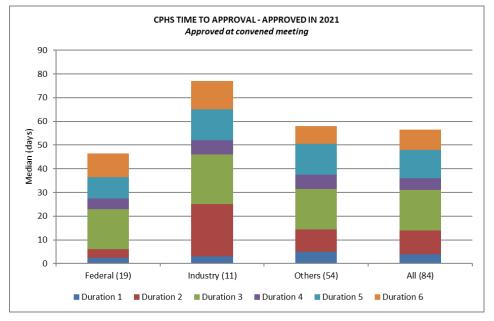
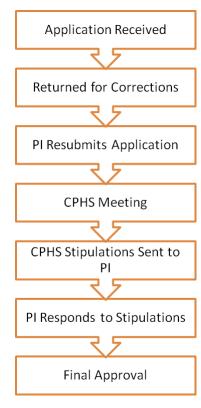
TIME TO APPROVAL—FULL BOARD ONLY





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 date of final approval .

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



REPORT TO FACULTY AND STAFF ON CPHS ACTIVITIES

-2021-

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

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

Panel 2

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

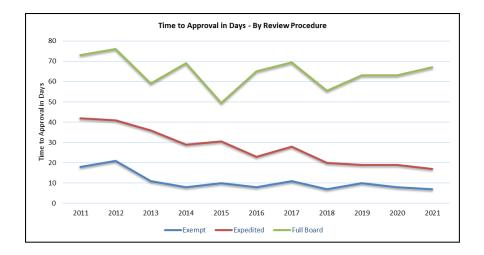
Director: Cynthia Edmonds, MLA Sr. IRB Coordinator: Sylvia Romo, BSBM Sr. Systems Analyst: Barbara Legate, BA Email: cphs@uth.tmc.edu Website: www.uth.edu/cphs Research Compliance Director: Sujatha Sridhar, MBBS, MCE Assistant Director: Elizabeth Gendel, PhD Sr.Compliance Specialist: Shwetha Pazhoor, MS, Compliance Specialist : Jessica Martinez, MPH 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

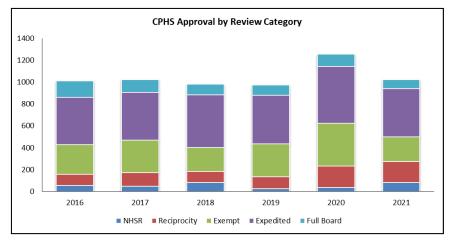


Acknowledgements: Dr. Manouchehr Hessabi, MD, MPH, Internal Medicine-CCTS for data analysis.

TIME TO APPROVAL: The median turnaround time (which is the time between initial submission of the protocol and final approval) has held steady for the past few 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.

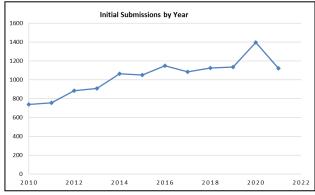


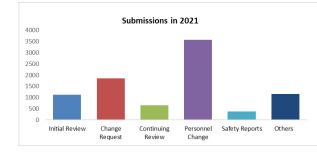
REVIEW CATEGORY: The UTHealth Human Research Protection Program has a continuous quality improvement component, which strives to improve the operation of CPHS by providing an efficient level of regulatory review and minimizing regulatory burdens while emphasizing protection of human subjects. In 2021, less than 10% of approved studies were reviewed by full board compared to almost 30% in 2009.



(NHSR-Non Human Subjects Research)

NEW APPLICATIONS: In 2021, CPHS received 1,122 initial applications for review. Additionally, in 2021 there were over 340 new submissions to the Quality Improvement Registry.





ALL SUBMISSIONS: In 2021, CPHS reviewed and processed 12,046 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. The responses are helpful in continuous quality improvement of CPHS processes.

