



# COOK COUNTY HEALTH

## Research Roundup June 2023

### Greetings CCH researchers!

In our effort to keep CCH researchers informed of human research protections and other developments in research, we are happy to share the June issue of the Research & Regulatory Affairs newsletter. This issue will focus on disclosing financial interests in research as well as some important reminders and updates.



I am excited to share some big changes coming to Research & Regulatory Affairs, the IRB, and the research community at CCH. We are in the process of implementing the **HRPP (Human Research Protection Program) Toolkit** from Huron Consulting Group. This is a comprehensive toolkit that includes new standard operating procedures, forms, checklists, worksheets, and templates. Our staff has completed training. Our IRB members are in the process of their training. Once this is complete, we will be reaching out the research community for training as well. As we implement the new toolkit, we are planning on updating IRBManager with these changes and look forward to a more streamlined process for IRB approval.



### FDA IRB Inspection

The FDA's Bioresearch Monitoring (BIMO) program is a comprehensive program of on-site inspections, data audits, and remote regulatory assessments designed to monitor all aspects of the conduct and reporting of FDA regulated research. This June, our IRB was inspected by the FDA. The FDA conducts IRB inspections to determine if IRBs are operating in compliance with current FDA regulations, statutory requirements, and the IRBs own written procedures.

We are happy to report that we had a successful inspection and were found to be in compliance with all regulations, requirements, and procedures. As always, the protection of our research participants is of the utmost importance for our IRB.

**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](mailto:CCHHSIRB@cookcountyhhs.org).**

## Disclosing Financial Interests

Remember to disclose your financial interests in accordance with CCH's Policy, Financial Conflict of Interest in Research CC.007.02

(<https://cookcountyhealth.ellucid.com/documents/view/209>). Please notice that the reporting threshold has been lowered from \$5000 to \$500. All Investigators and key study personnel must disclose whether they (or their spouse, domestic partner, or dependent child(ren)) have a financial interest in any external entity related to the research conducted or their Institutional Responsibilities that consist of:

- a. Remuneration received from an entity in the twelve months preceding the disclosure that **exceeds \$500** (including non-CCH-sponsored seminar or lecture income);
- b. Any equity or proprietary interest;
- c. Intellectual property rights and interests **over \$500**; and
- d. Sponsored or reimbursed travel costs, including information regarding the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Open payments will be updating data to include payments from 2022 in July. Please check and make sure that if you have any new payments to disclose them to the IRB if related to your research or institutional responsibilities. (<https://openpaymentsdata.cms.gov/>)



For Principal Investigators of expedited protocols without expiration dates, an Annual Check-In form must be submitted once a year. You can check if your study is missing an Annual Check-In form by visiting the study's dashboard in IRB Manager. If the "Other Expirations" date is in bright red text, this means your study is missing the required Annual Check-In form. If your expedited study is complete and needs to be closed, then a Progress Report/Final Report must be submitted.

Any research staff leaving Cook County Health must be removed from the rosters of all IRB protocols in which they are listed as personnel. This should be done **BEFORE** leaving. Amendments to remove personnel should be submitted for each study in IRB Manager.



Any documents that require IRB approval stamps (informed consent forms, HIPAA forms, flyers, etc.) should be submitted in Word format. This allows the IRB staff to adjust the documents to make room for the approval stamp.



# Clinical Research Office (CRO) Updates June 2023

## Clinical Research Office (CRO) Policies Update

Please be aware of the new CRO policies that are currently going through the CCH Policy Committee approval process:

- o RA.001.01 Institutional Requirements for Initiating Clinical Research
- o RA.003.01 Subject Compensation and Reimbursement
- o RA.004.01 Principal Investigator Eligibility Policy
- o RA.005.01 Clinical Research Quality and Education Policy
- o RA.006.01 Clinical Research Budgeting Policy
- o RA.007.01 Clinical Research Subject Registration

More information will be shared with the research community when these policies receive final approval.

## Cerner Billing Process Update

The CRO and Cerner team have been working together to ensure that there is a cohesive billing system in place for clinical research. The Cerner team has been busy testing system updates to support the clinical research billing processes in the CCH electric health record system. In order to support Cerner and all the work they are doing, we ask you to comply with and note the following:

1. Notify the CRO when you have a new research patient or when a research patient has an active status change by filling out this **Patient Registration Form**.
2. Prioritize the prompt identification of active research patients. This will help ensure that CCH is compliant with clinical research billing processes.
3. Clinical research patients do not require any special Cerner registration in the system. This is because charge segregation will occur on the back end.
4. Each active study will require a Coverage Analysis to ensure accurate clinical research billing. A Coverage Analysis is a review of the procedures detailed in the study protocol to determine how each service and/or procedure should be billed.

## Departmental Research Champions

The CRO is reaching out to department and division leaders to identify a research champion to be added to the research community distribution list. The research champion will be the “voice” for their colleagues and peers. The research champion will be responsible for sharing CRO updates and bringing forward questions and concerns. If you have not provided a research champion for your area, or if you would like to nominate someone and send their name, role and email to **CLINRES@cookcountyhhs.com**.

## Clinical Research Office Monthly Roundtable

Thank you to everyone who participated in the last Clinical Research Office (“CRO”) Roundtable call on 5/30. 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.com**. If you are unable to attend, Roundtable materials are posted to the CCH Research Champions Team Channel **HERE** after each meeting. The next Roundtable will be hosted on Tuesday June 27<sup>th</sup> from 12:00 – 1:00 CST.

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

1. Investigators are responsible for ensuring all key personnel are listed in IRBManager and they are current in their IRB training.
2. Pilot studies are exempt from filing a Investigational New Drug (IND) application.
3. It is possible for a quality improvement (QI) or a quality assurance (QA) project to be determined by the IRB to NOT be research.
4. It is good record keeping practice for all study-related materials and IRB



correspondence to be kept in a central location, particularly in a physical or an electronic folder.

5. All adverse events (AEs) and serious adverse events (SAEs) that are not related to a subject's participation in a study should be documented and submitted via IRB Manager within the reporting time frame.

Answers: T, F, T, T, F

