News & Announcements

News from the Regulatory Agencies

The Office for Human Research Protections (OHRP) recently hosted a two-part workshop series, Beyond Altruism - Exploring Payment for Research Participation.

As society moves away from a paternalistic view of protecting research participants, many are revisiting the ethics and utility of payment for research participation. The goal of this workshop was to explore the role of paying people for their participation, the impact of payment, as well as the challenges and considerations for how payments should be made. Session 1 focused on ethical and theoretical considerations. Session 2 explored the practical challenges and implementations.

Access videos and slides from both sessions [here](#)

¡El Informe Belmont está disponible en español!

The Belmont Report is now available in Spanish! The Belmont Report identifies the basic ethical principles that underlie the conduct of biomedical and behavioral research involving human subjects and includes guidelines to assure that such research is conducted in accordance with those principles.

Access The Belmont Report in Spanish [here](#)

We hope you join us for our next HRC METS this Thursday!

**IRB 101: Single IRB and Reliance**

**Thursday, November 17th, 2022**

11:00am until 12noon

Please join us for our next Monthly Education and Training Series (METS) session presented by our very own Single IRB Administrator and Reliance Manager, German Jimenez! The goal of Single IRB review is to enhance and streamline the IRB review process for multi-site research so that research can proceed without compromising ethical principles and protections for human research participants. This presentation will help provide education to WCM investigators, study teams and research administrators on the concept of a Single IRB model in multi-site research.

After this educational session, you will be able to:

- Understand what Single IRB review is
- Recognize what types of studies must comply
- Explain the overall process for obtaining Single IRB review
- Plan for Single IRB review for a multi-site research study

Registration is required to attend
Please register [here](#)

**Future METS:**
- 12/15/22: Tips and Tricks for Successful IRB Submissions and Reviews (register [here](#))
- 1/12/23: Cultural Competency and the Responsible Conduct of Research (register [here](#))
- 2/16/23: Data Security in Research: PHI, Email, HIPAA, and You (register [here](#))

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**Submitting a New IRB Application?**

As of 9/15/2022, all new applications must utilize the new IRB Initial Review Application (IRA). Forms, templates, and guidance are available on the [Forms, Templates, & Guidance](#) page on our [website](#).

**Why the new application?**

The IRA has been designed to capture the essential information needed by the IRB in their assessment of whether the protocol satisfies the regulatory criteria, facilitating faster turn-around times for protocol review.

**How does this benefit the researcher?**

In addition to decreasing the overall wait time from submission to approval, use of the IRA enables research teams to work on drafting their protocols **outside of the WRG-HS system**, thereby delaying the start of the 90-day submission completion clock that begins at initial intake.

**How do I use the IRA?**

We recommend utilizing our Consultation Service for assistance in preparing your new initial submission utilizing the new IRB Initial Review Application. Click the request button now or find it at any time on any page of our website, to book a consult!

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**Upcoming Changes**

**PRMC/PRMC-equivalent Review Required Prior to IRB Review**

The IRB will not review submissions that have not yet obtained approval from the Protocol Review and Monitoring Committee (PRMC) (or its equivalent). **Any Initial IRB Application submitted that has not received PRMC approval will be returned to the PI by our pre-review analyst.** Study teams are encouraged to submit their study protocols to the PRMC well ahead of their IRB submissions to ensure a faster turnaround time from IRB submission to approval.

**Policy Alert!**

**ClinicalTrials.gov Requirement for Informed Consent Forms**

The revised Common Rule requires awardees of clinical trials funded by a [Common Rule agency](#) (NIH, AHRQ, etc.) that were IRB-approved on or after January 21, 2019 to publicly post one (blank) informed consent form, used to consent participants, to ClinicalTrials.gov.

Only forms posted (1) after a study is closed to recruitment, and (2) where 60 or fewer days have passed since the last study visit by any enrolled subject satisfy the regulatory requirement.

To ensure your study adheres to the posting timeline required by this regulation, be sure to update OnCore once your study is closed to accrual. Our office uses this status to know when to email you a reminder about posting the informed consent.

**Still have questions? Contact [registerclinicaltrials@med.cornell.edu](mailto:registerclinicaltrials@med.cornell.edu) for assistance.**
We are pleased to announce the addition of Sabrina Paula to our Regulatory Compliance Team! Sabrina’s first day will be November 21st, when she will join us as our new General Data Safety Monitoring Committee (DSMC), Embryonic Stem Cell Research Oversight (ESCRO), and Audit Administrator. Sabrina is a Masters candidate in Biomedical Sciences at Rutgers University and brings research expertise she has gained during her time with the CDC Foundation as well as The Johns Hopkins University School of Medicine. 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.well.cornell.edu/irb