DATE:    July 2, 2018
TO:    Investigators Involved with Human Subjects Research
FROM:  Ann M. Arvin, MD  
Vice Provost and Dean of Research
Mark R. Cullen, MD  
Senior Associate Dean, School of Medicine
SUBJECT:   NEW COMMON RULE (Governing Human Subjects Research)

Dear Colleague:

The revised Federal Policy for the Protection of Human Subjects (45 CFR 46 Subpart A) known as the Common Rule has been adopted by HHS and 15 Federal Agencies. The compliance date is **January 21, 2019**. The Stanford IRB is beginning to make changes to relevant policies and procedures in accordance with the new Rule. A high-level summary of changes includes:

- **Continuing Review** – Some minimal risk studies will no longer require annual review. The IRB will begin identifying applicable studies in August 2018. More information will follow.
- **Informed Consent** – New “**Key Elements**” to facilitate subjects’ understanding of the research, and **future use** of de-identified specimens and information will be required effective January 21, 2019. Template consent language will be provided by the IRB for all relevant human subjects protocols, as guidance becomes available from the Federal Office for Human Research Protections.
- **Exemptions** – Broadened and new Exempt categories will be available effective January 21, 2019. Some studies previously reviewed as Expedited can now be reviewed under Exempt, for example certain research involving benign behavioral interventions.
- **Single IRB (sIRB)** – Most federally funded collaborative research projects based in the US will be required to use a sIRB **effective January 2020**. (As of January 25, 2018, NIH policy has required the use of a sIRB in accordance with NIH Policy.) See Stanford sIRB guidance.
- **Limited IRB Review** – A new review requirement for IRBs for some Exempt categories will be in effect January 21, 2019. This will mostly affect IRB process and workload.

In many cases, the Common Rule changes will not impact your ongoing research. In addition, the **FDA has not yet agreed** to the New Common Rule; therefore, changes outlined here will not be applicable to FDA regulated studies until we hear otherwise.

Please see the [IRB Common Rule](#) implementation website for ongoing updates.

You may contact Lisa Denney, Associate Director for Program Development in the Research Compliance Office, at (650) 736-6658 or Lisa.Denney@stanford.edu for questions.

Thank you for your attention to this important information.