



From the Director, Mildred Williamson, PhD, MSW



Holiday Greetings Everyone! This fourth quarter issue of the newsletter for the Department of Research & Regulatory Affairs marks quite a few milestones and transitions. First of all, just where did the year go in such a short period time??

Seriously though, during 2018, quite a few activities occurred and milestones have been achieved by this department team.

We've administered a cloud-based online protocol submission/review system for nearly two years, and successfully hired and trained staff to assure expert database management and end user support for now and into the future.

In anticipation of new federal Common Rule changes going into effect, (now scheduled for January 21, 2019), we've produced a monthly workshop education series, open to all interested CCH employees to prepare for the changes, along with other topical content on best practices in research ethics. A 2019

monthly workshop schedule is forthcoming. Our approach for revised Common Rule implementation for CCH research is to have all protocols reviewed and approved prior to 1/21/2019 to be governed by the current Common Rule guidelines. All research protocols reviewed/approved 1/21/2019 and thereafter will be governed by the new revised Common Rule guidelines.

Quality informed consent processes remain a high priority. Staffing now includes an informed consent coordinator to train/educate on best practices, monitor quality, including language needs for multicultural, and multilingual participant engagement. The informed consent template was revised this summer to conform to the federal recommendations and now incorporates the HIPAA authorization required content into the same document.

Once again, the Department staff has successfully moved our offices – this time into

permanent space on the 9th floor of the brand new Cook County Health Professional Building, which includes a new meeting space home for the CCH Institutional Review Board on the 5th floor.

I am proud to share that Betty Donoval, JD, MS, is now serving as the Interim Director for the Department of Research & Regulatory Affairs, as I have been asked to serve as Interim Executive Director for the Ruth M Rothstein CORE Center in this recent period. I want to take a moment here to state what great hands this Department is in with Betty's leadership, and to thank her, and all the Department staff and IRB members for such great cooperation and support. It has been my great pleasure and honor to work with the CCH research community over the past few years.

Many thanks to you all and happy holidays.

Legal Bulletin: Betty Donoval, JD, MS

Change is coming! The Revised Common Rule is coming January 21st, 2019! The compliance date for the mandatory use of single IRB review for all federally funded research is January 20, 2020.

In 1981, DHHS and FDA issued regulations based on the Belmont Report. DHHS issued Code of Federal Regulations (CFR) Title 45 (public welfare), Part 46 (protection of human subjects). The FDA issued CFR Title 21 (food and drugs), Parts 50 (protection of human subjects) and 56 (Institutional Review Boards). In 1991, the core DHHS regulations (45 CFR Part 46, Subpart A) were formally adopted by more than a dozen other Departments and Agencies that conduct or fund research involving human subjects as the Federal Policy for the Protection of Human Subjects, or "Common Rule."

This is the first revision to the rule since it was formally adopted in 1991. The FDA

says it will harmonize their regulations with the revised common rule. Stand by!

This issue's focus is to prepare our investigators on the changes to the law coming in the New Year. New year, new law! The major changes that we focus on in this issue are to informed consent, the exemption categories including limited IRB review, the elimination of continuing review for some research, and new/revised definitions.

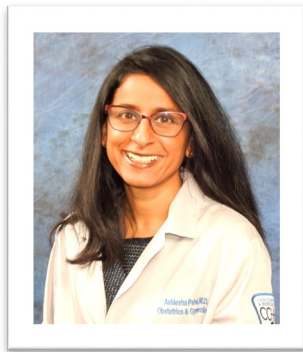
In order to transition to the new rule our office will **not be accepting any new research applications the week of January 14th**. Our last IRB meeting before the change is on **January 15th**. All research applications submitted before this date must be approved by **January 18th**. This includes all contingent approvals and forms that are in limbo awaiting signatures. This research will be approved under the current



rule. Starting on **January 21st**, we will accept applications under the revised rule and the new rule requirements will apply to these studies. The application forms in IRBManager will be changed in order to reflect the changes under the new rule and noted as such. As the forms are different, we will only accept this revised application form. Any applications received on the old form after January 14th will be rejected and must be resubmitted on the new revised form.

A Day with Dr. Ashlesha Patel by Tina LaGrone, BA

Dr. Patel has been a part of CCH's Department of Obstetrics & Gynecology in the Division of Family Planning for fifteen years. This department is near and dear to her heart, as is cultivating an environment that encourages research. Her mother first introduced her to the world of research as a young child, and it became a mainstay of her childhood.



“Research is a calling, a part of who I am.”

Dr. Patel and her brother would go to conferences and assist their mother, who was the first neonatologist at Cook County Hospital, with her research activities. This family also shares a love of practicing medicine, as Dr. Patel's father is in the Department of Hematology/Oncology, and her brother is also a physician at Cook County Health. During her time in medical school and in her residency, there was a natural inclination to become involved in research.

Dr. Patel champions the spirit of research in those around her. The many residents and students that come through the Department of Obstetrics & Gynecology are encouraged to become involved in research. The many studies initiated by this department create ample opportunities for research assistants to learn the ropes of the research cycle. As they go through the learning process, many feel that the Cook County Health IRB functions more as a mentor than an obstacle. Dr. Patel finds research fun, because it gives her a chance to figure something out and make things better for her patients. She feels that researchers must be innovative and progressive as clinicians.

Dr. Patel's favorite study thus far in her career is a collaboration with NCORP (NCI Community Oncology Research Program) called EROS. It is a NCI (National Cancer Institute) funded, randomized, controlled trial about Engendering Reproductive health into Oncologic Survivorship. It is a landmark study with over twenty cancer sites participating across the US. They are one third of a way through the study, so results are still pending. Incidentally, Dr. Patel also finds EROS to be the most challenging because being in charge of a national study requires a lot of time and coordination. She is also part of a wonderful and brilliant team called the Women's Health Research Collaborative

(WHRC). WHRC was created to foster connections between physicians, residents, graduate students, and researchers for the development of innovative women's health research. She admires and respects the fact that they take research very seriously.

Dr. Patel feels that family planning is an important area where women's health and public health intersect. She also understands that family planning can be a touchy subject. For example, reproductive rights are an area of concern and research proposals surrounding this topic can be challenged by the IRB because of concerns of potential harm to participants. In the future, Dr. Patel looks forward to Cook County Health promoting more national research leadership.

“There is more to share, and we need solutions for our patients.”

She feels that there is a lot more research to be done concerning women's health. Dr. Patel looks forward to seeing increased interest in research involving women's health as well as quality and safety. She is also hopeful that women's health will move to the forefront as the focus of new technological advances in the future.

Dr. Patel, the IRB would like to thank you and your team for your service here at Cook County Health!

Changes to IRBManager by Mario Rodriguez, MBA

As we approach the new year, Research and Regulatory Affairs has been working on new functionalities in IRBManager. These include the new elements of the exempt determination form required under the new rule to facilitate an easier transition when the rule goes into effect. The major modifications in the exempt application form will be primarily made to Exempt categories #2 and #3. For category #4, we'll be adding the HIPAA waiver questions if there are requests for waivers to use identifiable data and specimens.

Moreover, minimal risk studies reviewed via the expedited procedure after the new rule goes into effect will no longer require annual

continuing review, but we will require an abbreviated renewal (check-in) every year to keep the study active. This will automatically be prompted by our electronic submission system IRBManager. Remember that the requirement to submit amendments and reportable safety events to the IRB has not changed.

The new regulations do not impact studies approved prior to the proposed implementation date of January 21, 2019, and all new functionalities in IRBManager will be ready by this date. We will continue to review research under the guidelines of the pre-2019 rule until the new rule is implemented.

Finally, in case you missed our workshops or read our newsletters, we have added to our website the workshop slides and all the newsletters. Please make sure to check them out for important updates and information.

The workshop slides can be found at <http://www.cookcountyhhs.org/educationresearch/medical-research/office-of-research-regulatory-affairs/workshop-slides/>

Newsletters can be found at <http://www.cookcountyhhs.org/educationresearch/medical-research/office-of-research-regulatory-affairs/newsletters/>

Exempt Categories & Limited IRB Review

The categories of research that are exempt from review are changing! Many studies that previously went through expedited review will now be exempt from review with the caveat of "limited IRB review." Our exempt determination form in IRBManager will be changed to reflect the new categories and requirements for each category. Covered here are the changes to the categories that are most frequently submitted at Cook County Health.

Exemption Category #2 has been expanded. Investigators will now be able to do research that only includes interactions involving educational tests, surveys, interviews, or observation of public behavior if the information obtained is recorded where the participant's identity cannot readily be linked to the information, any disclosure would not reasonably place the subjects at risk of liability or harm (financially, employability, educational advancement, or reputation), or identifiable information is recorded and the IRB conducts a limited IRB review for the adequacy of privacy and confidentiality protection. This once expedited activity 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 if the information obtained is recorded where the participant's identity cannot readily be linked to the information, any disclosure would not reasonably place the subjects at risk of liability or harm (financially, employability, educational advancement, or reputation), or identifiable information is recorded and the IRB conducts a limited IRB review for the adequacy of privacy and confidentiality protection. 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. This is the first time an intervention is allowed to be exempt from review!

You may be asking yourself how these activities are exempt from IRB review, but technically require a "limited IRB review." Good question. What we do know about "limited IRB review" is that it must be completed by a

voting IRB member, but need not meet the criteria for normal IRB approval. The limited review is ensuring that the research plan for the protection of privacy and confidentiality is adequate. Therefore, you will now be asked to describe your plan in the application form.

Exemption Category #4 has also been expanded. This category allows 4 options for secondary research, for which consent is not required, using identifiable information or identifiable biospecimens that have been collected for some other primary or initial activity if they are: publically available, recorded so subjects cannot readily be identified, regulated by HIPAA (healthcare operations, research, or public health activities/purposes), or collected by or on behalf of the federal government for non-research activities.

This exemption has been expanded to include prospective data unlike the previous rule where the data had to be already existing. This allows for secondary research to be done on data otherwise subject to HIPAA, so you will need to apply for a waiver of HIPAA authorization.

Consent Corner by Stacey Kincaid, MPH

The New Year will usher in major changes to informed consent. Any new IRB submissions made on or after January 21, 2019 MUST contain the following informed consent elements:

- The prospective subject (or their legally authorized representative) 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.
- The consent document must begin a concise and focused presentation of the key information that is most likely to assist a prospective subject/LAR in understanding the reasons why one might or might not want to participate in the research. This section should facilitate comprehension, not just list isolated facts. The Key Information should include the following: Why is this research being done? What will happen to me during the study? How long will I participate? Will I benefit from the study? Will taking part expose me to risks? Do I have any

other options besides taking part in this study? Will I be paid to participate? Will it cost me anything to participate?

- If the research involves the collection of identifiable information or biospecimens, the consent must include a statement that if the identifiers are removed, the information/biospecimens will or will not be used for future research.

- If applicable to your study, a statement that biospecimens may be used for commercial profit (even if identifiers are removed) and whether the subject will or will not share in the commercial profit.

- If applicable to your study, a statement regarding whether clinically relevant research results, including individual results, will be disclosed to subjects, and if so, under what conditions.

- For research with biospecimens, whether the research will or might include whole genome sequencing.

- For each clinical trial conducted/

supported by a Federal department or agency, one IRB approved consent form must be posted by the awardee or the Federal department/agency conducting the trial after the study is closed to recruitment but no later than 60 days after the last study visit. The two currently approved websites are:

www.ClinicalTrials.gov

www.Regulations.gov Docket ID: HHS-OPHS-2018-0021

Feeling overwhelmed? Don't be! We have updated our informed consent template to reflect all of these changes. Even if you're not planning on using our template, there is an updated checklist at the beginning of the template that you can use to ensure your consent form is compliant! The new template checklist can be found at: <http://www.cookcountyhhs.org/educationresearch/medical-research/office-of-research-regulatory-affairs/templates-forms/>

Joseph's Corner - Joseph Sfeir

Revised Common Rule Definitions to keep in mind when doing research:

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This definition now lists activities specifically deemed not to be research:

- 1- Public health surveillance activities, defined as the collection and testing of information or biospecimens, conducted supported, requested, ordered, required or authorized by a public health authority, deemed as non-research activities and will now fall under the definition of research as secondary use.
- 2- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship) including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- 3- Collection and analysis of information, biospecimens, or records by or for a criminal

justice agency for activities authorized by law or court order solely for criminal justice investigative purposes.

4- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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.

Vulnerable: The definition of "vulnerable" is not included in the definitions section, but it has been updated in both 46.107 (IRB membership requirements) and 46.111 (criteria for approval of research). The Final Rule no longer includes pregnant women or handicapped and physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence.

The term "individuals with impaired decision-making ability" is now "mentally disabled persons."



The possibility of coercion or undue influence could affect the ability to make an informed decision about participating in research. Therefore, the vulnerability of the subjects in research studies should be taken into consideration as a function of the possibility of coercion or undue influence.

This type of vulnerability alone should be the IRB focus of concern in determinations about vulnerable populations. The assessment of the equitable selection of subjects should include factors like societal marginalization or discrimination. Likewise, the criterion at 46.111(a)(1) includes risks that some might term "vulnerabilities," which are not covered by the regulatory term.



What cell line was used to develop a vaccine for polio and is responsible for almost 11,000 patents?

Email your answer to:
CCHHSIRB@cookcountyhhs.org

Last Issue's Question: What is the name of the drug that led to the passage of the Kefauver-Harris Amendment/Drug Efficacy Amendment, which is a 1962 amendment to the Federal Food, Drug, and Cosmetic Act?

Answer: Severe birth defects in thousands of children caused by Thalidomide, which

was taken by mothers during pregnancy for morning sickness, led to increased drug regulations by the FDA. The Kefauver-Harris Amendment or Drug Efficacy Amendment requires drug manufacturers prove both the effectiveness and safety of their drugs before FDA approval. Previously manufacturers just had to show their new products were safe. It is notable that Thalidomide was never approved for use in the U.S., and the birth defects occurred in other countries. Frances Oldham Kelsey was the FDA reviewer who refused to approve Thalidomide in the U.S.

Tina's Tips by Tina LaGrone, BA

Now that we've moved to the new professional building, everyone must share the printers. Therefore, to ensure that investigators receive stamped approved consents in a timely manner, please upload all consents in Microsoft Word format. Be sure to leave at least two and half inches of free space on the right, lower side of all pages of the consent for stamping the expiration date.



Our workshop on January 23rd will be at noon location TBD. It will focus on the fall out from the Common Rule changes. Please join us! There will be no workshop in December. Happy Holidays! If you have any suggestions for workshop topics for 2019, please email us at CCHHSIRB@cookcountyhhs.org.



The Office of Research & Regulatory Affairs has moved to the 9th floor of the Professional Building! Our new address is 1950 W Polk, Room 9303, Chicago, IL 60612. As always, we are here for you from 8 am to 4 pm Monday through Friday.