Dear Colleague,

The Stanford IRB is making changes to its policies and procedures in accordance with the upcoming revised Common Rule*. Beginning in August, the IRB will begin implementing a new extended approval process. This process will no longer require continuing review for certain minimal risk studies.

The IRB approval letter and consent form (when applicable) will document that the study qualifies for extended approval under the Common Rule, and therefore will not expire in the future.

Extended approval will still require modifications be submitted for IRB approval prior to implementing changes; and events that meet prompt reporting criteria must be reported to the IRB in 5-10 days.

Initially, extended approval will not be considered for studies that involve:

- Federal funding
- VA
- FDA regulated components or FDA oversight
- “Medical Experimentation” per California state law
- Prisoners
- Stem Cells or SCRO protocols
- Other IRB issues

When the new Common Rule becomes effective on January 21, 2019, the extended approval process will be expanded to include minimal risk federally funded studies as well as minimal risk studies involving “Medical Experimentation” per California state law. See the IRB Common Rule implementation website for ongoing updates.

Please contact your Panel Manager for study-specific questions. You may also contact Lisa Denney, Associate Director for Program Development in the Research Compliance Office, at (650) 736-6658 or Lisa.Denney@stanford.edu for programmatic questions.

*Federal Policy for the Protection of Human Subjects (45 CFR 46 Subpart A) known as the Common Rule.