

**Request for Access to Protected Health Information for Research Purposes  
(Record Review, Computer Reports, Patient Specimens, Laboratory Results, Etc.)**

The purpose of this form is for the researcher to request access to protected health information for research purposes. The form is designed to prompt the appropriate HIPAA documentation for such access, including information required for accounting of disclosures by the custodian of the records from which PHI is requested.

NAME OF FEASIBILITY STUDY, RESEARCH STUDY OR PROTOCOL: \_\_\_\_\_

**I. HIPAA REQUIRED DOCUMENTATION:**

**Choose one of the following three categories of information – individually identifiable, limited data set or completely deidentified and check all applicable boxes under that category.**

**A Individually identifiable data.** There are four HIPAA options listed below for obtaining access to individually identifiable health information.

- I am requesting access to or disclosures of information that is individually identifiable, i.e. it may include identifiers of the individual, the individual's employer or the individual's household members beyond those permitted for a Limited Data Set. (Check at least one of the following four options):
1. For each individual whose information I am requesting to review or obtain, I have attached a copy of either an **authorization** signed by the individual or an **informed consent document signed by the individual prior to 4/14/03**. I have also attached a **copy of the IRB approval letter for this research**. I will not review records or record or use in research any information not authorized by these attached documents.
2. I have attached a copy of the **waiver of authorization** or **limited waiver of authorization** approved by the IRB, or of the **waiver of informed consent approved by the IRB prior to 4/14/03** for this research study. I have also attached a **copy of the IRB approval letter for this research**. I will not review records or record or use in research any information not authorized by the attached document. (Check one of the following two options)
- I will provide a complete list of all individuals whose records I have accessed under this waiver; or
- I will access the records of fifty or more individuals and am not providing a list of all individuals whose records I have accessed under this waiver.
3. I am solely assessing feasibility or preparing a research protocol for a research study (**review preparatory to research**) and **I hereby represent that:**
- I will review this information solely as necessary to prepare a research protocol or assess feasibility of performing a specific research protocol; and
  - I will not record or obtain copies of records of any information that includes any of the identifiers listed in Section C of this form; and
  - I will not review any information that is not necessary for the purposes of this preparation for research; and
  - I will not use information accessed in this review to prescreen individuals or make contact with individuals for recruitment or other research purposes. I understand that recruitment activities, including prescreening, may only be performed in accord with prior IRB review and approval.

(Check one of the following two options)

- I will provide a complete list of all individuals whose records I have accessed; or
- I will access the records of fifty or more individuals and am not providing a list of all individuals whose records I have accessed.

4. I am requesting access to or disclosure of information **only of deceased individuals** and I **hereby represent that:**

- I will not access or use information on anyone other than a decedent; and
- I will not access or use any information on decedents that is not required for the research study; and
- Upon UNC HCS request I will present documentation of the decedent status of the individuals whose information I am requesting; and
- I understand that I must request IRB guidance if this research on decedents has potential risks for living individuals.

(Check one of the following two options)

- I will provide a complete list of all individuals whose records I have accessed; or
- I will access the records of fifty or more individuals and am not providing a list of all individuals whose records I have accessed.

**B. Limited Data Set.** (See description in Section III)

I am requesting access to or disclosures of information that is in Limited Data Set form, i.e. information that does not contain any of the identifiers listed in Section C of this form with respect to the individual, the individual's employer or the individual's household members except dates and/or geographic information above the level of postal address. This form serves as a Data Use Agreement between the UNC Health Care System and UNC researchers. Disclosure of a Limited Data Set to non-UNC researchers requires the additional execution of a Data Use Agreement through the UNC Chapel Hill Office of University Counsel. I have also attached **a copy of the IRB approval letter for this research.**

- I will only use this Limited Data Set for the purposes of research and in accord with all applicable UNC IRB approvals.
- I will protect the Limited Data Set with appropriate safeguards to protect it from use or inappropriate disclosure and to prevent use or disclosure other than as permitted for the research project or otherwise required by law or regulation.
- I will only disclose this Limited Data Set to users outside of the University of North Carolina at Chapel Hill in accord with a separate Data Use Agreement executed by the University to cover that disclosure.
- I will not attempt to use this Limited Data Set to identify or contact any individual to whom the Limited Data Set information applies.
- If I become aware of any unauthorized use or disclosure of this Limited Data Set I will immediately notify the UNC Health Care System Privacy Officer and the UNC Chapel Hill Privacy Officer.

**C. Completely de-identified data.** (See description in Section III)

I am requesting access to or disclosures of completely deidentified information, i.e. information that does not contain any of the identifiers listed in Section C of this form with respect to the individual, the individual's employer or the individual's household members.

**II. ADDITIONAL INFORMATION**

A. For report information (please be specific): I am requesting information that meets the following search criteria and includes the following data fields:

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B. Obligations:

The Principal Investigator and each individual delegated to obtain or receive data directly from the data custodian through this request as a member of the investigator's team must sign below acknowledging her/his responsibilities. **The Principal Investigator is responsible for the compliance of all members of her/his research team:**

- I understand that charts must be reviewed in the Research Area of Medical Information Management.
- I understand that space limitations require that charts cannot be held more than two weeks un-reviewed. I understand that charts left without review activity for more than two weeks cannot be held.
- **I am aware that the data to which I have requested access is subject to HIPAA and other legal and regulatory protections and that violation of privacy and confidentiality protections for this data may incur civil and criminal penalties.**
- **I understand and agree to comply with the obligations listed in this section as well as with all obligations described for the boxes I have checked above, and to inform all research team members of their responsibilities for compliance with these obligations.**

Principal Investigator:

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Research study members delegated to directly obtain or receive the protected health information from the data custodian through this request (if not the PI:

Print Names:

Roles: (e.g. co-investigator, study coordinator, data manager, etc.)

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

C. Contact Information for Principal Investigator

Telephone number: \_\_\_\_\_ Pager number: \_\_\_\_\_

Deadline for completion: \_\_\_\_\_

Expected frequency of access to charts: \_\_\_\_\_

D. Approval by Department Chair or Director

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### III. Limited Data Sets and Deidentified Data Sets

#### A. Limited Data Set

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

<ul style="list-style-type: none"><li>• Names</li><li>• Any geocodes that identify an <u>individual household</u> such as street address</li><li>• Telephone numbers</li><li>• Fax numbers</li><li>• Electronic mail addresses</li><li>• Social security numbers</li><li>• Medical record numbers</li><li>• Health plan beneficiary identifiers</li><li>• Account numbers</li></ul>	<ul style="list-style-type: none"><li>• Certificate/license numbers</li><li>• Vehicle identifiers and serial numbers, including license plate numbers</li><li>• Device identifiers and serial numbers</li><li>• Web universal resource locators (URL)</li><li>• Internet protocol (IP) address numbers</li><li>• Biometric identifiers, including finger and voice prints</li><li>• Full face photographic images</li></ul>
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Note that a Limited Data set may include:

- All elements of dates directly related to an individual, including birth date, admission date, discharge date, dates of health care procedures or other services, and date of death.
- Geocodes above the level that would identify an individual household such as State, county, city, town, census track, precinct, zip code.

#### B. De-identified Data

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

<ul style="list-style-type: none"><li>• Names</li><li>• Geographic subdivisions smaller than a state</li><li>• Zip codes</li><li>• 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</li><li>• Telephone numbers</li><li>• Fax numbers</li><li>• Electronic mail addresses</li><li>• Social security numbers</li><li>• Medical record numbers</li><li>• Health plan beneficiary identifiers</li><li>• Account numbers</li></ul>	<ul style="list-style-type: none"><li>• Certificate/license numbers</li><li>• Vehicle identifiers and serial numbers, including license plate numbers</li><li>• Device identifiers and serial numbers</li><li>• Web universal resource locators (URL)</li><li>• Internet protocol (IP) address numbers</li><li>• Biometric identifiers, including finger and voice prints</li><li>• Full face photographic images</li><li>• Any other number, characteristic or code that could be used <u>by the researcher</u> to identify the individual</li></ul>
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**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 within the category of age 90 or above.