HUMAN SUBJECTS PROTECTION PROGRAM LEADERSHIP AND SUPPORT STAFF

Vice President, HRPP: Anne Dougherty, MD
Director: Cynthia Edmonds, MLA

Panel 1
Chair: Richard Kirkeeide, PhD
Vice Chair: Kathleen Kennedy, MD
Sr. Coordinator: Sylvia Romo, BSBM

Panel 2
Chair: John Ribble, MD
Vice Chair: Ralph Frankowski, PhD
Coordinator: Audrey Ester, PhD

Panel 3
Chair: F. Gerard Moeller, MD
Vice Chair: Catherine Thompson, RN, MPH
Coordinator: Deborah Dowlin, MA, CCRP

Panel 4
Chair: Max Buja, MD
Vice Chair: Francisco Orejuela MD
Coordinator: Cristal Casnova, BS

Support Staff
Sr. Business Systems Analyst : Barbara Legate, BS
Sr. Staff Assistant: Paula Alexander
Graduate Assistant: Spyridon Moraros, BS

CPHS Office
6410 Fannin, Suite 1100, Houston, Texas 77030
Phone: 713.500.7943
iRIS Support : 713.500.7960
Www.uth.tmc.edu/orsc
Email: cphs@uth.tmc.edu

Research Compliance, Education and Support Services
Director: Sujatha Sridhar, MBBS, MCE
Regulatory Specialist: Thea Troetscher, RN
Regulatory Specialist: Marilyn Perry, CCRP
Training Coordinator: Catrina Coverdale, BS, CCRP
Graduate Assistant: Ngozi Okafor, MPH
www.uth.tmc.edu/ctrc
Email: clinicaltrials@uth.tmc.edu

UTHealth™
The University of Texas
Health Science Center at Houston

from

VICE PRESIDENT FOR HUMAN RESEARCH PROTECTIONS

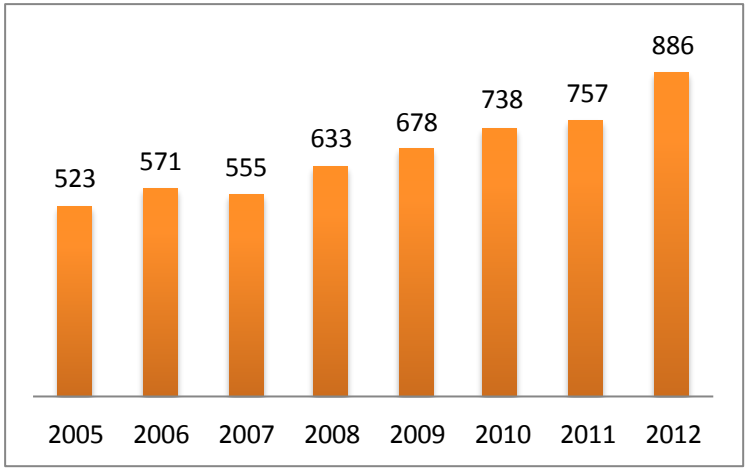
REPORT TO FACULTY AND STAFF ON CPHS ACTIVITIES

- 2012-

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

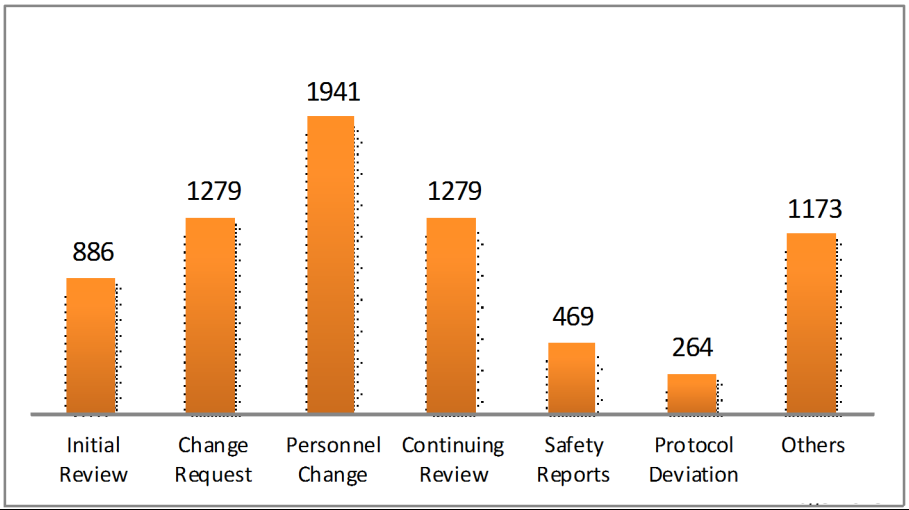
NEW PROTOCOLS SUBMITTED IN 2012

The number of initial applications to CPHS has been steadily increasing since UT Houston has been using iRIS. From just over 500 new applications in 2005, in the year 2012, CPHS received over 850 initial applications for review and approval.



CPHS SUBMISSIONS IN 2012

All initial and continuing applications are submitted by the research team via iRIS. In the year 2012, the CPHS office received over 7,000 submissions. As part of the quality improvement initiative, the number of safety reports submitted to CPHS was reduced from over 3000 reports in 2010 to 630 reports in 2011 and 469 in 2012.



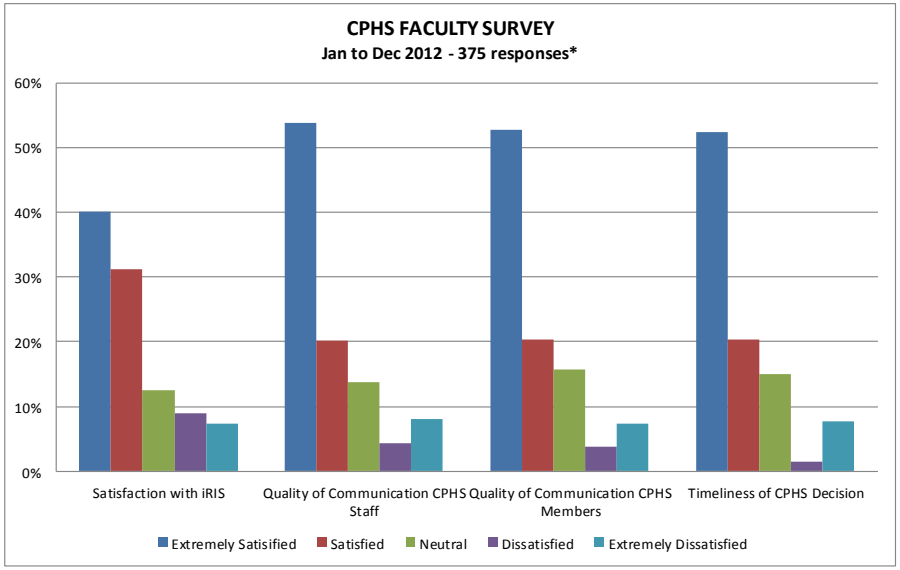
CPHS FACULTY SURVEY

The CPHS Executive Committee initiated a faculty survey in July 2011 to seek feedback from the research community on CPHS review and approval process. A link to the survey is included with the notice of outcome letters that are sent via iRIS . We received a total of 375 responses between Jan 1, 2012 and Dec 31, 2012.

This survey has 18 questions grouped into various categories including questions on the electronic IRB system, interaction with CPHS staff, overall CPHS review and approval process, hospital and sponsored projects review, protocol development and recruitment.

The survey is designed to be anonymous so we cannot be sure who is completing them. However the invitation to complete the survey is addressed to the Principal Investigator.

Over 70% of the respondents expressed their satisfaction with the electronic IRB system. About 63% of the respondents had completed the CPHS application themselves on iRIS while the rest of them stated that the application was completed in collaboration with a research coordinator.



The CPHS executive committee reviews the narrative comments and feedback when working policy and process changes as part of the HRPP QI initiative. Some of the areas that the CPHS is working on are listed on Page 6 of this report.

Researchers and research staff are invited to share their comments, feedback and concerns about the human research protection program via the survey or by writing to clinicaltrials@uth.tmc.edu.

HRPP QUALITY IMPROVEMENT

The CPHS Executive Committee launched the HRPP Quality Improvement initiative in 2010 with the objective of reducing regulatory burdens while enhancing human research protections.

QI Initiatives in 2012

Commercial IRB – In response to requests from faculty for an option to rely on another IRB to reduce duplicative reviews and hasten the review and approval process, UT Houston has signed a reliance agreement with Chesapeake Research Review Inc. Researchers participating in an industry sponsored multi-center clinical trial, can choose to rely on either UT Houston CPHS or on Chesapeake IRB.

Departmental Review— CPHS review process can be more meaningful if research proposals have been thoroughly vetted for feasibility and scientific merit by a departmental review process. The HRPP is working with various departments to help set up a process for departmental review.

iRIS Application – Based on feedback from a task force of iRIS users, the application has been revised to make it more user-friendly. Several steps that did not contribute to the CPHS review process were eliminated and the application itself has been shortened and several questions were reworded to make them clearer.

Upcoming QI Initiatives in 2013

Reciprocity Agreement with BCM IRB – In response to requests from faculty for an option to rely on one IRB for collaborative research with Baylor College of Medicine, UTHealth and BCM IRBs are negotiating a reciprocity agreement.

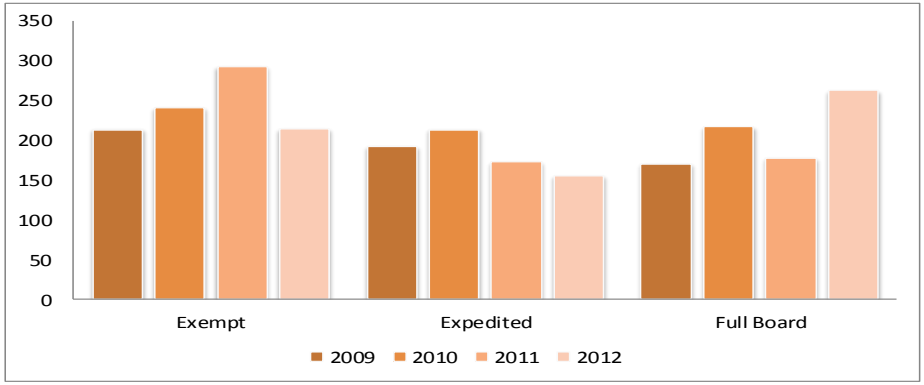
Center for Clinical Investigation— The Internal Medicine department is restructuring the research support infrastructure to provide dedicated central resources for clinical researchers in internal medicine.

Clinical Trial Management System — UTHealth is participating in a shared services project with UTHSC San Antonio, UT Medical Branch and UT Tyler. This project will involve implementing Velos, a clinical trial management system. The estimated timeline for implementation at UTHealth is fall of 2014.

Medicare Coverage Analysis— UTHealth Research Compliance is working with Center for Innovation and Research Institute at Memorial Hermann in developing a process to conduct formal Medicare coverage analysis for clinical trials. This process will begin in Internal Medicine in early 2013 and the plan is for it to dovetail with the CTMS project will full implementation in fall of 2014.

NEW PROTOCOLS AP-

In February 2012, UTHealth offered investigators an option to submit industry sponsored multicenter clinical trials to Chesapeake IRB for review and approval. From February 2012 to December 2012, 52 applications were submitted to Chesapeake IRB. In 2012, 581 total applications were approved by CPHS and Chesapeake of which 37% were approvals for exemption requests, 26% were reviewed and approved by the expedited procedure and the remaining 36% were approved by the full board.



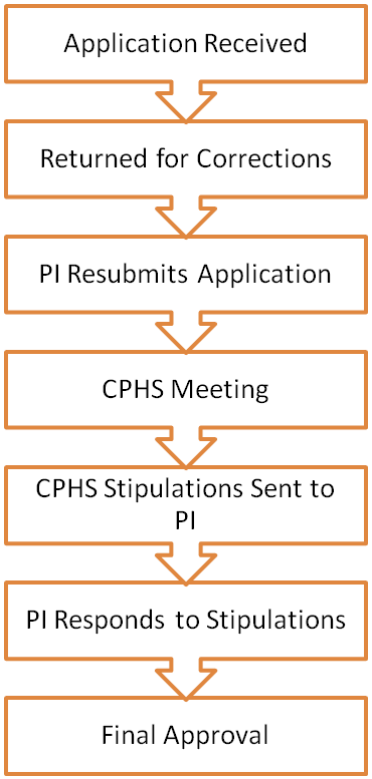
REVIEW TIME

The median turnaround time for full board reviews came down dramatically from 2009 to 2011 and has plateaued since then. Applications reviewed by the expedited review process have remained more or less constant.

The median turnaround time for the three types of review from submission to final approval (in days) :

	2009	2010	2011	2012
Exempt	26	19	18	21
Expedited	46	49	42	41
Full Board	106	90	73	76
Commerical IRB	-	-	-	42

TURNAROUND METRICS



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.

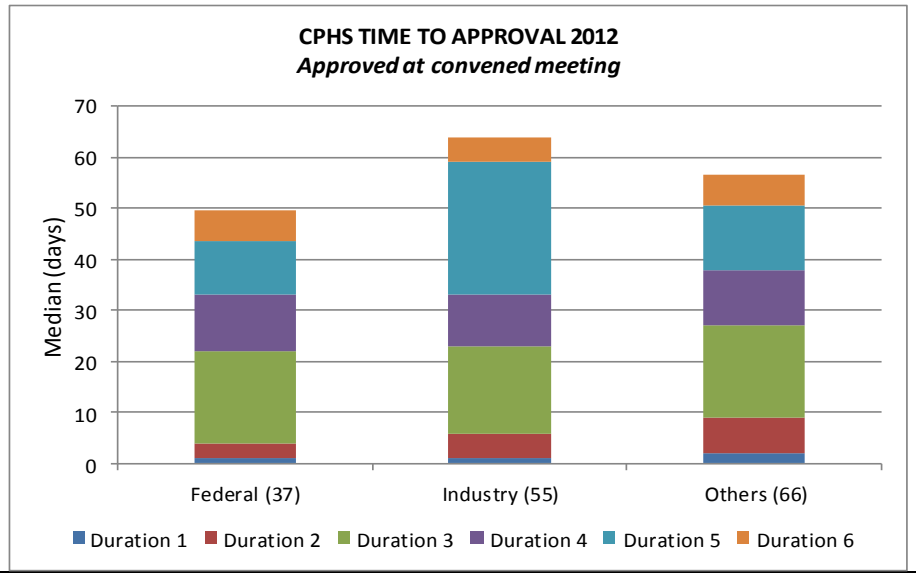
Duration 2 - Median time in days between the date the IRB office returns the application for corrections to PI and the date the PI re-submits a corrected application.

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 response to stipulations is received by the IRB office and the date of final approval granted by the IRB with no contingencies remaining.



STRATEGIES TO REDUCE TURNAROUND TIME

Only 75% of the submissions were accepted as submitted, about 38% were returned for correction one time, 20% were returned twice and the rest were returned three or more times.

COMMON ISSUES	STRATEGIES
Consent document does not meet regulatory requirements	• Use CPHS Consent Template to develop consent documents. • Run readability tests- www.uth.tmc.edu/ctrc/consentdevelopment.html
Inconsistencies in submission	• Ensure consistency between documents- consent, protocol, data collection tools etc.
Incomplete submission	• Key study personnel should have current human subjects training. • Key study personnel should have current CVs in their profile. • Submit appropriate HIPAA and hospital forms.
Insufficient information in protocol	• For investigator-initiated trials ensure all the required information is present. • Refer to or use protocol templates available at www.uth.tmc.edu/ctrc/protocoldevelopment.html
Clarification of information	• For particularly complex protocols, upon receipt of subcommittee assignment notice via iRIS, contact subcommittee members by email to offer clarification. • Respond promptly to request for more information and clarification.

RESOURCES FOR RESEARCHERS AND RESEARCH STAFF

TRAINING

Lets Talk Ethics - 11:30 am - 1:00 pm 2nd Thursday every month.
Clinical Research Education - 3 day course twice a year every spring and fall.
Study Coordinator Forum- 11:30 am - 1:00 pm every fourth Tuesday.
Clinical Research Orientation - 8 am to 1 pm four times a year.
iRIS Training Basic- www.uth.tmc.edu/orsc/training/iRISTrainReg.html

RESOURCES

CPHS Policies and Procedures- www.uth.tmc.edu/orsc/policies/index.html
CPHS Resources- www.uth.tmc.edu/orsc/resources.html
Consent Resources- www.uth.tmc.edu/ctrc/consentdevelopment.html
Study Management- www.uthouston.edu/ctrc