



COOK COUNTY HEALTH & HOSPITALS SYSTEM – RESEARCH & REGULATORY AFFAIRS

What's New in Research?

Ethics & Excellence at CCHHS



IN THIS ISSUE – FEBRUARY 2018

From the Director - Mildred Williamson, PhD, MSW

We launch this new edition of the CCHHS Research & Regulatory Affairs Newsletter in an effort to inform CCHHS health professionals on research with human participants. Our goal is to have a quarterly publication, with content input from everyone and every relevant source. In fact, your feedback from reading this first edition will certainly be welcomed. The theme of this initial issue is focused on the new, revised common rule, with an emphasis on new expectations with informed consent.

The US Department of Health & Human Services (HHS) Office of Human Research Protection (OHRP) has announced that the revised rule takes effect **July 19, 2018**. If you are interested in reviewing the full revised common rule document. You can obtain access through this link: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>.

Our Department reached the one year milestone moving from paper protocol submissions to electronic processing through IRBManager. This conversion was a major development for our small team. It occurred not a moment too soon, as we recently moved to the CCHHS Administration Building, which is a much smaller space - thus, less paper, fewer file cabinets needed over time.

We have updated contact information for each of our staff members in this newsletter. I am thrilled to announce that our staff has now grown by one. We now have a new **Informed Consent Coordinator. Welcome Stacey Kincaid, MPH!** Brief profiles of all our staff members, including new ones will be featured in the next newsletter.

Finally, we launch this newsletter during Black History Month. We're reminded why a formal process is needed to review and monitor the conduct of research activities, as history reveals persistent inequities in society, assuring some groups remain more vulnerable than others to potential harm as participants in research, regardless of researcher intent.

Our health system has a dedicated, thoughtful and compassionate group of IRB members - multidisciplinary in expertise, includes community members unaffiliated with CCHHS, and a small, hardworking staff. This diverse combination of people working together makes it possible to state with confidence that the protection of our patient population is assured. We're grateful to have such a team.



Ruth M. Rothstein **CORE** Center

Revised Common Rule Page 2



Informed Consent - New Developments
Informed Consent Workshop - March 28th
 New CCHHS Template -
 Keeping up with Best Practices - Page 2

Upcoming 2018 Workshops
 4th Wednesdays each month- Stroger Hospital Room 5300 - 12:00 noon Page 4

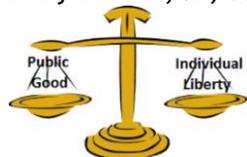
Ambulatory & Community Health Network of Cook County (ACHN)



Rendering of the proposed Central Campus Health Center

Legal Bulletin

Betty Donoval, JD, MS



The revised Common Rule implementation has been delayed 6 months. **July 19, 2018** is the new effective date and general compliance date for the revised Common Rule. The cooperative research (single IRB) provision compliance date remains January 20, 2020. Stay tuned for upcoming workshops to help CCHHS get ready for the revised Common Rule!

NIH policy mandates the use of a single IRB for multisite studies funded by NIH for applications with due dates on or after **January 25, 2018**. Be sure to incorporate the cost into your budget! For more information:

<https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

Reminder! HHS issued a final rule on **September 16, 2016** expanding registration requirements and results submissions of clinical trials in ClinicalTrials.gov. The rule requires submission of results information for completed clinical trials, even for unapproved products. Certification of Compliance is required for drug and device applicants in most applications. There are serious consequences for not complying with this rule, including civil actions, criminal actions, and/or penalties up to \$10,000 per day. For more information:

<https://clinicaltrials.gov/ct2/manage-recs/fdaaa>

Reminder! NIH issued a policy change to issuing Certificates of Confidentiality effective October 1, 2017. Come to our next workshop on February 28th at Noon in Room 5300 Stroger to learn about C of C and their requirements. For more information:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

INFORMED CONSENT - WHAT'S NEW?

By Betty Donoval, JD, MS

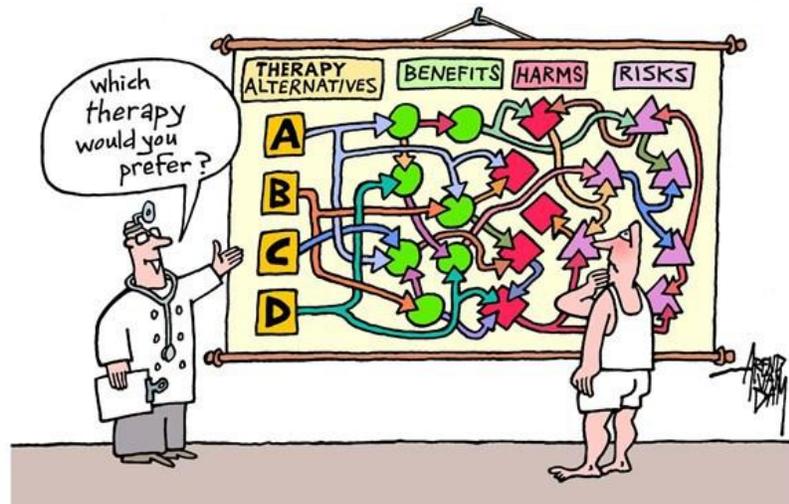
Trivia: Whose 1966 article on unethical practices, published in the New England Journal of Medicine, influenced current guidelines on clinical research and informed consent procedures?

Email your answers to CCHHSIRB@cookcountyhhs.org

Changes to Informed Consent

The revised Common Rule has brought big changes to informed consent, which we will be implementing before the general compliance date. We have revised our template and provided a checklist of the requirements to reflect these changes which will be available on our website after we discuss them at our March 28th workshop. The major changes are highlighted below.

- The prospective participant must be provided with information that a **reasonable person** would want to have in order to make an informed decision about whether to participate and an opportunity to discuss that information.
- Must begin with a **concise and focused presentation** of the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not participate in the research.
- Must include a statement if identifiers will be removed from the information or biospecimens and could be used for **future research** or not.
- If applicable, a statement that biospecimens may be used for commercial profit and whether the participant will share in this profit.
- If applicable, a statement regarding whether clinically relevant research results will be disclosed to participants and under what conditions.
- For research with biospecimens, a statement whether the research will or might include whole genome sequencing.
- It will be a federal requirement to post consent forms no later than 60 days after the last visit for federally conducted/supported clinical trials to a public website when the new rule is implemented.



informed consent

TINA'S TIPS – AUDREAN LAGRONE

Hey IRBManager users!



- 1- Make sure the consent document is on CCHHS letterhead.
- 2- The font size of the informed consent should be at least 12 pt.
- 3- Be sure to leave a 2 inch space at the bottom of each page of the consent for the approval stamp. This is very important because we have to be sure not to stamp over the words.

Joseph's Corner - Joseph Sfeir

Making IRBManager Submissions Easier
Before sending us your submission, please make sure that all research personnel for your protocol are IRB certified! One of the most common reasons for a submission to be returned is uncertified individuals being added onto protocols.

Link to learn more on becoming IRB Certified:
<http://www.cookcountyhhs.org/educationresearch/medical-research/office-of-research-regulatory-affairs/human-participation-research-training/>

Be sure the Designated Signatory on your Initial Submission is the correct individual (we will double check), and get in contact with that person! A common delay in the processing of an Initial Submission is the Designated Signatory fails to sign off on the submission in a timely matter.



Oak Forest Health Center

Community Triage Center



Our new behavioral health center in the Roseland community offers walk-in services for patients with mental health and substance abuse needs. The center is open 24 hours a day, 7 days a week, 365 days a year.

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CCHHS INSTITUTIONAL REVIEW BOARD (IRB) MEETING SCHEDULE:

1st & 3rd Tuesdays of each month-2:00pm

Heads Up - Principal Investigators!

CCHHS Salary Allocation Forms have been updated and are available on the Research page of the CCHHS website:
<http://www.cookcountyhhs.org/educationresearch/medical-research/>

DID YOU KNOW???

The CCHHS IRB reviews research protocols for all entities of the Cook County Health & Hospitals System - including Cermak Health Services at Cook County Jail and the Cook County Juvenile Temporary Detention Center.

Per federal regulations, all research protocols which include detained or imprisoned populations for study participation must have a prison health advocate IRB member to serve as a reviewer, and votes cannot be taken without this required input. CCHHS has such representation in place, with great population-specific expertise!



Cermak Health Services

FEBRUARY- BLACK HISTORY MONTH

Carter G. Woodson (1875-1950)
Father of Black History Month

"If you can control a man's thinking, you don't have to worry about his actions. If you can determine what a man thinks you do not have to worry about what he will do. If you can make a man believe that he is inferior, you don't have to compel him to seek an inferior status, he will do so without being told and if you can make a man believe that he is justly an outcast, you don't have to order him to the back door, he will go to the back door on his own and if there is no back door, the very nature of the man will demand that you build one." -CG Woodson



Carter G. Woodson - Google Doodle
Illustrator-Shannon Wright-Black Googlers Network
<http://time.com/5128456/carter-g-woodson-black-history-month/>

ORIGINS OF PROVIDENT HOSPITAL

Remembering **Dr. Daniel Hale Williams** (1856-1931), founder of Provident Hospital, the nation's first black hospital, which opened in 1891. Today, Provident Hospital remains in operation as a proud entity within the Cook County Health & Hospitals System.



Provident moved to its 426 East 51st Street location in May, 1933.

Historical image:
The Provident Foundation webpage
<http://www.providentfoundation.org/index.php/history/history-provident-hospital>



Provident Hospital of Cook County



What's New in Research?

Ethics &
Excellence at
CCHHS



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Issue #1 - February 2018

UPCOMING WORKSHOPS-2018

Research & Regulatory Affairs
4th Wednesdays - Stroger #5300
12 Noon - Everyone's welcome!



February 28
NIH Certificate of Confidentiality

March 28
Informed Consent Update

April 25
NIH Single IRB Update

May 23
Is it QA/QI or is it Research?

June 27
Exemptions

