Welcome Clinical Research Coordinators.
The quarterly clinical research updates have been well attended and have become a valuable resource to disseminate information to all clinical research coordinators. The next presentation is scheduled for June 12, from 11:30-1:00 in WHM 3034. This newsletter is a brief summary of the topics that were discussed during the March 18 meeting.

Process for Research Studies that Utilize the Radiology Department; Uploading
By Katie Penas, MHA, CNMT, RT(N)

Improved processes are now in place for research studies that utilize the Radiology Department. Descriptions of how to request services and reference documents to assist research coordinators and staff in uploading radiology images to sponsors for central review are now available online at: http://www.unmc.edu/cctr/cru_resources.htm

Key Points to Remember:
- If radiology scans are used in the protocol regardless of whether or not they are uploaded electronically, the matrix needs to be e-mailed to Marie Witthoft in radiology administration.
- If scans will be uploaded to the sponsor, the IRB application must reflect this in the confidentiality section of the protocol.
- If there are specific CRFs that need to be filled out by the technologist(s) performing the scan, the coordinator should:
  o Email the forms to lead technologist prior to scan
  o Communicate with lead technologist as to how the forms should be returned (ex: Campus mail, email, pick up in person, etc.)

The reference documents also include important scanner information and key radiology research contacts. Please contact Katie Penas at 402-552-6601 if you have any questions.
Research Billing

By Courtney Kennedy, RN, MSN, ACNP

Documentation is required in One Chart when enrolling a new subject and initiating an IRB protocol. Key points:

- In Centricity there was an order form that stated “Initiate IRB Protocol”
- In One Chart we now have an order “Initiate IRB Protocol” that should be entered for every patient.
- In the order you need to specifically document the IRB number

A new SmartPhrase has been added that can be used for external orders.

New resource in One Chart for External Orders: a SmartPhrase has been added that can be used for external orders

Please review the recent document NCD (310.1) Routine Costs in Clinical Trials issued by CMS http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&DocId=310.1&show=ncd&l=2010422105232&bc=qAAAAAgAAAAAAA%3d%3d

Changes coming in “research billing modifiers”
In the future research coordinators will see three Research Billing Modifiers:
1. Routine
2. Investigational
3. Routine (Oncology Invoice). The new modifier Routine (Oncology Invoice) should only be used by Oncology coordinators to invoice

Coordinator Credentialing

By LuAnn Larson, RN, BSN, Nurse Manager CRC

IMPORTANT REMINDER for all UNMC coordinators, credentialing must be completed before providing any patient care activities at TNMC, TNMC Clinics & Bellevue Medical Center. Please contact Deanne Kadlec, Human Resources, at: dkadlec@nebraskamed.com or call 402-552-3068.

Change in the Monitoring Process

By LuAnn Larson, RN, BSN, Nurse Manager CRC

New EHR processes will ensure monitors will only have access to subjects on their study. Monitors will no longer be able to access other patients in the system. This is effective immediately.

You will continue to contact the CRC staff at 402-559-7685 to assign user names and passwords (or if you work in Oncology you continue to contact your internal staff).
Understanding UNMC’s F&A Rate for Industry

By Deb Vetter, Director, Sponsored Programs

Key points to keep in mind when negotiating budgets with industry sponsors:

1. UNMC’s indirect rate for industry sponsored research is 26%.
2. Indirects are collected by the institution for all study costs except IRB fees (which are exempt) so departments should negotiate accordingly.
3. Sponsors may request to waive F&A for other costs, but SPA can help coordinators address this by:
   - Clarifying questions regarding facts and practices
   - Communicating with sponsors on your behalf
   - Providing formal documentation of UNMC’s F&A policies

For further information, please visit the SPA website:
http://www.unmc.edu/spa/

IRB Submissions (Without Paper!)

By Jenny Kucera, MS, CIP

Great news! No more paper packets are required for IRB submission.

- Submission deadline dates remain the same.
- Submissions must be received by NOON on the deadline date.
- Submission dates/times are firm

Requirements for Existing Paper Application

For ongoing studies which were submitted on paper prior to the conversion, future IRB documents (continuing review, request for change, deviation, noncompliance) will be submitted using the electronic system. To do so an “Existing Paper Format” application will need to be created. Additional documents will simply be attached to the electronic application. For complete instructions for submissions, consult the IRB website (www.unmc.edu/irb).

Professional Fees

By LuAnn Larson RN, BSN

Professional Fees; New Guidelines for Research

Effective March 17, 2014 all Pro-fees will automatically be discounted by 65% in EPIC. The only option for a change in the reduction is for a 100% discount, but this requires prior approval from UNMC-P and an accompanying approval letter.
Pharmacy Fees
By Chris Kratochvil, MD

Pharmacy fees have been standardized and updated for all protocols using medications or investigational products.

Standardized Research Pharmacy Fees are now in effect:

- Pharmacy start-up fees: $1500.
- Outpatient dispensing fees (oral): $20/Rx
- Standard infusions: $75 (Fees may vary based on complexity.)
- Annual Fee: $750 at end of year 2 and each year thereafter
- Contact Jon Beck, PharmD for questions at 402-559-5255 or jbeck@nebraskamed.com
- Copy of letter/fees on website
  http://www.unmc.edu/ccr/docs/Investigational_pharmacy_fee_letter_2_4.pdf

UNMC Research Handbook
By Chris Kratochvil, MD

UNMC now has a new Research Handbook that can be accessed electronically. Please take the time to use this valuable resource. It can be accessed at http://www.unmc.edu/media/ccr/docs/ResearchHandbook-web.pdf
If you have any comments or need to update material in the handbook please contact Linda Wilkie at: wilkie@unmc.edu

Research Billing
By LuAnn Larson RN, BSN and Chris Kratochvil, MD

Current issues with research billing were discussed, including ideas to improve the process. Recommendations and comments will help inform next steps in improving the process, with a plan for follow-up at the next quarterly meeting.