



## From the Interim Director: Betty Donoval, JD, MS

Greetings CCH Researchers! Our first issue this year catches us up on all of the changes that have developed since the beginning of the year and changes we plan to implement for the remainder of the year. We have successfully transitioned to the Revised 2018 Common Rule, which took effect on January 21, 2019. As you may have noticed, our forms in IRBManager and informed consent templates have been updated to reflect changes in the regulations. These templates along with all of our other forms and templates are available through our website, which has also changed. Click on the following link to access our new website:

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

These changes have also been incorporated into our human subjects research training. We are currently working very hard to update our SOPs and Guidance for Investigators as well. We are also working on bringing the CITI Program Research & Compliance Training, which will include GCP training, to CCH. In order to keep up with best practices and sponsor requirements, our human subjects training will soon start to have an expiration date. Online modules through CITI will have to be completed to renew your educational requirements every 3 years. First time researchers will still have to come to our in person training. Stay tuned for developments in our training program!

I would like to congratulate all of the great research going on at CCH. Congratulations to the students from the CCH Emergency Medicine Academic Associate Program on their presentations at the 2019 Illinois LSAMP Symposium. I would also like to congratulate all 5 of the Senior Research Associates who have all been accepted to medical school! A description of the program, which comes through our Research Onboarding process, and the poster presentation information are included in this issue. Finally, I would like to congratulate all of the third year residents from the Cook County Family Medicine Residency Program on their QA/QI presentations for their 2019 Annual Resident Research Day that took place on May 23, 2019. Have a great summer!

## The Belmont Report Turns 40!

We would like to acknowledge The Belmont Report as it turns 40 this year! Published in the Federal Register on April 18, 1979, this foundational document provides the framework on which our federal oversight system for human subjects research is based. It also serves as the basis for IRB deliberations regarding human subjects research. In response to the public outrage that stemmed from the shocking revelations from the Tuskegee Syphilis Study, Congress passed the National Research Act of 1974 and established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This group was charged with identifying ethical principles to guide all research involving human subjects and developing guidelines for the conduct of ethical research involving human subjects. The National Commission drafted *The Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Belmont Report identifies three principles essential to

the ethical conduct of research with humans: respect for persons, beneficence, and justice.

*“Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in the risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.”*

**Respect for persons** incorporates two basic ideas: individuals should be treated as autonomous agents, and that persons with diminished autonomy are entitled to additional protections. Not only must individuals be given the choice to participate in research, but they must be provided with sufficient information through the informed consent process and possess the mental competence to make that choice. Some individuals,

such as children, may lack the ability to comprehend the study procedures and their risks and benefits. Additional safeguards should be taken to protect those with diminished capacity. Challenges to investigators in applying this principle include making sure participants comprehend the risks and potential benefits of the research and avoiding influencing participants' decisions through coercion and undue influence.



# The Belmont Report

**Beneficence** includes two general rules: do not harm, and maximize possible benefits and minimize possible harms. This involves a risk/benefit assessment, which is concerned with the probabilities and magnitudes of possible harms and anticipated benefits, by the IRB. When aiming to minimize risks, investigators should consider all possible harms including: physical, psychological, social, legal, and economic. This includes risks to privacy and confidentiality of data. If appropriate, investigators should de-identify data by removing direct identifiers as well as properly dispose of records,

limit access to data, and store data in locked cabinets or secured databases.

**Justice** requires that the selection of subjects is equitable. The burdens and benefits of research to both individuals and groups must be distributed fairly. The selection of participants must be the result of fair selection procedures and must result in fair selection outcomes. Investigators should not select research participants because of ease of availability or manipulability, but rather take into account the purposes of the research and the setting

where the research will take place. Consideration should be given to those classes of subjects that should or should not participate in any particular research based on the ability of those subjects to bear burdens and on the appropriateness of placing burdens on those already burdened.

The challenge for researchers and the IRB is to balance these 3 principles. One principle does not outweigh another. Each case should be considered separately on its own merits while seeking to uphold all 3 principles.

## CCH Emergency Medicine Academic Associate Program

The Academic Associate Program provides UIC premedical undergraduates or medical students from neighboring institutions the opportunity to engage with medical faculty and staff in a high-acuity ED and contribute to ongoing Emergency Medicine (EM) clinical research projects. Students develop an appreciation for the art and science of medicine through exposure to a variety of EM physicians caring for a diverse underserved patient population, as well as an understanding for the fundamentals of clinical research and collaboration by contributing to ongoing projects.

Students are required to successfully complete the onboarding process, commit to at least five 3-hour shifts a month, and attend monthly research meetings. Additionally, students must complete a research crash course consisting of 3 Episodes. Students should have an enthusiastic attitude and strong work ethic; conducting research in an emergency department can be chaotic. Excellent communication skills and a pro-

fessional demeanor are critical when approaching patients, and students who thrive demonstrate grit and passion for the cause. Success is not losing sight of the big picture through the long haul. The Academic Associate Program is an opportunity for students considering a career in healthcare to practice clinical research in the hospital setting. In addition to firsthand experience, there are many benefits to joining the program including: the opportunity to shadow physicians, a flexible schedule, letters of recommendation from EM investigators, and UIC undergraduates can receive course credit for the program.

Emergency Medicine Research Associates (RAs) participate in various degrees of data collection in prospective as well as retrospective studies. As of June 2018, the RAs participated in 12 projects, of which 9,648 patients were successfully enrolled. Of the 12 studies, 9 were prospective, and 3 were retrospective. For 3

retrospective studies, RAs collected patient data via 6,705 electronic medical records and re-reviewed 4,249 records to ensure data integrity. For 9 prospective studies, the RAs enrolled 2,943 patients through an in-person questionnaire. The RAs also provide survey administration for longitudinal studies via telephone follow up phone calls as well as the design and management of REDCap survey tools and data quality assurance. The Academic Associate Program's capacity is robust, typically covering data collection for studies 5 days a week, both day and evening clinical shifts.



**All 5 of the program's Senior Research Associates who are graduating and applied to medical school have all been accepted!**

## IRB Manager Tips

1. If you are the form submitter, be sure to add yourself to one of the personnel tables in the application to have access to the study.
2. Remember that the PI cannot be the designed approval signatory. The designed approval signatory can be the division head, department chair, or the Chief Medical Officer.
3. When submitting a progress report, make sure the total number of patients enrolled/charts reviewed from the beginning of the study are included and continued from previous years. If there have been participants enrolled during the reporting period make sure to add that group in the "Participants During Reporting Period" section under the enrollment type, ethnicity, and gender charts.

# 2019 ILLINOIS LSAMP SYMPOSIUM



The Illinois Louis Stokes Alliance for Minority Participation program was established in 1993 and is funded by the National Science Foundation. Illinois LSAMP is one of a number of consortia of colleges and universities with the goal of significantly increasing the

number of undergraduate and graduate degrees awarded to underrepresented populations in Science, Technology, Engineering and Mathematics (STEM). This group participates to provide programs that improve the quality of STEM education for underrepre-

sented minority students. Each of these organizations has made a commitment of faculty, staff, research facilities and technical assistance to ensure successful opportunities for students participating in Illinois LSAMP programs. Also funded under the same NSF portfolio, the ILSAMP has a Bridge to the Doctorate activity at the University of Illinois at Chicago.

**Total Presentations from CCHEM Academic Associate Program: 3**  
**ILSAMP Total Presentations : 81**

**Oral Presentations: Science Education**  
Total: 4 presentations  
1st Place: *Correlating Demographics,*

*Screening Modalities, and Health Literacy in an Urban Emergency Department* Presenters: Max Ackerman and Ana Hernandez

**Poster Presentations: General Biology**  
Total: 14 presentations  
1st Place: *Is the HEART Score an Effective Clinical Tool to Reduce Admissions and Costs in the Public Hospital Setting?* Presenters: Samantha Hernandez and Diana Morales

3rd Place: *Screening Electrocardiograms in Cocaine-Positive Chest-Pain-Free Psychiatric Patients Requiring Medical Clearance* Presenters: Evelyn Castanon, Julian Pacheco, and Moriam Yarrow.

## A Day with Dr. Rebecca Roberts by Tina LaGrone

Dr. Roberts has always loved to help people, a trait that heavily influenced her decision to become a doctor. While rotating in the Department of Family Medicine in her third year of medical school, she developed a close friendship with a patient who unfortunately passed away, a devastating event for her. She decided to write about this loss in the school paper. Her dean became concerned for her well-being, so he called her to his office to ensure that she was ok. These events influenced her decision to switch medical specialties, and she joined the Department of Surgery in 1983. Unfortunately, some patients were not respectful of a woman surgeon. Rather than looking for a career where she would not get attached, she found Emergency Medicine, a career that suited her and where women were welcomed.

Dr. Roberts was an attending physician at Grady Hospital in Atlanta before starting at CCH in 1990. Her passion for helping people was the perfect impetus for getting involved in the ample research that was going on in the early 1990s. She realized cost-effectiveness research could involve a broad range of clinical topics- she was a pioneer in the field and published many influential papers.

Looking back over the course of her career, one of her most memorable events happened in the wake of a terrible tragedy. One day a man jumped from the hospital building, committing suicide. Soon after this event, she saw a man outside on one of the roofs of the administration building, repeatedly bending over then standing upright. Fearing another

jump, she asked the man several times if he was okay. He finally stood up with a petri dish and a cotton culture swab and told her that he was fine. The gentleman in question was none other than Dr. Robert Weinstein (former Chair of the Department of Medicine), and he was outside collecting pigeon droppings to determine which antibiotics worked best against Histoplasmosis infections in HIV patients. He had just arrived at County.



Among Dr. Robert's favorite studies is the Chest Pain study, which started in 1993, and helped her learn the ins and outs of economics. Interestingly, the Chest Pain study also proved to be one of her most challenging studies, as she had to work weekends and night shifts to ensure patient safety during treadmill stress tests. Another favorite was an infectious disease study she worked on with Dr. Weinstein that focused on the economic and social cost of antimicrobial resistant infections. Another challenge was the Chicago Surge study, where she was tasked with forming a database for treatments used in emergencies such as chemical spills and infections. Over 2,000 references were needed for the database.

With a little more time on her hands thanks to retirement, Dr. Roberts plans to write up six completed research projects. She will also be giving tours of the Admin Building. She shared some interesting and little known facts about the CCH campus. The nursing school and dorm, now the Admin Building, was built in 1931 in the shape of an H to supply natural light to all dorm rooms. At one time, the only cafeteria on campus was in the nursing school. Nursing students enjoyed amenities such as dumbwaiters that delivered food to them and a swimming pool. There was also an underground tunnel that staff could use to walk to different departments without going outside. This came in handy during the often-brutal Chicago winters! Even patients could be transported through the hospital, ICU building, clinic, pediatric hospital, laboratory building, and School of Nursing via the tunnels.

Dr. Roberts' career spans many academic appointments and positions, resulting in many awards and recognitions for her work. The advice Dr. Roberts offers to new and future researchers is to "simply work with those you respect and keep the focus on helping people/patients." In fact, the majority of her best friends are those she has worked on various research studies with over the years.

**Dr. Roberts, the Department of Research and Regulatory Affairs would like to thank you for your service and congratulate you on your retirement!**

## Consenting Non-English Speaking Study Participants by Stacey Kincaid

We have received several inquiries about obtaining translations and the use of short form consents with our non-English speaking study participants. The informed consent document should be presented in a language understandable to the participant. Translating the entire document in the participant's language is the gold standard. 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. You can submit documents for translation via an amendment to your IRB approved study in IRBManager.

In unexpected situations, when a full translation of a consent document is not available, an interpreter can make an oral presentation of informed consent in conjunction with a short form written consent form and a written summary of what is presented orally. Since the short form is a standard document, it is not necessary to obtain a new translation of this form for each study. The study summary can be in English, and with the IRB's approval, may be the full English version of the consent form modified to include space for a witness signature and date. Standard short form consents in several languages are made available by the CCH Office of Research & Regulatory Affairs (<https://cookcountyhealth.org/education-research/research/office-of-research-regulatory-affairs-irb/>).

An interpreter should be used for the short form consent process. Interpreters are competent in being fluent in the English language and trained in the cultural knowledge and subject matter language as per CCH policy. A family member or friend of the participant should not be asked to interpret, unless the patient declines the use of free interpreter services and requests to use a family member or friend. Minor children (age < 18 years old) may never serve as interpreters. The study staff obtaining consent must be present during the oral presentation to answer questions. (For more information see the Interpreter Services Policy #RI.001.05).

A third person must witness each oral presentation. The witness must be an individual who is fluent in both English and the necessary foreign language and will be physically present during the consent process to observe the process and sign consent forms. The witness may be the interpreter, a family member, another staff member, or another person. A member of the study staff who is also an interpreter may act as the interpreter and person obtaining consent, but may not act additionally as the witness in this scenario.

### Steps for using a short form consent for non-English speaking study participants:

1. An interpreter verbally delivers the information contained in the full consent document or study summary
2. The short form document is signed by the participant (or the participant's LAR)
3. The short form is signed by a witness (can be the interpreter, unless the interpreter is also the person obtaining consent)
4. The study summary or consent is signed by the person obtaining consent
5. The study summary or consent is signed by a witness (can be the interpreter, unless the interpreter is also the person obtaining consent)

The participant should receive a copy of both the signed short form and the signed study summary to keep for themselves. When either the short form or a full translated consent is used, copies of both the English version of the consent form and the signed translated or short form consent must be placed in the participant's research record.



**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?**

**Email your answer to: [CCHHSIRB@cookcountyhhs.org](mailto:CCHHSIRB@cookcountyhhs.org)**



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

**Answer:** The HeLa cell line, named after the first two letters of Henrietta Lacks' first and last name, was vital for developing the polio vaccine as well as research in cancer, HIV/AIDS, viruses, effects of radiation and toxic substances, gene mapping, cloning, *in vitro* fertilization, and many other scientific pursuits that are responsible for almost 11,000 patents. Ms. Lacks, born in 1920, was a poor African-American from the South whose cancerous cervical tumor was the source of the cells that gave rise to the "immortal" cell line at Johns Hopkins. These cells remain alive 68 years after her death. Her cells were special in that they could be kept alive and grow, while until then cells would die after a few cell divisions in the laboratory. It is estimated that the total weight of all HeLa cells globally is more than 50 million metric tons. Ethical issues that have been brought to light are informed consent and compensation. Although standard procedure at the time, the cells were removed from the tumor for research purposes without her knowledge or permission. Members of her family were unaware about the HeLa cell line for more than 25 years after her death. They have not seen any profits from the multimillion-dollar industry that has resulted from her cells.