EXECUTIVE SUMMARY

Changes to the Common Rule (45 CFR 46)
Compliance deadline: January 20, 2019
These are the first significant changes to human subject's research regulations since 1991

Deemed to NOT be research, thus not requiring IRB review

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters)

New Exempt Information

- Exempt Category 2(iii) has now been expanded to be able to collect potentially sensitive or harmful identifiable private information from adults if an IRB conducts a *limited review* and makes a determination that there are adequate provisions for protecting privacy and maintaining confidentiality
- New! Exempt Category 3 "Benign behavioral interventions" such as solving puzzles or online games. Can also collect sensitive information with a limited review under 46.104(d)(3)(i)(C)
- Exempt Category 4 (medical record review) can now be *prospective* as well
- A limited review will consist of a similar process to our current Expedited review process. We will send to two IRB members that have expertise in the area of the proposed project topic
- Essentially, an Exempt determination would allow investigators the ability to never have to submit a Continuing Review or Project Termination. Due to data storage restraints of our electronic system an Exempt Termination application will need to be submitted after study completion.
- New Exempt categories 7 & 8 include limited reviews and Broad Consent. Our institution has decided not to implement these categories at this time

Continuing review

- Continuing review will no longer be required for projects under an expedited category unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects
- Continuing review will also no longer be required for full board projects that have progressed to data analysis (even if identifiable) or observational follow-up
- The IRB Office will implement an "Annual Reporting Form" as a sort of check in with Investigators with the primary intention of capturing data corresponding with IRB metrics and AAHRPP accreditation tracking

Clinical Trials

- In addition, there is an added requirement for posting clinical trial consent forms on a publicly available Federal website (www.clinicaltrials.gov) as a repository for consent forms. One consent form for each study must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.