

Research & Regulatory Affairs



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Issue 6

Research Ethics & Compliance Training

Research & Regulatory Affairs is excited to introduce the CITI Program for Research Ethics & Compliance Training to CCH. In order to ensure the protection of our research participants, our Human Subjects Research (HSR)/IRB training will now expire every 3 years. With over 800 active users in IRBManager, on-line certification is necessary to keep up with best practices and changes in the law, standardize the educational platform across institutions for multi-site studies, and ensure our researchers meet single IRB and sponsor requirements.

Researchers looking to become certified for the first time will now complete the HSR CITI modules prior to their in-person training. Researchers who have already completed the in-person training will only have to complete the CITI modules. Researchers who have not taken the in-person training in the last 3 years are required to complete the HSR course by the end of 2019. Those that have completed the in-person training within the last 3 years will be required to renew at their 3-year expiration date.

The Human Subjects Research (HSR) coursework is required. You will have the option to select a biomedical or social/behavioral track. There are also 6 other optional courses each with their own modules you can complete. It is recommended but not required that all biomedical researchers complete the Good Clinical Practice (GCP) course. The other optional courses include Responsible Conduct of Research, Conflicts of Interest, Information Privacy and Security, Revised Common Rule, and Animal Care and Use.



Please see our website for instructions:

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

Link to the CITI Program: <http://www.citiprogram.org/login>

The Revised Common Rule's Single IRB Mandate

Starting on January 20, 2020, all federally funded, multi-site studies that are not exempt must use a single IRB of record to provide IRB oversight for their study. This is separate from the NIH single IRB mandate that went into effect in January 2018. Remember to allow ample time for setting up reliance and administrative review.

From the Interim Director

Betty Donoval, JD, MS

Greetings CCH Researchers!

As 2019 ends, Research & Regulatory Affairs is thankful for all of the important research occurring at Cook County Health and all of our investigators who work so hard to include and protect our population in their research endeavors. Please check out the CORE Center's research in this issue.

I am excited to announce that we are updating our education requirements and making them accessible to everyone through the CITI Program.

We have also revised our guidance for recruiting and advertising for research participants. The highlights are included in this newsletter, and the full document is on our website. As we update our guidance for investigators, new sections will be posted.

Happy Holidays! Betty

Recruiting & Advertising for Research Participants

The recruitment of research participants is a challenging aspect of research involving human participants. Federal regulations require the IRB to review the methods and materials that investigators propose to use to recruit participants to ensure that participant selection is equitable and includes racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition studied. All recruitment efforts must also respect personal rights to privacy and confidentiality, be compliant with the Health Insurance Portability & Accountability Act (HIPAA), and avoid coercion or undue influence of potential participants. The CCH IRB requires all recruitment and advertising methods and materials be reviewed and approved by the IRB prior to recruiting any participants. Highlights from our revised guidance for investigators on recruiting and advertising are below:

- You must have permission to go through medical records to identify prospective participants or when designing a research study. This is accomplished through a HIPAA authorization waiver or partial waiver and the preparatory to research provision respectively.
- Cold calls or direct mailings from an investigator without clinical access and unknown to the potential participant are not allowed. Contact must be initiated through a CCH provider who has clinical access or a treatment relationship.
- A clinician may provide information about research to patients with whom he/she has a clinical relationship on behalf of an investigator from another institution if he/she believes the patient would benefit from participation in the research without that study being approved by the CCH IRB. In this case only descriptive information is given to the patient without any stated or implied endorsement of the research (i.e., a summary of the research, and the name and phone number of the physician conducting the trial).
- If approaching a patient on behalf of an investigator from another institution, consent of the potential participant is required before identifying information is given to the study investigator. Recruitment for an outside institution must be reviewed and approved by the CCH IRB. Please see Appendix 1 of the guidance on our website for a sample of the consent that is required of the potential participant.
- Direct advertising for study participants is the start of the informed consent process. All advertising and recruitment materials must be reviewed and approved by the IRB to ensure they are not misleading, imply a favorable outcome beyond what is outlined in the consent form/protocol, or include any exculpatory language. This is especially critical when a study may involve participants who are likely to be vulnerable to undue influence and coercion. The IRB reviews all recruitment materials, including flyers/ads, posters, invitation letters/emails, "Dear. Dr." letters requesting referrals, videos, radio scripts, sponsor's national advertising materials, and ads placed on print or social media.
- When direct advertising is to be used, the IRB reviews the information contained in the advertisement and the mode of its communication. The IRB must approve the final copy of printed or electronically posted ads. The IRB will evaluate not only the verbal content, but the relative size of type used and other visual effects. When ads are produced for broadcast, the IRB should review the final audio or video tape. When posting advertising flyers in community settings, obtain approval from that facility.

Please see the full document on our website (<https://cookcountyhealth.org/wp-content/uploads/Recruiting-Advertising-for-Research-Participants-11-4-2019.pdf>) which includes details on recruitment methods, what can and cannot be included in advertisements, as well as guidance on using social media for recruitment, payments to study participants, recruitment bonuses and finder's fees, passive consent, and pre-screening.

QUIZ YOURSELF ON IRBMANAGER KNOWLEDGE: True or False

1. When you click "submit" on a new application for IRB review, the IRB automatically receives your submission.
2. If the form submitter is not the PI, the PI must sign off on the application.
3. The designated signatory does not need to sign off on the application if the PI is an attending.
4. All key personnel must sign off on an initial review application stating that they do not have a financial conflict of interest, and, if they do, they must submit a separate form.
5. Researchers can monitor the status of their application in IRBManager. (F,T,F,T,T)

Dr. Oluwatoyin Adeyemi

Dr. Adeyemi is the Senior Director of HIV Services for Cook County Health and has been involved in HIV research for 18 years. Her interest in this field stemmed from her passion to care for people who are living with HIV/AIDS. At CCH, over 80% of the people living with HIV/AIDS are people of color, and it is vitally important to include them in research so that they receive the benefits of being in clinical trials and studies. It is also imperative CCH be a part of the innovation and advances in HIV prevention and treatment.

CCH is a partner of the Getting to Zero Illinois initiative. The goal of this initiative is to end the HIV epidemic by 2030, which includes lowering new HIV transmissions to zero and having all individuals living with HIV in treatment. This means there would be less than 100 new cases of HIV in Illinois per year. "When we get to that point, the epidemic is no longer able to sustain itself," says Dr. Adeyemi. Another important goal is to increase the number of people without HIV receiving Pre-Exposure Prophylaxis or PrEP, a pill that is almost 99% effective if taken daily to prevent becoming infected. CCH has six convenient sites for HIV care including: the Austin Health Center, Cottage Grove Health Center, Oak Forest Health Center, Provident Hospital of Cook County, Robbins Health Center and the Ruth M. Rothstein CORE Center, collectively forming the Cook County Integrated Program (CCHIP). "So far, 86% of patients have reached the status of undetectable, which is great, but we still have work to do," Dr. Adeyemi adds. When people are undetectable they cannot transmit the virus sexually.

**Undetectable equals
Untransmittable**

U=U

Dr. Adeyemi has also been treating patients for Hepatitis C at the CORE Center since 2001. In the last several years, there have been great advances in Hep C treatment when Directly Acting Antivirals (DAA) were approved in 2015. Currently, over 980 patients have been treated for Hep C with a 97% cure rate by just taking medication once a day for eight to 12 weeks. Previous Hep C treatment was cumbersome with a weekly injection and four to eight pills daily for a year with cure rates of about 40% to 45% and even lower for people of color and people living with HIV. With the implementation of DAAs, cure rates are now higher regardless of race, gender, severity of the disease, and HIV status.



Dr. Adeyemi has worked on both the programmatic and research sides of health care. When describing the direct correlation between research and programs, she notes that the beauty of working in a system like CCH is that all of the research is patient driven. The research CCH does is directly applicable to our patients based on their unique needs. Even when we are one site in a multi-site clinical trial, we have a rigorous process to decide on a local level, if the research will be beneficial to our patients. We need to know things like: Is this a need for our patients? Is the research something that we need to contribute to the literature because our patients' voices need to be heard? Is the

research going to advance science? If we see there is a need for our patients, we actively seek to design those studies.

Over the years, Dr. Adeyemi has found the most challenging part of conducting research has been recruiting patients for some of our studies. Several barriers keep patients from participating in studies. Some feel they would just be guinea pigs, while others do not have the time or the energy to participate. Most prominently, there is a lack of trust in the researcher. It has been shown patients are three times more likely to participate in studies if their primary care provider talked to them about joining a study. Once patients participate in a study, they are more likely to participate in future studies.

"We would like to get 20% more people to an undetectable status in Illinois and 20% more people to take PrEP. To achieve getting to zero, we must screen, test and engage our patients in care, treatment, programs and education."

Dr. Adeyemi encourages researchers to follow their passion and really know why they are doing research. Researchers should never give up because of rejections for new grant funding or publications, and funding cuts, which are all common aspects of conducting research studies. Lastly, take the time to celebrate victories, both big and small. Getting a protocol revision approved, enrolling the first patient, and passing the monitor visits are all causes for celebration and will definitely motivate you to keep moving forward in your research endeavors.

Dr. Adeyemi, the Department of Research and Regulatory Affairs would like to thank you for all of the amazing work you do!

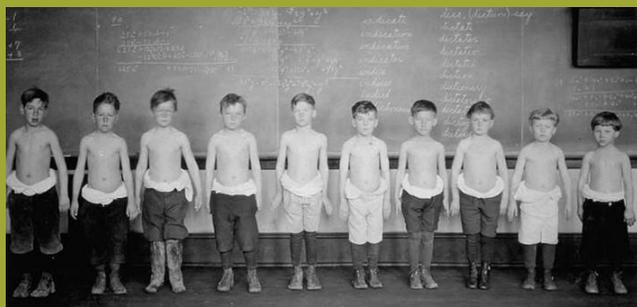
New Trivia Question: What document became the first international standard for the conduct of research by establishing the basic principles that must be followed to satisfy moral, ethical, and legal concepts when using humans in research?

Email your answer to: CCHHSIRB@cookcountyhhs.org

CORE Center Poster and Presentation Exhibit

We would like to congratulate the CORE Center staff on their posters and oral presentations that were presented at the 2019 Sexual Health Conference and at other conferences this past year. Thank you for inviting us to the Exhibit that took place on Friday, July 26, 2019!

- # 1 **Poster: Sexual Behavior and Beliefs Among Young Cisgender Men and Transgender Women Who Have Sex with Men Accessing Pre-Exposure Prophylaxis (PrEP).** Kody Keckler, Gregory Huhn, Sybil Hosek, Jennifer Brothers
- # 2 **Poster: #keepingitLITE: PrEP Uptake & Barriers to Usage Among a Young Sex & Gender Diverse Cohort.** Pedro Serrano, MPH, Alejandro Muñoz, John Kaleekal, Audrey French, MD, Sybil Hosek, PhD
- # 3 **Poster: Identifying Levels of Access to Healthcare & Sexual Health Outcomes among Underserved and High-Risk Communities** Meena Malhotra, MSc, Ryan Muench, MPH, Christopher Balthazar, MA, Kortez Davis, Sybil Hosek, PhD
- # 4 **Poster: Getting a Pulse on the HIV Prevention Revolution** Jessica Zamora, Jennifer Catrambone, Allison Precht, Dr. Adeyemi
- # 5 **Oral: U=U & PrEP: An in-depth look at the patients' perspective [on the HIV Prevention Revolution]** Allison Precht, Jennifer Catrambone, Jessica Zamora, Dr. Adeyemi
- # 6 **Workshop: Developing a Group Intervention Focused on Dismantling Toxic Masculinity** Rona Clark EdD, NCC, LPC, Patricia Aguado PhD, LCSW
Workshop: Mexican Men Living with HIV: Barriers and Facilitators to Treatment and Retention Patricia Aguado PhD, LCSW
- # 7 **Oral: Sexual and Reproductive Health for Youth Populations: What's in Your Toolbox?** Lisa Henry-Reid, MD
- # 8 **Oral: The Spectrum Ignited: The Cutting Edge of Sexual Health in the U.S.**
Brief, ignite-style presentation on cutting edge topics in different sexual health arenas.
Hector Vargas, JD—LGBTQ Health Equity; Ed Gardner, MD—HIV; David Harvey, MSW—Political Advocacy; Karen Wendel, ME—STD; Oluwatoyin Adeyemi, MD—Hepatitis C; Kaitlyn Marchesano, MPH—Reproductive Health
Hepatitis C Update Oluwatoyin Adeyemi, MD
- # 9 **Implementation and Impact of Clinical Decision Support (CDS) Tool to Increase Hepatitis C Virus (HCV) Screening Among Baby Boomers in a Large Urban Health System** H. Armstrong, M. Gonzalez-Drigo, O. Adeyemi, W. Trick, D. Taussig *Society of General Internal Medicine 4/2018*
- # 10 **HRSA SPNS Practice Transformation Model 2018** Marisol Gonzalez, RN, MPH, Hilary Armstrong, MPH, Jennifer Catrambone, MA, Daniel Taussig, MA, Allison Precht, MA, LPC, CADC *HRSA SPNS Grantee Meeting 8/2018*
- # 11 **Use of Patient Empanelment to Increase Retention and Engagement in Virally Unsuppressed HIV Positive Patients** M. Gonzalez, A. Kumagai, L. Spencer, A. Patino, M. Brower, B. Carminati *Conference on HIV Treatment and Prevention Adherence 6/2018*
- # 12 **Fibrosis surveillance by transient elastography in patients with Untreated HCV infection** Oluwatoyin Adeyemi, Kerianne Burke, Crystal Winston, Sara Markam, Dan Taussig, Benjamin Go, Greg Huhn *ID Week 10/2018*
- # 13 **Characteristics, social factors, and trends in HIV and AIDS-related lymphoma: a 23-year analysis since the implementation of cART, a County Hospital AIDS Malignancy Project (CHAMP) study** Camille E. DeMarco, Pei Lu, David F. Peace, Sunny Singh, Dennis F. Angelov, Kelly A. Benante, Ahmed T. Ahmed, and Paul G. Rubinstein *American Society of Hematology 12/2018*



Last Issue's Question: Quaker Oats teamed up with MIT on a research study that fed vulnerable boys living in a state institution radioactive iron and calcium tracers to compete in the hot breakfast cereal market against what product/brand?

Answer: Cream of Wheat

Winners: Melissa Palma & Emma Villareal!!!

During the 1940s and 50s, nutrition was important to consumers and scientists were eager to conduct studies about health as the first dietary guidelines were published in 1943. The hot breakfast cereal market was in competition with the cold cereal market both of which were in competition with a traditional breakfast of eggs and bacon. Initial studies showed that oats may inhibit the absorption of iron as compared to farina (Cream of Wheat). Quaker Oats, wanting science on their side, teamed up with MIT to conduct a series of experiments approved by the Atomic Energy Commission (AEC) where boys were fed oats coated with radioactive iron tracers, milk with radioactive calcium tracers, and were given injections of radioactive calcium.

These vulnerable boys were from the "Science Club" at Fernald State School, originally called The Massachusetts School for the Feeble-Minded, which housed mentally disabled children and those that were abandoned by their parents. The boys were promised field trips, baseball games, gifts, and "free" breakfasts for their participation in the Science Club. These children were especially vulnerable, as they did not have parents or guardians looking out for their best interests. The researchers never obtained informed consent or disclosed that the children would be fed/injected with radioactive tracers. These experiments were uncovered in the early 90s when a number of AEC documents were declassified. President Clinton formally apologized to the Fernald students in 1995 as the AEC was involved. Thirty former Fernald students filed suit against MIT and Quaker Oats and eventually reached a \$1.85 million settlement in 1998.