Continuation Review will be a thing of the past.

**Fact**

Most research reviewed by the Expedite criteria will be permitted to continue without continuation review! Status reports will still be required so that USU can track active research projects, but full-blown continuation review will be reserved for research projects with particular features, such as those which are greater than minimal risk or are working with sensitive information.

**Fiction**

While a decision tool was proposed in the Notice of Proposed Rulemaking, this approach was not adopted for the final updates to the Common Rule. As USU moves to a new protocol management system in the next year, we anticipate a more sophisticated questionnaire and protocol template that will act like the proposed tool in many regards. In the meanwhile, our Exempt protocol application turnaround times remain at the AAHRPP median and we look forward to speeding up those turnaround times.

Exempt projects are no longer subject to IRB review.

**Fiction**

The federal regulations have always required that exempt status be determined by someone with sufficient expertise to correctly make the determination. Additionally, “because of the potential for conflict of interest in this situation, Office for Human Research Protections’ long-standing recommendation is that investigators not be given the authority to make an independent determination that human subjects research is exempt.”

Accredited organizations are prohibited from permitting investigators to self-determine their own exemption status. No research institution in the West, and no Carnegie peer institution of USU’s, allows exemption decisions to be made outside of the IRB. The exemption categories will be broadened, but IRB review will remain in place.

Pregnant women are no longer a vulnerable category.

**Fact**

While there remains an entire subpart of the regulations dedicated to research with pregnant women, they are no longer categorized as a vulnerable population. While extra measures and protections will be required in order to remain compliant with subpart B of the Common Rule, the automatic categorization of “vulnerability” will no longer be present.

**Fiction**

While a decision tool was proposed in the Notice of Proposed Rulemaking, this approach was not adopted for the final updates to the Common Rule. As USU moves to a new protocol management system in the next year, we anticipate a more sophisticated questionnaire and protocol template that will act like the proposed tool in many regards. In the meanwhile, our Exempt protocol application turnaround times remain at the AAHRPP median and we look forward to speeding up those turnaround times.

OHRP is developing a tool that researchers can use to find out whether their research is exempt.

**Fiction**

While a decision tool was proposed in the Notice of Proposed Rulemaking, this approach was not adopted for the final updates to the Common Rule. As USU moves to a new protocol management system in the next year, we anticipate a more sophisticated questionnaire and protocol template that will act like the proposed tool in many regards. In the meanwhile, our Exempt protocol application turnaround times remain at the AAHRPP median and we look forward to speeding up those turnaround times.

Stay Tuned

Keep your eyes open for future issues of IRB: Fact or Fiction. Please contact the IRB office with any questions.