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.

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.
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.

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.

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:

<table>
<thead>
<tr>
<th>Type</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td>Expedited</td>
<td>46</td>
<td>49</td>
</tr>
<tr>
<td>Full Board</td>
<td>106</td>
<td>90</td>
</tr>
<tr>
<td>Panel 1</td>
<td>120</td>
<td>92</td>
</tr>
<tr>
<td>Panel 2</td>
<td>99</td>
<td>82</td>
</tr>
<tr>
<td>Panel 3</td>
<td>107</td>
<td>90</td>
</tr>
</tbody>
</table>

**CPHS SUBMISSIONS IN 2010**

**REVIEW TYPE**

**REVIEW TIME**

**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.
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.

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

<table>
<thead>
<tr>
<th>BARRIERS TO TIMELY APPROVAL</th>
<th>TIPS TO OVERCOME BARRIERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent document does not meet regulatory requirements</td>
<td>• Use CPHS Consent Template to develop consent documents.</td>
</tr>
<tr>
<td></td>
<td>• Run readability tests- <a href="http://www.uth.tmc.edu/ctrc/consentdevelopment.html">www.uth.tmc.edu/ctrc/consentdevelopment.html</a></td>
</tr>
<tr>
<td>Inconsistencies in submission</td>
<td>• Ensure consistency between documents- consent, protocol, data collection tools etc.</td>
</tr>
<tr>
<td>Incomplete submission</td>
<td>• Key study personnel should have current human subjects training.</td>
</tr>
<tr>
<td></td>
<td>• Key study personnel should have current CVs in their profile.</td>
</tr>
<tr>
<td></td>
<td>• Submit appropriate HIPAA and hospital forms.</td>
</tr>
<tr>
<td>Insufficient information in protocol</td>
<td>• For investigator-initiated trials ensure all the required information is present.</td>
</tr>
<tr>
<td></td>
<td>• Refer to or use protocol templates available at <a href="http://www.uth.tmc.edu/ctrc/protocoldevelopment.html">www.uth.tmc.edu/ctrc/protocoldevelopment.html</a></td>
</tr>
</tbody>
</table>

# 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

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