REQUEST FOR ACCESS TO HEALTH INFORMATION FOR RESEARCH

The purpose of this form is for the researcher to request access to health information maintained by DHHS for research purposes. This form is designed to prompt the appropriate documentation for such access, including information required for accounting of disclosures by DHHS. Incomplete forms, or forms submitted without the required accompanying documentation, will be returned to the requester without being approved.

SECTION I GENERAL INFORMATION

IRB STUDY NUMBER		TITLE OF STUDY or PROJECT	
NAME OF PRINCIPAL INVESTIGATOR		ORGANIZATION/AFFILIATIONS	
MAILING ADDRESS	CITY	STATE	ZIP CODE
TELEPHONE ( ) - x	PAGER ( ) -	FAX ( ) -	
NAME OF SPONSOR/FUNDING SOURCE		TELEPHONE ( ) - x	
MAILING ADDRESS	CITY	STATE	ZIP CODE

SECTION II DATA REQUESTED/REQUIRED DOCUMENTATION

Choose one of the following three categories of information (A, B, or C) – Individually Identifiable, Limited Data Set, or completely De-identified Health Information and **check all applicable boxes under that category**.

A. Requests for Individually Identifiable Health Information

☐ I am requesting access to individually identifiable health information, which may include data that identifies a client, the client's relatives, household members, or employer(s). **(Check one of the four, and corresponding sub-options as appropriate, below.)**

☐ **1. Research with Authorization / Informed Consent**

a) For each client whose information I am requesting to review or obtain, I have attached a copy of either:

- ☐ the **authorization and informed consent document(s) signed by the client**;
- ☐ the **informed consent document for research signed by the client prior to 4/14/03**; or
- ☐ a **combined authorization/informed consent form that has been approved by an IRB for the client to sign**.

b) I have also attached **a copy of the research protocol** and **a copy of the IRB approval letter for this research**.

c) I will not review DHHS client records or record or use in research any information not authorized by these attached documents.

☐ **2. Research with Waiver of Authorization / Informed Consent**

a) I have attached either a copy of **one of the following** for this research study:

- ☐ the **waiver or limited waiver of authorization** approved by an IRB or Privacy Board **and waiver/limited waiver informed consent** approved by an IRB; or
- ☐ the **waiver of informed consent for research approved by an IRB prior to 4/14/03**.

b) I have also attached **a copy of the research protocol** and **a copy of the IRB approval letter for this research**.

c) I will not review DHHS client records or record or use in research any information not authorized by the attached documents.

d) Check one of the following:

- ☐ I will provide a complete list of all DHHS clients whose records I have accessed under this waiver; or

☐ I will access the records of 50 or more DHHS clients and am not providing a list of all clients whose records I have accessed under this waiver.

☐ 3. Review Preparatory to Research

a) I am solely assessing the feasibility of 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;
- I will not record or obtain copies of records of any information that includes any of the identifiers listed in Section V-B (De-identified Health Information) of this form;
- 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 DHHS clients or make contact with clients for recruitment or other research purposes. I understand that recruitment activities, including prescreening, may only be performed in accordance with prior IRB review and approval.

b) Check one of the following:

☐ I will provide a complete list of all DHHS clients whose records I have accessed under this waiver; or

☐ I will access the records of 50 or more DHHS clients and am not providing a list of all clients whose records I have accessed under this waiver.

☐ 4. Research on Decedents

a) I am requesting access to or disclosure of the health information **for deceased DHHS clients only** and **I hereby represent that**:

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

b) Check one of the following:

☐ I will provide a complete list of all DHHS clients whose records I have accessed under this waiver; or

☐ I will access the records of 50 or more DHHS clients and am not providing a list of all clients whose records I have accessed under this waiver.

B. Limited Data Set (See description in Section V and select this category if appropriate)

☐ 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 V-A (Limited Data Sets)** of this form with respect to a DHHS client, the client's relatives, members of the client's household, or the client's employer(s) except dates and/or geographic information above the level of postal address. I have attached **a copy of the IRB approval letter for this research, if required.**

I understand that a Data Use Agreement between the DHHS agency disclosing or providing access to the limited data set and my organization must be executed before I can access or receive the limited data set.

C. Completely De-identified Health Information (See description in Section V and select this category if appropriate)

☐ I am requesting access to or disclosures of completely de-identified health information, i.e., information that **does not contain any of the identifiers listed in Section V-B (De-identified Health Information)** of this form with respect to a DHHS client, the client's relatives, members of the client's household, or the client's employer(s).

SECTION III RESEARCH INFORMATION (Add additional sheets if necessary)

A. Purpose Statement (explain the purpose (intent, objective) of the research)

B. Methodology (process of the research, analysis procedures, etc)

C. Data/Information requested (please be specific) (if additional space is needed, please submit on a separate sheet)

D. Benefit and/or potential risk to DHB and/or DHB beneficiaries/members

E. What will be the format of your results (e.g. publication, grant application, poster, presentation, brochure, Web page, etc.)? Prior to publication, all materials should be reviewed and approved by Division of Health Benefits. All materials should be submitted to the Privacy Officer 45 calendar days prior to publication. Submit findings to Freya.Hardy-Lynch@dhhs.nc.gov.

F. Obligations

The Principal Investigator and each individual delegated to obtain or receive data directly from DHHS 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 am aware that the data to which I have requested access is subject to Health Insurance Portability and Accountability Act of 1996 (HIP) 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**

Please describe all research and other staff who will have access to the confidential data. These include personnel, subcontractors, and affiliated agencies.

Print Name	**Role/Organization**

SECTION IV DHHS APPROVAL (by DHHS Agency/Facility/Research Director)

Print Name	**Signature/Date**

Title

SECTION V LIMITED DATA SETS AND DE-IDENTIFIED HEALTH INFORMATION

A. Limited Data Set

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

- Names
- Any geocodes that identify an individual household such as street address or post office box number
- 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
- Medical 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 created for de-identification purposes that could be used by the researcher to identify the client

Note that a limited data set may include:

- All elements of dates directly related to a DHHS client, 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, and ZIP code.

B. De-identified Health Information

De-identified health information **may not include** any of the following direct identifiers of the DHHS client or of the client's relatives, employers, or household members

- Names
- Geographic subdivisions smaller than a state
- ZIP codes (except first three digits **if** the combined population of all ZIP codes beginning with those three digits is **greater than 20,000)**
- All elements of dates except year (i.e., month/day; however, year must be excluded for clients age 90 and older) directly related to a DHHS client, 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
- Medical 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 client

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