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be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

- 3.17. The office within the Department of Health and Human Services, responsible for implementing DHHS regulations (45 C.F.R. Part 46) governing research involving human subjects.
- 3.18. The scientist or scholar with primary responsibility for the design and conduct of a research project.
- 3.19. 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).
- 3.19.1. is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- 3.19.2. is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- 3.20. The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology

				
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- < (ii) 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).
- < (iii) 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.
- < (iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3.23.