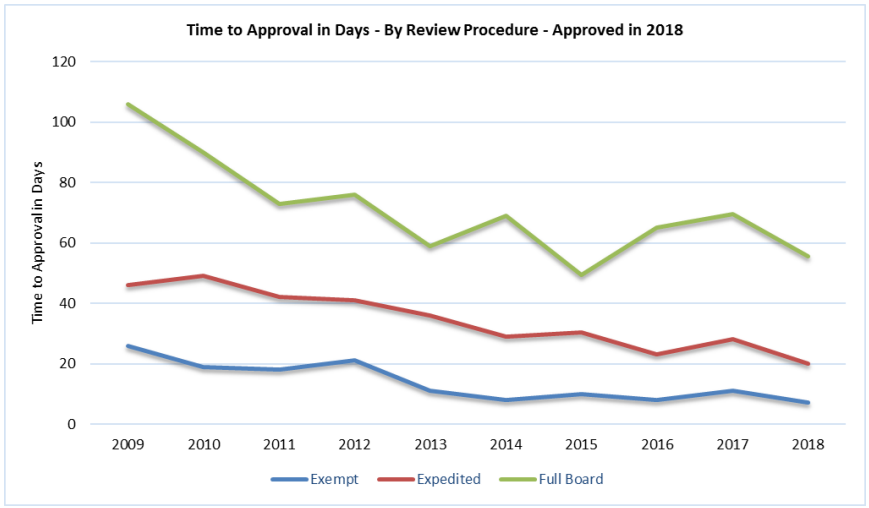
IRB Support Staff
Director: Cynthia Edmonds, MLA
Sr. IRB Coordinator: Sylvia Romo, BSBM
Sr. Systems Analyst: Barbara Legate, BS
Email: cphs@uth.tmc.edu
Website: www.uth.edu/cphs

Research Compliance
Director: Sujatha Sridhar, MBBS, MCE
Sr. Compliance Specialist: Elizabeth Gendel, PhD
Compliance Specialist: Shwetha Pazhoor, MS, CCRP
Graduate Assistant: Adeyinka Aladejare, MBBS
Email: clinicaltrials@uth.tmc.edu
Website: www.uth.edu/ctrc

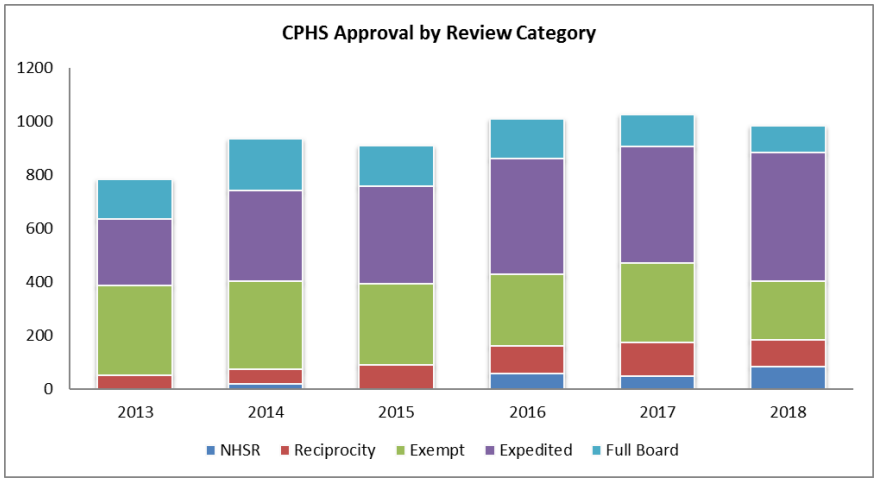
CPHS Office
6410 Fannin Street, Suite 1100
Phone: 713.500.7943
iRIS Support : 713.500.7960

Association for the Accreditation of Human Research Protection Programs, Inc.
Full Accreditation

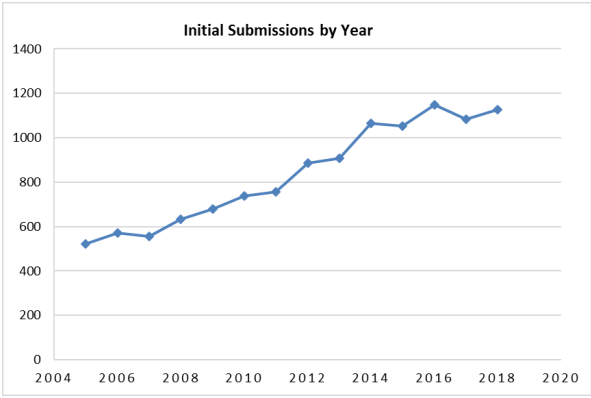
TIME TO APPROVAL: The median turnaround time (which is the time between initial submission of the protocol and final approval) has steadily decreased. This includes the time that the protocol was on the researcher's queue to address pre-screening concerns, such as missing documents and post review stipulations.



REVIEW CATEGORY: The UTHealth human research protection program has a continuous quality improvement component, which strives to improve the operation of the CPHS by providing an efficient level of regulatory review with emphasis on human subjects protection. In 2018, less than 10% of the approved studies were reviewed by full board as compared to almost 30% in 2009. (NHSR—Non Human Subjects Research)



NEW APPLICATIONS: The number of initial applications to CPHS has been increasing . From just over 500 new applications in the year 2005, CPHS received 1,127 initial applications in 2018 for review. In addition to these there were nearly 200 new submissions in the QI Registry.



ALL SUBMISSIONS: In 2018, CPHS reviewed and processed 13,564 submissions. Safety reports include reportable adverse events, DSMB reports and unanticipated problem reports. The 'others' category includes miscellaneous submissions.

CPHS FACULTY SURVEY: Researchers are invited to complete a survey when they receive an initial approval letter. Responses to the CPHS Faculty Survey, including free text responses, are shared with the CPHS Executive Committee each quarter.