Announcements

The next Clinical Coordinators Quarterly Update is scheduled for Tuesday, March 24, 2015. The session will be held from 11:30—1:00 PM in the Wittson Hall Amphitheater (WHM 3034).

Welcome these new Clinical Coordinators:

Kim Mueller, RN Clinical Research Center
Lace Petry, RN, Anesthesiology
Julie Hoffman, RN, Anesthesiology

Registries and Subject Lists

It is important to have an updated subject list in the matrix for registry studies that have billable items. To ease confusion on when the subject list does not have to be updated use the guidelines below.

<table>
<thead>
<tr>
<th>Registries with NO billable items</th>
<th>• Maintaining the matrix subject list is NOT necessary</th>
</tr>
</thead>
</table>
| Registries with ONE billable item | • Maintaining the matrix subject list is NOT necessary  
  • Scan in the consent form and add a note that patient was enrolled in the registry for a one time blood draw etc.  
  • Add the date of consent & date of blood draw  
  • When complete change status to “Follow-Up” in One Chart |
| Registries with TWO or MORE billable items | • Must maintain the matrix subject list as with any other study |

Ask Grace Videtech for a waiver if there are no billable items and a subject list is not required for your matrix.
One Chart

Presented by Courtney Kennedy, RN, MSN

Updating Enrollment Status. Failure to update subject status leads to billing questions and should be kept-up-to-date. Use the “Patient Research Enrollment” tab in One Chart to update enrollment, assist with billing, and add an active end date. Select “Completed” if no further interventions or data collection will be done for the subject. Select “Follow-up” if data will continue to be collected after the interventions. Follow-up status is commonly used in long-term oncology survivorship studies and registries after the sample collection. Note: Registries with only one draw do not require a matrix subject list, this is all tracked through One Chart.

Updating Study Build Status. “Closed” status does have different implications in the Study Build than defined and used by the IRB. A “Closed” study in One Chart means: there are no further interventions or billing, the study is closed to accrual although data collection may continue.

Research Order Set/Smart Set. Approved workflow can include a standard Order Set or “Smart Set” for each study. All non-oncology studies will need to have Smart Sets built in One Chart and templates will be sent to coordinators shortly. “Treatment Plan Build” and Smart Sets already fulfill this requirement for oncology. Jill Kestel and Meg Peters remain the contact for oncology Smart Sets. PI’s must still acknowledge that the orders are correct.

Pend Orders. To improve the ease and response time for PI’s to locate and sign pending orders you can now send a copy to the PI’s In-Basket in One Chart. This new feature lives in the “Follow-up” window for non-oncology studies and the “Send Chart” window for oncology studies.

A tip sheet is available detailing the steps for these new features. Contact Courtney Kennedy if you have questions or review the Tips and Tricks in the One Chart Command Center.

Scope of Practice

There will be a panel presentation to address questions regarding Scope of Practice as it relates to roles in clinical research. A Question and Answer format will enable free discussion of the interpretation of Scope of Practice and implications for pending orders, creating smart sets and other issues vital to the clinical coordinator.

Eppley Science Hall (3010)
January 21, 2015
1:00 PM—2:00 PM
e-IRB Updates

Presented by Sue Logsdon, MS

Some innovations have been added to the electronic IRB applications. In the “Forms” menu a drop-down feature has been added so that you may select relevant forms without leaving your current screen.

Users have reported some issues when completing Request for Change forms. You must complete every justification for change field/section even if no change is made for that section. Simply write “no changes needed” in these sections and submit.

Changing personnel roles in the application can be complicated and individuals have found themselves locked out of protocols during the process. It is critical to add the person into the new role before deleting their old role. This is particularly important if the role you are changing is your own.

Please be aware that email addresses are not automatically updated in the e-IRB. Change email addresses in the “additional info” section and refresh to see the changes live. Also remember to update email addresses in the alternate address field in consent forms if you have them listed there.

A reminder to please remove old, un-submitted protocols from the system. Large numbers of protocols that will never be used just clog the system and decrease its performance. Simply change the name to “Trash” and list one of the IRB administrators as the lead coordinator. IRB administrators can then remove them from the system.

IRB Education

Presented by Jenny Kucera, MS

AMA Category 1 credit is now available for the IRB Education Series. AMA Credit is not restricted only to physicians, other professionals who require continuing education (nurses, pharmacists, allied health professions) can receive credit for attendance at the IRB Education Series lectures. In order to receive credit, a new electronic sign-in system is being utilized which will log the lectures you have attended into your individual transcript. Attendees must electronically log in the day of the event to receive credit. (See attachment for instructions to obtain a copy of your transcript.) It is important to note that this credit can only be given by attending a presentation, it is not available by watching live stream or archived presentations.

Please remember that the IRB administrators are always available to speak at special seminars or departmental meetings.
Sponsored Research

Provided by Deb Vetter

NIH Biosketch

A new format for the commonly used NIH Biosketch will be required for National Institutes of Health (NIH) and Agency for Healthcare Research & Quality (AHRQ) proposals effective May 25, 2015. The NIH is recommending that PI’s begin to utilize the new format ahead of the deadline.

Changes to the biosketch include:

- Increases the page limit from 4 to 5 pages.
- Allows for descriptions of up to 5 of a researcher’s most significant contributions to science along with historical background that framed their research.
- Outline central findings of prior work and the influence of those findings in their field.
- Can describe their specific role in Team Science projects.
- Descriptions can include up to 4 relevant peer-reviewed publications or other non-publication research products
- Investigators can provide a link to a full list of their published work found in a publicly available digital database such as MyBibliography or SciENcv.

The full notice, forms and examples can be read on-line at NOT-OD-15-032. The McGoogan Library, Sponsored Programs Administration, and the Vice-Chancellor for Research are partnering to provide training materials and tutorial sessions in tools to create the new biosketch. Watch the Resources for Researchers page (www.unmc.edu/vcr) for further information.

Uniform Guidance

December 26, 2014 marks the effective date for changes to federal regulations that experts consider to be the most significant grant reform in 50 years. The new regulations, 2 CFR 200 or Uniform Guidance, merge eight federal circulars into one. Publication of the rule in the December 19th Federal Register documents 28 federal agencies’ formal adoption of the Uniform Guidance and includes agency-specific exceptions or additions to the Uniform Guidance.

The next step is for universities (hospitals, state government and Indian Tribes) to revise their institutional policies and procedures to align with the Uniform Guidance—not a small task. Currently, UNMC central research offices are partnering to identifying how our policies and practices will change. They will update departmental administrators and faculty on Uniform Guidance changes implemented by federal agencies and UNMC through campus announcements, emails, workshops and more.
Meet Cassie Cruz-Montes, BA
Research Billing Senior Associate

Cassie Cruz-Montes has worked at Nebraska Medicine for 5 years in Patient Financial Services doing patient billing, insurance verification, and reimbursement review. She started working with research billing in May of 2014 and started in the Clinical Research Center in October of 2014.

Cassie’s responsibilities include monitoring and consolidating the matrices, working with coordinators to resolve billing problems, and random audits of matrix and patient billing to ensure compliance.

You can reach Cassie at ccruz-montes@nebraskamed.com or by phone at 402-559-4939. Cassie will begin maternity leave in January and Amy Swenson will handle billing questions during her absence. Courtney Kennedy will continue to address One Chart questions.

Welcome Cassie!

Matrices Updated

Provided by Cassie Cruz-Montes, BA

Review of matrices and patient billing is an ongoing process. Currently over 600 matrices are scheduled for review of complete subject listings, nearly 350 have been completed by the Research Billing Senior Associate, Cassie Cruz-Montes. Due to the review 120 studies were able to be closed in One Chart.

The review process revealed many instances of duplicate copies of the matrices in study folders. It is very important to have only one working copy of the matrix in the folder. Duplicate copies should be moved to an archive folder. The billing associates has been working on this but it would be most helpful if coordinators would move their duplicate matrices into the archive folder. Having only one working copy visible in the folder ensures that billing reviewers have access to timely and accurate information.