COOK COUNTY HEALTH

Research Roundup December 2023

Greetings CCH Researchers!

Welcome to the December edition of our monthly newsletter! As we delve into the final month of the year, we aim to keep you informed about crucial aspects of our research community and provide essential updates for your awareness and engagement. Happy Holidays to all!

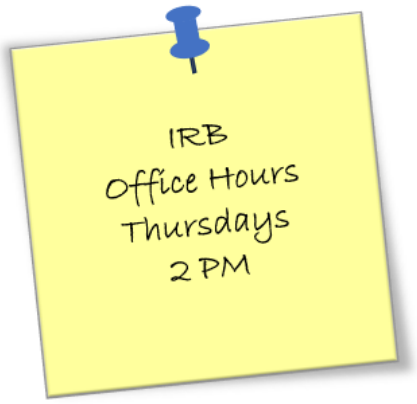
As always, please contact us with any questions or concerns: CCHHSIRB@cookcountyhhs.org

Informed Consent Reminder!!!

Please remember to use an IRB approved, stamped consent document and HIPAA authorization that is current (not expired) and not cut off the page.

IRB Office Hours & Workshops

Starting in January 2024, the Research & Regulatory Affairs staff will be hosting weekly virtual IRB office hours and monthly workshops both virtually and in-person to help with the transition to the HRPP Toolkit and answer your IRB questions. Both can be accessed from the links provided. Please email: CCHHSIRB@cookcountyhhs.org to reserve a space if you plan on attending the workshop in person, which is recommended.



Microsoft Teams Meeting

Join on your computer, mobile app or room device
Click here to join the meeting
Meeting ID: 235 329 202 815

Microsoft Teams Meeting

Join on your computer, mobile app or room device
Click here to join the meeting

Passcode: jsYuCc
Join with a video conferencing
cookcountyhhs@m.webex.com
Video Conference ID: 118 122 957 4
Alternate VTC instructions
Or call in (audio only)
+1 312-667-5356,,510934269#
United States, Chicago
Phone Conference ID: 510 934 269#

Meeting ID: 233 082 163 693
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Join with a video conferencing
cookcountyhhs@m.webex.com
Video Conference ID: 112 326 899 2
Alternate VTC instructions
Or call in (audio only)
+1 312-667 5356,,495866178#
United States, Chicago
Phone Conference ID: 495 866 178#

January 9th Workshop: Consenting Non-English Speakers

Do you have a non-English speaker you'd like to enroll in your study but are unsure how the consent process works? Join us for a review of the consent procedures, role-play scenarios, and an opportunity to ask the IRB staff any questions that you may have!

Upcoming Workshops:
February: Who's Afraid of the IRB?
March: Protocol Templates & New Application
April: Consent Templates & Process
May: Using a Single IRB
June: Reportable Events

Research & Grant Terms

In our decentralized research community, effective communication channels and clear procedures are fundamental. We understand that the language used in research can be complex and specialized. To assist you, we have compiled glossaries for various terms frequently referenced in Cook County Health research documents. These glossaries encompass definitions from:

- Cook County Health Human Research Protection Program **HRP-001-SOP-Definitions**
- **NIH Central Resource for Grants and Funding Glossary**
- **Food and Drug Administration Glossary**
- **NIH Public Health System Glossary**

Institutional Signatory Authority & Agreement Types

Participation in multi-site projects often necessitates formal agreements between involved parties, even without financial compensation. Please note that faculty members cannot sign as institutional signatories on behalf of Cook County Health. These agreements require formal review and routing by the Sponsored Program Office (SPO), Clinical Research Office (CRO), and/or the Human Research Protection Program (HRPP/IRB) for institutional signatory execution.
The following are examples of research or grant agreements you may encounter:

- **Letter of Intent (LOI)** Some funders request prospective applicants to submit letters of intent prior to the submission of a grant application. The letter usually includes the name, address, and phone number of the PI, identifies other key personnel and participating institutions, and the RFA or PA identification. Although

a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows institute staff to estimate the potential review workload and plan for the application.

- **Confidential Disclosure Agreement (CDA)** A Confidential Disclosure Agreement [(CDA), also referred to as non-disclosure agreement (NDA) or secrecy agreement],is a legal agreement between a minimum of two parties which outlines information the parties wish to share with one another for certain evaluation purposes but wish to restrict from wider use and dissemination. The parties agree not to disclose the non-public information covered by the agreement.CDAs are commonly executed when two parties are considering a relationship/collaboration together and need to understand the other's processes, methods, or technology solely for the purpose of evaluating the potential for a future relationship**.** Many commercial clinical trial sponsors will require an executed CDA prior to sharing their proprietary protocol with a potential Principal Investigator (PI) and site. **At CCH signatory authority has been granted from the CEO to the Chief of Compliance**. Sponsors may also request that the PI acknowledge the CDA, but the institutional signatory may not be the PI.
- **Letter of Support (LOS)** letters of support from your institution, key personnel, collaborators, and other significant contributors are often required to be submitted with grant applications. Relevant letters of support will assure your peer reviewers that your collaborations and institutional commitments are on the right track.
- **Corporate Funded Agreements (CFA)** Funded agreements with a corporate entity include agreements such as **Sponsored Research Agreements** (SRAs), **Corporate Research Agreements** (CRAs), and **Clinical Trial Agreements** (CTAs). The scope of research activities conducted under these kinds of agreements ranges from basic benchwork to pre-clinical animal work to interventional human subject clinical trials.
- **Material Data Transfer Agreements (MDTA)** are contractual documents used for the acquisition of various biological and research materials, and occasionally, data, developed by nonprofit, government, and private industry. Often these materials are a necessary component of a research project and are available only from a sole source, often industry. Industry may view their materials as important proprietary resources and may want to assert ownership of any inventions made with those materials or restrict publication of unfavorable results.
- **Data Use Agreement** A Data Use Agreement (DUA) is a contractual document used for the transfer of data that has been developed by nonprofit, government, or private industry, where the data are nonpublic or is otherwise subject to some restrictions on its use.Often, this data is a necessary component of a research project, and it may or may not be human subject data from a clinical trial, or a Limited Data Set as defined in HIPAA.
- **Reliance Agreement** – Institutional agreement that CCH Human Subject Protection Program (IRB) will rely on an outside Institutional Review Board involved in the same multi-site research that provides a mechanism to delegate IRB review, and that sets forth the authorities, roles, and responsibilities of the IRB and participating institutions. The agreement may apply to a single study or to certain categories of studies.
- **Award Agreement** Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements in the form of money or property in lieu of money, by the federal government to an eligible recipient. The term does not include technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; and contracts which are required to be entered into and administered under federal procurement laws and regulations.
- **Sub-Award Agreement (incoming) –** Federal award is granted to the prime site and CCH is identified as a sub-award recipient by the prime.
- **Sub-Award Agreement (outgoing)** – CCH receives the prime Federal award

and negotiates with external sites to be secondary sites.

Clinical Research Office Monthly Roundtable

A big thank you to everyone who participated in the previous Clinical Research Office (CRO) Research Roundtables this year. These sessions are open to the entire research community and provide an excellent opportunity to stay updated, ask questions, and contribute your insights.

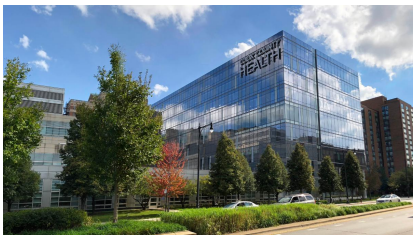
If you missed the roundtable or have topics you'd like to discuss, please reach out to **clinres@cookcountyhhs.org**. Roundtable materials are shared on the CCH Research Champions Team Channel **HERE** after each meeting.

We invite you to suggest topics for discussion in December or for the upcoming year. The next Research Roundtable will be held on Tuesday, December 26, from 12:00 PM to 1:00 PM CDT.

We encourage your active participation and look forward to your valuable contributions in our upcoming sessions. Thank you for your ongoing commitment and dedication to advancing research initiatives here at Cook County Health.

Quarterly Research Town Hall

Speaker: – Dr. Osei, Clinical Research Medical Director
Date: Monday January 22nd, 2024
Time: 12- 1 pm
Teams Link: **Click here to join the meeting** / Meeting ID: 239 307 970 419 / Passcode: B4vYoF



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