Use iRIS for AWC Submissions

We are pleased to announce the completion of the implementation of the Animal module in the iRIS system. You can use iRIS to submit new applications and also for submitting Change requests, Personnel Change requests, Continuing Reviews, and Study Closures for all active protocols that were approved before going live with the iRIS system.

The use of iRIS for submitting animal research protocols is now “optional” however, the system will be REQUIRED for all submissions sometime in May. If you are interested in training, please contact Barbara Legate at 713-500-3470. Read more.

Updated Clinical Trials Budget Template

Last year as part of the Center for Clinical Investigations, Christopher Denman and team developed a more robust clinical trial budget template.

The budget template was recently amended to make the cost analysis section clearly. The template also includes billing forms for easy accessibility. Additional worksheets have been added to incorporate the UTP EG account set up form, billing request form and the charge document. When working on a budget for a new study, always access the Clinical Trials Budget Tool from the OSP website to make sure you are working on the latest version.

NCT Number on Medicare Claims

Effective January 1, 2014, CMS requires inclusion of the National Clinical Trial (NCT) number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination Manual. National Clinical Trial (NCT) number is the number issued by ClinicalTrials.gov registry that is unique to each trial registered. The format for the ClinicalTrials.gov registry number is “NCT” followed by an 8-digit number, e.g.: NCT00000419. More information here.

To assist in identifying clinical trials that have routine costs, the Clinical Trials Resource Center is working on a process to assist research teams to conduct a formal coverage analysis. More information will be provided soon.

Welcome!

The CTRC is happy to announce that Trae Rohan, BA, CHRC has joined our team as a Regulatory Specialist. Trae comes to us from the Clinical Innovation and Research Institute at Memorial Hermann Health System. Trae has over 10 years of experience working in the research administration field with specific expertise in the area of clinical trial billing compliance.

Trae has earned a Bachelor of Arts degree with a major in Health Care Administration. Trae is a certified health care research compliance professional. Please join us in welcoming Trae to CTRC and to UT Health.
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: February 25, 2014; March 25, 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: April 15 – 17, 2014.
Time: 8 am to 4 pm
Location: Cooley University Life Center.
Register here.

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; June 24, 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: March 18, 2014, 1:30 pm – 4:00 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/ctrc for more information.

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The study “A Natural History Analysis of Rapid Eye Movement Sleep Behavior Disorder as Prognostic for Parkinson’s Disease” is currently being conducted by Dr. Mya Schiess in the CRU.

The objective of this study is to establish a profile of behavioral, motor, non-motor, cognitive, structural, and molecular measures from a large population of PD patients, REM Behavior Disorder (RBD) patients, and healthy controls that identifies pre-motor PD, and predicts the development and course of progression of PD. The variable expression of Parkinsonian Diseases (PD) makes it likely that the best predictor for PD onset and progression will be a pattern of symptoms (not a single marker). These patterns are expected to improve diagnosis and eventually, the prognosis of Parkinsonian patients by looking beyond the cardinal motor symptoms to the preceding cognitive and non-motor symptoms. It is hoped that these analyses will also yield subtle differences that could be used to distinguish between the various Parkinsonian Diseases. Last year alone Dr. Schiess’ research in this area led to four publications that came from her CRU work:

Brian J. Copeland, MD; Albert Fenoy, MD, Tim Ellmore, PhD; Qinghua Liang, MD, PhD; Vicki Ephron, RN; Mya Schiess, MD. Deep brain stimulation of the internal globus pallidus for generalized dystonia associated with spinocerebellar ataxia type 1: case report. Neuromodulation, May, 2013. DOI:10.1111/ner.12081.


Lynnae Smith; Mya Schiess; Mary Coffey; Andrea Klaaver; David Loeffler, Ph.D., D.V.M.. Alpha-Synuclein and Anti-alpha-Synuclein Antibodies in Parkinson's Disease, Atypical Parkinson Syndromes, REM Sleep Behavior Disorder, and Healthy Controls,  PIOS ONE, 2012.


Dr. Schiess is the Director of the Neurology Residency Training Program and the Director of the Movement Disorders & Neurodegenerative Diseases at The University of Texas Medical School in Houston.
What is new in the CRU?

Cary Warner, MS, CCRC who worked as Senior Regulatory and Compliance Specialist in the CRU for the last 7 years, retired on January 31, 2014. We wish Cary a happy retirement!!

Kara Kime, who joined the CRU team in September 2013, is now working in the CRU as a Senior Regulatory and Compliance Specialist.

CRU Scope and Services: Things to Know!!

Administrative services at the CRU include budget development, parking validation, meal tickets, and Petty Cash services. For investigators that want to use the CRU’s petty cash services, based on the University of Texas Health and Science Center Houston guidelines a number of points need to be considered:

1. Researchers can only use petty cash accounts if the estimated payments to the Research Participant are not expected to exceed $100 or more per incident.
2. Any single payment of $100 or more has to be paid by check and the Research Participant will have to be set up as a vendor in the system. In this case, the research coordinator must obtain a completed W-9 or W-8BEN form. To access more information about UTHealth Research Study Participant Payment Processing go to [https://inside.uthouston.edu/finance/budget/](https://inside.uthouston.edu/finance/budget/)

In addition to the nursing, lab and coordinator services, the CRU also offers:

1. Freezer storage space at $40 per month
2. Dry Ice at $12 per block

To request a copy of our budget and fees please contact Kathy Franco RN BSN, CCRC by phone at 713-704-4137, or via e-mail at Kathy.D.Franco@uth.tmc.edu.

ABOUT CRU

Dr. Michael Fallon
Medical Director

Kathy Franco BSN RN, CCRC
Manager

Theresa Dancsak MSN RN
Assistant Manager

Kara Kime, MS
Regulatory Specialist

Monika Ruscheinsky, MS
CPhT – Lab Manager

Cristina Dyke, BA
ASO I