COOK COUNTY HEALTH

Research Roundup October 2023

Greetings CCH Researchers!

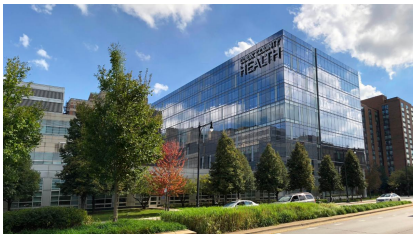
We have some exciting new developments in research to share. CCH is now ready to accept 10 pilot clinical trials to test the new system and ensure that all requirements for clinical trails are being met. Please see the announcement and instructions for submission from the CRO below for details.

The HRPP/IRB staff continues to implement our new HRPP Toolkit. We now have finalized and posted the checklists on our website for your reference and transparency into the IRB review process. We discuss the checklists that are especially relevant to researchers including vulnerable populations and requesting waivers below. The information in these checklists should assist researchers in identifying the federally required criteria for approval to include in their protocol in order to minimize returns of applications for changes and approval time.

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

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 combined 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



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

HRPP Toolkit Checklists

The HRPP Toolkit Checklists are designed to provide support to IRB members when reviewing studies to ensure all of the regulatory criteria are met and documented. These checklists should also be used by researchers when developing their protocol to ensure they have provided sufficient information to the IRB to review the study.

Checklists for Vulnerable Populations

If your research involves involves individuals who are vulnerable to coercion or undue influence, such as pregnant women, non-viable neonates or neonates of uncertain viability, prisoners/detainees, children, or impaired adults, you must describe additional safeguards to protect their rights and welfare. Please see the links below to access the checklists from our website.

HRP-412-Checklist-Pregnant Women
HRP-413-Checklist-Non-Viable Neonates
HRP-414-Checklist-Neonates of Uncertain Viability
HRP-415-Checklist-Prisoners
HRP-416-Checklist-Children
HRP-417-Cognitively Impaired Adults

For example, if your research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (children), review the HRP-416 Checklist to ensure you have provided sufficient information in your protocol. You will want to include information about the risk level and potential benefits, provisions to solicit assent of the children or why assent is not necessary, and provisions for soliciting the permission of parents or guardians or justifications a waiver of parental consent is requested.

Checklists for Waivers

We have also uploaded checklists that should be used when applying for a waiver or alteration of the consent process, a waiver of written documentation of consent, and HIPAA waivers. These are the documents that IRB reviewers will use when determining if your research meets the criteria for a waiver. These checklists contain all of the information that should be included in your protocols.

HRP-410-Checklist-Waiver or Alteration of Consent Process
HRP-411-Checklist-Waiver of Written Documentation of Consent
HRP-441-Checklist-HIPAA Waiver of Authorization

For example, in order to be granted a HIPAA waiver, you will have to include the specific Protected Health Information (PHI) elements you will be using in your research, detailed plans for protecting and subsequently destroying identifiers, and written assurances that the PHI will not be reused of disclosed to any other person or entity. You will also need to justify why the research could not practicably be done without the waiver and without access/use of the PHI. As an example, for retrospective chart reviews, it is not practicable to go back and obtain permission as patients' contact information may be outdated or the patients may be deceased. Requiring a written authorization or consent would bias the results of the study as you would be unable to include those that have outdated information or may be deceased. The study cannot practicably be done without use of PHI as identifiers are needed to access the appropriate records and retrieve study data.

Study Start Up Reminders

Research & Regulatory Affairs would like to thank all of the researchers who have welcomed us for our audit process. We have summarized reminders for study conduct in a one-page guide based on our most common audit findings. This document will provide both new and seasoned investigators as well as key personnel

important items to consider prior to study commencement in order to maintain HRPP compliance throughout the duration of the study. Study team members can also consult with a member of the HRPP staff to ensure the study is in good standing from the start. If you have any questions or would like to schedule an in-person consultation, feel free to contact us anytime at cchhsirb@cookcountyhhs.org. Please see the link below.

Getting Started: Important Tips to Consider Prior to Study Launch

Clinical Research Office (CRO) Updates October 2023

New Clinical Research Office Medical Director Announcement

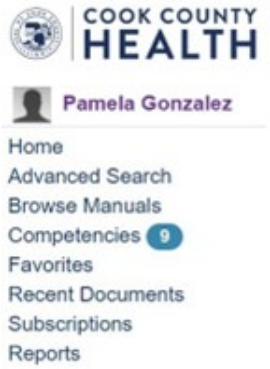
Effective September 24, 2023, Dr. Albert Osei has accepted the position of Clinical Research Office (CRO) Medical Director. Please join me in welcoming and congratulating Dr. Osei on this new role. Dr. Osei has been a member of the CCH medical staff for over two decades and has prior research and IRB experience. We look forward to his leadership. He presented his first quarterly research operations townhall Monday 10/16/2023. A copy of the presentation can be found **HERE**. Recruitment is also underway for the Life Sciences Department Chief Scientific Officer, CRO Director and CRO Financial Manager.

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.
- Ensure the Principal Investigator meets **eligibility criteria** and has completed the Research Affairs Policy attestation of understanding and compliance.

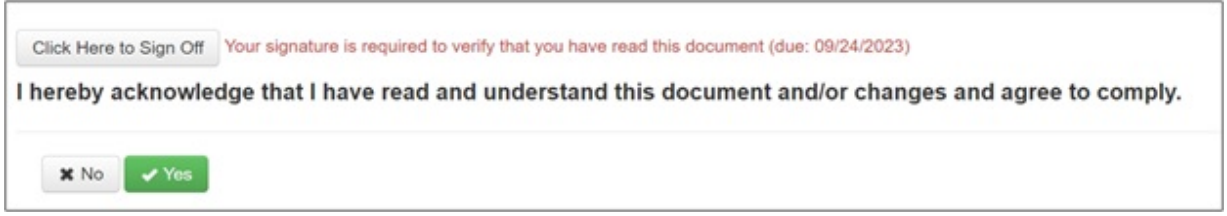
A rubric for clinical trial pilot priority was created by the CRO steering committee that will be used to score and identify the ten studies to be piloted. Thank you to Dr. Lad, Dr. Hart and Dr. Lewis for their engagement and guidance serving on the Steering Committee.



Principal Investigator Attestation of Research Administration Policies

Reminder that Institutional Feasibility Review will not be performed for Principal Investigators who have not completed their Research Affairs Policy review and attestation of understanding and compliance. Steps for completion:

1. Go to outlook email from September 6th, 2023 that has the direct link to the **CCH New Policy Portal**. OR
2. Sign directly into the **CCH New Policy Portal** and navigate to the left column and right click the “Competencies” link.
   a. Read the policy.
   b. Complete attestation.



Clinical Research Feasibility Assessment Required for New Protocols

In compliance with **RA.001.01 Institutional Requirements for Initiating Clinical Research Policy**, protocol feasibility assessment is required prior to beginning start up activities. Regulatory and grant/contract submissions will not be accepted without institutional approval of protocol feasibility.

What studies are impacted? All human subject clinical research studies that:

- Require **IRB full board** approval
- Obtain **outside funding**
- Require **Data Sharing Agreement**
- All Interventional **Clinical Trials**

What is required?

- Complete the **Feasibility Checklist** form
- Route the completed feasibility checklist with a copy of:
  - the final **protocol**,
  - the draft **informed consent**,
  - external funder **draft budget** (if applicable),
  - external funder **draft contract** (if applicable) and
- Send feasibility documents via outlook to: Clinical Research Office **clinres@cookcountyhhs.org**

What is the expected Feasibility Review Timeline?

- The Clinical Research Office (CRO) will review the submitted materials for completeness and provide **written confirmation of receipt** within **96 hours**.
- **Expedited Feasibility Review** determinations will be made within **10 business days** of receipt.
- **Full Feasibility Review** determination by the Clinical Research Operations Committee (CROC) will be made within **20 business** days of receipt.
- Written documentation of the feasibility review determination will be sent to the Principal Investigator.

Why is this required?

- Time spent in **startup activities** is a significant **burden** on faculty and research staff and should be focused on protocols that are aligned with the CCH mission and match our capabilities, patient populations and expertise.
- Provides early institutional assessment of the **research pipeline** to help identify future budget and staffing needs.
- Allows for early coordination of **research billing** and **institutional support** to operationalize the protocol.

Clinical Research Office Monthly Roundtable

Thank you to everyone who participated in the last Clinical Research Office ("CRO") September 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