COOK COUNTY HEALTH

Research Roundup November 2023

Greetings CCH Researchers!

Happy Thanksgiving! As we move to closer to the end of this year, we are thankful to have made progress in getting research rebuilt and restarted at CCH in a compliant manner. We hope to continue this forward motion as we continue to implement our HRPP Toolkit. Please take a look at our website for the the new SOPs, Worksheets, and Checklists available.

We will continue to post new documents as they become available and encourage everyone to start using them, particularly the protocol and consent templates, when submitting their research for review to the IRB. We are in the process of revising our application for initial submissions in IRBManager and will require the use of the protocol and informed consent templates (if required for your study) once the revised application in is use.

As always, please contact us with any questions or concerns. CCHHSIRB@cookcountyhhs.org

IRB Fee Updates - November 1, 2023

The CCH IRB charges a review fee for industry sponsored research. IRB review fees are not charged for non-profit sponsored studies supported by the National Institutes of Health (NIH), other government agencies, or investigator-initiated studies. Any industry sponsored budget and clinical trial agreement submitted after November 1, 2023 will be subject to these updated fees. There will be no charge for amendments/modifications, protocol deviations, unanticipated events involving risk, or final reports. Please click on the link below to access the current fee structure. These fees are subject to review and change. **Cook County Health Fee Structure Memo**

Investigator Manual Posted!

Our new Investigator Manual has been posted to the Research & Regulatory Affairs Website. This serves as a “How-To” manual for study teams.

- Outlines study team responsibilities for conducting research at CCH
- Identifies activities requiring IRB review
- Specifies qualification and training requirements
- Provides submission, protocol and consent guidance
- Identifies regulatory considerations such as criteria for IRB approval

Please check it out!
Research & Regulatory Affairs Website

Investigator Manual

This document, HRP-103-Investigator Manual, is designed to help investigators through policies and procedures related to the conduct of Human Research that are specific to all affiliates of Cook County Health.

Investigator Manual Version 1.0 (11/20/23)

HRPP Toolkit & FCOI Trainings

Both the in-person and virtual live HRPP (Human Research Protection Program) Toolkit and FCOI (Financial Conflict of Interest) trainings for researchers have concluded. This required training is now available through the CCH LMS (Learning Management System) for those that were not able to attend any live sessions, are new to research at CCH, or just want to review the content. The link will take you to the training in the LMS. Please see the course description below. There is an attestation clause researchers will have to sign to confirm they have watched and understand the HRPP Toolkit & FCOI training and agree to comply.
https://learningmanager.adobe.com/app/learner?accountId=97436#/course/7966950

Clinical Research Office (CRO) Updates November 2023

Clinical Trials to be Re-opened as Pilot

The minimum requirements for reopening clinical trials have been met, and now the new paradigm needs to be tested. Ten pilot protocols will be selected to test the new workflows. To submit a protocol for consideration study teams are asked to:

- Complete the **Feasibility Assessment Form**, along with the final protocol, draft Informed Consent, and Draft sponsor/funder budget and Clinical Trial Agreement. All documents are requested to be routed to **clinres@cookcountyhhs.org** for consideration as a pilot interventional clinical trial.
- Ensure the Principal Investigator meets **eligibility criteria** and has completed the Research Affairs Policy attestation of understanding and compliance.

A rubric for clinical trial pilot priority was created by the CRO steering committee that will be used to score and identify the ten studies to be piloted. Thank you to Dr. Lad, Dr. Hart and Dr. Lewis for their engagement and guidance serving on the Steering Committee. To date, there have been two interventional clinical trials submitted for pilot consideration.

Clinical Research Billing Policy

Clinical Research Billing Policy was published to the **Cook County Health New Policy Portal** earlier this month, and all active Principal Investigators were assigned to read, review and document attestation for compliance. This policy outlines the requirements for compliant research billing with the Center for Medicare and Medicaid **National Coverage Decision 310.1 Routine Costs in Clinical Trials.** Study teams

responsibilities include submitting **Patient Research Registration Form** at the time of obtaining informed consent; billing alignment with the Coverage Analysis, and periodic reconciliation of clinical research accounts receivables. The Clinical Research Office responsibilities for subject and protocol registration into CERNER, Charge Review, Claims Modifications and Charge segregation are also outlined.

FY2024 Clinical Research Quality Assurance Plan

The Clinical Research Office will be initiating quality assurance activities in FY2024. This is in alignment with **RA.005.01 Clinical Research Quality and Education Policy**. Activities include internal auditing for Good Clinical Practice, FDA, CCH Policy and protocol compliance, internal research billing compliance, and key performance metric surveillance. Any study team that will be inspected should expect to receive a "Notification of Inspection" and "Audit Plan" prior to the review.

Clinical Research Documentation Standards

The Center for Medicare and Medicare Services (CMS) has requirements for source documentation for clinical research that is conducted within standard care encounters. CCH has outlined requirements for study teams to follow in **RA.008.01 Research Documentation Policy**. Reminder that all executed Informed Consents need a copy and the **Cover Sheet** sent to HIM to be scanned and uploaded to the Electronic Health Record/Consents/Research Consents tab. The person obtaining informed consent is also required to write a research informed consent note as a source, outlining the details of the encounter. All research encounters that completed in alignment with the schedule of events for a qualifying clinical trial are required to include the following elements:

- CCH IRB #
- Protocol Title
- PI Name
- Study ID#
- Date and research visit description (Screening / Day 1 – Cycle 1 etc.) that is aligned with the protocol calendar of events.

Training Opportunity – FDA Clinical Investigational Training Course (CITC) 2023

This course is designed to promote professionalism in the clinical trial industry for individuals involved with submissions to FDA (Investigational New Drug (IND) application, New Drug Application (NDA), Biologics License Application (BLA)), and to familiarize stakeholders with the regulatory and scientific issues involved in the development and approval of medical drugs and biological products. Participants will acquire a practical understanding of:

- FDA's approach to trial design
- Safety concerns in the development of medical products
- Statistical issues in the analysis of trial data
- Clinical investigator responsibilities

INTENDED AUDIENCE

This is a clinical investigator training course targeted at all stakeholders in the clinical trial enterprise including industry, academia, and regulators (both local and foreign). The agenda is designed for:

- Clinical investigators
- Health care professionals (physicians, nurses, pharmacists, other healthcare workers), and
- Individuals involved in biomedical research and the development of drugs and biological products.

TOPICS COVERED

- Design and conduct of clinical trials
- Innovative trial designs
- Considerations for rare disease drug development
- Enhancing diversity in clinical trials
- Addressing specific populations in drug development

- Statistical evaluation of clinical trials
- Understanding the investigator brochure
- Clinical trial quality

This live session is offered virtually December 6th, and 7th. Registrants will have access to tapings of the training and slide decks. **Registration is free.** **HERE**

Clinical Research Office Monthly Roundtable

Thank you to everyone who participated in the last Clinical Research Office ("CRO") October Research Roundtable virtual meeting. This call is open to the research community, and we encourage everyone to attend as it is a great way to receive updates as well as ask questions / provide input. Have a question or topic to discuss? Please email **clinres@cookcountyhhs.org** if you are unable to attend, Roundtable materials are posted to the CCH Research Champions Team Channel **HERE** after each meeting.

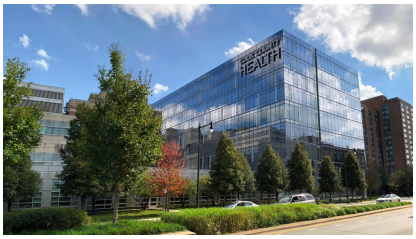
There will not be a monthly **Research Roundtable** in November. Please send topics you would like to be covered in December or in 2024 to **clinres@cookcountyhhs.org.**The next Research Roundtable will be hosted on Tuesday December 26 from 12:00 – 1:00 CDT.

5th Annual Institutional Research Day

The GMEC Research and ScholarshipSubcommittee is proud to invite you to the5 th annual CCH Institutional ResearchDay. Institutional Research Day is an opportunity for physicians in training and health care professionals to share their research projects, case series and reports with the CCH research community.

The event will be held in the Professional Building in April of 2024. All training programs are encouraged to make submissions to highlight the academic projects at CCH. Research that has been presented at other meetings is also welcome. Submissions may be made for both oral and poster presentations, and all research abstracts will require prior CCH IRB approval.

More details regarding the event, as well as a link to the electronic abstract submission portal, will be provided in the December newsletter. If you have any questions regarding the event, please contact GMEC Research and ScholarshipSubcommittee **gmecsubfacultydevelopment@cookcountyhhs.org.**



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.

Research & Regulatory Affairs Website