Ascension

Ascension Wisconsin

Research Integrity and Protection Newsletter

September 2018

IRB Eliminating Paper Forms and Implementing Electronic Signatures, Starting with Reportable Events

The IRB is updating Mentor to eliminate paper forms and use electronic signatures. This change was initiated after input from researchers, staff, and the IRB. The goal is to reduce administrative work and decrease the time to receive IRB approval.

Changes Include:

- Elimination of paper report forms
  - All questions will be entered directly into Mentor
  - You can start and come back to the questions
  - You can print the answers submitted to keep in the study file
- Electronic collection of the PI signature via Mentor
  - PI's will get an email to sign a submission
  - Click to review and sign the submission, NO log in required
  - The PI must sign before the report is submitted to the IRB

Time Line for Implementation:

- Reportable event submissions beginning October 19th, 2018
- Amendments and Continuing Reviews in November
- New Study's November-December

Announcements will be made when each new review type is scheduled to update. The submission and electronic signature process will be the same for all review types.

Learn More about the New Submission and PI Signature Process

Updated Mentor User Guide provides tips for using Mentor and step-by-step submission instructions. The current and updated User Guides are available in Mentor HERE.

Training Webinar RI&P will present the new process via Skype.

October 10th, 9-9:30am
→ Join Skype Meeting
Join by phone +1 (888) 444-5443, ID:3203 3207

The slides and recording will be available afterwards sign-up HERE to receive them.

OHRP Resources for Researchers and Participants

Explaining complicated research concepts for prospective research participants can be challenging. OHRP has a public outreach website, About Research Participation, www.hhs.gov/about-research-participation, to help potential volunteers better understand research and make informed decisions. All the resources, including the videos, are available in English and Spanish.

Resources include short videos that explain the differences between research and clinical care, and things to think about when considering a study. There is also a list of questions for prospective participants to consider and a set of infographics that explain the HHS regulations. Users can learn about the history of the regulations and how OHRP and other federal entities help protect human subjects.

New Option to Designate a Primary Study Coordinator in Mentor

You may have already noticed a new feature in Mentor on the main protocol page for new studies. When selecting individuals for the Research Coordinator role, you can now select a primary coordinator.

When completing new study information, a checkbox will be visible next to each coordinator. Selecting a primary coordinator is not required, but can help to identify the best contact person for the IRB.