

Key Definitions

09.03.2018

HUMAN SUBJECT (REVISED)

- The definition is revised to explicitly mention biospecimens and the possibility of generating identifiable private information or identifiable biospecimens.
- The US Department of Health and Human Services is now required to provide guidance within the first year and then at least every four years regarding how identifiable private information or identifiable biospecimens might be generated.
- A research activity that does not involve human subjects today may in the future involve human subjects.
- HIPAA regulations can still apply to research involving deceased individuals.
- **Once the New Rule takes effect on January 21, 2019:** A Human Subject is defined as “a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
- **Current Regulations:** A Human Subject is defined as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information.”

CLINICAL TRIAL (NEW)

- *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- This definition is relevant to the requirement that each clinical trial that is conducted or supported by a Federal department or agency post one consent form used to enroll subjects to a public Federal Web Site.
- See also **REQUIREMENTS FOR FEDERALLY-FUNDED RESEARCH** and the obligation for such clinical trials to post one consent form to a public Federal Web site.

LIMITED REVIEW (NEW)

- Several categories of exempt research require the IRB to conduct a “limited review” to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
- This is not new for UMMS. The exemption criteria already include such considerations, and all human subjects research - including exemptions - requires prior IRB review and approval.
- Under the new regulations, the Federal Government is required to provide guidance as to what provisions are considered adequate.