Is the activity a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

Yes → Activity is NOT "research" as defined by DHHS.

No → Activity is "research" as defined by DHHS.

Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)]

Yes → Does the research involve interaction or intervention with the individuals? Interaction includes communication or interpersonal contact between investigator and subjects. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the research purposes. [45 CFR 46.102(f)(1), (2)]

Yes → Is the information individually identifiable? (i.e., the identity of the participant is or may readily be ascertained or associated with the information?) [45 CFR 46.102(f)(2)]

No → Activity is "research involving human subjects" as defined by DHHS.

Yes → Is the information private? (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 record).

Yes → Activity is "research involving human subjects" as defined by DHHS.

No → Activity is NOT "research involving human subjects" as defined by DHHS.