Weill Cornell Medicine

IRB *NEWS*

News & Announcements

Important ClinicalTrials.gov Update

ClinicalTrials.gov is experiencing significant delays in its review of new ClinicalTrials.gov registrations. As a reminder, ClinicalTrials.gov registration is required for interventional Weill Cornell Investigator-initiated trials prior to the enrollment of the first study participant. To minimize the impact of these delays, The Office of Human Research Compliance recommends that study teams check the Study Activation Page (SASP) in WRG-HS to determine if ClinicalTrials.gov registration is required, and if so, initiate the process as soon as possible using the resources on the WCM ClinicalTrials.gov website. If you have any questions, please contact us at registerclinicaltrials@med.cornell.edu.

Did you know?

The IRB has a **guidance document for obtaining an expanded access IND for an individual patient in emergency and non-emergency situations**! We have a combination guidance document and checklist for investigators and their research teams to use! This document provides regulatory information about the requirements and procedures for submitting, obtaining, and maintaining an expanded access IND for an emergency or non-emergency use for an individual patient.

Click here to view and/or download the document.

Have you tried BRANY*plus*?

One of our New Year's Resolutions was to restructure our IRB operations so we are able to better serve our research community. In order to accomplish this, we have entered into a temporary partnership with the Biomedical Research Alliance of New York (BRANY), an independent IRB. This **BRANY***plus* initiative will go on through Spring 2022; thus, all **new** submissions from all departments must be submitted through **BRANY***plus.*

We recently presented a TWIST on **BRANY***plus* focusing on recent updates to submission processes, as well as an overview of the **BRANY***plus* workflow. You can watch the recorded session here!

For more information on this initiative, and instructions on using **BRANY***plus*, please visit BRANYplus online.

Using the JCTO Enrollment Report Template

When your enrollment information is not in WRG-CT (OnCore) and you are using the JCTO Enrollment Report Template (*download link*) instead, please remember:

- The Hispanic Enrollment Report section only provides a breakdown of the racial category of those subjects indicated to be Hispanic or Latino in the Ethnic Category table.
- Unless **all** subjects enrolled are Hispanic or Latino, it is expected that the Total number of the subjects in the Hispanic Enrollment Report section would be less than the overall Total number of subjects reported in the general Ethnic Category and Racial Category sections.

The JCTO maintains a Researcher's Toolbox, where you can find various tools and templates that may be utilized throughout the process of study activation and during the conduct of your study. Please visit their website for more information.

Upcoming Changes

Beginning February 11th: Amendment Submissions in WRG-HS

Beginning **Feb 11th**, Amendment submissions in the WRG HS application will be locked down with fields **closed to editing** unless designated as part of the new "Amendment" section of the application. Please contact HRPO@med.cornell.edu if you have questions about this process.

Launching this Spring: The Key Information Section

In a little over one month, the IRB will require investigators to include a **Key Information Section at the beginning of their** informed consent forms. Pursuant to the Revised Common Rule, the key information section will include "key" information such as information about the purpose, the risks, the benefits, and alternatives to allow the participant the ability to determine whether they want to, or might not want to participate in the study. A template will be provided for use on our webpage.

What goes into the Key Information Section?

There are five required elements for this 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

More detailed information will be sent out in late February, including training dates for members of our research community. Please look out for an email from us!

New Hires

Anjani K. Singh, MD
IRB Analyst
General Expedited Team

Kortney Rogers
IRB Analyst
General IRB Team

Cecilia Brooke Cholka, PhD, CIP
Human Research QA & Education Manager
HRP Operations Team

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.