



COOK COUNTY HEALTH & HOSPITALS SYSTEM

Institutional Review Board

From the Director, Mildred Williamson, PhD, MSW



Our second issue of the CCHHS Research & Regulatory Affairs Newsletter has some timely information and good news combined. First, we're excited to report that our own Sybil Hosek, PhD, with the JH Stroger Hospital Department of Psychiatry, RM Rothstein CORE Center and CCHHS IRB member, served as the lead investigator for a study which proved that the use of pre exposure prophylaxis (PrEP) is safe and effective with adolescents in the prevention of HIV infection, when

used along with other safer sex practices. The results of this ATN 113 study (Adolescent Medicine Trials Network for HIV/AIDS), with 15-17 year old at-risk youth, supported by the National Institute of Child Health and Human



Dr. Sybil Hosek

Development (NICHD), led to the US Food and Drug Administration (FDA) approving PrEP, or Truvada (brand name) for use with this population as of 5/15/2018. This means that youth under the age of eighteen, who are disproportionately at risk for acquiring HIV infection, even while new HIV infections are declining in other populations, can access this prevention tool that when used as prescribed, can reduce probability of HIV infection by 92%. Congratulations Dr. Hosek!

If you would like to read the full press release on this accomplishment, here is the link to access it: <http://www.gilead.com/news/press-releases/2018/5/us-food-and-drug-administration-approves-expanded-indication-for-truvada-emtricitabine-and-tenofovir-disoproxil-fumarate-for-reducing-the-risk-of-acquiring-hiv1-in-adolescents>

Moreover, our small but mighty Department of Research & Regulatory Affairs has grown once again by one. Welcome Mario Rodriguez, MBA, who is our new Research Database Coordinator! Mario comes to us with a wealth of experience in data management, analysis and end user support service. He will be our lead person in all things IRBManager (our online protocol submission/review system), and he will provide technical support to our team and the CCHHS research community. We can now report that our staff is complete! Yea!

UPDATE! On April 19, HHS and 16 other federal agencies released a new [Notice of Proposed Rulemaking \(NPRM\)](#) that would delay the general compliance date for the revised Federal Policy for the Protection of Human Subjects, or "Common Rule," an additional six months, to January 21, 2019. There is also a proposal to implement 3 burden reducing provisions of the new rule July 19, 2018. Stay tuned for more information on the finalized date of implementation, as we are looking to receive updated federal guidance. At present, we are already working with

the updated federal recommendations on informed consent and our revised template for CCHHS informed consent language can be accessed through this link: <http://www.cookcountyhhs.org/educationresearch/medical-research/office-of-research-regulatory-affairs/templates-forms/>. If you are interested in reviewing the full revised common rule document, access can be obtained through this link: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>.

Finally, check out the rest of this newsletter for additional information on how to think about a decision making process to determine if your study needs IRB review; there is also an update on Certificates of Confidentiality, and much more. Also, look out for our monthly topical workshop announcements going forward.

It is now Spring at last in the Chicago area, and not a moment too soon.

Enjoy it while it lasts!



Legal Bulletin: Betty Donoval, JD, MS

As of October 1, 2017, Certificates of Confidentiality (CoC) are now automatically issued by NIH. However, for these to be valid and effective, certain rules need to be followed. Not only must investigators, research participants, and IRBs be aware of these requirements, but they must educate their study teams and anyone that will receive identifiable data as well. (The FDA, CDC, HRSA, and SAMHSA also issue CoC, however these are not automatically issued. Investigators must apply to the appropriate agency at least 3 months prior to the date enrollment is expected to begin. Please see <http://humansubjects.nih.gov/coc/index> for the appropriate agency to apply.)

A CoC is a legal protection issued by agencies in HHS to protect identifiable information from forced disclosure in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. They specifically prohibit disclosure in response to legal demands, public record requests, and FOIA requests. CoC are used in research studies where identifiable data on a sensitive topic that if disclosed could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation is collected. Typically this includes research on drug use, HIV/AIDS, STIs, illegal conduct, mental health, and sexual practices/attitudes.



Although there is much debate on the validity of CoC and their effectiveness in court, they generally function as intended and can be an advantageous tool to protect research participants if used correctly. Follow these rules to help ensure that we do everything we can to protect our research participants!

- The informed consent MUST include a description of the protections and limitations of the CoC, including the circumstances in which the investigators plan to disclose voluntarily identifying information about research participants (such as to report child abuse/communicable diseases or audits). We have included this language in our informed consent template that is available on our website under templates and forms. Be sure to remove this language if you do not have a CoC. (<http://www.cookcountyhhs.org/educationresearch/medical-research/office-of-research-regulatory-affairs/>).
- Inform study participants that if they disclose the information the CoC may no longer protect them even if disclosed for their medical treatment.
- EVERYONE must be mindful to avoid inadvertent waiver. In addition to not disclosing any data, it is best to even avoid confirming the individual's participation in research. Pls must educate and ensure all members of the study team adhere to the disclosure restrictions, including anyone outside the institution that receives data.

Researchers who receive a legally based request for information, should follow CCHHS Policy and also contact the Director of Research and Regulatory Affairs. Do not disclose any identifiable information or even confirm/deny that the participant is even involved in the research!

DOES MY STUDY NEED IRB REVIEW? By Betty Donoval JD, MS

One of the biggest changes coming to the Common Rule is the revised exemption categories. Changes to the definition of human subject and carve outs to the definition of research will also have an impact on if a study needs IRB review. To determine if a study needs IRB review, investigators will have to ask themselves if this is research, if it involves a human subject, and if falls into one of the exempt categories in that order.

Changes to Definitions of Research and Human Subject

Research refers to a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Although the definition of research is unchanged, the Common Rule will now carve out four specific activities deemed not to be research. These activities, include: scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected; public health surveillance activities limited to those necessary to identify, monitor, assess, or investigate conditions of public health importance; collections and analysis of materials for criminal justice purposes; and authorized operational activities for national security purposes. If your activity falls into one of these categories, it does not qualify as research and you do not have to submit an application to the IRB.

The definition of a human subject is expanded in the revised rule. A **human subject** is an living individual about whom an investigator conducting research 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, analyzes, or generates identifiable private information or identifiable biospecimens. Private information means information an individual can reasonably expect that will not be made public. If someone were to Tweet information, it would no longer be considered private information as it has been made public. Individually identifiable means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information of biospecimens. So, even if the information is currently de-identified, but all it would take to re-identify that information is asking your fellow researcher, this means that it would be considered identifiable. Therefore, if research involves only coded biospecimens or coded private information and is not collected specifically for the research in question and the investigator cannot readily ascertain the identity of the individual(s) to whom the data/specimens pertain, then it is not human subject research.

Changes to Exempt Categories!

The current rule has six exempt categories. In the revised rule, they are eliminating one and adding three new categories for a total of 8 exempt categories as well as revising existing categories. Keep in mind that all exemptions will apply to pregnant women, fetuses, and neonates. No exemptions apply to prisoners, except research that incidentally includes prisoners. All exemptions apply to children, except the new behavioral intervention exemption #3 and parts of exemption #2. Here, we will cover the changes to the categories that are most frequently submitted at CCHHS.

Exemption Category #2 has been expanded. The exemption allows for research that only includes interactions involving educational tests, surveys, interviews, or observation of public behavior if at least one of the following criteria are met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be linked to the subjects (No kids unless investigator does not participate in the activities being observed);
- ii. Any disclosure would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation (No kids unless investigator does not participate in the activities being observed); or
- iii. Identifiable information recorded, and IRB conducts a limited IRB review for privacy and confidentiality protection (No kids).

Section iii is the new part of this exemption. This allows for the listed activities even if information is identified and disclosure could place participants at risk of liability or be damaging to the participant, if the IRB determines in a limited review that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. This means that you will no longer have to submit an expedited application for this activity as it is now exempt.

Exemption Category #3 is brand new. This exemption allows for research involving benign behavioral interventions with adults who prospectively agree when information collection is limited to verbal or written responses or AV recording, and:

- i. The information recorded cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ii. Any information disclosure would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;
- iii. Identifiable information recorded, and IRB conducts a limited IRB review for privacy and confidentiality protection (There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data).

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. This is a big change to the exemption categories and allows for the first time an intervention to be exempt from review.

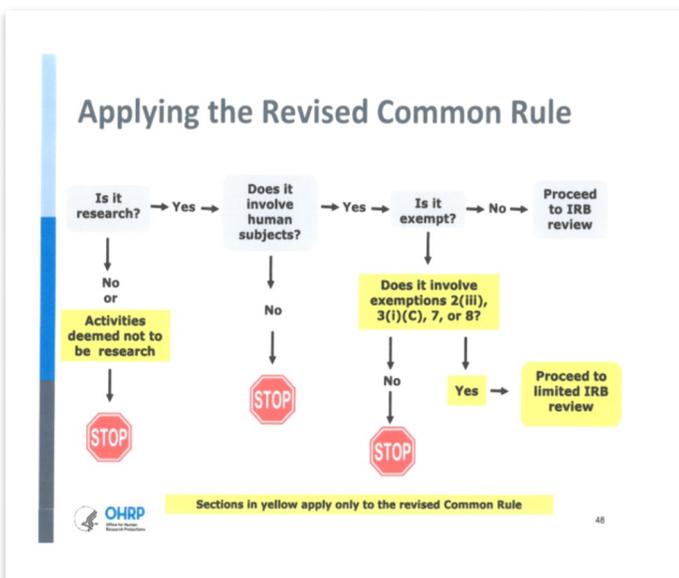
Exemption Category #4 has also been expanded. This exemption allows for secondary research with identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- i. The identifiable private information or identifiable biospecimens are publicly available;
- ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- iii. Investigator's use of identifiable health information is regulated under HIPAA for the purposes of "health care operations," "research," or for "public health activities and purposes"; or
- iv. Research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, and the information is protected by federal privacy standards.

Although mostly unchanged, this expansion gives a specific exemption for the use of identifiable health information for health care operations and public health activities that we have not seen before.

Exempt Categories #7 & #8 are also brand new. They allow for the storage or maintenance of identifiable private information or identifiable biospecimens with broad consent for potential secondary research use if an IRB conducts a limited IRB review and secondary research involving the use of identifiable private information or identifiable biospecimens when broad consent has been obtained, documentation of informed consent or waiver was obtained, and the IRB conducts a limited IRB review. This creates future regulatory flexibilities and will likely be implemented at CCHHS with additional guidance and support in the future.

Remember, you must submit a new request for exemption from review in IRBManager for an official exempt determination before you begin your research!



Tina's Tips

Who can be the Principal Investigator (PI)?

Must be a fully qualified professional employed by a CCHHS affiliate. This is typically an attending physician, but other health professionals will be considered with proper documentation. Residents, fellows, and students may never serve as the PI.

Who can be the Designated Signatory?

- If the Principal Investigator has a division head, the division head is their signatory.
- If the Principal Investigator does not have a division head, the department chair is their signatory.
- If the Principal Investigator is a division chair, the department chair is their signatory.
- If the Principal Investigator is a department chair, the Chief Medical Officer is their signatory.

A designated signatory may allow someone to sign on their behalf, but this delegation must be made to the IRB in advance.

A Day with Geraldine Peacock: by Tina LaGrone



Ms. Geraldine Peacock is a nurse research coordinator in the Division of Cardiology in the Department of Medicine at CCHHS and also a veteran. She has long been what our department considers a "super coordinator," and after sitting down to talk to her, it is easy to see why. She was a nurse in the U.S. Army and held the honorable and distinguished position of Major retiring after 24 years. During her military career, Ms. Peacock did tours in

Iraq and Afghanistan where she managed Combat Support Hospitals and ICUs during difficult and violent times. Transitioning from being a soldier in the medical field to a civilian in the medical field was difficult. Working on injured patients during war time took its toll on Ms. Peacock. When her army service was completed, she transferred to Cardiology and is now heavily involved in medical research. Ms. Peacock has been employed by Rush University for 43 years and has served here at CCHHS for ten of those years on a contract agreement between Rush and CCHHS.

Ms. Peacock loves her work in the Department of Cardiology. She uses key skills that she learned in the military to be a great research nurse. Her military experience has especially prepared her for working with the CCHHS population. "In the Army, I learned to utilize leadership skills. Everyone is from different backgrounds and ethnicities and being accepting and respectful of everyone's differences is a must. You have to be open minded especially in a career that caters to serving people." The most rewarding part of her job is helping patients with remedies to their illnesses. Educating and assisting patients to understand and become

empowered to deal with their disease, no matter the disease entity, is her passion. Patients with heart failure tend to come back to the hospital every three to six months. Therefore, patients with heart failure have been her focus. She has been helping them to understand and manage their heart failure in the hope that they stay out of the hospital.

Ms. Peacock feels as though research at CCHHS is moving forward in a big way. Dr. Doukky, the System Chair for Cardiology, encourages research. She also finds the new online submission system, IRBManager, less stressful than the old paper based system. "It gives the research team more time to focus on the research without having to worry about carrying heavy paperwork or storage." One of Ms. Peacock's favorite studies was the IMPROVE-IT study, which lasted for seven years. It was a cholesterol study where Dr. Sattar was the principal investigator. It is one of her favorites, because good relationships were formed with the research participants whom she still sees to this day. One of her least favorite studies was the Cardiogenic study where Dr. Nathan was the principal investigator. Her pager would go off at all times of the day or night. Ms. Peacock would have to go to the hospital to sit with patients through six hours of medical infusion.

When it comes to success, Ms. Peacock says she is self-motivated and believes that you have to keep moving no matter what obstacles may come. The desire to help people keeps her going as well. "The advice that I would give to new researchers is to be self-motivated, love learning new information, and be patient. Be OK with being alone because sometimes you just need to focus on details." Ms. Peacock will be retiring in a few months. She plans to complete her PhD and open a CNA school. She believes CNAs will be the gateway of nursing and plans to instill good moral and ethical values at the primary level. The Department of Research and Regulatory Affairs would like to thank you, Ms. Peacock, for your military service and your service as a research nurse in the hospital system.

Congratulations Ms. Peacock on your upcoming retirement!!!



Trivia: In 2010, President Obama offered an official apology on behalf of the federal government for which PHS funded study?

Email your answer to CCHHSIRB@cookcountyhhs.org

Trivia Winners from Last Issue: **Geraldine Peacock** and **Diana Nowicki!** Congratulations!

Last Issue's Question: Whose 1966 article on unethical practices, published in the New England Journal of Medicine, influenced current guidelines on clinical research and informed consent procedures?

Answer: Dr. Henry K. Beecher's 1966 article entitled, "Ethics and Clinical Research" reviewed 22 cases of unethical conduct in clinical research that endangered the lives of participants in order to draw attention to the topic. Examples of cases reviewed in this article include the Jewish Chronic Disease Hospital Case (1963) and the Willowbrook Hepatitis Study (1955). He especially objected to experiments that seemed to exploit participants, some from vulnerable populations.

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