

CERTIFICATION OF LIMITED DATA SET FOR RESEARCH

Pursuant to 45 CFR 164.514(e)(1) a covered entity may use or disclose a limited data set if the covered entity enters into a data use agreement with the limited data set recipient. The limited data set must meet the requirements of 164.512(e)(2). The limited data set created by the covered entity must be used for only the research purposed defined in the data use agreement (164.514(e)(3 and 4)). The data use agreement should be submitted to the IRB along with this form.

All Health Center research and administrative staff involved with this study are required to complete the UCHC HIPAA training course prior to starting work on this project. All research and administrative staff affiliated with this project (internal and external to UCHC) must have completed the required human subjects training. Individuals external to UCHC may submit proof of human subjects training from their home institution or from the NIH.

IRB Protocol #

(Assigned by IRB Office)

PI Name:

Protocol Title:

Direct Identifiers Excluded From Limited Data Set (164.514(e)(2)):

A limited data set is protected health information that **excludes the following direct identifiers** of the individual or of relatives, employers, or household members of the individual.

- Names
- Phone numbers
- Fax numbers
- Social security numbers
- Account numbers
- Certificate/license numbers
- Device identifiers and serial numbers
- Internet Protocol (IP) addresses
- Postal address information, other than town or city, State and zip code
- Full face photographic images and any comparable images
- E-mail addresses
- Medical record numbers
- Health plan beneficiary numbers
- Vehicle identifiers and serial numbers, including license plates
- Web Universal Resource Locators (URLs)
- Biometric identifiers, including finger and voice prints

Contents of Limited Data Set:

The limited data set created for use with the above research project contains the following information:

(Point, click and type in first cell. Tab into other cells to continue to list contents of limited data set. Tabbing out of the last cell will insert another row.)

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Data Recipients:

The intended data recipients of this limited data set are:

(Point, click and type in appropriate cell or tab through table. Tabbing out of the last cell will insert another row.)

Name and Title	Institution

Certification of Limited Data Set

I certify that this limited data set 1) is created for the sole use of the research project noted above, 2) does not contain any direct identifiers as defined by HIPAA, 3) contains only those elements listed above and 4) will be disclosed only to the data recipients indicated above.

Signature of Principal Investigator and Date

Approved: Signature of Institutional Review Board Chairperson and Date