Term	Pre-2018 Common Rule Definition	2018 Revised Common Rule Definition	Notes
Research	*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.	*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: (1) 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. (2) 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	The 2018 Revised common rule largely maintains the definition of research, but adds four categories to clarify activities that are *not* research.

		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). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.	
Human Subject	*Human subject* means 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) Identifiable private information.	*Human subject* means 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	Clarifies the requirements of research activities that would define research involving human subjects.

		(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.	
Clinical Trial	*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.	*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 nearly-identical to the NIH definition of a clinical
Identifiable Private Information	*Private Information* includes 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical recorded). Private information must be *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.	*Private information* includes 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* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.	The definitions of private information and identifiable private information have remained unchanged; however, the 2018 Revised Common Rule now includes the definition of an identifiable biospecimen. The Revised Common Rule also requires that within one year of implementation, and then at least every four years after that, Common Rule agencies will: 1. reexamine the meaning of identifiable private information and identifiable biospecimen and 2. assess whether there are analytic technologies or techniques that should be considered by investigators to generate identifiable private information or an identifiable biospecimen
Identifiable Biospecimen	n/a	An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be	

		ascertained by the investigator or associated with the biospecimen.	