

# HUMAN RESEARCH PROTECTION

## Secondary research with de-identified data

Number **198**  
Resource type **GUIDANCE**

Version date **02 FEB 2020**

Secondary research involving **only de-identified data that meets ALL the following criteria** does NOT meet the definition of *research involving human subjects*; therefore, such research is NOT subject to IRB oversight.

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- The research is **NOT subject to FDA regulations**.
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- The research data include **NONE of the following HIPAA identifiers**:
1. Names
  2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
    - (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
    - (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
  3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
  4. Telephone numbers
  5. Vehicle identifiers and serial numbers, including license plate numbers
  6. Fax numbers
  7. Device identifiers and serial numbers
  8. Email addresses
  9. Web Universal Resource Locators (URLs)
  10. Social security numbers
  11. Internet Protocol (IP) addresses
  12. Medical record numbers
  13. Biometric identifiers, including finger and voice prints
  14. Health plan beneficiary numbers
  15. Full-face photographs and any comparable images
  16. Account numbers
  17. Any other unique identifying number, characteristic, or code
  18. Certificate/license numbers
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- The private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals.
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- The researcher(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertains because of **(at least one of)** the following:
- The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances (note that the HHS regulations do not require the IRB to review and approve this agreement).
  - For data received via ACE/VDW: any key crosswalks will be stored on secure servers only available to ACE/VDW analysts and will not be available to investigators, and there are written policies/procedures that prohibit the release of the key to the investigators in accordance with HIPAA.
  - There are other legal agreements prohibiting the release of the key to the investigators.
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- The researchers do not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.
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