University of Oklahoma- Norman Campus Research Privacy Form 8

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Research on De-Identified Information

IRB No.:

**Investigator Representation for Research on De-Identified Protected Health Information\***

I. Principal Investigator:

1. Protocol Title:
2. Regulatory Criteria for Research on De-Identified Information

The Privacy Rule does not apply to the use or disclosure of PHI that has been de-identified (45 CFR 164.512).

3.1 Describe the PHI you wish to use/disclose without authorization:

3.2 Will the information used and/or disclosed include any of the following direct identifiers of the individual, or of relatives, employers, or household members of the individual? If yes, explain.

Yes No

Names.

Any geographic subdivisions smaller than a State (including street address, city, county, precinct, zip codes, and their equivalent geocodes) EXCEPT for the initial three digits of a zip code if, (i) current Census Bureau data indicate that the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, or (ii) the three digits are changed to 000.

Any elements of dates (except year) for dates directly related to an individual; all ages over 89 and all elements of such dates (including year) for ages over 89, except that all such ages and elements may be aggregated into a single category for age 90 or older.

\* Protected Health Information includes all identifiable information relating to any aspect of an individual's health whether past, present or future, created or maintained by a Covered Entity.

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Yes No

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Telephone numbers,

Fax numbers.

Electronic mail addresses.

Social security numbers.

Medical record numbers.

Health plan beneficiary numbers.

Account numbers.

Certificate/license numbers.

Vehicle identifiers and serial numbers, including license plate

numbers.

Device identifiers and serial numbers.

Web Universal Resource Locators (URLs).

Internet Protocol (IP) address numbers.

Biometric identifiers, including finger and voice prints.

Full face photographic images and any comparable images.

Any unique identifying number, characteristic, or code by which you could identify or could reasonably expect to identify the participant not assigned by the University of Oklahoma

pursuant to 45 CFR 164.514(c).

If you and the University 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 AND IF "No" is marked for all of the above items, the information will be considered de-identified.

3.3 In the alternative to 3.2, if you are relying on an expert's determination and documentation that the risk is statistically small of identifying an individual with the data used in this research, please provide the following information:

|  |  |  |
| --- | --- | --- |
| Name of expert, degree (s):  Phone (s): Fax: | | E-Mail: |
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Address:

Briefly describe the expert's knowledge and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable.

Please attach the expert's determination and documentation regarding the level of risk that the information used in the research could be used, either alone or in combination with other reasonably available information by an anticipated recipient, to identify an individual.

4. Investigator's Representation

*I certify that the information used in this research represents the minimum necessary to accomplish the research and does not include identifiable information or contain information that can reasonably be used to identify a participant. I will protect the information and maintain it in a de-identified form.*

Signature of Principal Investigator Date

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**FOR IRB USE ONLY IRB No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Reviewed by: Convened IRB**

**IRB Chair or Vice Chair pursuant to expedited**

**The representation for use of de-identified information is:**

**Approved because:**

**no regulatory identifiers will be used**

**an expert statistician determined that risk of identification is very small**

**Not approved (*explanation*):**

**Comments:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of IRB Chair or Vice Chair Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Name**

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