

CERTIFICATION OF DE-IDENTIFICATION

Research that involves the use of de-identified protected health information is exempt from HIPAA requirements. Methods by which data may be classified as de-identified are 1) by certifying that none of the 18 HIPAA-defined identifiers are used, reviewed or recorded by the researchers or staff 2) by certifying that as a member of our covered entity the individual using phi to create a de-identified data set a) keeps all information seen in the process of creating the de-identified data strictly confidential, b) does not record any of the identifiers defined by HIPAA, and c) cannot link the data back to the individual in any way or 3) by certifying through statistical analysis on each identifier that is contained within the data that the likelihood of an individual being identified by using the data in whole or in part is very small. Statistical de-identification must be done by a qualified statistician and the methods and results of the analysis must be documented.

All research and administrative staff involved with this study are required to complete both the human subjects training tutorial and the online UCHC HIPAA training course prior to starting work on this project.

IRB Protocol #

PI Name:

(to be assigned by IRB Office)

Protocol Title:

The following list of HIPAA-defined identifiers is provided for your reference.

If you have questions on any of the identifiers listed below contact the IRB Office at x 8729 or 3054

- | | |
|---|--|
| <input type="checkbox"/> Names | <input type="checkbox"/> Geographic Subdivision Smaller Than a State |
| <input type="checkbox"/> Phone #s | <input type="checkbox"/> All Elements of Date Except Year* |
| <input type="checkbox"/> Fax #s | <input type="checkbox"/> E-mail Addresses |
| <input type="checkbox"/> Social Security #s | <input type="checkbox"/> Medical Record #s |
| <input type="checkbox"/> Account #s | <input type="checkbox"/> Health Plan Beneficiary #s |
| <input type="checkbox"/> Certificate/License #s | <input type="checkbox"/> Vehicle Identifiers and Serial #s |
| <input type="checkbox"/> Device Identifiers and Serial #s | <input type="checkbox"/> Web URLs |
| <input type="checkbox"/> IP Addresses | <input type="checkbox"/> Biometric Identifiers |
| <input type="checkbox"/> Photographic Images | <input type="checkbox"/> Any other unique identifying number, characteristic or code |

*any ages over 89 must only be reported in an aggregate category of age 90 or older

Certify Use of Either Method 1, 2 or 3

Method 1 – No Identifiers Used, Reviewed or Recorded (45 CFR 164.514(b)(2))

I certify that the protected health information (phi) used, reviewed or recorded by research personnel for this research project does not include any of the 18 HIPAA-defined identifiers as related to the individual, relatives, employers or household members of the individual.

Signature of Principal Investigator and Date

Method 2 – No Identifiers Recorded During the Creation of a De-identified Data Set (45 CFR 164.502(d)(1))

I certify that the protected health information (phi) recorded by research personnel to create a de-identified data set for this research project does not include any of the 18 HIPAA-defined identifiers and that no link can be made back to the individual. Personnel reviewing records have agreed to keep any phi seen during the course of records review as strictly confidential.

Signature of Principal Investigator and Date

Printed Name and Signature of Individual Performing Record Review if other than PI and Date (Backside of this sheet may be used for additional names and signatures of individuals recording data.)

Method 3 – De-identification Via Statistical Analysis (45 CFR 164.514(b)(1)(i and ii))

(i) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable has performed such analysis on each of the identifiers included in the data set **as checked above**. It has been determined that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the intended recipient to identify an individual who is the subject of the information.

(ii) **I have attached** documentation from the statistician that indicates 1) the date of the analysis, 2) the method(s) used, 3) the results obtained, 4) a statement that the likelihood of re-identification is very small, 5) the name of the statistician, 6) the credentials of the statistician 7) the signature of the statistician, and 8) the date signed

Signature of Principal Investigator and Date