Paula Knudson has been selected as the 2014 recipient of the Public Responsibility in Medicine and Research (PRIM&R) Distinguished Service Award. The award recognizes PRIM&R members who have made a valuable and unique contribution to the field of research ethics and who have attained distinction in promoting PRIM&R's purpose and ideals through writing, teaching, or research.

A longtime mentor of Institutional Review Board (IRB) members and administrators, Knudson has actively supported the education of anyone who expresses an interest in learning about ethical research. She has inspired generations of medical students and researchers, imparting the importance of ethical conduct in research, while teaching ways to operationalize the principles codified in The Belmont Report in everyday practice.

For the past 10 years, Knudson has served as the special advisor for human subject research and faculty in the Center for Clinical Research and Evidence Based Medicine at UTHealth. Previously she was the executive coordinator for the Committee for the Protection of Human Subjects for 27 years.

Left to right: Alex Capron (PRIM&R Board Chair), Paula Knudson, and Elisa Hurley (PRIM&R’s Executive Director)

“Paula has been the heart and soul of the UTHealth human subjects protection program since its inception and prior to Belmont. Moreover, she has been a national and international leader in articulating the principles and standards for responsible research practiced today. In delivering her award, Alex Capron described Paula as a ‘formidable woman.’ She remains forward-thinking and continues to advocate for progressive, practical research review honoring the Belmont principles of respect for persons, beneficence, and justice while remaining respectful of the needs of researchers and the community we serve,” said Anne Dougherty, MD, Vice President of the Human Research Protection Programs at UTHealth.

Congratulations, Paula!
Effective 1/1/15, the Centers for Medicare & Medicaid Services began requiring the reporting of an 8-digit National Clinical Trial (NCT) number on claims that involve clinical research patients. The NCT number is in addition to other requirements for research patient claims, including Condition Code 30, ICD-9 code V70.7, and Q0 and Q1 modifiers.

In an effort to address these requirements, Sponsored Projects Administration in conjunction with Revenue Cycle Management, the CTRC, and the CRU have developed a Clinical Research Billing Policy, **HOOP 214**. HOOP 214 offers additional guidance on the procedures for Coverage Analysis and Clinical Research Billing. The goal of these procedures is to provide a structure for designating clinical charges related to research and to ensure that the appropriate NCT number and modifiers are included on research patient claims.

All steps outlined in the Clinical Research Billing Procedure are currently being moved from the test environment to production in GE Centricity. Training related to this procedure will be held in the coming weeks. Stay tuned for announcements with additional information.

Contact: Clinical Research Finance Team, 713-500-3999, CRF@uth.tmc.edu.

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**CPT Code Cheat Sheet**

Clinical Research Finance (CRF) invites you to try its newest resource, a CPT Cheat Sheet. This spreadsheet is a great reference for looking up CPT codes for coverage analysis documents. The spreadsheet is not comprehensive, but it offers a user-friendly starting point.

If you have additional codes that you commonly use and would like to add to the resource, feel free to share them with CRF.

Contact: Clinical Research Finance Team, 713-500-3999, CRF@uth.tmc.edu.

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**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 February and March 2015. Applications are due by February 1, 2015, and you can find more information [here](#).
The NIH has recently revised its definition of “clinical trial,” per NOT-OD-15-015.

The purpose of this revision is to clarify the distinction between clinical trials and clinical research studies. This distinction is important because the NIH has additional requirements for studies that they consider to be clinical trials.

The revised definition will apply to proposals due on or after January 25, 2015.

Not sure if your study is a clinical trial per the NIH definition? The NIH has provided many clear and useful resources at their Clinical Research Policy webpage, including the following:

- Decision Tree
- Case Studies
- FAQs
- Detailed Explanation of the New Definition

Virtually Attend an NIH Workshop on Enrollment and Retention

Elizabeth Massey Gendel, PhD

You probably were not able to attend the NIH workshop on enrollment and retention in Bethesda, MD; however, you can be a virtual attendee, as the NIH has generously posted a webcast of the event.

Discussions focused on promising strategies and new avenues to address.

You can find the webcast, as well as slides and an agenda, at this link.

Congratulations, Catrina, on the Promotion!

We are pleased to announce that Catrina VanAllen has been promoted to the position of Senior Research Compliance Specialist within the Clinical Trials Resource Center (CTRC). Catrina originally joined the CTRC in 2013 as a Regulatory Specialist/Training Coordinator, and she has been responsible for coordinating all of the training programs organized by the CTRC. Additionally, she has participated in the post-approval monitoring program and other projects as a part of the human subjects quality improvement program.

Catrina earned a Bachelor of Science degree in biochemistry and microbiology from Texas State University, and she is a certified clinical research professional with about 7 years of experience working in the clinical research field.
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: January 27, 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: 8:00 am – 4:00 pm
Location: Cooley University Life Center
Registration is required and will open soon.

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: February 4, 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: February 9, 2015
Time: 2:00 pm – 3:00 pm
Location: UCT 1100.55
Registration is not required.

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/ for more information.

Catrina VanAllen, BS, CCRP
Senior Research Compliance Specialist
713-500-3578

Elizabeth Massey Gendel, PhD
Regulatory Specialist
713-500-3587

Sujatha Sridhar, MBBS
Director
713-500-3622

Ngozi Okafor, MPH
Graduate Assistant
713-500-3551