Summary of Changes to IRB Procedures Due to Final Common Rule

Federally funded studies - The changes outlined below will not go into effect until January 21, 2019 for human subjects research funded by any agency that has adopted the Final Common Rule (most federal agencies).

Pre-2018 Studies - Studies approved before the implementation date will not be affected by these changes. They will continue to be governed by the pre-Final Common Rule regulations. Active studies cannot be transferred to the new Common Rule unless the study is reviewed again as an Initial Submission, or unless the study would now qualify for closure (see Renewals and Closures) and is not funded by a Common Rule entity.

Exempt Research - Some research that used to be considered "expedited" will now be considered "exempt" when the only risk is privacy or confidentiality and those risks are appropriately safeguarded. This means the exempt category has expanded. Some exempt research will require "limited review" by an IRB member and may take just as long in the review process as an expedited study.

Renewals and Closures - Previously, the regulations required a study to remain active if the investigator completed data collection and was still analyzing *identifiable* data. Now, a study may be closed once all subject enrollment and data collection is complete. If the investigator has only to complete an analysis of data, whether identifiable or not, the study may be closed. Please keep in mind that data management described by the investigator and approved by the IRB in the initial application must be followed.

Privacy and Confidentiality - OHRP recognizes privacy and confidentiality to often be the main risk in most minimal risk research and will soon release guidance for IRBs to use during the review of research. It is possible that more changes to the initial application are forthcoming and will further expand the Exemption category of review.

Consent Forms – Consent forms must be clearer and more focused. Many changes to consent have been added to emphasize that information provided must facilitate a potential subject's understanding of why one would participate in research.

Definition of Research – The following activities are deemed not to be research: certain journalistic, public health surveillance, and criminal justice or intelligence activities.

Definition of Human Subjects – The definition now includes "information or biospecimens" obtained through intervention and interaction with individuals or "identifiable private information or identifiable biospecimens."