Weill Cornell Medicine
Research Integrity
Human Research Compliance

IRB NEWS

May 17th, 2023

Special Announcement

New Informed Consent Form (ICF) templates are here and ready for use!

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

These new and improved ICF templates are now available on our dedicated ICF Template page on our website, and replaces all previous versions issued by our office as of today, May 17th, 2023.

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

- WCM Assent Template
- WCM Biomedical Informed Consent Template
- WCM Humanitarian Use Device Informed Consent Template
- WCM Informed Consent Addendum Template
- WCM Intermediate-Size Investigational Treatment Informed Consent Template
- WCM Pregnant Partner Non-Subject Informed Consent Template
- WCM Pregnant Partner Research Subject Informed Consent Template
- WCM Repository Informed Consent Template
- WCM SBER Informed Consent Template
- WCM Single Patient Investigational Treatment Informed Consent Template

Frequently Asked Questions

Q: Will I have to start using these new consents today?
A: No. They will be available starting 5/17 on the WCM IRB website, but you can continue to use the existing templates. Any new studies initiated in WRG-HS starting 6/17, must use the new ICF templates.

Q: Do I have to transition my existing study consent(s) to these new templates?
A: No. Any existing study using the previous consent templates can continue to use their IRB-approved consent. Any new studies initiated in WRG-HS starting 6/17, must use the new ICF templates.

Q: Do these new ICF templates need to be used under a ceded/sIRB study with an external IRB as the IRB of record?
A: No. Studies with an external IRB are expected to use consent forms provided by the lead IRB. Once the externally reviewed ICF is provided to the WCM IRB, we will conduct a local context review to confirm any required

language (i.e. research-related injury, NYS Genetic testing requirements, etc.). The new WCM ICF templates are available as a resource if needed, but not required for externally reviewed studies.

Q: If I am updating my protocol and the change requires a new ICF, will I need to use the new ICF templates?
A: No. You can continue to use the same ICF.

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