COOK COUNTY HEALTH & HOSPITALS SYSTEM
CCHHS

Research & Regulatory Affairs

From the Director, Mildred Williamson, PhD, MSW

Greetings all – and a lot is going on. Thanks to our recent expert staffing additions, we are now able to provide aggregate reports to all CCHHS department chairs and affiliate leads of research activity conducted by CCHHS investigators occurring within their clinical sites. Our initial report is comprised of studies approved or renewed by the CCHHS IRB, January through June 2018. Each quarter thereafter, reports will be developed and distributed for leadership review.

Educational workshop sessions on a variety of topics on ethical research continue to occur on the **fourth Wednesday of each month in Room 5300 of JH Stroger Hospital at 12:00 noon.** The workshop topic scheduled for **August 22** is on Ethical considerations for conducting Research with Prisoners and other Vulnerable Populations.

We are especially pleased to share that the **September 26** workshop is being collaboratively developed and jointly presented by the CCHHS Departments of Research & Regulatory Affairs, Corporate Compliance, Health Information Systems, and the Collaborative Research Unit. This workshop will address HIPAA privacy compliance, confidential record keeping, electronic data security, and an overview of the REDCap data system and its utility. Speakers will be Francisco Angulo, MBA, CHPS, CISSP, CISM; Betty Donoval, JD, MS; Ashley Huntington, JD, CHC; and Dean Sorensen, CCHHS Security Information Officer. The **October 24** workshop topic will be on Informed Consent and the final workshop for 2018 will occur on **November 28**. That topic will be Good Clinical Practice. Please mark your calendars – we look forward to your attendance. Finally, more good information follows in this newsletter edition, thanks to the contributions of our staff, IRB members, and research investigators. Take a look!

AIDS 2018

There is also more great news to report of accomplishments by CCHHS investigators. The 22nd International AIDS Conference just concluded July 27 in Amsterdam, Netherlands, with more than 15,000 researchers, clinicians and activists from all over the world in attendance. Among them was a delegation of CCHHS clinical investigators from the Ruth M. Rothstein CORE Center who delivered five poster presentations on their research findings. Listed below are the titles and authors for each one. CCHHS affiliated authors are highlighted in bold. **Congratulations to all!**

1.Predictors of PrEP Continuation among Young Men who have Sex with Men (YMSM) in the U.S. that Participated in the EPIC (**E**nhancing **Pr**EP **I**n **C**ommunity) Study Authors: **Kelly A. Bojan, DNP, APN,C-FNP**[1], **Rachel Jackson, APN, CFNP**[1], E. Vittinghoff[6], **Pedro Serrano, MPH**[1], P. Vonfelton[5], **Ixchell Ortiz-Estes, MSN, CPNP-PC**[1], **J. Brothers**[2], K. Rivet Amico[3], J. Rooney[4], **Sybil Hosek, PhD**[1,2], J. Fuchs[5,6], A. Liu[5,6] Ruth M. Rothstein CORE Center[1], Stroger Hospital of Cook County[2], University of Michigan School of Public Health[3], Gilead Sciences[4], San Francisco Department of Public Health[5], University of California, San Francisco[6].

2. Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) in a Test-and-Treat Model of Care for HIV-1 Infection: Interim Analysis of the DIAMOND Study Authors: **Gregory D. Huhn, MD, MPH&TM**[1],* Gordon Crofoot[2], Moti Ramgopal[3], Joseph Gathe Jr.[4], Robert Bolan[5], Ceyhun Bicer[6], Richard Bruce Simonson[7], Richard E. Nettles[7], Keith Dunn[7], The Ruth M. Rothstein CORE Center[1], Chicago, IL, USA; Crofoot Research Center[2], Houston, TX, USA; Midway Immunology and Research Center[3], Fort Pierce, FL, USA; Therapeutic Concepts[4], Houston, TX, USA; Los Angeles LGBT Center[5], Los Angeles, CA, USA; BICER Consulting & Research[6], Antwerp, Belgium; Janssen Scientific Affairs[7], LLC, Titusville, NJ, USA.

3."Sleep and Circadian Disruption Interact with HIV, Contributing to Inflammation and Immune Activation" Authors: Kathleen M. Weber MS[1], Helen J. Bugess PhD[2], Elizabeth Daubert MPH[1], Jane Burke-Miller PhD[1], Leah McClellan RN, MSN, FNP-BC[1], Caitlin Bond MPH[1], Ralph Morack MS[1], **Mardge H. Cohen MD**[3], & **Audrey L. French, MD**[3,4], for the **Chicago Women's Interagency HIV Study (WIHS)**.

4."Barriers and Facilitators of Higher Patient Activation Levels Among HIV-Infected and Uninfected Midlife U.S. Women" Authors: Kathleen M. Weber MS[1], Caitlin Bond MPH[1], Elizabeth Daubert MPH[1], Leah McClellan RN, MSN[1], **Audrey L. French MD**[3,4] **Mardge H. Cohen MD**[3] for the **Chicago Women's Interagency HIV Study (WIHS)**.

5. "Cardiac Vagal Tone is Low in HIV+ Women and Correlates With Markers of Immune Activation/Inflammation" Authors: Kathleen M. Weber MS[1], Elizabeth Daubert MPH[1], Caitlin Bond MPH[1], Leah McClellan RN, MSN1[1], **Audrey L. French MD**[3,4] **Mardge H. Cohen MD**[3] for the **Chicago Women's Interagency HIV Study (WIHS)** Hektoen Institute of Medicine[1], Chicago, Illinois, United States of America, Departments of Behavioral Sciences & Internal Medicine[2], Rush University Medical Center, Departments of Medicine[3], Cook County Health and Hospitals System and Rush University Medical Center, Chicago, Ilinois, United States, Divisions of Infectious Diseases[4], Stroger Hospital of Cook County, Chicago, Illinois, United States.

In addition to the poster titles listed above, by clicking on the link below, you will access the Infectious Disease Advisor webpage which has an "Expert Perspective" presentation entitled: "Rapid Initiation of HIV Care: Assessing Safety and Efficacy," delivered by our own **Dr. Gregory Huhn**. https://www.infectiousdiseaseadvisor.com/ask-the-experts-gregory-huhn-md/section/8278/

Legal Bulletin: Betty Donoval, JD, MS

Research with Children

Children are considered as being vulnerable to coercion. To safeguard their interests and protect them from harm, additional protections exist for research involving children. According to federal regulations, children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." Generally, not always, the age of consent is the age at which minors reach the age of majority and are considered adults. In the US, the legal age of adulthood is a matter of state and local law. In a large majority of states, including Illinois, 18 years of age is the legal age of adulthood. Illinois law also addresses specific circumstances in which a person younger than the age of adulthood is legally authorized to consent to medical procedures.

In Illinois, if a minor has been adjudicated as a "mature minor" or an "emancipated minor" by an Illinois court, they are able to consent to medical treatment and research relating to such treatment. Investigators must review and document the court order. A minor seeking birth control services if married, a parent, pregnant, referred by physician, clergy, planned parenthood agency, to prevent serious health hazard, or testing for HIV can also consent to those procedures. In addition, the Illinois Consent by Minors to Medical Procedures Act grants minors the legal capacity to consent to medical treatment in certain situations. Our IRB extends the provisions of the Act to research. However, the minor cannot provide consent for research involving conditions not covered by the Act.
-Minors who are married, pregnant, or parents can consent to medical or surgical procedures for themselves or their children
-Emergency treatment/first aid or dental treatment
-Medical care and counseling related to diagnosis and treatment of any disease or injury resulting from sexual assault
-Minors ≥ 12 for STI care and counseling related to diagnosis/treatment, counseling or psychotherapy for mental illness, substance abuse care and counseling related to diagnosis and treatment

Research involving children must follow the regulations in the Common Rule (45 CFR 46 Subpart A). In addition, Subpart D provides additional protections for children involved in research. All 6 exemptions apply to children, however, exemption #2 is narrowed (research involving educational tests, interviews or survey procedures, or observation of public behavior). Where children will be involved as research subjects, the use of survey or interview procedures is eliminated from this exemption, and so is research involving the observation of public behavior if the investigators participate in the activity being observed. The new exemption category #3 in the revised common rule will NOT apply to children. This exemption allows for benign behavioral interventions in adults only. There are no restrictions on expedited review with children. Below are the 4 allowable categories of research with children.

Generally parents provide permission for their children to participate in research. This must be documented in the same manner as required for informed consent of adults. Children then provide assent to participate. Assent is a child's affirmative agreement to participate. The absence of dissent should not be construed as assent when the child is old enough that assent is meaningful. Parental permission can only override child's dissent when the health of the child is at stake.

Assent should provide the child with an explanation of the proposed research and procedures, why they are being asked, how long it will take, an understanding of what is being requested of them, risks and potential benefits, and whether it may involve any pain or discomfort in a format (oral and/or written) and language that is appropriate. Investigators must consider the research activity, age and maturity of the children, psychological state, and degree of literacy when developing the child assent process. Cultural differences including nationality, ethnicity, and socioeconomic status should also be considered. We have developed a template for child assent, which will be posted on our website.

Children developmentally between the ages of 7 and 12 are generally capable of providing assent on a separate assent document written in simple language directed toward children in this age range and presented orally. Children developmentally over the age of 12 are generally considered capable of indicating their consent on a written document written in a 6th to 8th grade reading level. If a study involves children of different ages, appropriate assent processes need to be developed for each age group. As the child grows older, the assent process should be revised and provide more detail, and the child should reaffirm assent. When reach majority, they should sign the adult consent form.

In some situations parental consent may not be a requirement. If the criteria for a waiver of informed consent is met, parental consent is not required. If parental consent is not a reasonable requirement, for example children who are abused by their parents, and there is appropriate substitute mechanism to protect the child, a 408 waiver may forgo the requirement of parental consent. Also, if the participant is a minor, but not considered a child by Illinois law, the child can consent for themselves without parental consent.

45 CFR 46.404 21 CFR 50.51	**Research not involving greater than minimal risk.**	**Permission of one parent Assent of Child**
45 CFR 46.405 21 CFR 50.52	**Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual subjects.**	**Permission of one parent Assent of Child**
45 CFR 46.406 21 CFR 50.53	**Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the disorder/ condition.**	**Permission of both parents unless one is dead, unknown, incompetent, or when one has custody. Assent of Child**
45 CFR 46.407* 21 CFR 50.54 (Only HHS & FDA approve)	**Research not otherwise approvable that presents the opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**	**Permission of both parents unless one is dead, unknown, incompetent, or when one has custody. Assent of Child**

Right to Try

On May 30th, the "Right to Try" bill was signed into federal law. This controversial bill allows patients fighting life threatening illnesses, who have exhausted all available treatment options, expanded access to experimental treatments that are not yet approved by the FDA or the IRB. Under a current process, expanded access or compassionate use, patients can already apply to the FDA for access and must seek IRB approval. The FDA approves 99.5% of applications is receives through its expanded access program, however critics say the process is overly cumbersome and time consuming even though applications are normally approved within days. Those opposed to the legislation find that the lack of FDA oversight, who can request modifications to the individualized treatment protocols to improve safety, will compromise patient safety. Ultimately, neither pathway removes the biggest hurdle: access to the drug by the developer.

Collaborative Research Unit

The Collaborative Research Unit (CRU) is dedicated to improving the health of the people of Cook County through collaboration, innovation, scientific inquiry, and continuous learning. The CRU was created in 1998 to facilitate, coordinate, and lead interdisciplinary research within the Cook County Health & Hospitals System.

Its goal is to promote action research on highly prevalent problems affecting the health of the diverse patient population of CCHHS. CRU physician investigators include Drs. Keiki Hinami, Romina Kee (Vice-Chair of the CCHHS IRB), and William Trick. Francisco Angulo is Director of Information Technology and Diana Garcia is the Project Director. Below we highlight a project, and a software system for research that is supported by the CRU.

CAPriCORN

The Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) is a partnership of research institutions, clinicians, and patient advocates throughout Chicago. CAPriCORN is part of a larger research data network (PCORnet), an innovative initiative of the Patient-Centered Outcomes Research Institute (PCORI)). Within the Chicago metropolitan area, CAPriCORN seeks to address the needs of an estimated 9.5 million residents, including groups that experience significant health inequities partly due to variable access to high-quality care.

Click on the link below for a recent interview with Dr. Trick about a creative strategy to reduce homelessness in Chicago. The goal of this study is to have clinical data support decisions for housing the most vulnerable homeless, primarily through a housing pool funded by health systems. The collaboration is between All Chicago, the Alliance to End Homelessness in Suburban Cook County, and Chicago's public health agencies.
https://pcornet.org/2018/05/pcornet-partner-network-launches-creative-strategy-to-reduce-homelessness-in-chicago/

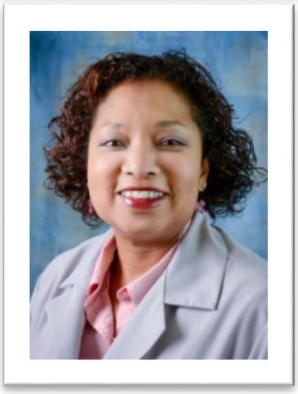
"Public health advocates have long theorized that people experiencing homelessness are among health systems' most expensive patients because their living condition puts them at risk for so many health problems."

-Dr. Bill Trick

REDCap

REDCap is a free survey software system and database that is a national resource for research, developed and supported by Vanderbilt University. REDCap software is a tool that does not require client software and can be accessed from anywhere on the Intranet secured on CCHHS' server. The system is currently used by almost 3,000 partners. The local instance of REDCap at CCHHS is maintained through support from the CRU in collaboration with Hospital Information Systems (HIS) and the Emergency Department. The CRU has partnered with HIS at CCHHS to implement REDCap. Since the HIPAA compliant instance of CCHHS REDCap went live in August 2017, more than 40 research, QA/QI, and operations projects have been hosted by this system. REDCap provides:
1) a streamlined process for building a database;
2) an intuitive interface for collecting data (with data validation and audit trail);
3) automated export procedures for data downloads to common statistical packages (Stata & SPSS);
4) branching logic and calculated fields
The CCHHS REDCap Committee, chaired by the CRU, is responsible for managing the system for REDCap. Information about how to request new projects can be found in this url: https://redcap.cookcountyhhs.org or via email at redcap@cookcountyhhs.org. Training resources can be found here: https://redcap.cookcountyhhs.org/index.php?action=training

A Day with Dr. Romina Kee, MD, MPH: by Tina LaGrone, BA



Dr. Romina Kee is physician who first joined CCHHS in 2001 and currently is a part of the Collaborative Research Unit (CRU). The CRU, founded in 1998, is a division of the Department of Medicine and is responsible for designing, applying for, and monitoring research activities that fit the mission of CCHHS. The fourteen members of the CRU include physicians, investigators, technical experts, and support staff.

As a young attending physician, Dr. Kee first became interested in research while being mentored by a physician in New York City. This physician was an investigator on a landmark HIV research study that determined the medicine zidovudine (AZT) could prevent the transmission of HIV from a pregnant woman to her child. Later on, Dr. Kee grew more interested in research during a clinical scholarship program at the University of Washington in Seattle.

Dr. Kee has served on the CCHHS IRB for approximately 14 years and currently the Vice-Chair! She is also a member of CHAIRb, the Chicago Area Institutional Review Board, which is a part of the University of Illinois. CHAIRb serves as the central IRB for CAPriCORN (Chicago Area Patient-Centered Outcomes Research Network). Her involvement with these two boards has provided her an opportunity to review and offer input on a variety of research studies over the years. Looking back on all of the studies she has been involved with, one of her favorites centered around looking at homelessness and health. This study found that the provision of housing to homeless individuals lowered their number of hospital stays as well as emergency room visits.

This study also proved to be the most challenging for Dr. Kee because a total of 400 people were enrolled and had to be tracked for 18 months. It is difficult to maintain large cohorts of participants for long periods of time. When asked about the future of research and the various directions it might take, Dr. Kee said she envisions a growing role for information technology and its ability to gather data and administer surveys over a broader range of platforms. She also sees the development of larger data sets that span longer time periods. Researchers will be able to use these datasets to look for patterns and predictors of illness as well as wellness. Dr. Kee would advise new researchers to become familiar with the newest federal guidelines of research. She encourages collaborating with others, making use of available technology, and always looking for opportunities to apply for grants.

Dr. Kee, the Department of Research & Regulatory Affairs would like to thank you for your exemplary service!

Consent Corner by Stacey Kincaid, MPH

Do you know the most common languages CCHHS patients speak besides English? If you guessed Spanish, Polish, Arabic, Russian, and Mandarin (Chinese), you're correct! Although the IRB does not require that all informed consent forms be translated into languages other than English, if you anticipate that research recruitment will occur from a population with a substantial number of non-English speakers, full translations of consent forms are required.

When a full translation of a consent document is not available, an interpreter may translate the English consent document verbally. The interpreter would then sign both the English consent form and a short form consent document written in the participant's own language.

Currently, there are short form consent documents in Spanish and Polish posted to the Office of Research & Regulatory Affairs website (http://www.cookcountyhhs.org/educationresearch/medical-research/office-of-research-regulatory-affairs/templates-forms/) available for use. We are pleased to announce that the IRB is collaborating with Interpreter Services to develop additional short form consent documents in other languages. These will be posted as they become available.

If you would like more information about obtaining translation services for your research-related materials, please contact Stacey Kincaid, Informed Consent Coordinator, at Stacey.Kincaid@cookcountyhhs.org

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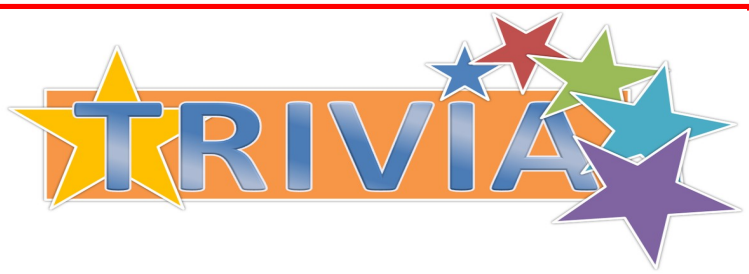


What is the name of the drug that led to the passage of the Kefauver-Harris Amendment or Drug Efficacy Amendment, which is a 1962 amendment to the Federal Food, Drug, and Cosmetic Act?

Trivia Winner from Last Issue: Diana Nowicki! Congratulations!

Last Issue's Question: In 2010, President Obama offered an official apology on behalf of the federal government for which PHS funded study?

Answer: President Obama apologized for the research activities associated with the United States Sexually Transmitted Disease Experiments in Guatemala. These experiments occurred between 1946 and 1948 in the U.S. and in Guatemala. Over 1,300 individuals were intentionally infected with syphilis, gonorrhea, and chancroid by investigators without their informed consent to test the value of different medications. Some were infected through injections into the spine, others through sex with commercial sex workers who had been infected by U.S. government public health doctors. Some study subjects had the bacteria rubbed into scrapes on their bodies and faces.

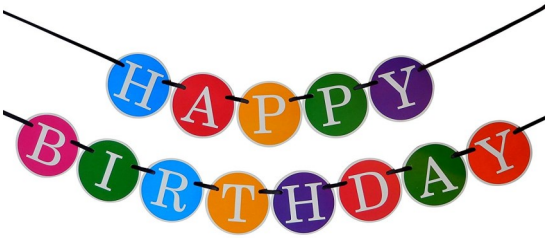
We received a lot of answers for the PHS study, Tuskegee Study of Untreated Syphilis. President Clinton apologized for this study in 1997. This study started in 1932 and went on for 40 years until 1972. Researchers followed 600 black men to record the natural history of syphilis. The study was conducted without the participants' informed consent. Participants were told they were being treated for "bad blood," in truth, they did not receive the proper treatment. Penicillin became the drug of choice for syphilis in 1947, but was not offered to the subjects. In exchange for participation, the men received free medical exams, meals, and burial insurance.

Tina's Tips by Tina LaGrone, BA

Department Chairs will now be copied on the approval letters/emails for all studies. We will also be providing quarterly reports to the Chairs, so they are aware of what studies have been approved in their department.

Our Workshop on **September 26th** is on Confidentiality, Privacy, & Data Security. This will be a joint workshop with Research & Regulatory Affairs, HIS, Compliance, and the CRU. Please bring all of your questions about HIPAA, data use agreements, business associate agreements, PHI, how to send and store PHI, REDCap, etc. This is a great opportunity to have everyone in one place to answer any questions.

Location: 5300 Stroger
Time: Noon



Research & Regulatory Affairs would like to wish the Ruth M. Rothstein CORE Center, who will be celebrating their **20th** birthday in October, a **Happy Birthday!** Thank you for all the great patient care and research work that you do!