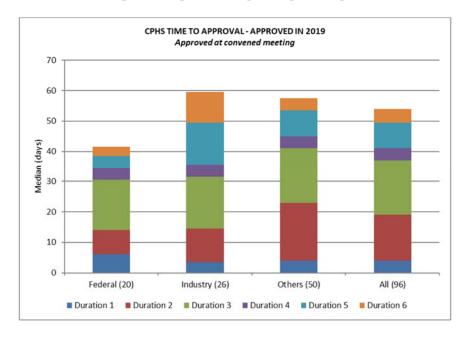
TIME TO APPROVAL—FULL BOARD ONLY



Application Received

Returned for Corrections

PI Resubmits Application

CPHS Meeting

CPHS Stipulations Sent to
PI

PI Responds to Stipulations

Final Approval

All durations are median time in days

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

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

Duration 3 - Date PI re-submits the application to the 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 that the PI submits responses to the stipulations.*

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

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



REPORT TO FACULTY AND STAFF ON CPHS ACTIVITIES

-2019-

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

Panel 3

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

Panel 2

Chair: Deborah Brown, MD
Vice Chair: George Delclos, MD, PhD
Sr. Coordinator: Jasmine Rosario

Panel 4

Chair: Max Buja, MD
Vice Chair: Kristofer Charlton-Ouw, MD
Coordinator: Laura Lincoln, BS

Research Compliance

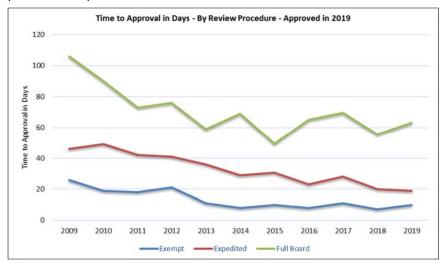
Director: Sujatha Sridhar, MBBS, MCE
Sr. Compliance Specialist: Elizabeth Gendel, PhD
Compliance Specialist: Shwetha Pazhoor, MS, CCRP
Research Assistant: Jessica Martinez, BS
Email: clinicaltrials@uth.tmc.edu
Website: www.uth.edu/ctrc

CPHS Office

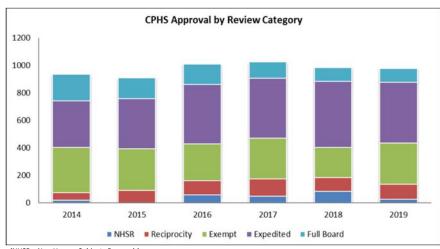
6410 Fannin Street, Suite 1100 Phone: 713.500.7943 iRIS Support: 713.500.7960



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.

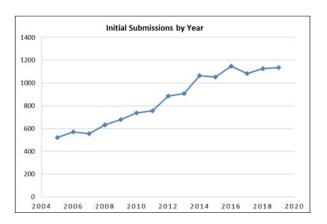


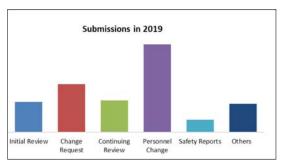
REVIEW CATEGORY: The UTHealth human research protection program has a continuous quality improvement component, which strives to improve the operation of CPHS by providing an efficient level of regulatory review with emphasis on human subjects protection and minimizing regulatory burdens. In 2019, less 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 initial new applications in the year 2005, CPHS received 1,137 initial applications in 2019 for review. In addition to these there were nearly 200 new submissions in the Quality Improvement Registry.





ALL SUBMISSIONS: In 2019, CPHS reviewed and processed 12,077 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 the CPHS Faculty Survey when they receive an outcome letter from CPHS. Responses to the survey, including free text responses, are shared with the CPHS Executive Committee each

