

Common Rule Revisions: January 2019

Research Terms: New/Revised

Several frequently used terms have been newly codified or revised:

- **Human subject:** a living individual about whom an investigator conducting research obtains
(1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens;
or
(2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
- **Research:** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Activities deemed not to be research:**
 - Scholarly and journalistic activities
 - Government functions with separately mandated protections
- **Clinical trial:** research study in which human subjects are prospectively assigned to interventions to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- **Legally Authorized Representative:** individual/judicial/body authorized under applicable law to consent on behalf of prospective subject
- **Benign behavioral intervention:** interactions that are brief harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing
- **Interaction:** communication or interpersonal contact
- **Intervention:** physical procedures/environmental manipulations by which information or biospecimen are gathered
- **Private information:** information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- **Identifiable private information:** private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable biospecimen:** a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.