

Human Subjects Research

The definition of “human subject” includes, but is not limited to, human organs, tissues, and body fluids from living individuals, as well as private graphic, written, or recorded information about living individuals, if (1) there is interaction or intervention with a living individual to obtain the specimens or data for research purposes, or (2) the identity of the subjects can be readily ascertained by the investigator or other members of the research team.

Research that involves only coded private information/data or coded human biological specimens may not constitute human subjects research if:

- the specimens and/or private information were not collected specifically for the currently proposed research project through an interaction/intervention with living individuals AND
- the investigator(s) (including collaborators) on the proposed research cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher’s access to subject identities is prohibited by written repository procedures and policies and/or through an agreement signed between the recipient researcher and the repository providing the specimens and/or data)

Note: If research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other collaborating site or institution, then your answer to this question is "Yes", even if the research is determined to be exempt from U.S. Department of Health and Human Services regulations for the protection of human subjects per [45 CFR Part 46](#).