



News & Announcements

CANCELLED: HRC METS May Edition

Our May edition of our Monthly Education and Training Series (METS) has been cancelled due to unforeseen circumstances. We apologize for the inconvenience and do hope to see you at our June METS, when we present “The Informed Consent Form: Regulatory Requirements and Ethical Obligations” and discuss **our new ICF templates** (see Upcoming Changes below)!

A New Abbreviated IRB Review Application (IRA) form is available!

A new [Medical Education IRB Review Application](#) (IRA) is now available for use by study teams engaged in **minimal risk studies that qualify for Exempt Category 1** only:

*Research, conducted in **established or commonly accepted educational settings**, that specifically involves **normal educational practices that are not likely to adversely impact students’ opportunities to learn required educational content or the assessment of educators who provide instruction**. This includes most research on regular and special education instructional strategies, and research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.*

IRAs have been developed to facilitate an improved application submission process by greatly reducing the length of the WRG-HS application, thus increasing the efficiency of IRB review. The IRAs have been designed to collect all IRB-required information with more targeted and less repetitive questions, making it easier for study teams to complete the application and for a quicker turnaround time for IRB determinations.

View and download the full suite of IRAs available on our [Forms, Templates, & Guidance page](#).

Did You Know?

Your study may need Maternal-Fetal Research Committee approval

Obstetrics & Gynecology has started a new committee, the **Maternal-Fetal Research Committee (MFRC)**, to provide oversight of research involving pregnant and postpartum individuals. **Committee approval is now required for all studies that plan to recruit pregnant and postpartum patients in the WCM system.** This includes research studies in which:

- Pregnant and postpartum individuals are the participants
- Fetuses or newborns are the participants and consent is sought from a birthing parent in one of our prenatal/postpartum clinics, on labor and delivery, or on the antepartum or postpartum wards

The purpose of this new process is twofold:

1. To ensure that both the burden of and the opportunity for research is spread across our population/clinics without undue weight given to any one population; and
2. To ensure that research conducted on OB-GYN patients is done without interference with clinical care or research procedures

The process for approval is simple! Researchers complete a short Qualtrics form available [on the MFRC web site](#), then send the IRB protocol, recruitment materials, and a one-page description of the study for clinicians by email to MaternalFetalResearch@med.cornell.edu. Applications can be submitted before or after IRB approval.

For more information, please email the Committee at MaternalFetalResearch@med.cornell.edu.

Upcoming Changes

New Informed Consent Form (ICF) templates are coming!

You asked, we are answering! As part of our continued efforts to improve the IRB application and review process, we have developed new ICF templates that address the issues identified by you, our researchers:

- Different templates have been created for different types of studies (SBER, Biomed, etc.)
- Guidance language has been added to each template to reduce confusion about which template to use, as well as how to complete sections
- The Key Information section has been simplified
- An Assent Template has been created, with guidance included to identify applicable populations
- All language utilized is at the 8th grade reading level, and has been improved to promote clarity of instructions
- The template has been shortened and simplified to facilitate completion
- All signatures have been moved to the end of the document

Any new studies *initiated* within WRG-HS as of June 12th, 2023, must utilize these new templates.

These new and improved ICF templates are available on our **dedicated ICF Template page**, which will go live this **Wednesday, May 17th**

Look for a separate email to arrive in your inbox on Wednesday, May 17th with answers to some frequently asked questions as well as links to the templates and ICF Template page!

HRC Team Member Spotlight



Lauren Odynocki

Sr. Human Research Compliance Specialist

Lauren has been proudly serving the Weill Cornell Medicine research community in various regulatory compliance roles for over 15 years. She currently coordinates the IRB's review of unanticipated problems, serious and continuing noncompliance, and runs the institution's ClinicalTrials.gov program.

As part of a national taskforce of ClinicalTrials.gov professionals, Lauren serves as a member on the taskforce's education subcommittee, collaboratively creating and conducting educational sessions for 700+ ClinicalTrials.gov professionals at peer institutions across the country. She is also a member of the taskforce's web subcommittee, which is charged with providing the taskforce with resources that meet web accessibility standards. She has served as a peer reviewer for CITI Program's course for Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov and presented her poster, entitled, "Reducing ClinicalTrials.gov Problem Records," at the PRIM&R 2020 Advancing Ethical Research (AER) Annual Conference. She created WCM's ClinicalTrials.gov training program to provide more hands-on guidance to WCM's researchers and looks forward to helping your team next! In her free time, she enjoys reading, recording original music, and taking the occasional nap.



Have general questions about the IRB, or need help with your submission? [Email the IRB Team!](#)



Would you like to set up training for your lab or department? [Email the Operations Team!](#)

For more information, visit us at <https://research.weill.cornell.edu/irb>