UTHealth

The University of Texas
**Health Science Center at Houston**

VICE PRESIDENT FOR HUMAN
RESEARCH PROTECTION PROGRAM

REPORT TO
FACULTY AND STAFF ON
CPHS ACTIVITIES

- 2010-

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 2010, CPHS received over 700 initial applications for review and approval.


2005	2006	2007	2008	2009	2010
523	571	555	633	678	738
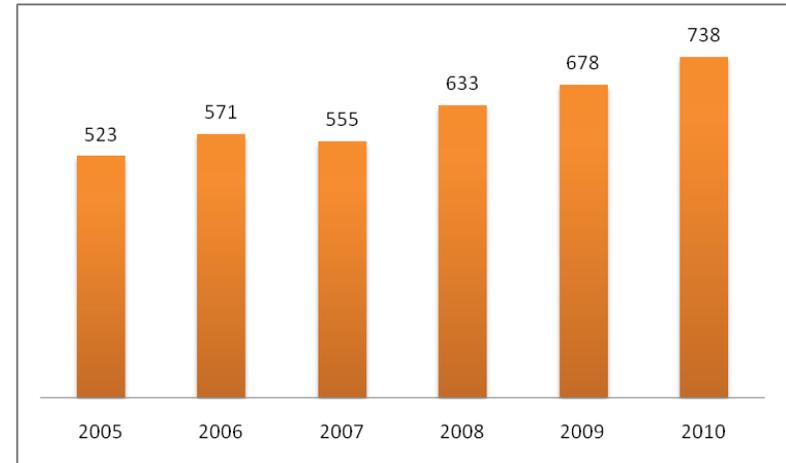
NEW PROTOCOLS SUBMITTED

The number of new protocols submitted to CPHS for review and approval has been steadily increasing. The chart below shows that the number of protocols submitted has increased in all the three categories of review—exempt, expedited and full board.
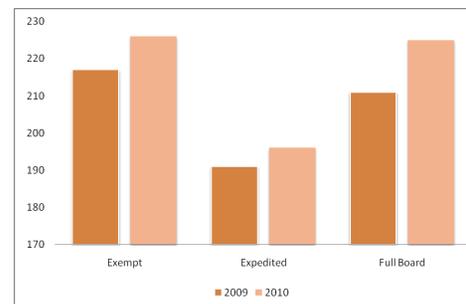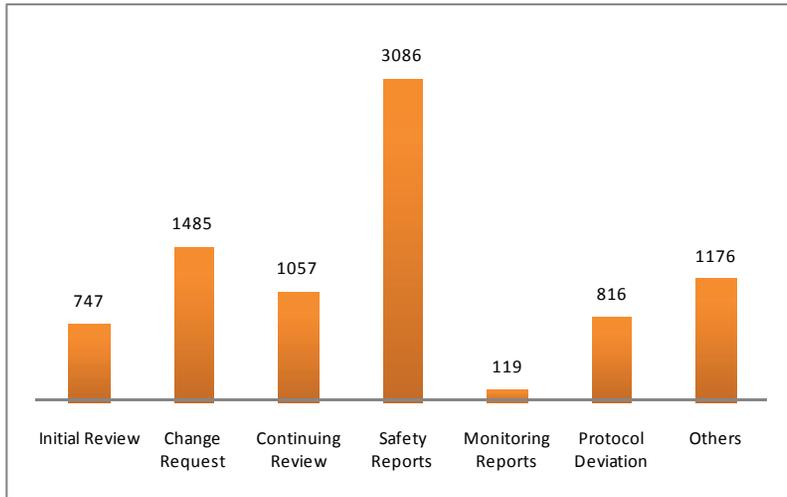

NEW PROTOCOLS APPROVED

The number of new protocols approved by CPHS has also been increasing. The chart below shows that the number of protocols approved has increased in all the three categories of review—exempt, expedited and full board.
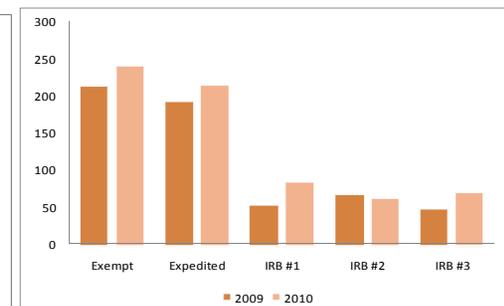
CPHS SUBMISSIONS IN 2010

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 2010, the CPHS office received over 10,000 submissions. In addition to these submissions, the office also received over 3000 submission corrections and submission responses.


Bar chart values: Initial Review 747, Change Request 1485, Continuing Review 1057, Safety Reports 3086, Monitoring Reports 119, Protocol Deviation 816, Others 1176
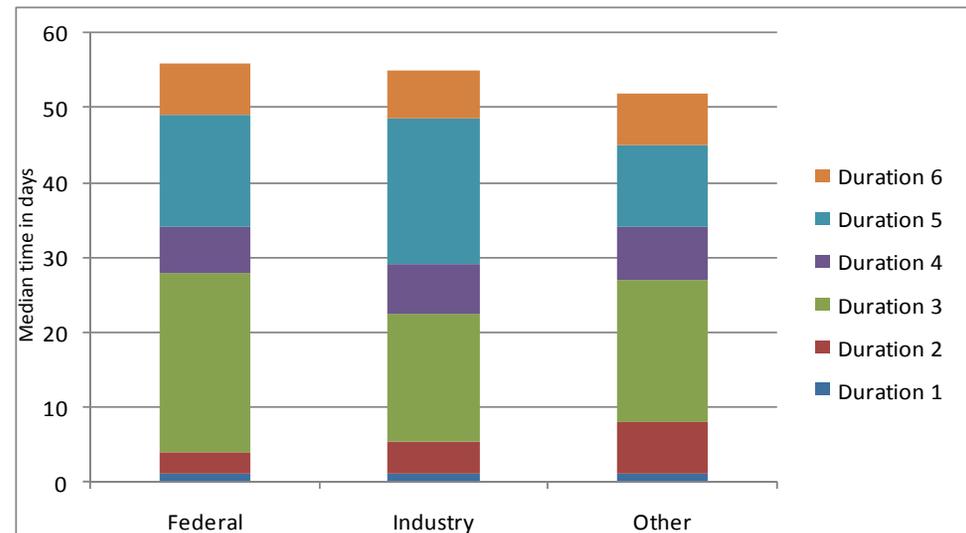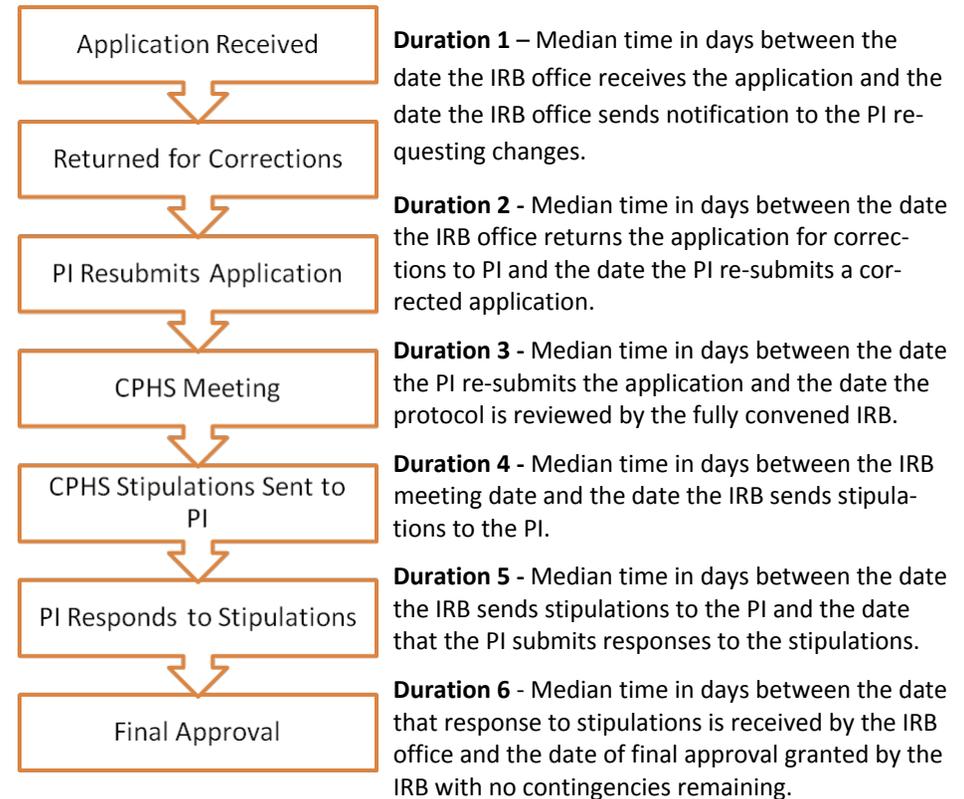
REVIEW TYPE

Of the 738 new applications to the IRB, 226 were exempt, 196 were expedited and 225 were reviewed by one of the three IRB panels at a convened IRB meeting.

Pie chart: Full Board 35%, Exempt 35%, Expedited 30%

REVIEW TIME

The median turnaround time for two of the three categories has been reduced. The median turnaround time (including time taken by scientific pre-review) for the three types of review from submission to final approval (in days) was:
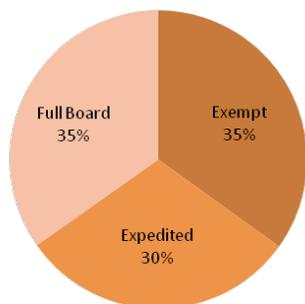
	2009	2010
Exempt	26	19
Expedited	46	49
Full Board	106	90
Panel 1	120	92
Panel 2	99	82
Panel 3	107	90

TURNAROUND METRICS

Flow chart:
Application Received → Returned for Corrections → PI Resubmits Application → CPHS Meeting → CPHS Stipulations Sent to PI → PI Responds to Stipulations → Final Approval

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.

Stacked bar chart: Median time in days for Federal, Industry, Other categories showing Duration 1 through Duration 6.

HRPP QUALITY IMPROVEMENT

The CPHS Executive Committee reviewed the CPHS process and made recommendations to reduce regulatory burdens while enhancing human research protections. Some of the initiatives that were implemented in 2010:

Initiatives in 2010

- **Reciprocity Agreement**—UT Houston has signed a Reciprocity Agreement with the 14 other UT Components. Protocols being conducted at more than one UT component may be reviewed by just one IRB. UT Houston has also signed an agreement to rely on NICHD IRB for National Children Study protocols.

- **Reducing IND Safety Reports Submission**—In 2010 almost a third of iRIS submissions were IND safety reports. The IRB is not in the best position to evaluate IND safety reports in multi center trials. Usually these trials have a data and safety monitoring board that assesses continued safety of the trial. CPHS has developed a new reporting policy. IND safety reports no longer need to be submitted to CPHS.

- **Protocol Deviations**— Researchers submitted over 800 protocol deviations to CPHS in 2010. New CPHS policy will require only protocol deviations that place the subjects or others at risk of harm to be reported immediately. A summary of other protocol deviations may be submitted during continuing review.

- **Pediatric Risk Assessment** — CPHS will no longer require researchers to obtain a pediatric risk assessment from an independent reviewer.

- **Internet Research**— A workgroup consisting of representatives from public affairs, privacy office, CPHS members and CPHS staff met several times over the year to develop a policy on safe and ethical research over the internet. This policy will help researchers in designing and conducting research over the internet including social media platforms. This policy will be available on the CPHS website.

- **CPHS Meeting Agendas** — A review of the meeting agendas for the three panels in Jan 2010 revealed that over 2/3 of the change requests could have been reviewed by the expedited process. CPHS staff were provided with training materials and guidance documents to assist them in assigning items to the most efficient review process. This resulted in reduction of change requests that are scheduled for full board review by more than 50 percent.

HRPP QUALITY IMPROVEMENT

The CPHS Executive Committee reviewed the CPHS process and made recommendations to reduce regulatory burdens while enhancing human research protections. Some of the initiatives that will be implemented in 2011 are::

New Initiatives in 2011

- **Streamlining iRIS Application**—CPHS Executive Committee has appointed a workgroup of researchers, research staff, IRB members and IRB staff to review the iRIS application to make recommendations to simplify and clarify the application. The group will also discuss strategies to help reduce the number of protocols returned with stipulations.

- **Consent Document Changes**— In order to simplify the consent process, researchers will have the option to include HIPAA language within the consent form. Researchers will not be required to develop an adolescent consent form for teenagers. An assent form and parental permission will be adequate. Consent forms will not have an expiration date and so the same consent form may be used for the life of the protocol unless it is revised during the course of the research by the researcher.

- **Departmental Review**— CPHS review process can be more meaningful if research proposals have been thoroughly vetted by a departmental review process. CPHS will assist departments in setting up a process best suited to its research profile.

- **Boundaries of Research**—CPHS is working to develop guidelines for review of QA/QI protocols that may not meet the definition of human subjects research as defined by the federal regulations. Once this guidance is in place, faculty would have a mechanism to quickly determine which activities are clearly not human subjects research and which require IRB approval.

The CPHS Executive Committee will continue to work with the research community in lowering regulatory barriers in the review and approval process for clinical research.

To discuss problems and concerns; obtain information; and offer input about the Human Research Protection Program here at UT Houston, please write to clinicaltrials@uth.tmc.edu.

BARRIERS TO TIMELY APPROVAL

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

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- 4:30 pm - 6:00 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
iRIS Training Intermediate- www.uth.tmc.edu/orsc/iris/intermediate.html

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

CONSULTATION
Clinical Trials Resource Center- clinicaltrials@uth.tmc.edu
CPHS Office- orsc@uth.tmc.edu

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: Max Buja, MD
Coordinator: Sylvia Romo

Panel 2
Chair: John Ribble, MD
Vice Chair: Ralph Frankowski, PhD
Coordinator: Tina Marin, MPH

Panel 3
Chair: F. Gerard Moeller, MD
Vice Chair: Catherine Thompson, RN, MPH
Coordinator: Arlene White-Brisco, MBA, CIP

Support Staff
Sr. Business Systems Analyst : Barbara Legate
Monitor: Lisreina Toro, MD
Panel Support: Jassmyn Carr, MHA
Staff Assistant: Paula Alexander

Office of Research Support Committees
6410 Fannin, Suite 1100, Houston, Texas 77030
Phone: 713.500.7943
iRIS Support : 713.500.7960
Email: cphs@uth.tmc.edu

Clinical Trials Resource Center
Director: Sujatha Sridhar, MBBS, MCE
Training Coordinator: Linda Gilbert
www.uth.tmc.edu/ctrc
Email: clinicaltrials@uth.tmc.edu