COOK COUNTY HEALTH

Research Roundup May 2023

Greetings CCH researchers!

We are very excited to relaunch our newsletter in an effort to keep CCH researchers informed of human research protections and other developments in research. Our goal is to put out a monthly publication with content input from everyone involved in research at CCH. With the many changes to research infrastructure, policies, and procedures occurring, we want this newsletter to keep the research community informed and connected. We are excited to welcome the Clinical Research Office (CRO) to CCH. Make sure you see the updates from the CRO below. This issue will focus on events that are reportable to the IRB as well as some important reminders.

We welcome any feedback as well as any ideas, contributions, or news that you would like to share with the CCH research community. Please email us at CCHHSIRB@cookcountyhhs.org.

As a reminder, our website contains information including: IRB calendar and roster, consent templates, short consent forms in our top languages, IRBManager manual, and CITI training among others. Please see the link below.
Research & Regulatory Affairs Website

Events Reportable to the IRB

Investigators are required to report certain study events or reportable events to the Cook County Health Institutional Review Board (CCH IRB). If any member of a study team becomes aware of a reportable event, the event must be reported to the CCH IRB within 48 hours, 7 days, or 14 days depending on the nature of the event. Both adverse events and protocol deviations must be assessed to determine if they are unanticipated problems involving risk (UPIR). When in doubt about whether to report or when to report an event or deviation, please call the IRB- we are happy to help you determine the right approach.

Criteria for UPIR. Events meeting the three criteria below are UPIR and must be reported.

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the study participant population;
2. Related or possibly related to participation in the research (in this guidance

document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, which is often a judgment call. If the event is serious, the participants' risk of harm is automatically considered increased. **Serious** adverse events are those that result in death, are life threatening, result in hospitalization, result in persistent or significant disability/incapacity, result in congenital abnormalities/birth defects, or are based on medical judgment to be serious.

Protocol deviations, may or may not rise to the level of reporting. This will be a judgment call. Protocol deviations that increase risk should be reported within the timeframe above (e.g. improper dosing of medication, release of PHI). Protocol deviations with no risk (e.g. performing a survey or blood draw out of the study window) do not need to be reported promptly unless required by the sponsor. If not reported promptly, protocol deviations should be reported at the time of the annual progress report.

Prompt reporting is defined as notifying the IRB within 7 days for most internal unanticipated events (local to CCH). Serious internal unanticipated events must be reported to the IRB within 48 hours. External unanticipated events (outside CCH) must be reported within 14 days from the date the local study staff becomes aware of the event. Fourteen days is also the timeframe for internal events which were not serious and quickly resolved.

Reporting for Studies Reviewed by a Central IRB. Investigators must report events to the reviewing IRB according to their requirements. This may be different from CCH reporting requirements. The investigator must report internal SAEs and internal UPIR to the CCH IRB as well. If the reviewing IRB makes any of the following determinations, this should also be reported to the CCH IRB. Determinations include: study suspension, serious non-compliance, continuing non-compliance, and/or any UPIR. Where the CCH IRB is the IRB of record, reportable events must be submitted to the CCH IRB in accordance with the reporting requirements in this guidance. These reporting requirements apply to CCH researchers and all external relying sites.

- Remember to close any studies that are complete and no longer active.
- Check to see that key personnel are current. Remove anyone from the study that is no longer active.
- Ensure that your CITI training is up to date as well as any key personnel listed on the study.

- When submitting progress reports and annual check-ins, make sure the enrollment numbers match with your last progress report or check-in.
- Leave at least an inch on the bottom of your consent documents and flyers for the IRB approval stamp.

Research Roundtable Kickoff Meeting:

Pam Gonzalez, the interim director of the Clinical Research Office, hosted a successful Research Roundtable meeting on April 25th with over 30 attendees. During the meeting, Pam shared information about the clinical research ecosystem at CCH, communication strategy and needs, overall CRO goals, and next steps. A recap is available here (**SLIDES**) for those who were unable to attend. There was great turnout for this inaugural meeting, and we are excited to host the next Research Roundtable on May 30, 2023.

Please reach out to **clinres@cookcountyhhs.org** to be added to the roundtable attendee list, have questions, or suggested topics for the next roundtable discussion.

Informed Consent Scanning Reminder:

Reminder that in the next few months the CCH electronic health record (EHR) will incorporate additional fields for clinical research use. The first production, which went into effect the week of April 12th, was the creation of a new research consent folder. Research staff will be responsible for providing the signed informed consent document to Health Information Management (HIM) so that it can be scanned into the patient's electronic health record. For a copy of the **HIM cover sheet form** or more information please refer to the **email**.

The links will take you to the content via CCH computers or the CCH intranet.

Quiz Yourself on Human Subjects Research Knowledge: True or False?

1. For IRB approved studies that require informed consent documentation, a researcher is required to have a witness sign a consent form for all participants.
2. For expedited studies, a progress report or annual check-in is usually required to be submitted in IRBManager a year from the date of approval.
3. For FDA regulated studies, all study team members are required to complete the CITI Program Good Clinical Practice and Working with Horses in Agricultural Settings trainings.
4. In an IRB approved study where survey data was collected from participants, it is customary for the investigators to store the raw survey data for a minimum of three years following the close of the study.
5. An example of a protocol deviation is when a study participant informs the research staff during a scheduled follow up visit that they no longer want to be enrolled in the study.

Answers: F, T, F, T, F

4th Annual Institutional Research Day

The GMEC Subcomittee for Research and Scholarship hosted the 4th annual Institutional Research Day on Thursday, April 13th. It was attended by approximately 80 attendings, residents and various other stakeholders in the CCH research community. The event's keynote speaker, Dr. Trevonne Thompson, was a 2005 graduate of the CCH Emergency Medicine residency program and shared some his experiences during residency that prepared him for a successful career as a professor and associate dean for admissions at the University of Illinois at Chicago.

There were 40 live presentations and 39 pre-recorded presentations, all of which generated a great deal of

interest and discussion. The winning presenters are currently being determined and will be announced at the next CCH board meeting. Feel free to browse the event content via CCH computers or the CCH intranet below.

4th Annual CCH Institutional Research Day