Research Coordinators Newsletter

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Announcements

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

Introducing these new staff in the Clinical Research Center:

Elizabeth Blowers, PhD—Regulatory
Michelle Cook, BS—Finance Analyst
Natasha Fields, BS—Regulatory
James White, BS—Finance Analyst
Timothy Widman, BA—Clinical Research Outreach Coordinator

Information Security Updates

Presented by Sharon Welna, Information Security Officer

October is Cyber Security Month and a number of tips and tricks have been released to the campus community for safe-guarding their workstations, datasets, and protecting personal information. The campaign this year is called “Stop. Think. Connect” and reference material for safeguarding your information including instructional videos can be found at: http://www.unmc.edu/its/security/index.html

While it has been policy (UNMC 6085) since 2007, there is a formal project at UNMC to minimize the use of social security numbers (SSN). The policy governs the use of SSN within the UNMC campus and does include research subjects.

The SSN of a research subject is considered confidential information and should not be used to identify a research subject unless legally mandated. If you have IRB approval to use a SSN in your study, you must fill out the “Request to Use Social Security Number” form (http://www.unmc.edu/hipaa/policies/). Be prepared to provide why you need to use a SSN, where you will store the SSN, and how you intend to maintain the confidentiality of the data. ITS recommends that you don’t keep a SSN in a protocol if it is not really necessary.
Use of Central IRBs

Presented by Gail Paulsen, RN, BSN, CIP

The UNMC IRB allows the use of Central IRBs (CIRBs) under certain circumstances. Currently the use of three CIRB processes is routinely allowed:

- NCI CIRB for oversight of oncology trials sponsored by the NCI National Cooperative Groups
- Greater Plains Collaborative (GPC)/PCORI studies
- NEW—Chesapeake IRB, an independent commercial IRB, for review of certain categories of commercially sponsored clinical studies

There are also other less frequently used instances where a CIRB may be used. Federally funded studies requiring the use of a CIRB process or other consortiums or collaborative groups sponsored by academic medical centers may, upon case by case review, be allowed to use a CIRB.

Researchers now have the option to use Chesapeake IRB for review of Phase II/III, III and IV commercially sponsored research. You can still use the UNMC IRB for oversight of your study, you are not required to use Chesapeake, but it is available. The sponsored agreement must include language allowing Chesapeake IRB to work with the sponsor on issues in the protocol as well as to bill the sponsor directly for their services. Gail Paulsen and Kristi DeHaai in the IRB office are the gatekeepers for use of Chesapeake IRB. They will verify for Chesapeake IRB when all the institutional requirements have been met. (e.g. P&T, SRC, IBC, CITI, COI, Pathology Approval, Contract Execution, etc.).

The CIRB process requires an IRB Authorization Agreement to be executed between the institutions. For Questions contact Gail Paulsen (402-559-3853 or email.)

MS40 Policy: Vendor Visits & Clinical Trials

Lori Peters, Drug Information Pharmacist

MS 40 clearly defines rules of conduct for interaction of healthcare vendor representatives (HCVRs) with Nebraska Medicine staff. This also governs representatives who are on campus for visits related to Clinical Trials, i.e. Site Monitors. The policy includes registration and appropriate identification and pertains to all Nebraska Medicine facilities and entities.

During visits related to clinical trials Representatives:

- Contact is restricted to Nebraska Medicine staff associated with that trial only
- Representatives are not permitted in patient care areas unless required for work associated with a clinical trial.
Updated!

Radiologic Image
Uploading Documents

Please discard any old copies and access the new documents at:
http://www.unmc.edu/cctr/resources/rad-images.html

- Representatives must obtain a basic membership in REPtrax (free)
- Representatives must sign-in and out to REPtrax for each visit.
- On campus visits representatives must use a REPtrax kiosk. REPtrax mobile apps may be used only for off-site clinic visits.
- Representatives must wear the orange badge (prominently displayed above the waist) generated at the REPtrax kiosk as well as a company identification badge. When off-site, representatives must wear their company identification badge and show proof of login to REPtrax on their smartphone.

Staff must ensure that the HCVR has appropriate identification, a confirmed appointment, and is not in a patient care location unless required.

HCVR can register for a free basic membership in REPtrax at REPtrax.com and clicking on “Register”. Instructions for completing the REPtrax registration and answers to common questions can be found on the nhssecure drive (clinical trials, #5 resource folder.) A copy of which has been included as a supplement to this edition.

Honest Broker Policy

Tara Scrogin, JD, Interim Privacy Officer

The Honest Broker Policy was established to create standard operating procedures for de-identification of PHI for the purpose of safely and securely linking together or sharing clinical data to support research in compliance with HIPAA and IRB requirements. Both Nebraska Medicine (IM40) and UNMC (6074) have Honest Broker Policies.

Honest Brokers facilitate access to patient health information. Honest Brokers are workforce members who are Neutral Intermediaries (persons or systems). They are certified to:

- Collect specified health information from the tissue or data bank
- Remove all patient identifiers
- Provide the de-identified health information or tissue to research investigators, clinicians, or other healthcare workforce members, in such a manner that it cannot be reasonably possible for any individual to identify the patients directly or indirectly

Honest Brokers shall not be part of the research team for which they are performing honest broker services. There are appointment and training criteria, in addition to submitting an application and signing an attestation of agreement required to become an Honest Broker.

If you have a dataset of clinical information AND you provide information for research purposes you may need to apply to become an Honest Broker. The application can be found at: http://www.unmc.edu/hipaa/policies/
In Vitro Diagnostic (IVD) Products

Grace Videtich, BS
Gail Paulsen, RN, BSN, CIP
Katie Penas, MHA, CNMT, RT(N)

The use of In Vitro Diagnostic (IVD) products in research studies is on the rise. In some studies IVDs are clearly identified while in others they are briefly mentioned.

Regardless of how the device is identified in the Protocol/Informed Consent Document, our responsibility for recognizing and reporting the use of the IVD is clearly defined in federal regulations.

In Vitro Diagnostic Devices, not approved by the FDA for use, may have an Investigational Device Exemption (IDE) and must be submitted to Centers for Medicare & Medicaid Services (CMS) for a billing determination prior to enrolling any patients on a trial.

If the IVD has an IDE for a study that was approved by the FDA prior to January 1, 2015 then review and approval from the local Medicare Administrative Contractor (MAC) is required and the IDE study is administered by the MAC. In these cases Nebraska Medicine/UNMC submits a review packet to the J5 MAC Medical Director for billing determination.

If the IVD has an IDE for a study approved after January 1, 2015 then review and approval by the central CMS Coverage and Analysis Group is required and the sponsor is responsible for submitting the review packet to the CMS Central Office. CMS then posts the approved studies on the CMS website and the sponsor is responsible for updating Clinicaltrials.gov to include each participating site.

Sometimes it is difficult to know if the IVD has an IDE, when in doubt ask the sponsor if the test performed at central labs or other facilities are approved by the FDA. If not, is the device being used under the authority of an IDE?

The Clinical Research Center (Katie Penas), the IRB (Gail Paulsen), and SPAdmin (Grace Videtich) have all added safeguards to their review cycle to help departments identify those studies containing IVDs.

If an investigational IVD is involved, study enrollment is placed on hold pending notification that CMS approval has been received.

UNeHealth Update

Karla Klaus, BS
Chris Kratochvil, MD

UNeHealth has moved into offices in the College of Nursing, 5th floor. Look for the UNeHealth team; Tara Scrogin, Amy Carson, Augustine Osuala, and Karla Klaus in their new location, phone numbers remain the same.

UNeHealth handles the following types of agreements:

- CDAs for industry-funded clinical trials
- CTAs for industry-funded clinical trials [Phase I-IV]
- Compassionate use
- Master CTAs for industry funded clinical trials [Phase I-IV]
- Subcontracts “in” for industry funded clinical trials [Phase I-IV]
- Amendments to UNeHealth contracts (WBS 888)