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Announcements

The next Clinical Coordinators Quarterly Update is scheduled for Tuesday, June 23, 2015. The session will be held from 11:30—1:00 PM in the Wittson Hall Amphitheater (WHM 3034).

Welcome these new Clinical Coordinators:
- Jen Sinden, BS Eppley Research Institute
- Faye Park, RN, Clinical Research Center

2014 One Chart Update live 4/12/15. A new Enrollment Status field has been added which allows you to link subjects during screening and follow them through to enrollment. Also included is the addition of four different types of clinical trials to the study type field. The types of Research studies available are listed below and are single select.
- Interventional/Therapeutic: Any trial that has investigational medication is therapeutic in its intent and/or specimen collection.
- Investigational Device: Any trial that uses an Investigational Device
- Observation or Registry: Any trial that is data collection only from the Medical Record or other documentation.
- Registry with Sample: Any trial that collects specimens as part of the trial in addition to data collection (i.e. collection of blood, urine, bone marrow, etc.).

Addressing Clinical Research Needs

Presented by Christopher Kratochvil, MD

Several initiatives are underway to help facilitate clinical research at UNMC and Nebraska Medicine. One key approach is the plan for the Center for Clinical & Translational Research (CCTR) to become a “one-stop shop” for clinical research support. The goal is to centralize resources to assist clinical researchers with budgeting, contracting, and regulatory services for clinical trials. Stay tuned for updates on this process.
Progress continues in implementation of centralized IRBs for certain multi-center clinical trials. It is hoped that efficiencies can be realized by taking advantage of central IRBs, which review multiple sites for large studies. The goal of streamlining the approval process is to decrease redundant efforts and speed the study initiation process. Certain NIH and PCORI multi-site trials will be eligible to use central IRBs, and by fall of 2015 plans are for the first use of a centralized IRB for Phase III/IV commercial multi-site protocols. Details are still being formalized.

Subject recruitment continues to be an area in need of improvement. Features are being added to One Chart and My Chart to help promote study participation. It is hoped that centralizing recruitment around web-based applications will help promote available studies to the public.

**UNeHealth Invoicing**

*Presented by Jeffrey Miller, CPA, MBA*

The invoicing process for clinical trials contracted through UNeHealth is changing. UNeHealth has teamed with UNMC Business and Finance to automate the invoicing process through the Accounts Receivable module of Management Resources.

Departmental staff can now enter invoices directly into Management Resources and be assured that Business and Finance will follow the invoice through to completion including; billing the sponsor, collecting payment, and depositing to the appropriate accounts. Coordinators will gain the ability to see what the invoice status is at any point in the process.

Management Resources can be accessed from the UNMC Intranet Home page login buttons or directly from [https://net.unmc.edu/mgmt/](https://net.unmc.edu/mgmt/) If you don’t have access to Accounts Receivable through Management Resources you can contact Terry Lilla in Accounts Receivable/Cashiering (terry.lilla@unmc.edu or 9-5828) to request access and training. If you have questions about UNeHealth invoicing contact Craig Poole, UNeHealth Accounts Representative (cpoole@unmc.edu or 9-5817)

**Insurance Pre-Authorization**

*Presented by James White*

There is a new SOP that applies to all patients who are eligible to participate or who have consented to participate in a therapeutic clinical trial. This SOP describes the insurance verification and pre-determination process for clinical trial patients within Nebraska Medicine. All patients who are eligible to participate or who have consented to participate in a therapeutic clinical trial will be subject to...
primary and secondary insurance verification by Patient Access Services (PAS) Financial Counselors.

For the patient who has been identified as eligible for consent or a patient who has already consented, the Research Coordinator will submit the Clinical Trial Insurance Predetermination Form to Patient Access Services. The patient should be made aware that a request will be submitted for information from their insurance payer.

Information that should be included with the form:
- Study synopsis and
- Study Matrix

The form, including the attachments should be emailed to PAS: PASFinancialCounselor@nebraskamed.com. The subject line should read: Clinical Trial Patient Protocol Preauthorization Request. If your patient is high priority (i.e. inpatient Leukemia, urgent treatment needed) please communicate this in your subject line and in the body of the email.

The Patient Financial Counselor will review the patient’s insurance coverage and complete the Predetermination section of the form and email it back to the coordinator with the insurance information. PAS will inform the coordinator whether or not to proceed with the study treatment and if there are any other concerns related to insurance or personal financial obligations for the patient.

If the policy has a clinical trial exclusion clause, the patient should be made aware by the Research Coordinator. The patient should know that he/she is financially liable for all costs related to the clinical trial in this case and what those costs include at this point by PAS. The patient has the option to request a waiver from their insurer which may cause a delay in treatment or they may proceed without waiting for a response. The patient should be informed by the coordinator that they are financially liable for charges if the request for waiver is denied. The patient may decide at this point not to participate in the clinical trial. Coordinators should notify the IRB if a patient is denied coverage and choose to continue participation in the trial. They will be provided with a cost estimate from PAS to inform them of their out-of-pocket costs and will need to sign a non-cover waiver to proceed.

Miscellaneous Information

Presented by LuAnn Larson, RN, BSN, CCRP

Changes have been made to the (CCTR) Pilot Grant Program application form. The update form can be accessed from the Center for Clinical Translational Research (CCTR) website: http://www.unmc.edu/cctr/resources/pilot-grant/
**Investigational Medication Orders**

*Contributed by Courtney Kennedy, RN, MSN*

To promote safety, follow policies and procedures outlined by the institution, and facilitate continuity of care, electronic medication orders are necessary. Complete and accurate medication orders need to be accessible to independent practitioners and appropriate health care professionals and staff participating in medication management. Electronic medication orders create an accurate medication history and allow all healthcare providers precise and specific direction. The detailed order allows the Investigational Drug Service Pharmacist every detail to safely prepare and dispense medication. It also provides the nurse/Coordinator guidance for medication administration.

Per Medical Staff Policy, an order is required to request and dispense medication. In policy MS09, it states that a complete medication order shall contain:

- **a. Patient name**
- **b. Date & time**
- **c. Patient weight** (for drugs that are dosed based by weight such as chemotherapy and all doses for pediatric patients). Prescribers are asked to indicate a Dosing Weight (DBW) for patients upon admission (in the admission navigator). Note: nursing staff documents dosing body weight on their documentation flowsheets. This is the weight that is programmed into the smart (Alaris) pump.
- **d. Drug Name** (generic names are utilized unless the product is a combination product.)

**index.html** If you have old copies of the form please destroy them and access your form through the website; it will always have the most current forms and requirements.

The Clinical Research Center (CRC) is placing a display monitor outside of the CRC to advertise eligible clinical trials. Soon visitors to UNMC and employees will be able to see a scrolling display of clinical trials being conducted at UNMC. Anyone will be allowed to submit their study to be uploaded (in the form of a powerpoint slide). Reminder, you must have IRB approval to advertise using this medium.

A gentle reminder that although a Billing Associate reviews clinical trial billing for compliance the Coordinator is still responsible for oversight of the trial billing. A review session will be coming soon to review tips for catching billing omissions, a frequent oversight during the billing process.

Hope Jones will be filling in as interim research biller during Amy Swenson’s absence this summer. Contact her at: hjones@nebraskamed.com or 9-2279.
Research Pricing

A Coding and Pricing “cheat sheet” has been developed as a resource to assist research personnel in finding correct codes and prices for use in preparing their research Matrices and Budgets.

This new resource is located on the Nhssecure drive and can be accessed by those who have permission to access the Clinical Trial Master Matrix (CTMM). The file path is: –Nhssecure (L)->Clinical Trials->Resources->Coding & Pricing Information->Coding and Pricing Cheat Sheet.

The Cheat Sheet contains such helpful information as CPT Codes, hospital (technical fee) Codes, and Department/Modifiers needed for Price Inquiry Searches that are necessary when completing your CTMM and Budgets. The Cheat Sheet includes the codes for tests and procedures for Technical Fees, Professional Fees, and Ancillary Items. Included in the PowerPoint presentation accompanying this newsletter are detailed instructions for populating Price Inquiry field for the various fee types. Examples show how the data in the Cheat Sheet corresponds to the fields required in Price Inquiry.

Pricing for complex procedures, such as biopsies, lumbar punctures, and PICC line placements which have multiple charges associated with them in addition to the standard technical and professional fees can be a challenge. The CRC staff have experience with complex pricing and can provide assistance to the clinical coordinator.

Training sessions can be set up for individuals interested in learning more about how to use the Price Inquiry function in One Chart. Contact Katie Penas, Cassie Cruz-Montes, LuAnn Larson or Peggy Heires for pricing questions. (Please do not contact Amy Swenson or Hope Jones for pricing questions. Contact them with billing issues.)