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Announcements

The next Clinical Coordinators Quarterly Update is scheduled for Tuesday, December 16, 2014. The session will be held from 11:30–1:00 PM in the Wittson Hall Amphitheater (WHM 3034).

IRB Update

Presented by Jenny Kucera, MS, CIP

The IRB will now allow simply referencing existing full protocols for sponsored studies in certain sections of the IRB Application, rather than retyping or “cutting and pasting” the information into the electronic IRB. Sections which may now be referenced include: Background (II.3), Inclusion Criteria (II.9), Exclusion Criteria (II.10), Methods (II.12B), Statistical Methods (II.12F), Risks (II.16), Subject Withdrawal Criteria (II.18F), Study Stopping Rules (II.18G), and References (II.34). When referencing the full protocol in an IRB Application you must include the protocol Version #, Date, Section, and Page Number(s) being referenced. Please note that if a change is made to a referenced section in the IRB Application you must include the updated version #, modified date, section changed, and page numbers referenced. A change summary should also be attached to the application along with a tracked change version of the protocol if available.

Questions seem to arise regarding the differences between statuses in Section I of the Continuing Review Application fairly frequently; in particular the difference between status C and D and which requires full board review or qualifies for expedited review. Contact the IRB Office at 402-559-6463 if you have questions regarding continuing review. Use the Continuing Review (CR) from the previous year as a template for completing CR.

If a study’s approval expires, all work on the study must stop and CR must be completed and submitted within 20 days. Subjects may not be enrolled and patients may not be seen until the study’s status has been approved through continuing review. If the CR has not been submitted within the 20 day limit the
IRB will change the status to study ‘closed’. If subjects need to continue to be seen while the study approval status is “expired”, the PI must complete and submit to the IRB the ‘Approval Expired-Request to Continue Current Subjects’ form found on the IRB website.

Upcoming IRB educational events including webinars can be found on the IRB website:  http://www.unmc.edu/irb/education.htm .

**Research Billing**

*Presented by LuAnn Larson, RN, BSN, CCRP and Chris Kratochvil, MD*

*Study coordinators will soon no longer be responsible for billing research charges in One Chart.* The billing department will be responsible for billing research charges in One Chart. These changes will go into effect October 6th, 2014; coordinators need to check their matrices for accurate visit dates, clean-up any problems and clear all billing out of the work queue before then. Matrix Workbook Version 5.0 must be utilized for all new studies starting on or after October 6th

*Cassie Cru-Montes has been hired as the new Research Billing Specialist.* The new Research Billing Specialist will be a resource for training, questions, and problem-solving and serve as a liaison to the billing office. Coordinators still play a significant role and are responsible for building studies, completing the comprehensive matrix (including sending a copy of the matrix to Courtney Kennedy or Jill Kestel for Oncology), entering patient data by the next business day (2 business days in extenuating circumstances), and submitting consent documents to HIM within 24 hours (48 in extenuating circumstances). Coordinators also need to continue to link study visits so that the charges fall into the research work queues of the billers.

**Insurance Pre-Authorization**

*Presented by Katie Penas, MHA CNMT, RT(N)*

Some insurance companies have exclusion clauses that do not allow for billing of routine costs for patients participating in clinical trials. This is primarily a problem of self-insured groups which include large, local employers. Pre-Authorization forms and processes are available. Insurance pre-authorization determines the coverage available, starts the appeals process if needed, and allows patients to make informed financial decisions regarding study participation. A formal policy is in the approval process; although the draft forms are currently available from LuAnn Larson or Katie Penas and have already been implemented by the Oncology department.
Creation of a Standard Research Orders Set can streamline the order processes

Research Orders

*Presented by LuAnn Larson, RN, BSN, CCRP and Chris Kratochvil, MD*

Investigators may create a ‘Standard Research Order Set’ (also called a “Standard IRB Order Set” in One Chart) by developing and signing a set of orders that are to be used for all patients in a particular study. A copy of this order set must be sent to Courtney Kennedy so that it can be entered into One Chart.

The PI can either enter all of their own orders or they can sign a copy of the trial’s ‘Standard Research Order Set’ for each patient that includes the patient name and medical record number (MRN). These order sets must entered as written and then scanned and sent to HIM if being entered by the RN Coordinators or Non-credentialed/licensed Coordinators.

The workflow for research orders for RN Coordinators and Non-credentialed/licensed Coordinators/Research Assistants is different. RN Coordinators can take and implement a research order that is either written or verbal, whereas Non-licensed Coordinators/Research Assistants cannot.

*Research Order Work Flow Diagrams*

One Chart News

*Presented by Courtney Kennedy, RN, BSN*

Changes have been made to allow Principal Investigators to enroll research patients into One Chart using the ‘Patient Research Enrollment Activity’ screen. One Chart Research Providers must complete a training class available 24/7 in the “Learning Connection” in order for this permission level to be available. Contact the Learning Connection help number at 9-4260 for further information.

Signed research consent forms are now accessible from the Patient Research Enrollment activity window. All consent forms should be copied and sent to Health Information Management (HIM) for scanning and uploading into the patient chart. You must note that they are to be scanned into the patient chart when sending to HIM. Documents may be faxed if immediate uploading is necessary (402-559-2650). You must provide the number of the sending fax machine and the number of pages when requesting urgent uploads so that the HIM staff can locate the document for immediate processing. Contact HIM at 9-8141, 9-8153, 9-8189, 9-6240, 9-1349, or 9-1348. When requesting urgent uploads by fax follow these requirements:
So that consents forms are viewable in the Patient Research Enrollment Activity you are encouraged to send all consent forms from current studies, even if the patient is already enrolled,

- Each patient’s consent must be faxed separately.
- MRN and CSN must be in the upper right corner of the first page of the record.
- Page number is limited to 10 or fewer per fax. If the fax is larger, call and speak to the imaging lead or manager prior to faxing.
- There must be a cover sheet with contact information so that questions can be addressed promptly.
- It is the responsibility of the sending department to verify the fax is in the medical record before destroying the original document. Once the document is in One Chart, do not send the paper copy to HIM!
- Faxes that do not adhere to these requirements will be deleted and not processed.

A special scanner is required to directly upload consent forms into One Chart, departments that wish to scan their own documents may enter a PWR for the scanner; please be aware that there is likely to be a charge for the scanner. You are encouraged to send all consent forms from current studies, even if the patient is already enrolled, so that consents forms are viewable in the Patient Research Enrollment activity.

Effective 9/22/2014 the research collection orders ‘RN Draw, No Charge’ is no longer available and has been removed from all orders. Patients which have an ‘RN Draw, No Charge’ order scheduled will have that order deleted automatically; Coordinators will need to go in and change those orders to the new selections ‘Research Collection Only Blood (LAB)’ or ‘Research Collection Only Non-Blood (LAB)’. Once signed, orders cannot be amended but must be deleted and re-ordered by the physician. Please be aware that accessing the port of a chemo patient for a research only draw will incur a charge. The Cancer Center is actively working to get a grant account set up to cover these charges. Further information will be communicated to coordinators when it has been set up by the Oncology Managers.

Invoicing: UNeHealth vs UNMC Studies

*Provided by Sponsored Programs Administration, Karla Klaus*

**UNeHealth Studies (WBS ends in 888)**

- Department generates invoice using standard UNeHealth invoice template and emails it to Linda Vondras (lvondras@unmc.edu) or Jeff Miller (Jeffrey.Miller@unmc.edu)
- Receivable is recorded in UNeHealth accounting records and invoice is forwarded to the sponsor by UNeHealth accounting.
- Sponsor pays UNeHealth and UNeHealth pays UNMC for direct costs and a portion of the indirects.
Contact Karla Klaus (kklaus@unmc.edu) to request the invoice template.

UNMC Studies (WBS ends in 001)

- Department submits invoice through electronic A/R system
- Accounting records receivable and routes the invoice to the sponsor
- Sponsor pays UNMC

Contact your SPA accountant to request A/R access and training.

One Chart Research Enrollment Definitions

Provided by Courtney Kennedy, RN, BSN

<table>
<thead>
<tr>
<th>Status</th>
<th>Definition</th>
<th>Pink Research Active</th>
<th>Route Billing to Research Account (link orders and visits)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identified</td>
<td>Marked as possible research patient</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Interested</td>
<td>Patient is thinking about enrolling in a research Study</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Ineligible - did not meet full criteria</td>
<td>Patient fails screening</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Declined</td>
<td>Patient chooses to not participate</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Waiting for Consent</td>
<td>Patient has been identified and is ready to sign consent</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Enrolled</td>
<td>Patient has signed consent (screening or full IRB consent)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Completed</td>
<td>Patient has finished the study</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>Patient is unable to continue in the study per choice or medical failure</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Patient is having standard data collection but no billable items</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>