



Research Roundup September 2023

Greetings CCH Researchers!

Thank you all for attending our HRPP Toolkit Training for Researchers! If you missed it, the training is now available on the LMS, please see below. We now have all the protocol and consent templates posted on our website as well as the informed consent SOPs, checklists, and worksheets. These documents will assist investigators in the process of obtaining informed consent from participants, documenting the informed consent process, and requesting waivers or alterations of the consent process or waivers of written documentation of consent. We are working hard on implementing more pieces of the toolkit. We are currently finalizing our Investigator's Manual, single IRB documents, and many more checklists!

HRPP Toolkit & FCOI Trainings for Researchers

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>

The Human Research Protection Program Toolkit & Financial Conflict of Interest Training for CCH Researchers will ensure that CCH researchers meet federal research regulatory requirements by familiarizing the CCH research community with the SOPs, templates, checklists, worksheets, and investigator manual from the HRPP toolkit as well as providing training on how to submit financial disclosures for potential financial conflicts of interest.

The HRPP Toolkit & FCOI sessions will focus on providing:

- Overview of the Toolkit
- Review of new consent templates
- Review of new protocol templates
- How to use the new templates as part of the submission process
- Guidance on disclosing financial interests in research

At the end of the course, learners will be able to:

- Be familiar with the HRPP toolkit documents including templates, investigator manual, SOPs, checklists, and worksheets
- Use the appropriate protocol template for submitting their research to the IRB
- Use the informed consent templates and processes to meet applicable regulations
- Know when and how to submit a financial disclosure

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.



New Consent SOPs, Worksheets and Checklists Posted!

The new SOPs (Standard Operating Procedures), Worksheets, and Checklists for informed consent from the HRPP Toolkit have been posted to our website.

<https://cookcountyhealth.org/education-research/research/office-of-research-regulatory-affairs-irb/>

HRP-012-SOP-Observation of Consent Process

HRP-090-SOP-Informed Consent Process for Research

HRP-091-SOP-Written Documentation of Consent

HRP-317-WORKSHEET-Short Form of Consent Documentation

HRP-419-CHECKLIST-Waiver of Consent Process for Emergency Research

HRP-410-CHECKLIST-Waiver of Written Documentation of Consent

HRP-411-CHECKLIST-Waiver or Alteration of Consent Process

These SOPs describe how study teams should conduct and document the consent process and include the consent process for populations such as non-English speakers and children. Remember, you must describe your consent process in your protocol. If you will be following HRP-090-SOP Informed Consent Process for Research, you can say that you will be following this process in your protocol and just describe where the consent process will take place, any waiting period, and any process to ensure going consent, see section 22.0 of the protocol template.

Worksheets are used by the IRB during review to support regulatory decision making that does not have to be documented. Checklists are used to document required regulatory decision making. Both worksheets and checklists have been made available as a reference tool for researchers. HRP-317-WORKSHEET-Short Form of Consent Documentation can be used by researchers to ensure they are meeting all of the steps required when using the short form process for non-English speakers. HRP-410-CHECKLIST & HRP-411-CHECKLIST are helpful to researchers who plan on requesting a waiver of consent or a waiver of documentation of consent and the difference between the two. These should be used by researchers to ensure all of the elements needed for IRB review are included in the protocol to minimize application returns by the IRB staff and shorten the time to IRB approval.

Clinical Research Office (CRO) Updates September 2023

Principal Investigator Attestation of Research Administration Policies

On September 6th, all current Principal Investigators received an outlook notification that they had been assigned competencies for the newly published Research Administration Policies. Following the prompts, the individual will be asked to open, **read**, **attest** to understanding, and agree to comply with the policies. Compliance will be assessed when new projects are submitted for institutional feasibility review.

- **RA.001.01 Institutional Requirements for Initiating Clinical Research**
- **RA.003.01 Subject Compensation and Reimbursement**
- **RA.004.01 Principal Investigator Eligibility Policy**

- [RA.005.01 Clinical Research Quality and Education Policy](#)
- [RA.006.01 Clinical Research Budget Policy](#)
- [RA.007.01 Clinical Research Subject Registration](#)
- [RA.008.01 Clinical Research Documentation](#)
- [RA.009.01 ClinicalTrials.Gov Policy](#)
- [RA.010.01 Clinical Research Residual Balance Policy](#)

All policies are published to the [CCH New Policy Portal](#).

Clinical Research Office New Positions Open for Recruitment

Cook County Health has published new positions for [Chief Scientific Officer](#) – the senior leader that will oversee the Life Sciences Department, the [Clinical Research Office, Medical Director; CRO, Director](#) ; and [CRO, Financial Manager](#). Please share these opportunities with your professional colleagues to help in targeting recruitment.

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 including:
 - o **Retrospective chart reviews** requiring IRB full board approval
 - o **Biorepository studies**
 - o **Observational** trials
 - o Interventional **Clinical Trials** (once the institutional pause is lifted)

What is required?

- Complete the [Feasibility Checklist](#) form
- Route the completed feasibility checklist with a copy of:
 - o the final **protocol**,
 - o the draft **informed consent**,
 - o external funder **draft budget** (if applicable),
 - o 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.

Who will be reviewing the Feasibility Checklists?

- The **Clinical Research Operations Committee (CROC)** is chartered to oversee institutional feasibility review. During the CRO implementation this is being delegated to the CRO Implementation Executive Sponsors. We are pleased to announce that **Dr. Albert Osei** has accepted the role as designee to oversee this body. After implementation of the CRO is established, the CROC will be soliciting research champions to serve on this committee.

If you have questions regarding the Feasibility Assessment Process, please contact clinres@cookcountyhhs.org

CCH Invited to Join Clinical Translational Scientific Award (CTSA) Institution of Translational Medicine (ITM)

CCH has been granted affiliate status for the **CTSA ITM**. All **clinical** research faculty and staff are welcome to join the research training and networking programs. This includes:

- Essentials of Patient Oriented Research (EPOR) begins 9/26/2023 - Learn more [HERE](#).
- ITM Studio – Get Expert Feedback on Your Research Aims – Learn More [HERE](#).
- CHeSS – TL1 Post Doctor Program in Clinical Research, Biomedical Informatics and Health Equity - Learn More [HERE](#)
- ITM Grand Rounds – the 9/22/2023 3 pm - topic will include translational science [REGISTER](#)
- ITM Loyola – the 9/18 seminar topic will include community-based implementation science – Learn More [HERE](#).
- ITM Northshore Virtual – the 9/19 topic includes outcomes research workshop – Learn More [HERE](#).

Clinical Research Office Monthly Roundtable

Thank you to everyone who participated in the last Clinical Research Office (“CRO”) August 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. The next Roundtable will be hosted on Tuesday September 26th from 12:00 – 1:00 CDT.

