

**HIPAA Limited Data Set Certification Form**

Protocol #\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The HIPAA Privacy Rule (45 CFR, Parts 160 and 164(A) and (E)) allows a covered entity (the Institute and its employees) to use limited data sets by removing certain direct identifiers of the individual or of relatives, employers, or household members of the individual that are specified in the Privacy Rule. They are not de-identified information under the Privacy Rule.

This form should be used when researchers at the Institute wish to use or create a limited data set for their research projects. **The following identifiers must be removed from the data set to create a limited data set:**

1. Names

2. Postal address information, other than town or city, State, and zip code

3. Telephone numbers

4. Fax numbers

5. E-mail addresses

6. Social security numbers

7. Medical record numbers

8. Health plan beneficiary numbers

9. Account numbers

10. Certificate/license plate numbers

11. Vehicle identifiers and serial numbers

12. Device identifiers and serial numbers

13. Web URLs

14. Internet Protocol (IP) address numbers

15. Biometric identifiers, including fingerprints and voiceprints

16. Full-face photographic images and any comparable images

Unlike de-indentified data, limited data sets may include the following: city, state and zipcodes; all elements of dates; and unique codes or identifiers not listed as direct identifiers.

**\*If you do not wish to include identifiers such as city, state, and zipcodes, all elements of dates or other unique identifiers that are not listed as direct identifiers above, please see our de-identified data set certificate form.**

Please indicate the source of the de-identified data:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please list below the information requested in the de-identified data set:

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**Principal Investigator’s Certification**

I certify that the protected health information that will be received or reviewed by research personnel for the research project referenced above will not include any of the 16 identifiers listed above. I also certify that I do not have knowledge that any of the remaining information could be used, alone or in combination with other information, to identify an individual who is the subject of the information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

Additional information: Covered entities may also use statistical methods to establish de-identification instead of removing all 18 identifiers. The covered entity may obtain certification by “a person with appropriate knowledge of an experience with generally accepted statistical and scientific principles and methods for rendering information not individual identifiable” that there is a “very small” risk that the information could be used by the recipient to identify the individual who is the subject of the information, alone or in combination with other reasonably available information. See *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule* for further information.