HUMAN SUBJECTS PROTECTION PROGRAM LEADERSHIP AND SUPPORT STAFF

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

Panel 3
Chair: F. Gerard Moeller, MD
Vice Chair: Catherine Thompson, RN, MPH
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Panel 4
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FROM VICE PRESIDENT FOR HUMAN RESEARCH PROTECTION

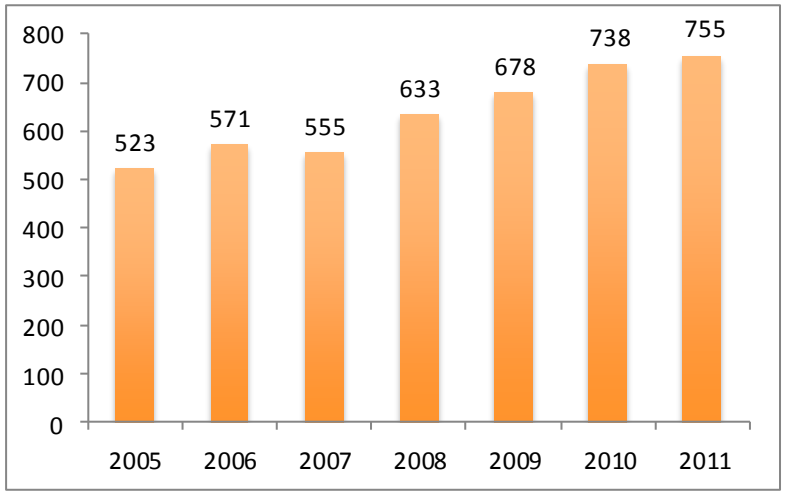
REPORT TO FACULTY AND STAFF ON CPHS ACTIVITIES

- 2011-

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

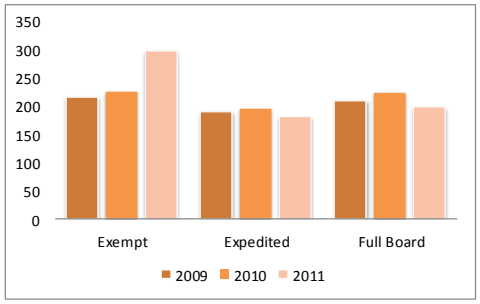
NEW PROTOCOLS

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 750 initial applications for review and approval.



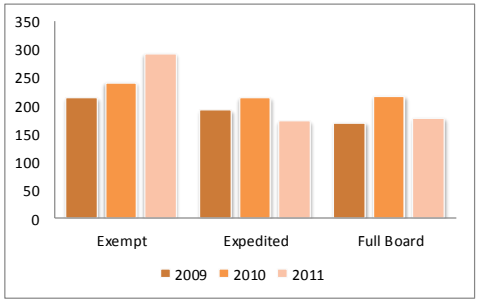
NEW PROTOCOLS SUBMITTED

The number of new protocols submitted to CPHS for review and approval has been steadily increasing. There was a substantial increase in the number of exemption requests in 2011.



NEW PROTOCOLS APPROVED

There was an increase in the number of exemptions approved in 2011 and decrease in the number of protocols approved under expedited and full board reviews.



HRPP QUALITY IMPROVEMENT—2012 INITIATIVES

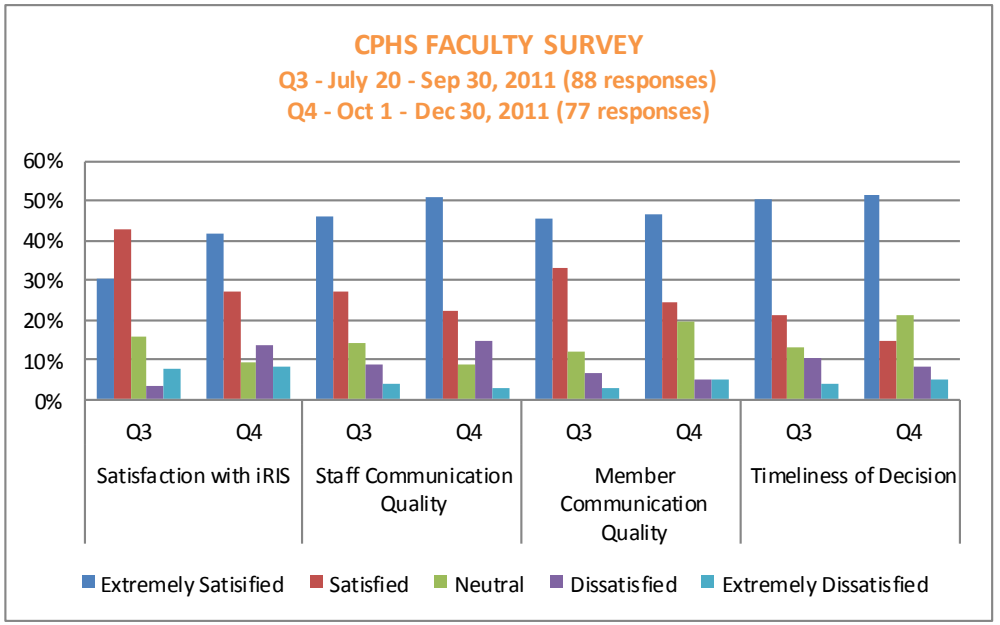
The CPHS Executive Committee will continue to evaluate the human research protection program and recommend improvements. Some of the initiatives available in 2012 are:

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.

CPHS FACULTY SURVEY

The CPHS Executive Committee initiated a faculty survey in July 2011 to seek feedback from the research community on CPHS processes. A link to the survey is included with the notice of outcome letters from CPHS.



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 2011

More Frequent CPHS Meetings - The time to approval for full board studies was reduced from 106 days in 2009 to 90 days in 2010 by re-engineering the committee composition to have 4 IRB Panels. Each panel meets once a month on the 1st to 4th Fridays.

CPHS Faculty Survey – In July 2011, the CPHS Faculty Survey was launched to give faculty an opportunity to provide feedback about their CPHS experience. Results from this survey have been very encouraging. The human subjects protection program looks forward to receiving more comments and suggestions in the future to help improve the program.

Simplifying Consent Documents - To reduce the number of consent documents to keep track of while conducting research involving children, CPHS will no longer require separate assent forms for younger children and adolescents. For research involving children, only one assent form needs to be submitted. The new assent template is available on the CPHS website. In response to requests from the research community, CPHS staff have published new consent document templates that include HIPAA language.

Restructuring Research Support Services: In order to provide more efficient, effective, and seamless service to the UT Houston research community, several functions previously carried out by different offices/units have been re-organized and consolidated under the Office of Research Compliance, Education and Support Services. "Education" and "Service" are linked with "Compliance" in this new organizational structure to indicate the philosophy that faculty and staff training and support, not simply monitoring activities, are central to its mission.

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.

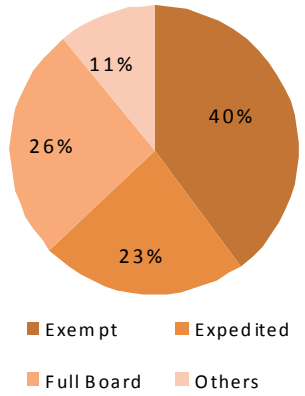
Boundaries of Research—CPHS has posted guidelines for review of QA/QI protocols that may not meet the definition of human subjects research as defined by the federal regulations. Since the addition of this panel in the iRIS application form, several applications requesting a formal determination have been reviewed.

CPHS SUBMISSIONS IN 2010

The CPHS Office uses iRIS as its primary communication mechanism and all initial and continuing applications are submitted by the research team via iRIS. In the year 2011, 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.

REVIEW TYPE

Of the 755 new applications to the IRB in 2011, 300 were exempt, 175 were expedited and 198 were reviewed by one of the three IRB panels at a convened IRB meeting.

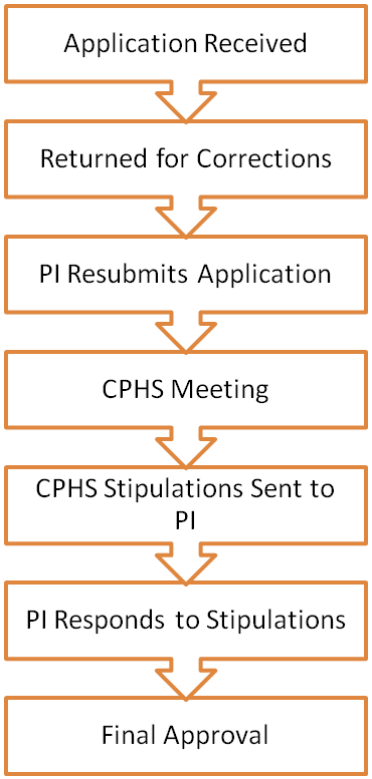


REVIEW TIME

The median turnaround time for all the three categories has been reduced from 2009 and 2010 levels. The median turnaround time for the three types of review from submission to final approval (in days) was:

	2009	2010	2011
Exempt	26	19	18
Expedited	46	49	42
Full Board	106	90	73

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.

Metric	N	50th percentile	75th percentile	95th Percentile
Duration 1 (IRB)	142	2 days	3 days	10 days
Duration 2 (PI)	138	8 days	22 days	88 days
Duration 3 (IRB)	123	19 days	26 days	37 days
Duration 4 (IRB)	165	8 days	10 days	12 days
Duration 5 (PI)	169	23 days	47 days	162 days
Duration 6 (IRB)	169	10 days	20 days	36 days

BARRIERS TO TIMELY APPROVAL

Only 20% of the submissions were accepted as submitted, about 50% were returned for correction one time, 18% were returned twice and the rest were returned three or more times.

BARRIERS TO TIMELY APPROVAL	TIPS TO OVERCOME BARRIERS
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

Demystifying the IRB Process- 11:30 am - 1:00 pm 2nd Tuesday every other month
Good Clinical Practice- 11:30 am - 1:00 pm 2nd Tuesday every other month
Study Coordinator Forum- 11:30 am - 1:00 pm every fourth Tuesday
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.uth.tmc.edu/ctrc/quickreference.html