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Dear Colleagues,

This is a follow-up to our communication regarding implementation of the revisions to Federal Policy for the Protection of Human Subjects (known as the Common Rule). The final Common Rule revisions were published in the Federal Register by the Office for Human Research Protections (OHRP) on January 19th, 2017. You can read a summary of the changes to the Rule here.

As of today (8/29/17) we have had no new information regarding any additional modifications to the Rule or its initial stated implementation date of January 19th, 2018. Currently the Revised Common Rule is under administrative review at OHRP. However, several agencies, including COGR, APLU, and AAMC have sent a letter to OHRP asking for up to a year delay for compliance. While the implementation date will remain the same, this would allow institutions until January 19th, 2019, to be compliant with the Revised Rule. This letter was sent to OHRP on June 21st, 2017, and so far there has been no response from the government.

At this time the IRB staff at UC Merced is examining our program and documentation that will have to be modified to be in compliance with the Revised Common Rule in 2018. We will review policies, electronic procedures, modify web page information, and engage with committee members and users to ensure we are ready to implement the Revised Rule when required to do so.

Some of the changes that may affect our campus include:

- Changes to the consent form process that provides subjects with a better understanding of the research. These changes require the prospective participants be given the information that a "reasonable person" would want in order to make the decision, that sufficient detail be provided and that the form be organized to facilitate understanding. The form must also begin with a "concise and focused" presentation of the key information.
- Requirement for a single IRB review for multisite studies that eliminates the time and effort associated with multiple IRB review
- The establishment of new exempt categories for low-risk studies, including secondary research using identifiable private information if the research has been regulated by, and the participants are protected under, HIPAA rules.
- Removal of the requirement to conduct continuing review of ongoing studies when the research is eligible for expedited review, limited IRB review, research that has progressed to data analysis only (de-identified and identifiable), or access to follow-up clinical data.

We are closely following the status of the revisions to the Common Rule and its implementation and compliance dates. We will inform campus constituents and stakeholders once we have more definitive information with

regard to status and deadlines and in the meantime will begin to modify our program to comply with the changes.

You will find additional resources below.

Until then, please feel free to contact us at irboffice@ucmerced.edu if you have any further questions or concerns.

Resources:

http://science.sciencemag.org/content/357/6352/650.full

http://www.nejm.org/doi/pdf/10.1056/NEJMp1700736