

Guidance for Determining Whether Data Constitutes Individually Identifiable Information Under 45 CFR 46

As a general rule, if gaining access to identifiable information is more involved than either using a key that links coded information to identifiers, or combining information that is either already in the possession of the investigator or easily accessible to the investigator, the investigator may not be considered to be in possession of individually identifiable information.

The following elements (either individually or in combination) may constitute an identifier (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information). Certain demographic or clinical characteristics of the subjects may impact whether their data or biospecimens are individually identifiable to an investigator, e.g. the sample size; the location of the original collection (i.e. small town or the zip code); the disease or condition being studied, particularly if a rare disease; and membership in a unique cultural group. If an investigator has a prior relationship with the subjects and is able to re-identify the data based on past experience with the subjects or the data set, we would consider the data to be identifiable to him or her.

The list below is not intended to be exhaustive. Investigators should consult with OHSRP if they are unsure whether data or biospecimens being used in a specific research project would be considered individually identifiable.

- A. Names (or initials)
- B. Street address or geocode data
- C. Date of birth
- D. Telephone numbers
- E. Fax numbers
- F. Electronic mail addresses
- G. Social security numbers
- H. Medical record numbers
- I. Health plan beneficiary numbers
- J. Account numbers
- K. Certificate/license numbers
- L. Vehicle identifiers and serial numbers, including license plate numbers
- M. Device identifiers and serial numbers
- N. Internet protocol (IP) address numbers
- O. Biometric identifiers, including finger and voice prints
- P. Full face photographic images and any comparable images
- Q. Any other unique identifying number, characteristic, or code (when a key to the identifier/characteristic/code is readily accessible to the investigator or given the context or circumstance could make a participant identifiable to the researcher)