Ascension

Ascension Wisconsin

Research Integrity and Protection Newsletter

December 2017

Final Rule Updates

Changes to the Common Rule, the primary rule regulating human subject research, go into effect on January 19, 2018.

A number of Ascension Wisconsin IRB policies, procedures, and systems will be updated as a result of the changes to the rule. Please note that only studies approved or altered after 1/19/18 will be governed by the new rule. Studies already approved under the pre-2018 Common Rule may transition to the New Rule on a case-by-case basis at the time of the next continuing review.

Summary of the Impact at Ascension Wisconsin:

	Summary of Change	IMPACT
Effective Date	January 19, 2018 (single IRB review compliance date is January 20, 2020)	- Common Rule changes will impact **new** studies submitted on/after January 19, 2018 - If a study is approved prior to the 1/19/18 effective date of the new rule, it will remain on the old rule until its next Continuing Review. At that point, it will be determined if it transition to the new rule.
Scope	Changes to the Common Rule Regulations apply to studies under the scope of the rule	- Common Rule regulations are separate from FDA regulations. FDA regulations have NOT changed, so FDA still requires annual continuing review for FDA-regulated studies, even those relatively rare Minimal Risk FDA-regulated studies.
Exempt Research	New Categories of Exempt Research	- No changes to studies already determined to be exempt by the IRB. - Research determined to be exempt on or after 1/19/18 will follow the new Final Rule.
Expedited Research	New Categories and reduced frequency of Continuing Review	- Most studies that were originally expedited under the pre-2018 rule will now be eligible for less frequent review, beginning on 1/19/18. - At the time of the next renewal or significant amendment affecting the informed consent form that occurs after 1/19/18, you will be requested to update the waiver and consent form to meet the new requirements. - Modifications, reportable events and notification of closure are still required to be submitted to the IRB (no changes to these requirements).
Full Board Research	Protocols reviewed by a full board will see the fewest changes under the new Rule.	- At the time of the next renewal or significant amendment affecting the informed consent form that occurs after 1/19/18, you will be requested to update the waiver and consent form to meet the new requirements.
Consent	New Consent format and required elements	- These changes were previously incorporated into the AW IRB consent template. - The IRB will not require re-consent, except when other significant changes are made.

IRB Consent Template UPDATE

The IRB posted a new Consent template on 12/19 that updates the section for documenting the Physcian Investigator risk/benefit/alternatives discussion.

This section now has two checkboxes that users can mark: 1) if the PI signs at a different time than the subject and 2) if the form is being used to inform current subjects of changes where the risks and benefits didn't change.

These do not replace the consent note, but can help to improve documentation clarity and reduce administrative burden.

FDA Allows Waivers of Consent for Minimal Risk Research

The FDA has introduced a new guidance document, "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects." The guidance, issued July 2017 and effective immediately, is a step toward better alignment between FDA and Common Rule regulations, as required by the 21st Century Cures Act.

The FDA had previously not allowed the IRB to grant a waiver of informed consent, except in emergency situations. This guidance now outlines that the FDA will allow a waiver to be granted if it meets the same criteria as outlined in the common rule.