



IRB NEWS

News & Announcements

ClinicalTrials.gov Training

We are pleased to announce that our quarterly **ClinicalTrials.gov training** is now available to you whenever you want [right here!](#) You can also find information on our [FAQs page](#) at your convenience. And of course you can always contact us for assistance by emailing our team at: registerclinicaltrials@med.cornell.edu.

Updated Regulatory Requirement: The Key Information Section

Starting April 4, 2022, all Informed Consent Forms will require a Key Information Section at the beginning of the consent form. Please see the Upcoming Changes section below for detailed information.

Topic of the Month

Did you know?

[The Center for Cultural Humility \(CHUM\)](#) is a new multi-dimensional training and outreach center focused on facilitating culturally humble research and clinical practice with cultural minorities, including people of color, people who identify as LGBTQ+, low-income individuals, rural individuals, and individuals with physical, psychological, and cognitive disabilities. CHUM provides tailored, evidence-based trainings and facilitates community partnerships for Cornell staff, faculty, and students, including members of the Weill Cornell community.

In the spring and summer of 2022, **CHUM trainers will be in NYC** conducting trainings on cultural humility and equitable research design that will be broadly available to departments and individuals at Weill Cornell. Trainings are certificate-based and CEUs may be available.

Learn more and sign-up for a training at humility.cornell.edu.

To contact CHUM, please email humility@cornell.edu

Upcoming Changes

The Key Information Section – Anticipated Rollout 4/4/2022

The Key Information Section is a part of the Informed Consent Form (ICF) that provides enough information – the “key” information – a prospective participant needs to determine whether they should participate in your study. The Key Information Section is designed to facilitate prospective participants’ (or a legally authorized representative’s) understanding of the research study, and the reasons why one might wish to participate, or not participate, in the study.

What is ‘Key’?

Per the 2018 Common Rule, there are five required elements included in the Key Information Section:

1. That the prospective participant’s consent is being sought for research and that participation is voluntary
2. The purpose(s) of the research, the expected duration of participation, the research procedures to be followed, and any other important information about the research
3. The reasonably foreseeable risks or discomforts to the prospective subject
4. The benefits to the prospective participant or others that may reasonably be expected
5. Appropriate alternatives to the research, if any

Note: Key information provided to participants is not limited to these five elements. Researchers may include other types of information that they deem necessary and appropriate to include in the key information.

When will the Key Information Section be required?

The Key Information Section is required for any and all **Full Board** and **Expedited** studies that will receive initial approval **after 4/4/2022**, **unless** the ICF for your **Expedited study** is short (6 pages or less including the signature pages).

What if the study received initial approval before 4/4/2022?

If your study was approved between 1/20/2019 and 4/3/2022 **AND** is still open to accrual:

- **Full Board studies:** A KI section **must** be added to your previously approved ICF. We will require it at Continuing Review or another major amendment submission, but you may submit this update at any time.
- **Expedited studies:** A KI section will not need to be added to approved consent documents when you submit your PAM-AR form, but we **strongly recommend** you upgrade to the new version of the ICF (which includes the KI section) when it is released in Summer 2022.

What support will the IRB offer?

There will be multiple sources of support:

- **Templates:** A template for the KI section will be available on April 4th.
- **Decision Trees:** Decision trees will be distributed at our upcoming trainings.
- **Training:** Several **pre-launch** training sessions will be offered throughout March on the following dates, with additional post-launch trainings to be scheduled:
 - Thursday, 3/10, 1:00pm – 2:30pm (click [here](#) to register for this session)
 - Tuesday, 3/15, 10:00am – 11:30am (click [here](#) to register for this session)
 - Monday, 3/21, 10:00am – 11:30am (click [here](#) to register for this session)
 - Thursday, 3/24, 10:00am – 11:30am (click [here](#) to register for this session)

New Hires



Jessica Kisenwether, PhD, CCC-SLP, CIP
Human Research QA & Education Manager

Jessica comes to us from the National Aeronautic and Space Administration, where she served as the manager of the IRB and Human Research Protection Program. She is also a licensed and certified speech-language pathologist specializing in speech science, voice, and swallowing.



Isabel Bustamente
Human Research QA & Education Manager

Isabel comes to us from Columbia University, where she spent the past 7 years honing her expertise in IRB Operations, and is currently completing her graduate studies in Bioethics. When not at work, Isabel runs a skincare and dance school business while also finding time to volunteer in her local community.



Antoinette Kohlman, MHROD, MA, PhD
Sr. IRB Analyst

Antoinette comes to us from Northcentral University, where she worked as an IRB Analyst and as a faculty member in the Department of Psychology. She combined her expertise in the protection of human research participants with roles as a dissertation chair, subject matter expert, and academic reader for studies in industrial organizational psychology, health psychology, trauma and disaster relief, and the psychology of gender and sexual fluidity.



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 our website.