



COOK COUNTY HEALTH

Research Roundup July 2023

Greetings CCH Researchers!

Thank you to those that have attended the HRPP Toolkit trainings for researchers. If you have not joined a session yet, we have some remaining live and virtual sessions available. For dates and times, please see below. We would love to see you in person on Thursday, August 24th at 3pm in 5501PB!

We have finalized the new consent and protocol templates, and they have been posted to our website (**Research & Regulatory Affairs Website**). We are now in the process of finalizing our Investigator Manual and hope to have that posted soon as well.

HRPP Toolkit Trainings for Researchers

As our implementation of the **HRPP (Human Research Protection Program) Toolkit** continues, we are educating our research community about the upcoming changes. We are still offering live in-person and live virtual sessions that will last an hour and 15 minutes. HRPP Toolkit sessions will focus on providing:

- Overview of the Toolkit
- Review of new consent templates
- Review of new protocol templates
- How to use the new templates as part of the submission process

Following the HRPP Toolkit training, Nicole Almiro, Chief Compliance and Privacy Officer, will provide a short training on **disclosing financial interests** in research.

All members of the research team are required to attend either the live in-person, live virtual, or recorded session.

In-Person Research Team Sessions

- Thursday, August 24th @ 3pm in 5501 PB

Virtual Research Team Sessions

- Thursday, September 7th @ 12 pm
- Monday, September 18th @ 2 pm

Please email CCHHSIRB@cookcountyhhs.org to register and indicate which session you will be attending. If you are unable to attend any of the above sessions, please let us know, and we will add you to the recorded session when available.



We welcome any feedback as well as any ideas, contributions, or news that you would like to share with the CCH research community. Please email us at CCHHSIRB@cookcountyhhs.org.

Research & Regulatory Affairs Website

New Protocol Templates!

We are excited to share our new protocol templates with the research community. The HRPP Toolkit templates are designed to assist study teams with providing the information needed for the IRB review process. By using these templates, we hope to streamline the IRB approval process by eliminating the back and forth with study teams in obtaining the necessary information for IRB review.

Each template focuses on a different type of research with a specific template for biomedical and social-behavioral studies. There is also a template that can be used as a site supplement to a sponsor protocol. So, if you have a sponsor or main study protocol already, there is no need to reinvent the wheel and use these protocol templates, but you can use the site supplement template to provide the local information needed for IRB review. The templates include instructions for study teams to follow when preparing their materials. Researchers only need to provide information for sections that apply to their research. If a section does not apply, just enter NA in the section. If you have any questions or concerns about using the new templates, please reach out to our office.

HRP-503-Template Protocol (Biomedical)

HRP-503a-Template SBS Protocol (Social-Behavioral)

HRP-508-Template Site Supplement to Sponsor Protocol

New Consent Templates!

We are also thrilled to share two new consent templates. The first is a general consent template and the second is available for emergency treatment with an unapproved article or compassionate use of an unapproved medical device. The general consent template can be used for most study types and includes required elements specific to various sponsoring agencies, including the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Department of Defense (DoD). Another great feature of the new general consent template is the inclusion of a variety of signature blocks that you can select from depending on the nature of your study. These include a block for capable adults, a block for adults unable to consent, and a block for children. As with the old CCH consent template, you can delete any template sections or signature blocks that are not applicable to your study.

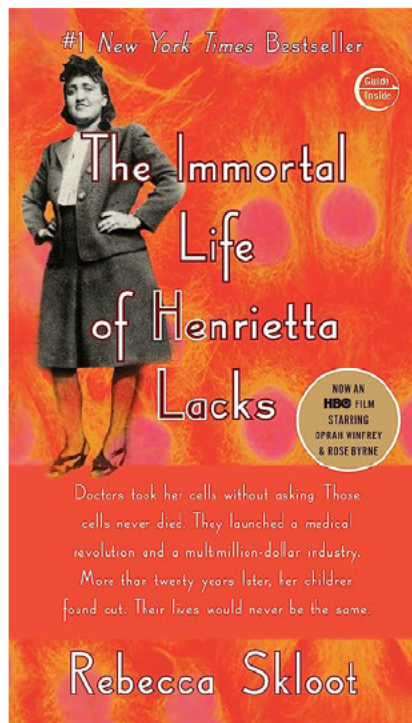
HRP-502-Template Consent Document

HRP-506-Template Consent Document for Emergency or Compassionate Device Use



Henrietta Lacks Update

In 1951, Henrietta Lacks, a young wife and mother of five, began receiving treatment from The Johns Hopkins Hospital for her cervical cancer diagnosis. During her treatment, researchers who routinely collected cancer cell samples from the biopsies of patients at Hopkins, collected her cells as well, without the consent or knowledge of any patient. At the time, there were no laws or regulations governing the collection of human tissue for the purposes of research.



While all of the other samples collected had expired shortly after retrieval, Mrs. Lacks' cells were found to have thrived—doubling once every 20 to 24 hours. These cells, nicknamed “HeLa” cells for the first and last initial of her first and last name, continue to provide countless innovations in medicine, from understanding the effects of radiation and poisons on tissue, AIDS research and interventions, to even facilitating the development of the COVID-19 vaccine. Accordingly, there are estimated to be more than 11,000 patents linked to the mass production and distribution of these unique cells.

While many have benefited from the discovery and use of the HeLa cells, the Lacks family continued over the years to raise questions regarding their privacy and the initial lack of consent of their matriarch to cede authority and the subsequent commercialization of her tissue— with no compensation. In October 2021, the Lacks estate filed a lawsuit against Thermo Fisher for profiting off of the cells without her consent. On July 31st, 2023, Thermo Fisher settled with Henrietta Lacks' family, issuing a degree of justice for the generations that languished while others profited immensely, but also serving as a reminder of the importance of a robust regulatory system that protects all humans involved in research from such egregious incidents.

Clinical Research Office (CRO) Updates August 2023

New Feasibility Review Process

The CRO has launched a new feasibility process that is required for all new clinical research studies. A copy of the feasibility checklist is available [here](#). As a reminder, you will need to attach a copy of the final protocol with your feasibility checklist submission. The Clinical Research Operations Committee (“CROC”) will review completed feasibility checklist submissions every two weeks. Start-up activities such as IRB submission, budget and contract negotiations, and grant submission should not begin until you receive feasibility approval from the CROC. Formal feasibility review provides visibility to the pipeline for future research projects to aid budgeting, staffing and collaboration with the goal of shortening time to implementation.

Clinical Research Office (CRO) Research Support Staff Roles and

Responsibilities Survey

Recently the CCH Clinical Research Office (CRO) sent out a brief roles and responsibilities survey to the individuals with an active IRB manager account and/or an active study with clinical research billing to better identify the individuals that are conducting research within CCH and their areas of responsibility. If you received the survey link, please complete this survey as soon as possible. If you are participating as research staff on a clinical research project and did not receive the survey link, please complete the survey, available [here](#).

Clinical Research Office Monthly Roundtable

Thank you to everyone who participated in the last Clinical Research Office (“CRO”) Roundtable call on 7/25. This call is open to the research community, and we encourage everyone to attend as it is a great way to receive updates as well as ask questions / provide input.

Have a question or topic to discuss? Please email clinres@cookcountyhhs.org if you are unable to attend, Roundtable materials are posted to the CCH Research Champions Team Channel [HERE](#) after each meeting. The next Roundtable will be hosted on Tuesday August 29th from 12:00 – 1:00 CST.

Clinical Research Office (CRO) Policies Update

Just another reminder about the new CRO Research Administration policies that went into effect in July:

RA.001.01 Institutional Requirements for Initiating Clinical Research

RA.003.01 Subject Compensation and Reimbursement

RA.004.01 Principal Investigator Eligibility Policy

RA.005.01 Clinical Research Quality and Education Policy

RA.006.01 Clinical Research Budget Policy

RA.007.01 Clinical Research Subject Registration

RA.008.01 Clinical Research Documentation

RA.009.01 ClinicalTrials.Gov Policy

RA.010.01 Clinical Research Residual Balance Policy

All policies are published to the [CCH New Policy Portal](#). Please note Principal Investigator (PI) attestation that he/she has reviewed the new CRO policies will be required for all new clinical research projects going forward.