The CPHS Executive Committee initiated an HRPP quality improvement program in 2010 to identify strategies to reduce regulatory burdens not only for researchers but also for CPHS members and IRB staff, while enhancing human research protections. As part of our effort to improve the transparency of CPHS activities, I’m pleased to present the fifth annual CPHS Faculty Report. This document provides metrics describing CPHS activities in 2014, including workload and time to approval data. We also include an analysis of feedback we have received on our CPHS Faculty Survey.

Despite the increase in new applications (from 678 in 2009 to 908 in 2013 and 1,064 in 2014), there has been a steady decrease over the years in the time to approval (Fig 1), which is the time between initial submission of the protocol and final approval. This includes the time taken by the CPHS staff to process applications and for CPHS members to review the submissions, as well as the time taken by investigators to respond to deficiencies, queries, and stipulations.

The median time to approval for exempt applications was reduced from 26 days in 2009 to 11 days in 2013 and further reduced to **8 days** in 2014. Expedited reviews were reduced from 46 days in 2009 to 36 days in 2013 and **29 days** in 2014. The time to approval for initial submissions reviewed at a full board meeting increased from 59 days in 2013 to **69 days** in 2014, but was nonetheless lower than the median time to approval in the years 2009 through 2012 (Fig 1).

**Fig 1: Median time to approval by year.**

191 initial submissions were approved at a convened meeting in 2014, and of these, only 23% were accepted for subcommittee review as submitted. The remaining 77% were returned for corrections. These most common issues for prompting return at prescreening were missing signatures and incomplete application packets.

The CPHS Executive Committee continues to monitor the CPHS review process to improve the quality and efficiency of UTHealth’s human research protection program. To read the entire report visit **CPHS Faculty Report**. Please send your comments, concerns, and feedback to clinicaltrials@uth.tmc.edu.
Research billing is a “hot topic” in industry, as well as here at UTHealth. In an effort to ensure that UTHealth staff members are apprised of what is required when it comes to research billing, the Clinical Research Finance (CRF) team, as well as other personnel from several areas across the system, have been working as a “research billing group” to create the new Clinical Research Billing policy, HOOP 214.

HOOP 214 addresses the mechanism for registering research patients so that they are properly identified and their services appropriately charged.

The CRF team has conducted numerous trainings on this new policy. There is one more scheduled for Tuesday, 03/24/15 at the School of Dentistry from 12:45pm to 4:15pm. Space is still available, if you would like to attend. Additionally, in the coming weeks, an online version of this training will be available for Principle Investigators (PIs).

For more information on the new HOOP policy, registering for the training, or Coverage Analysis, please visit the CRF website or contact CRF via email at crf@uth.tmc.edu.

The CRF team has created a revised version of the budget tool, which is now called the “Cost Analysis Template.” The template was updated in an attempt to simplify its completion, as well as to make it a little more user and printer friendly.

Some of the new features include the addition of a “Summary” page, as well as the combining of former tabs 3b and 4. We hope that the added features will help not only in your budget creation but in your Coverage Analysis as well.

The “old” template is still available to use at this time, but it will eventually be phased out and replaced by this new version. We encourage you to go look at the new template and to even use it for your next new study. It is still in “prototype” mode, so we welcome any feedback you may have regarding it.

For more information on Coverage Analysis or the Cost Analysis Tool, please visit the CRF website or contact CRF via email at crf@uth.tmc.edu.

Upcoming Certification Testing Dates

CCRP certification: For those of you interested in becoming a Certified Clinical Research Professional, the next test date in Houston, TX is at The Methodist Hospital on May 30, 2015 with a registration deadline of April 17, 2015. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in September and October 2015. Applications are due by August 15, and you can find more information here.
Recruiting Tool – Add Your Trial to CTRC’s “Ongoing Trials” Page
Elizabeth Massey Gendel, PhD

CTRC is placing a call for additions to the “Ongoing Trials” page of the CTRC website. The postings on this page are directed toward potential study participants and can thus serve as a recruiting tool.

If you would like to add actively recruiting studies, please email Elizabeth Gendel at Elizabeth.M.Gendel@uth.tmc.edu with the following information (preferably in the format used on the “Ongoing Trials” page):

- Brief study title
- Coordinator name, email, and phone
- PI name
- ClinicalTrials.gov NCT # (optional)
- Relevant links (optional)
- Study overview (optional)
- Target population (optional)

Additionally, please alert Elizabeth of any studies that should be removed or of any posted study information that should be updated.

For more information, contact Elizabeth Gendel (Elizabeth.M.Gendel@uth.tmc.edu, 713-500-3587).

ClinicalTrials.gov in the Media
Click here for a story from NPR’s All Things Considered.

Changes to ClinicalTrials.gov’s User Interface
Elizabeth Massey Gendel, PhD

ClinicalTrials.gov has redesigned their user interface. After logging in, users are now taken to an interactive record list rather than to a “Main Menu.” Options for navigation that were previously accessible from the “Main Menu” are now located at the top left section of the interactive record list, with drop down menus for “Records,” “Accounts,” and “Help.”

New functions have also been added, and include:
- A “Show/Hide Columns” feature for choosing items to include in the Record List
- Sorting by any column of the Record List
- A “Download Record List” function that produces a comma-separated values (.csv) file that can be loaded into a spreadsheet
- A “Problems” column that indicates which records are in need of attention.
- Addition of a new type of Problem (“Record has Errors”)

For assistance, please contact Elizabeth Gendel (Elizabeth.M.Gendel@uth.tmc.edu, 713-500-3587).
Upcoming Training

**Study Coordinator Monthly Forum**

**Objective:** Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.

**Date:** March 24, 2015

**Time:** 11:30 am – 1:00 pm

**Location:** MSB 2.135

*Lunch provided for the first 40 participants.*

Registration is not required. Information [here](#).

**Clinical Research Education Program**

**Objective:** Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. Days 1 and 2 focus on clinical trial management, and day 3 focuses on clinical trial finance and contracting.

**Date:** April 21 – 23, 2015

**Time:** 8:30 am – 4:30 pm

**Location:** Cooley University Life Center

Registration is required. Register [here](#).

**iRIS Training**

**Objective:** Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth’s CPHS and AWC.

**Date:** April 7, 2015

**Time:** 1:30 pm – 4:00 pm

**Location:** UCT 1160

*Parking will be validated.*

Registration is required. Register [here](#).

**Center for Clinical Investigation (CCI) Meeting**

**Objective:** Aid clinical research while reducing the burden on individual teams by identifying best practices, streamlining clinical research management processes, and providing education, training, and support to clinical research staff.

**Date:** April 13, 2015

**Time:** 2:00 pm – 3:00 pm

**Location:** UTPB 1100.55

Registration is not required.

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**About the Clinical Trials Resource Center**

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Please visit [www.uthouston.edu/ctrc/](http://www.uthouston.edu/ctrc/) for more information.

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