

*OHRP: 45 FR 46.102(f)*

**HUMAN SUBJECT:** 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.

*FDA: 21 CFR 50.3(g); 21 CFR 56.102(e)*

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

The following are *generally not considered to involve human subject(s)*:

- *Cadaveric or autopsy specimens or data.*
- *Data or specimens that were not initially collected for the proposed study and there is no code or link that could allow identification of the individual.*
- *Data or specimens received by the investigator where a code exists, but there is an agreement prohibiting access to the code key by the investigator or any research team member.*

See also [Examples of “Not Human Subjects”;](#)  
[Definitions.](#)