Payment to Research Participants
Sujatha Sridhar, MBBS, MCE

For the last several years, CPHS has required addition of language in consent forms to inform subjects that they would be required to complete a Form W-9 or Form W-8BEN before receiving payments for participation in a research study. This was required for any payment including cash or gift cards. Collecting Form W-9 or Form W-8BEN from participants who receive payment is important for the University to stay in compliance with tax laws.

Researchers and research staff have expressed concerns with obtaining Form W-9 or Form W-8BEN from participants, especially for research studies being conducted in the community and the amount paid was very low e.g. $10 or $15. Most research studies pay well under the $600 per calendar year limit established by the tax laws. In order to address these concerns, the UTHealth Office Budget and Financial Reporting has developed guidelines to address these concerns. This guideline will be effective Jan 1, 2014.

The key feature of this new policy allows researchers to pay research participants up to $100 per visit and less than $600 per calendar year without collecting a Form W-9 or Form W-8BEN from the participant after establishing that the individual is not participating in any other research studies at UTHealth.

If the payment to a participant exceeds $100 per visit or $600 per calendar year, a vendor setup is required. A completed Form W-9 or Form W-8BEN is required for vendor set up. Any single payment of $100 or more must be paid by check.

Upon receipt, completed Form W-9 or W-8BEN should be forwarded to Procurement by secure fax at 713-383-3722. The original forms should be shredded after confirming that they were received by Procurement. Procurement will retain the forms in accordance with UTHealth retention policies set forth under HOOP 181 (see link below).

For children under 16 years of age, payments should be directed to the child’s parent or guardian. The new guidelines require researchers and research staff track all payments to participants.

For more information on the guidelines visit Office of Budget and Financial Reporting website.
Clinical Research Unit at Memorial Hermann Hospital

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***To avoid protocol deviations please be aware of the university’s holiday calendar when scheduling your patients***

Study Spotlight

The Bicuspid Aortic Valve (BAV) disease study is supported in part by a KL2 award from the Center for Clinical and Translational Sciences and the John Ritter Research Program in Aortic and Vascular Diseases.

Dr. Siddharth Prakash, assistant professor in the Department of Internal Medicine Division of Medical Genetics, is the principal investigator. BAV is the most common congenital heart malformation in adults, but very little is known about the genetic causes or risk factors for adverse outcomes. Currently, it is estimated that most cases of aortic stenosis in patients less than 65 years old are caused by BAVs. BAV patients also are at high risk to develop aneurysms of the ascending aorta, which may lead to aortic dissections. Dr. Prakash and his colleagues are committed to use knowledge gained from this study to improve the clinical care of BAV patients.

This Study is being conducted at Lyndon B. Johnson General Hospital, the Michael E. Debakey Houston Veterans Affairs Medical Center, St. Luke’s Episcopal Hospital, Memorial Herman Hospital and The University Of Texas Health Science Center Clinics as well as the Harris County Institute of Forensic Sciences. Brigham and Women’s Hospital UT Southwestern Dallas are among 15 centers that are participating in a large consortium of researchers to study the genetics and clinical outcomes of BAV. Patients do not need a referral from their providers and can volunteer directly for the study by contacting study coordinator Turner. The study will follow patients with bicuspid aortic valves (BAV) to determine why some BAV patients develop aortic stenosis or aortic aneurysms and dissections.

The Clinical Research Unit will be closed for business Dec 21 through Jan 1.

Just as a friendly reminder, please plan ahead and make note of the upcoming holidays when scheduling patients visits that involve sending specimen to central laboratories. FedEx will not be open on December 25th and January 1st to deliver specimens. Many laboratories also have special closings due to the holidays. Please also note that many sponsors want you to refrain from shipping any frozen batch shipments during this time so please double check before shipping out these types of specimens.

Since the CRU will also be closed December 21st, 2013 through January 1st, 2014; we will not have dry ice available during this time.

Most importantly, we hope everyone has a safe and happy holiday!
Representatives from the Center for Clinical Investigations (CCI) will continue discussion concerning subject billing and Medicare Coverage Analysis will be discussed at the Regulatory Team Meeting. The Operations meeting will begin to cover Memorial Hermann Credentialing and CRU/MHH registration changes. Anyone is welcome to attend these meetings.

**Finance Team meetings**: UTPB 1100:55 from 2 to 3 pm every third Monday.

**Regulatory Team meetings**: UTPB 1100:55 from 2 to 3 pm every second Monday.

**Clinical Research Operations Team meetings**: UTPB 1100:55 from 2 to 3 pm every fourth Monday.

Attention Research Coordinators: As of June 1, 2013, the UTHealth payment address has changed!

Please make the necessary revisions to all invoices, and make sure all of your sponsors on each of your trials are aware of the new payment address. After December 31, 2013 all payments sent to the old lockbox address will be returned to the sender and will therefore be substantially delayed in posting to your project accounts. The new address is:

P.O. Box 301418, Dallas, TX, 75303-1418.

Please feel free to contact paf@uth.tmc.edu if you have any questions.

**CCRP certification**: For those of you interested in becoming a Certified Clinical Research Professional, the next test date at The Methodist Hospital in Houston, TX is February 12, 2014 with a registration deadline on December 20, 2013. You can find more information [here](#).

**CCRC certification**: The next test date for a Certified Clinical Research Coordinator is February 27 – March 22, 2014 and application deadline is December 2, 2013 for “early-bird” registration and February 4, 2014 for final registration. You can find more information [here](#).
UPCOMING TRAINING

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management and network with research administrators and staff from various research groups within UTHealth.
Date: January 28, 2014
Time: 11:30 a.m. – 1 p.m.
Location: MSB 2.135
Lunch provided to the first 40 participants
Registration is not required.
More information here.

Clinical Research Education
Objective – This educational program aims to promote excellence in clinical trial management for research nurses, study coordinators and other research staff. Day 1 and 2 focus on clinical trial management and day 3 on clinical trial finances and contracting.
Date: Spring 2014.
Time: 8 am to 4 pm
Location: Cooley University Life Center.
Registration will open in January 2014.

Orientation for Clinical Research Staff
Objective – This one day program provides an overview of clinical trial research at UTHealth. The first half of the day focuses on CPHS review and approval process, MHH hospital review process and clinical trial management. In the afternoon, the focus will be on clinical trial finances – including budgeting and billing.
Date: Feb 25, 2014.
Time: 8 am to 3 pm
Location: MSB 2.104B
Registration is required. Register here.

iRIS Training
Objective: Hands on training in the iRIS system to submit research protocols involving human subjects to the IRB.
Date: December 17, 2013 at 01:30 pm – 04:00 pm
Location: UCT 1160 (subject to change).
Register here.

About Clinical Trials Resource Center
It is the mission of the Clinical Trials Resource Center to provide a single portal of expertise, and best practices for the study team to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Visit www.uthouston.edu/ctr for more information.

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