

# UNC Center for Maternal & Infant Health Data Use Agreement

The Principal Investigator (PI) and Co-Investigators of the “\_\_\_\_\_” study, hereafter known as the “Recipients”, require access to data sets (defined below) in order to conduct their research. The content of these data sets is outlined in their IRB application, dated \_\_\_\_\_.

As Health Information Director for the Center for Maternal & Infant Health (CMIH), I agree to make available such data sets, provided that the Recipients agree to abide by the terms and conditions of this Agreement as well as applicable CMIH policies and IRB requirements.

The Recipients will have access to this data until the completion of the project, which is expected to be on or before \_\_\_\_\_. At the conclusion of the project, the data will be destroyed.

## PERMITTED USES AND DISCLOSURES

1. Recipients agree to limit the use and disclosure of the data set to the explicitly enumerated purposes outlined in the IRB application.
2. Recipients shall not provide nor allow access to the data by any other persons.
3. Recipients acknowledge that they have an explicit need to access the data set to carry out their duties.

## ASSURANCES

1. Recipients shall not use or further disclose the data set other than as permitted by this Agreement or as otherwise required by law.
2. Recipients shall use appropriate safeguards to prevent use or disclosure of the data set other than as permitted by this Agreement.
3. Recipients shall report to the CMIH Health Information Director any use or disclosure of the data set not provided for by this Agreement of which Recipients become aware.
4. Recipients shall not re-identify the information or contact the individuals for whose records are contained within the data set.

**BREACH AND TERMINATION**

1. In the event that this Agreement is breached by Recipients, CMIH, at its sole discretion, may a) terminate this Agreement upon written notice to Recipients or b) request that Recipients, to the satisfaction of CMIH, take appropriate steps to cure such breach. If Recipients fail to cure such breach to the satisfaction of CMIH or in the time prescribed by CMIH, CMIH may terminate this Agreement upon written notice to Recipient.
2. Should this Agreement be terminated for any reason, including, but not limited to Recipients' decision to cease use of the data set data, Recipients agree to destroy or return all data set data provided pursuant to this Agreement (including copies or derivative versions thereof).

**GOVERNING LAW**

This Agreement shall be governed by, and construed in accordance with, the laws of the state of North Carolina and the United States of America.

**CMIH**

Name (print): \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

**Recipients**

Name (print): \_\_\_\_\_

Signature: \_\_\_\_\_

Name (print): \_\_\_\_\_

Signature: \_\_\_\_\_

Name (print): \_\_\_\_\_

Signature: \_\_\_\_\_

**IRB Approval:**

Name (print): \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ IRB#: \_\_\_\_\_

# DEFINITIONS

## Limited Data Sets

A limited data set **may not include** any of the following direct identifiers of the individual or of the individual's relatives, employers, or household members:

- Names
- Any geocodes that identify an individual household such as street address
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary identifiers
- Account numbers
- Certificate / license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web universal resource locators (URL)
- Internet protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images

## De-Identified Data Sets

A de-identified data set **may not include** any of the following direct identifiers of the individual or of the individual's relatives, employers, or household members.

- Names
- Geographic subdivisions smaller than a state
- Zip codes
- All elements of dates except year directly related to an individual, including birth or death or dates of health care services or health care claims
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary identifiers
- Account numbers
- Certificate / license numbers
- Vehicle identifiers and serial numbers, including license plate numbers

- Device identifiers and serial numbers
- Web universal resource locators (URL)
- Internet protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images
- Any other number, characteristic or code that could be used by the researcher to identify the individual

**Note:** Although a de-identified data set cannot contain a birth date, it may contain the individual's age expressed in years, months, days, or hours, as appropriate, except for individuals who are aged 90 years or more. For persons aged 90 years and above, the age in a de-identified data set can only be stated as being with the category of age 90 or above.