Research Coordinators Newsletter

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Announcements

The next Clinical Coordinators Quarterly Update is scheduled for Tuesday, September 22, 2015. The session will be held from 11:30–1:00 PM in the Wittson Hall Amphitheater (WHM 3034).

Introducing these new Clinical Coordinators & Research Personnel:

- Natalia McCain—CT Surgery
- Fayez Jawed—Ophthalmology
- Emily Schram—Ophthalmology
- Chris Wurtele—IM Rheumatology
- Augustine Osuala—UNeHealth
- Rachel Brantley—Hematology/Oncology
- Amanda Fletcher—Clinical Research Center
- Nick Miller—Neurological Sciences

News from the Clinical Research Center

Presented by LuAnn Larson, RN, BSN, CCRP

The CRC is adding additional personnel to flesh out the services available to researchers. A recruiter to help market clinical trials and assist researchers in subject recruitment, two regulatory persons to assist with IRB submissions, and two budget developers to who will assist researchers in developing consistent and complete budgets for their clinical trials. Positions are posted in JOBS at UNMC and CAREERS at Nebraska Medicine, if you know a candidate who would be a good fit please refer them to these sites.

A monitor has been installed outside the CRC to advertise clinical trials to patients and visitors to Nebraska Medicine. Submit a PowerPoint slide of your IRB approved clinical trial advertisement to Peggy Heires for posting. An example of a trial advertisement can be found at: http://www.unmc.edu/cctr/education/clinicalcoordinators.
IRB Updates

Presented by Jenny Kucera, MS

Adult IRB Full Board submission deadlines will be one day earlier effective for the August 6th meeting. Deadlines will now be Thursday at 12 PM rather than Friday to allow the IRB staff time to prepare meeting materials. This change does not affect PedsIRB nor Pre-Review deadlines.

Certain classes of commercially sponsored research (Phase II/III, III, IV) will soon be eligible for use of a centralized IRB. Chesapeake IRB will serve as the IRB of record will likely allow direct billing to the sponsor for their services. Currently centralized IRB (CIRB) processes are in place for NCI Cooperative Group Studies and the Greater Plains Collaborative/PCORI. The specialized form for use of these centralized IRB is available in the eIRB, however the form for Chesapeake is not yet available; contact Gail Paulsen for questions.

A reminder that naming conventions and descriptions are critical when uploading documents into the eIRB. The “file” field has a limit of 20 characters; file names that exceed that limit will truncate often times resulting in the loss of the file extension which tells the system what kind of document and how to read it. Always name your files so that the name is consistent with the protocol version and that you can see the file extension in the field window. While description fields do not have a character limit it is suggested that the text is concise and consistent with the protocol ID and attachments. If you need to attach password protected documents either remove the password protection or put the password in the file name.

Human Research Protection Program (HRPP) Policy #8.5 refers to the procedures for reporting allegations of noncompliance but sponsors/CROs and the FDA may also conduct announced or unannounced audits without evidence of noncompliance. In the event of a sponsor/CRO audit follow HRPP Policy 8.5 and report noncompliance issues to the IRB. In the event of an FDA audit notify the IRB immediately so that appropriate personnel can be mobilized to answer any questions. Other parties that may need to be notified are the sponsor, Principal Investigator, other research personnel, Research Pharmacist, Compliance Officer, and other committees/individuals as applicable.

Promoting Patient Safety

Erin Iselin, Pharm D, Research Pharmacist

Electronic medication orders create an accurate medication history and allow all healthcare providers precise and specific direction. Therefore Nebraska Medicine is transitioning investigational medication orders away from the traditional green prescription pad and into the electronic health record. Electronic orders are now required to comply with Medical Staff Policy (MS22), facilitate continuity of care (MM01), and promote safe and accurate preparation and dispensing of investigational products (MS09).
Questions about the Medication Policies?
IDS pharmacists are available to speak at small group sessions and departmental seminars.

Medical Staff Policy MS22 outlines the contents of the medical record should include all medication orders. When investigational medication orders are entered electronically, it will contain all the required components of a medication order outlined in Medical Staff Policy MS09. Detailed orders provide Investigational Drug Services (IDS) Pharmacists every detail necessary to safely prepare and dispense medication and gives the nurse/coordinator guidance for medication administration. Medication Management Policy MM01 states that patient specific information including current medications, will be readily accessible to all of those involved in medication management.

Both inpatient and outpatient medication orders will be built in One Chart although there are differences in how they are built. Courtney Kennedy is available for training on how to build order sets for either.

Electronic medication orders are necessary to promote safety, follow policies and procedures outlined by the institution, and facilitate continuity of care.

Research Recruitment Survey

Courtney Kennedy, MS, RN-BC (Informatics)

The results from the recently circulated research recruitment survey are in. Nearly 70 Clinical Research Coordinators took the time to respond to the questions regarding support for research recruitment and perceived barriers. While most respondents felt that they had adequate resources for recruitment there were a number of barriers cited in successfully recruiting subjects. A general lack of awareness regarding available trials and a lack of referrals from clinical providers topped the list of barriers. Suggestions for improved recruiting tools included:

- General PR regarding the research being conducted at Nebraska Medicine
- Contacting potential subjects through One Chart
- Centralized recruitment staff
- Improved recruitment website
- Advertising coordinator

A working group to improve the Clinical Trials Database has been formed to address the lack of centralized information. A new position for a Recruitment Coordinator in the Clinical Research Center has been posted and candidates are being solicited. If you have other suggestions for improvements in the recruitment process contact Dr. Chris Kratochvil.
Spotlight on Clinical Trials

Meghan Langel  
Andrea Anderson  
Bryan Ludwig  
Grace Rodrigues

A new feature to the Clinical Research Coordinators Quarterly meeting is a spotlight on current clinical trials at Nebraska Medicine/UNMC. If you would like to promote your clinical trial at the upcoming meeting contact Deb Meyer to get on the schedule.

The following trials are currently recruiting subjects:

**Heartland Osteoporosis Prevention Study** — Principal Investigator(s): Laura Bilek/Nancy Waltman. Coordinator: Meghan Langel. Study information can be found at: [www.unmc.edu/alliedhealth/research/hops](http://www.unmc.edu/alliedhealth/research/hops)

**Non-Invasive Treatment of Abdominal Aortic Aneurysm Clinical Trial (NTA3CT)** - Principal Investigator: Jason MacTaggart. Coordinator: Andrea Anderson. Double blind medication trial with recruitment completion target of December 2015


**D2d Preventing Diabetes with Vitamin D** — Principal Investigator: Cyrus DeSouza. Coordinator: Grace Rodrigues. Patients with Pre-Diabetes or at high risk for diabetes.


Center for Clinical & Translational Research (CCTR)

Support services offered under the umbrella of the Center for Clinical & Translational Research include the following

- Clinical Research Center
- Research Subject Advocate
- Research Pharmacy (Investigational Drug Services)
- One Chart Research
- EHR Data Access Core
- Nebraska Biobank
- UNeHealth

Read about all the services offered through the CCTR at: [http://www.unmc.edu/cctr/](http://www.unmc.edu/cctr/)

SPAccounting

Need assistance with your clinical trial invoicing? Don’t know who to call?

Craig Poole prepares upfront invoicing, creates and applies payment allocations, and is the person to contact for invoicing concerns.

Gina Bohac sets up the awards in SAP, coordinates invoicing and payment issues with Craig, and is the person to contact on budget and expense related matters, and closes the award.

A General Note Concerning Indirects (F&A): All monies are subject to indirects, except IRB & Patient Travel Reimbursement. The Industry F&A Rate for Clinical Trials is 26%.