

Weill Cornell Medicine
Research Integrity
Human Research Compliance

IRB*NEWS*

March 28, 2022

Upcoming Changes

Important Reminder

The Key Information Section

This updated regulatory requirement takes effect next Monday, 4/4/22

As stated in our March newsletter, the Key Information Section for Informed Consent Forms will be required as of next Monday, April 4th, 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 Key Information section will be available on our website (https://research.weill.cornell.edu/irb) by the end of day on Monday, March 28th.
- **Decision Trees**: Decision trees will also be available on our website by end of day on Monday, March 28th.
- **Training**: Several **pre-launch** training sessions were offered throughout March to educate researchers on the requirements and to discuss what types of studies will require the Key Information Section. A video will be made available on our website shortly.

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