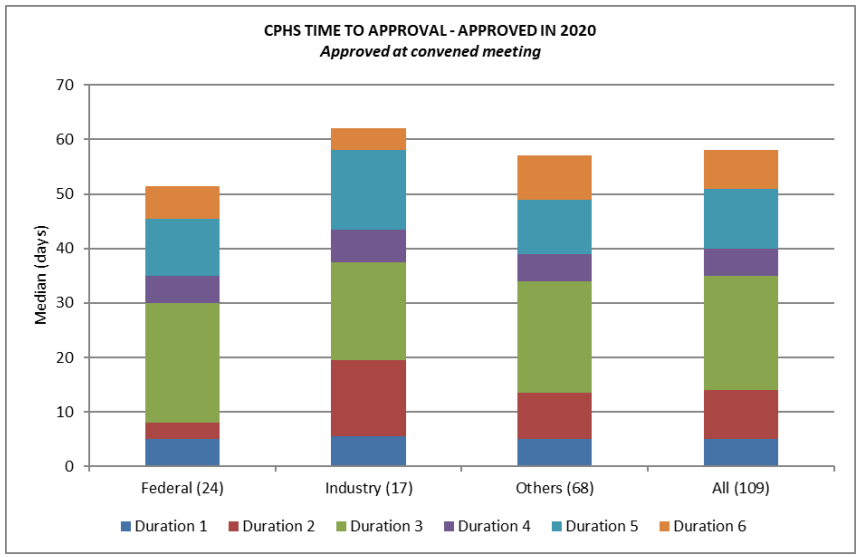
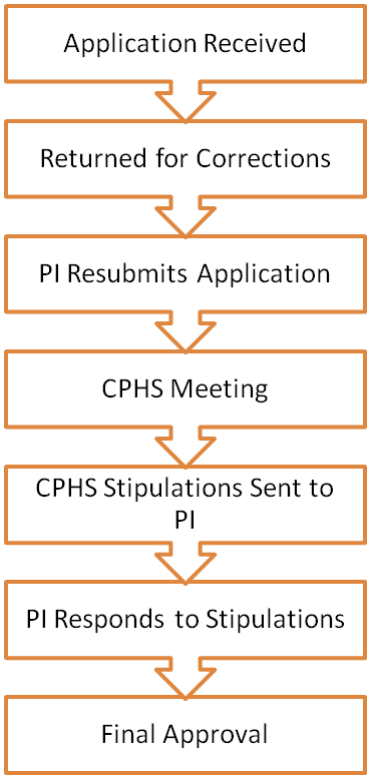
TIME TO APPROVAL—FULL BOARD ONLY





All durations are median time in days.

Duration 1 - IRB office application receipt date to date the IRB office returns the application to the PI for corrections.

Duration 2 - Date IRB office returns the application to the PI for corrections to date the PI re-submits a corrected application.*

Duration 3 - Date the PI re-submits the application to date the protocol is reviewed by the fully convened IRB.

Duration 4 - IRB meeting date to date the IRB sends stipulations to the PI.

Duration 5 - Date the IRB sends stipulations to the PI to date the PI submits responses to the stipulations.*

Duration 6 - Date the PI submits responses to final approval date.

* Duration 2 and 5 are time with PI and study team

Acknowledgements: Dr. Manouchehr Hessabi, MD, MPH, Internal Medicine-CCTS for data analysis.

UTHealth
The University of Texas Health Science Center at Houston

REPORT TO FACULTY AND STAFF ON CPHS ACTIVITIES

-2020-

from

Anne Dougherty, MD
Vice President, Human Research Protection Program

Panel 1
Chair: Rebecca Lunstroth, JD
Vice Chair: Rita Swinford, MD
Coordinator: Alba Zeigler, BS, CPhT

Panel 2
Chair: Deborah Brown, MD
Vice Chair: George Delclos, MD, PhD
Sr. Coordinator: Chandni Chaudhari, MD

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

Panel 4
Chair: Max Buja, MD
Vice Chair: Joy Schmitz, PhD
Coordinator: Laura Lincoln, BS

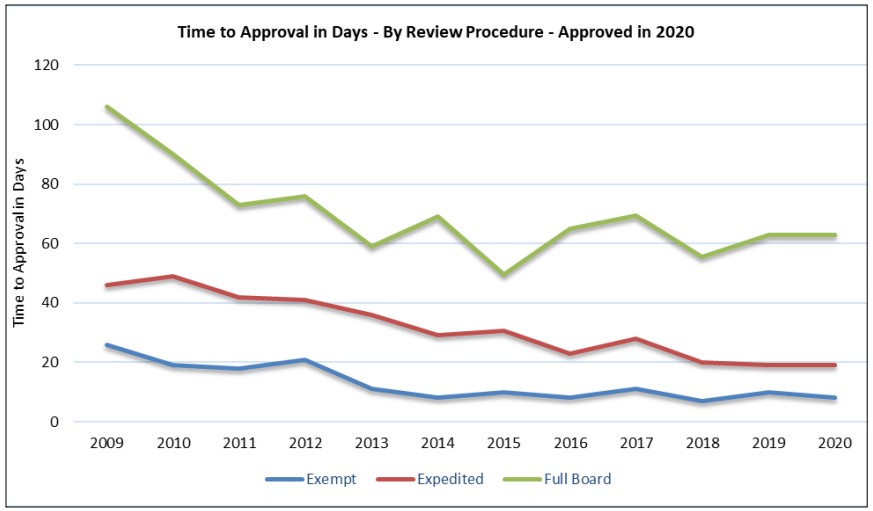
IRB Support Staff
Director: Cynthia Edmonds, MLA
Sr. IRB Coordinator: Sylvia Romo, BSBM
Sr. Systems Analyst: Barbara Legate, BS
Email: cphs@uth.tmc.edu
Website: www.uth.edu/cphs

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

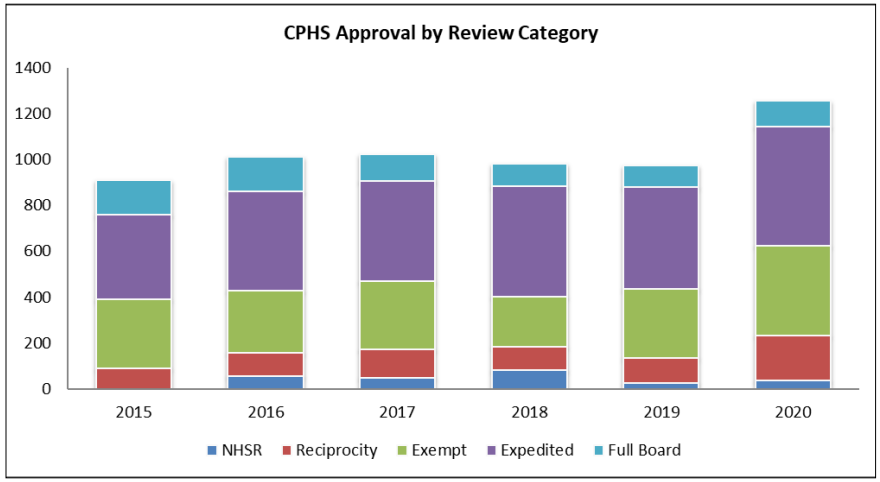
CPHS Office
6410 Fannin Street, Suite 1100
Phone: 713.500.7943
iRIS Support : 713.500.7960

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 over the years. Turnaround time includes the time the protocol was on the researcher's queue to address pre-screening concerns, such as missing documents and post-review stipulations.

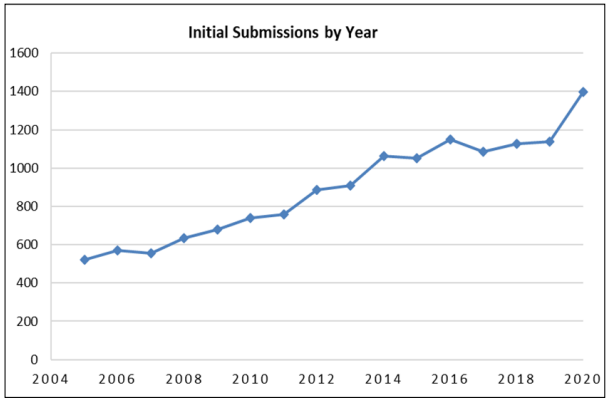


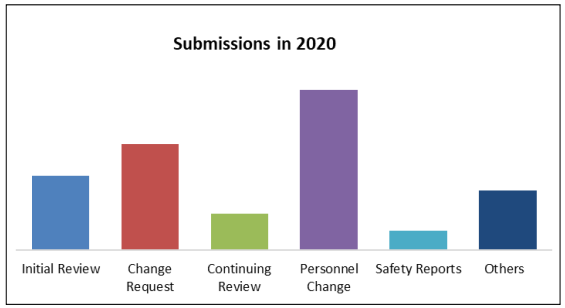
REVIEW CATEGORY: The UTHealth Human Research Protection Program has a continuous quality improvement component, which strives to improve the operation of CPHS by providing an efficient level of regulatory review and minimizing regulatory burdens while emphasizing protection of human subjects. In 2020, less than 10% of approved studies were reviewed by full board compared to almost 30% in 2009.



(NHSR—Non Human Subjects Research)

NEW APPLICATIONS: The number of initial applications to CPHS markedly increased in 2020, with CPHS receiving 1,397 initial applications for review, about three times the amount received in 2005. Additionally, in 2020 there were nearly 200 new submissions to the Quality Improvement Registry.





ALL SUBMISSIONS: In 2020, CPHS reviewed and processed 11,717 submissions in total. Safety reports include reportable adverse events, DSMB reports, and unanticipated problem reports. The 'Others' category includes miscellaneous submissions.

CPHS FACULTY SURVEY: When researchers receive an outcome letter from CPHS, they are invited to complete the CPHS Faculty Survey. Responses to the survey, including free text responses, are shared with the CPHS Executive Committee each quarter. The responses are helpful in continuous quality improvement of CPHS processes.