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<b>Chapter:</b>	<b>III. Use and Disclosure Policies, Research</b>
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## **Purpose**

The purpose of the Division of Public Health (DPH) research privacy policy is to define how individually identifiable health information within DPH must be protected when it is accessed, used, or disclosed for research purposes. This policy is in compliance with the [DHHS Policy and Procedure Manual, Section VIII, Security and Privacy](#), that establishes the NC Department of Health and Human Services (DHHS) research requirements.

### ***Policy Scope:***

- ***HIPAA covered health care components***
- ***Internal Business Associates***

Note: Division work groups that are not HIPAA covered components or internal business associates should continue to follow their guidelines and protocols for conducting and participating in research according to the NC statutory and administrative rule requirements.

## **Background**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule establishes the conditions under which individually identifiable health information may be used or disclosed by covered health care component and their internal business associates for research purposes. Research is defined in the Privacy Rule as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The HIPAA definition of research also applies to the development of research repositories and research databases. For the purposes of this policy, this definition of research is expanded for institutions operated by the Division of Mental Health, Developmental Disabilities and Substance Abuse Services (DMH/DD/SAS) to include the definition of research provided in North Carolina Administrative Code (NCAC), 10A NCAC 28A.0102, in which “‘research’ means inquiry involving a trial or special observation made under conditions determined by the investigator to confirm or disprove an [sic] hypothesis or to explicate some principle or effect.”

The Privacy Rule also defines the means by which clients will be informed of uses and disclosures of their individually identifying health information for research purposes, and their rights to access their health information held by covered health care components and internal business associates. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research.

Currently, most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the Food and Drug Administration's (FDA) human subject protection regulations (21 CFR Parts 50 and 56), which have some privacy and confidentiality provisions that are similar to, but separate from, the HIPAA Privacy Rule's provisions for research.

Research, except minimal risk research (defined in the note below), is subject to the Common Rule. 'Minimal risk research' is defined in 10A NCAC 28A.0201 as research in which "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

**The HIPAA Privacy Rule does not replace or act in lieu of these human subject protection regulations**, so DPH researchers who are also covered health care components or internal business associates may find themselves responsible for complying with multiple sets of regulations.

The following publications provide guidance about the impact of HIPAA Privacy regulation on public health research:

- [NIH Research HIPAA Booklet](#)
- [NIH IRB FAQ](#)
- [NIH HIPAA and research repositories](#)
- [OCR guidance on research presentation 2003](#)

### **Research and De-Identification under HIPAA**

An individual identifier is information that could reasonably enable the identification of a specific DPH client or a relative, guardian, employer, or household members of that client. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule primarily addresses the protection of individually identifiable health information and specifies when such information can be used or disclosed. HIPAA allows a covered entity to de-identify health information by removing all identifying elements so that the remaining information cannot identify an individual and therefore is not subject to the protections specified for IIHI.

The HIPAA definition of completely de-identified health information is not the same as what many providers, program managers, and researchers have been familiar with as de-identified data. The HIPAA de-identification strips out all geographical subdivision smaller than a state, including zip codes, and as such, HIPAA de-identified data may not be sufficient for many research studies nor for public health data analysis and reporting.

In addition to de-identifying health information, HIPAA permits the creation of a “limited data set” that can contain specific individual identifiers when such information is needed for **public health, research, or health care operations** activities and a “data use agreement” (DUA) has been executed. There are provisions in HIPAA, state laws, and other federal laws that authorize when PHI can be used and disclosed for public health, research, and health care operations without the necessity for a limited data set or data use agreement (e.g., public health disclosures required by law).

Data use agreements would only be needed for those public health, research, or health care operation uses and disclosures that are not otherwise permitted by federal or state laws.

Refer to the DPH Privacy Policy, [Use and Disclosure Policies, De-Identification of Health Information and Limited Data Sets](#) for information about the applicability of HIPAA-defined de-identification within DPH.

## Policy

### DPH Researchers

Researchers within DPH covered components conducting research on clients shall have access to an Institutional Review Board established in accordance with the Common Rule (45 CFR 46, Subpart A) that will:

- Review and modify, disapprove, or approve research protocols and informed consent for research forms **and**
- Conduct periodic reviews of the research.

DPH covered components and internal business associates shall obtain client authorization using the [DHHS Authorization to Disclose Health Information for Research](#) (DHHS-1001 (12/03)) form prior to using or disclosing individually identifiable health information for research purposes, **unless one** of the criteria listed below is met.

- The researcher is required by contract to use a HIPAA compliant authorization form developed by a research facility (e.g., University of North Carolina researchers).
- The authorization requirement is waived by either an Institutional Review Board established in accordance with the Common Rule, or a Privacy Board that is established according to the requirements defined in this policy.
- The research requires the use of a decedent's individually identifiable health information and that decedent's information is used only for research purposes.
- The individually identifiable health information is used in reviews preparatory to research and **both** of the following conditions are true:
  - The use of the individually identifiable health information is necessary for the preparatory review wherein protocol and goals are established for the proposed research **and**
  - The individually identifiable health information is not removed from the covered health care component's site.
- A limited data set is used that contains specific limited identifiers **after** the required data use agreement has been signed by the researcher and the DHHS agency that maintains the health information (see the DPH Privacy Policy [Use and Disclosure Policies, De-Identification of Health Information and Limited Data Sets](#)).
- Only de-identified health information is used for the research (see DPH Privacy Policy [Use and Disclosure Policies, De-Identification of Health Information and Limited Data Sets](#)).

Researchers within a DPH covered component shall request the individually identifying health information that is the minimum necessary to conduct the research, in accordance with the DPH Privacy Policy, [Use and Disclosure Policies, Minimum Necessary](#). Whenever possible, DPH researchers shall request either de-identified data or a limited data set as necessary if either of these is the minimum necessary for conducting the research.

A researcher within DPH covered component that is a recipient of a limited data set shall sign a data use agreement with the DHHS agency that maintains the information and shall comply with the conditions of that agreement, in accordance with the DPH Privacy Policy [Use and Disclosure Policies, De-identified Health Information and Limited Data Sets](#).

A researcher within a DPH covered component that receives individually identifiable health information from a DHHS covered health care component or internal business associate shall ensure that the information is protected in accordance with the DHHS and DPH Privacy Policies.

The requirements in this policy are in addition to (not a replacement for) other policies and regulations for human subjects research.

For treatment purposes, DPH covered health care components shall contact researchers (either internal or external to DHHS) if a research subject seeks additional health care services from or is admitted into the component for additional treatment.

### **Researchers External to DHHS**

DPH covered components that that receive requests for individually identifying health information from researchers external to DHHS shall require the researcher to submit the request in writing. Research requests must be documented in accordance with the requirements identified in this policy.

## Implementation Procedures

### Applicability with DPH

As the only covered health care provider in the Division, the State Laboratory for Public Health will follow the procedures for research defined in this policy.

The following DPH internal business associates will also follow the procedures defined in this policy:

- Administrative, Local, and Community Support Section – HSIS Business Liaison
- Administrative, Local, and Community Support Section – Medicaid Liaison and Reimbursement
- Administrative, Local, and Community Support Section – Information Technology
- Women’s and Children’s Health Section – Children’s Special Health Services

The State Center for Health Statistics (SCHS) will follow its statutory requirements as defined by NC General Statute and implementing rules. The SCHS will develop policies and implement protocols regarding the release of medical records for research purposes according to the requirements defined in NC administrative rules. In addition, the SCHS will follow the requirements regarding NC Medicaid data as defined in a Memorandum of Understanding between DPH and the Division of Medical Assistance.

Division work groups that are not HIPAA covered components or internal business associates should continue to follow their guidelines and protocols for conducting and participating in research according to the NC statutory and administrative rule requirements. These provisions are summarized below:

- |                                     |  |
|-------------------------------------|--|
| • GS 130A-131.17, 10A NCAC 46C.0106 | Birth Defects Monitoring                     |
| • GS 130A.143, 10A NCAC 41A.0.104   | Communicable Diseases                        |
| • GS 130A-374, 10A NCAC 47A.0102    | State Center for Health Statistics           |
| • GS 130A-9310A, NCAC 41H.0702      | Vital Records                                |
| • GS 130A-212, 10A NCAC 47B.0106    | Chronic Disease, Cancer and Cancer Registry  |
| • GS 130A-131.17                    | Maternal and Child Health and Women’s Health |
| • 10A NCAC 43G.0409                 | CDSAs  |

The DPH HIPAA Office and the Chair of the DPH Institutional Review Board are available to provide guidance regarding the impact of the HIPAA Privacy Rule of research in which Division staff participates.

## **Institutional Review Boards**

Institutional Review Boards (IRBs) are responsible for reviewing and modifying (to secure approval), disapproving, or approving the following for research involving human subjects:

- Research protocols
- Forms to be used by researchers to obtain authorizations for the use or disclosure of client's individually identifying health information for research
- Forms to be used by researchers to obtain informed consents from research subjects
- Requests to waive or alter the requirement for client informed consent for participation in research study
- Requests to waive or alter the requirement for client authorization for the use or disclosure of client individually identifying health information for research.

IRBs must also conduct periodic reviews of the research.

All research conducted by the Division, in which the Division participates, or using individually identifiable public health data is approved by an IRB, as required by the Common Rule. In most of the research studies, the IRB affiliated with the Principal Investigator's institution (e.g. University of North Carolina, School of Public Health, Centers for Disease Control, National Institutes of Health). When DPH staff participates in or collaborates with other in research studies, the IRB is also often affiliated the institution participating in the research. When another institution's IRB has not approved a DPH research study, research can be reviewed, approved, and monitored by the DPH IRB.

The DPH IRB has implemented and document procedures for normal review as defined in 45 CFR 46.108(b), or expedited review according to the procedures defined by 45 CFR 46.110.

The DPH IRB shall document all decisions regarding the modification, approval, or disapproval of research protocols, documentation, and requests to waiver or alter the informed consent or authorization requirements. The IRB shall also document continuing review activities.

Procedures for the DPH IRB are available from the Chair of the IRB, Chief, Legal and Regulatory Affairs.

## Privacy Boards

If DHHS agencies determine the IRB cannot provide timely reviews of researcher requests to alter or waive the client authorizations requirement, the agency can establish or designate an external Privacy Board that:

- Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests
- Has at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities
- Does not have any members participating in a review of any project in which the member has a conflict of interest.

DHHS Privacy Boards shall implement and document procedures for normal and expedited reviews of requests to alter or waive the client authorization requirement for research. Privacy Board normal review procedures shall state that:

- The proposed research will be reviewed at convened meetings at which a majority of the Privacy Board is present:
  - At least one of the Privacy Board members present at the review meeting will not be affiliated with the covered entity or the entity sponsoring or conducting the research, nor will that member be a relative of any person who is affiliated with such entities
  - Requests for the alteration or waiver of client authorization must be approved by the majority of the Privacy Board members present at the review meeting, unless the Privacy Board elects to use an expedited review procedure.
- Privacy Board expedited review procedures shall state that:
  - Expedited procedures will be used only to review requests for waiver of authorization for research that involves no more than minimal risk to the privacy of the subjects and their individually identifying health information; and
  - Either the chair of the Privacy Board or one or more members designated by the chair will conduct the review and decide on the approval, modification, or disapproval of the request for waiver.

**NOTE:** Privacy Boards only have the authority in regards to approving, modifying (to secure approval), and disapproving requests to alter or waive the client authorization for research. All other approvals for the research study (protocol, informed consent for research documents, and requests for waivers or alterations of informed consent requirement) and periodic reviews **must** be conducted by an IRB.

DPH has not implemented a Privacy Board and relies on an affiliated IRB or the DPH IRB for all decisions regarding research using individually identifiable public health data.

## Research Conducted with Client Authorization

Unless otherwise permitted by this policy, or required by state or federal law, a client authorization must be obtained prior to the use or disclosure of the subject's individually identifiable health information for research purposes. Authorizations for research initiated by DPH covered components shall be completed prior to research activities using the [DHHS Authorization to Disclose Health Information for Research](#) form.

**Note:** Client authorization for use and disclosure of individually identifiable health information for research purposes does not replace the informed consent to participate in a research study required by the Common Rule, the FDA Protection of Human Subjects Regulations, NCGS 122C-57 (f), 10A NCAC 26C.0200, 10A NCAC 26D.1300, or 10A NCAC 28A.0305.

Any authorization form received by a DPH covered component from a researcher external to DHHS must contain all of the following elements required to be a HIPAA-compliant research authorization:

- A specific and meaningful description of the information to be used or disclosed;
- The name of the entity (e.g., NC Division of Public Health) authorized to disclose the individually identifying health information for research purposes
- The name of the researcher or entity conducting the research to whom the disclosure of individually identifying health information for research purposes can be made
- A description of the specific research study in which the information will be used (authorizations cannot be used for nonspecific research or future, unspecified projects)
- An expiration date or event (e.g., client discharge) for the authorization that relates to the client or the research. The following statements meet the requirements for an expiration date or an expiration event if the appropriate conditions apply:
  - The statement “end of the research study” or similar language
  - The statement “none” or similar language if the purpose of the authorized disclosure of individually identifying health information is for the researcher to create and maintain a research database or repository

**Note:** If the database or repository is created by a DPH covered component, client authorization or alteration/waiver of the authorization requirement must be obtained before the data can be disclosed for a different research study.

- Signature of the client and the date of the signature. If a client's personal representative signs the authorization form, a description of the personal representative's authority to act on behalf of the client must also be provided.

In addition to the above required elements, the research authorization form must also contain the statements listed below:

- A statement that the client has a right to revoke the authorization and a description of how the authorization may be revoked. The authorization must also state that the researcher may continue to use and disclose the individually identifiable health information obtained before the authorization was revoked if needed to maintain the integrity of the research and for reporting purposes such as reporting adverse events and conducting investigations of scientific misconduct.
- A statement that either:
  - Any treatment received from the covered entity is not dependent upon whether the client signs the authorization to use or disclose information for research purposes (this statement can be used only if the treatment is not delivered as part of the research study), **or**
  - The provision of research-related treatment is conditioned on a client authorizing the use or disclosure of individually identifiable health information for such research.
- A statement that information authorized for disclosure for research use could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA.

A research authorization is always required for access, disclosure, or use of psychotherapy notes for research purposes. An authorization for access, use, or disclosure of psychotherapy notes for research may not be combined with any other authorization except other authorization for access, disclosure, or use of the same notes.

If a client elects to revoke his/her authorization for the use and disclosure of individually identifying health information for research purposes, the revocation must be documented on the original authorization form in the Revocation section. This revocation shall become a permanent part of the research record and the client's medical record. Researchers within DPH shall report the revocations to the Institutional Review Board at the time of continuing review.

DPH covered components shall provide a copy of the signed research authorization to clients or their personal representatives.

## **Alteration or Waiver of Client Authorization to Use or Disclose Individually Identifying Health Information for Research**

A DPH researcher may submit a request to an IRB or Privacy Board for a waiver or alteration of client authorization for the use or disclosure of individually identifying health information for research if the researcher determines that obtaining client authorizations is not feasible. For example, a researcher may need to request an alteration or waiver of requirement for client authorization for the use or disclosure of individually identifying health information for research in the following cases:

- The researcher cannot practicably obtain a potential research subject's authorization for the review of individually identifying health information in advance of contacting the potential subject; or
- The research will only involve the use of existing client records or specimens and no intervention, interaction, or direct contact of any kind with the research subjects will occur.

In the first case, an IRB or Privacy Board may elect to approve the researcher's request for a limited waiver of authorization that will permit specified access and use of individually identifying health information solely for prescreening and recruitment contact pursuant to the approved research protocol. In the second case, the volume and/or age of records to be examined during the research may be such that it would not be practicable for the researcher to obtain client authorization beforehand. If the risk to the client's privacy is minimal, the IRB or Privacy Board may also elect to approve a waiver in this instance.

DPH researchers shall submit all requests for the alteration or waiver of client authorizations for research in writing to an Institutional Review or Privacy Board. Researchers may document their alteration or waiver request via the [DHHS Application for Waiver/Limited Waiver of Authorization for Research](#) template or the application form required by the IRB or Privacy Board that will decide whether to honor the request.

If the IRB or Privacy Board approves the request for alteration or waiver of client authorization, the board shall document that the following criteria are satisfied:

- The use of disclosure of the individually identifiable health information involves no more than a minimal risk to the privacy of individuals, based on, *at least*, the presence of the following elements:
- An adequate plan to protect the individual identifiers (more information on individual identifiers is provided in the DPH Policy [Use and Disclosure Policies, De-Identification of Health Information and Limited Data Sets](#) and [Administrative Policies, Privacy Safeguards](#).
  - An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law
  - Adequate written assurances that the individually identifying health information will not be reused or disclosed to any other person or entity, except:
    - As required by law:
  - For authorized oversight of the research project or
  - For other research for which the use or disclosure of the individually identifiable health information would be permitted by this policy;
- The research could not practicably be conducted without the alteration or waiver; and
- The research could not practicably be conducted without access to and use of the individually identifying health information.

The documentation of the alteration/waiver of authorization approval shall also include the following elements:

- A statement identifying the IRB or the Privacy Board and the date on which the alteration or waiver was approved
- A brief description of the individually identifiable health information for which use or access has been determined by the IRB or the Privacy Board to be necessary to the research
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited procedures
- A signature from the chair of the IRB or Privacy Board, or from another member of the board who has been designated by the chair.

If an IRB or Privacy Board does not approve a request to alter or waive the client authorization requirement for research, the board must inform the researcher of the decision in writing. Similarly, if the board requires a change to the request for the alteration or waiver of client authorization prior to approving the request, the required changes must be documented and sent to the researcher.

If a research project is taking place at multiple sites and/or requires the use and disclosure of individually identifying health information created or maintained by more than one agency (collectively referred to as 'multi-site projects'), more than one IRB may be involved in research study reviews, or researchers participating in the multi-site project may elect to use a single IRB. The same situation is expected to occur with Privacy Boards. In some circumstances, Privacy Boards and IRBs will coexist. Regardless, a DPH covered component may rely on a waiver or an alteration of authorization approved by any IRB or Privacy Board, without regard to the location of the approver.

### **Use and Disclosure of Individually Identifying Health Information without Authorization Preparatory to Research**

DPH covered components may allow researchers to access individually identifying health information *without* a client authorization, IRB/Privacy Board waiver of authorization, or data use agreement if the access is for the development of a research protocol, an assessment of feasibility of a research protocol, or other reviews preparatory to research.

Researchers requesting the information must provide written documentation, via the [DHHS Request for Access to Health Information for Research](#) template, to the DHHS agency that the following criteria are met:

- The use or disclosure of individually identifying health information is solely to prepare a research protocol, or for similar purposes preparatory to research
- The researcher shall not record or remove the individually identifying health information from the agency
- The individually identifying health information sought is necessary for purposes of the research.

Only the workforce of the covered health care components may contact that component's without authorization for purposes of recruiting them to participate in a research study. Therefore, researchers external to DPH covered health care components that identify potential research subjects during their reviews preparatory to research must submit a written request to the DPH covered component if the researcher wishes the agency to notify the client about a possible opportunity to participate in the research.

This request can be submitted via the [DHHS Request for Access to Health Information for Research](#) template, or a separate letter. The researcher can choose to accompany this request with an authorization form he/she has already developed (either a stand-alone authorization form, or preferably, one combined with the informed consent form) or the researcher could request that the covered component use the [DHHS Authorization to Disclose Health Information for Research](#) form. Alternatively, the researcher can pursue approval to alter or waive the client authorization requirement so he or she can conduct the recruitment activities.

DPH researchers that are part of the DPH covered component's workforce may contact the client directly for the purposes of recruitment for the research study. However, researchers must obtain authorization from a client who has indicated interest in participating in a study prior to asking the client any screening questions that involve individually identifying health information.

**Note:** If the preparatory research activity involves human subjects research (e.g., research subject recruitment, prescreening), the preparatory research activity must be reviewed and approved by an IRB and must satisfy the informed consent requirements unless otherwise waived by an IRB.

### **Use of Individually Identifiable Health Information for Decedents in Research**

DHHS agencies may use or disclose individually identifying health information relating to deceased clients *without* executing a data use agreement or obtaining an authorization from the executor, administrator, or other person with the authority to act on behalf of the deceased client or the client's estate, *if* the researcher requesting the information provides written documentation, via the [DHHS Request for Access to Health Information for Research](#) template, to the DPH covered component that the following criteria are met:

- The information to be used or disclosed is solely for research on the individually identifiable health information of the deceased client;
- The researcher has documentation of the death of the client who is the subject of information being sought and can make such documentation available to the DPH covered component upon request

**Note:** If the researcher does not specify clients, but requests individually identifiable health information for "deceased clients" in general, then the DPH covered component will not need to request proof of client death.

- The information sought is necessary for the purposes of the research.

## Use of De-identified Health Information in Research

DPH covered components may use or disclose health information for research purposes without obtaining either client authorization or an IRB/Privacy Board waiver for authorization, or executing a data use agreement if the information has been ‘de-identified’. In de-identified health information, all the elements that could identify a client have been removed so that there can be no reasonable basis to believe that the resulting data may be used, with or without other available information, to identify a client.

Researchers must submit requests for de-identified data to the DPH covered components via the [DHHS Request for Access to Health Information for Research](#) template.

For more information on de-identified health information, see the DPH Policy [Use and Disclosure Policies, De-identification of Health Information and Limited Data Sets](#).

## Use of Limited Data Sets in Research

DPH covered components may use or disclose a limited number of individual identifiers via a ‘limited data set’ for research without client authorization or IRB/Privacy Board alteration or waiver of authorization whenever the limited data set will meet the researcher’s request.

Researchers must submit requests for a limited data set to the DHHS agency via the [DHHS Request for Access to Health Information for Research](#) template.

Before using or disclosing the limited data set, DPH covered components must enter into a data use agreement, using the [DPH Data Use Agreement](#) template, with the researcher unless the use or disclosure is required by state or federal law.

The minimum necessary rule, as stated in the DPH Privacy Policy [Use and Disclosure Policies, Minimum Necessary](#), shall apply to limited data sets; therefore, only data elements that are necessary to perform the purpose(s) specified in the data use agreement should be included in the limited data set released to the researcher.

Refer to the DPH Privacy Policy [Use and Disclosure Policies, De-identification of Health Information and Limited Data Sets](#) for more information about limited data sets and data use agreements.

## Research Requests Received from Organizations External to DPH

All requests for access to health information (e.g., individually identifying health information, limited data sets, de-identified health information) for research purposes, including those from researchers external to DPH covered components, must be submitted in writing to DPH covered components using the [DHHS Request for Access to Health Information for Research](#) template.

In addition to the Request form, researchers must submit the following documentation, as indicated on the form for their type of request:

- Research protocol
- IRB approval letter for the research protocol
- Informed consent forms for research signed by DHHS clients that have agreed to participate in the research study as subjects, **or** IRB approval of informed consent alteration or waiver
- Either:
  - Authorization forms signed by DPH covered component clients that have agreed to become research subjects
  - IRB/Privacy Board approval of client authorization alteration or waiver
  - Request that the DPH covered component obtain client authorization via the [DHHS Authorization to Disclose Health Information for Research](#) form, or the authorization form or combined authorization/informed consent form provided by the researcher.
- Upon a DPH covered component request, documentation of the decedent status of the client(s) who is the subject of the individually identifying health information requested.  
**Note:** If the researcher does not specify clients, but requests individually identifiable health information for “deceased clients” in general, then the DPH covered component will not need to request proof of client death.

## Transition Provisions for Research in Progress

For research that involves the use of individually identifying health information and is being carried out according to a protocol reviewed and approved by the Institutional Review Board **prior to** April 14, 2003:

- A research study may continue to use or disclose a client's individually identifiable health information created or received prior to April 14, 2003.
- A research study operating under a waiver of informed consent approved by the Institutional Review Board prior to April 14, 2003, may continue to create, receive, use, and disclose a client's individually identifiable health information for the study after April 14, 2003, without an IRB or Privacy Board waiver of authorization **unless** the research study subsequently seeks informed consent, in which case a client's authorization would be required together with the client's informed consent.
- If the research protocol approved by an IRB before April 14, 2003, required a client's informed consent, no additional authorization is required to continue to create, receive, use and disclose that client's identifying health information for the approved study.
- Informed consent obtained on or after April 14, 2003 also requires authorization for use or disclosure of the client's individually identifying health information. If a previously approved research project will be enrolling clients on or after April 14, 2003, the researcher must submit a protocol revision to the IRB that specifies this requirement.

## Disclosure of Individually Identifying Health Information from Research Data

Researchers in DPH covered components may disclose individually identifying health information that has been gathered or created during the research study if the disclosure is:

- Permitted by client authorization
- Permitted by the approved alteration or waiver of authorization
- Permitted by the data use agreement
- Made to the sponsor of the study **if** the protocol includes a FDA regulated product or activity for which the sponsor is responsible, and the disclosure is for the purposes of quality, safety, or effectiveness (e.g., adverse event/safety reports for investigational new products)
- Made to a health oversight agency that is performing oversight activities authorized by law (e.g., disclosure to the Office for Human Research Protections for the purposes of determining compliance with the Common Rule)
- Required by law (e.g., disclosure to cancer registries, other public health reporting).

If a revision to the authorization or alteration/waiver of authorization is necessary to allow the desired disclosure, an IRB or Privacy Board must approve the revision to the protocol. If the terms of the data use agreement must be changed to permit the disclosure, a revised data use agreement must be signed by the researcher and the covered component.

Individually identifying health information gathered during the research study may not be included in presentations or publications of any type unless explicitly permitted by:

- The client via authorization or informed consent for research
- Waiver of the client's authorization by an IRB or Privacy Board
- Waiver of the client's informed consent by an IRB or
- The data use agreement signed by the DPH covered component disclosing the health information and the researcher.

DPH covered components may not allow the authorization, alteration/waiver of authorization, or data use agreement obtained for one research project to be used for another research project. However, the IRB or Privacy Board may reanalyze such disclosures and grant a waiver for other studies.

### **Retention of Research Documentation**

DPH covered components receiving requests for access to individually identifying health information for research shall maintain a copy of the following in the client records:

- The approved [DHHS Request for Access to Health Information for Research](#) template
- The research protocol and IRB letter of approval
- Client authorization or IRB/Privacy Board documentation of approved alteration/waiver of authorization and
- Client informed consent or IRB documentation of approved alteration/waiver of informed consent.

Research documentation filed in the client record must be retained according to the Division's retention and disposition schedule for such records.

Researchers within DPH covered components must maintain copies of authorizations for research and approved waivers of authorization for a minimum of six (6) years from the date of creation, or the date on which the document was last in effect, whichever is later.

## Accounting of Disclosures of Individually Identifying Health Information for Research Purposes

Clients have a right to request access to an accounting of all disclosures of their individually identifying health information for research purposes, unless such disclosure was made:

- Pursuant to the client's authorization or
- As part of a limited data set.

Similarly, clients will not receive an accounting of disclosures of their health information if the information was de-identified.

Documentation of disclosures must be kept in the circumstances listed below and provided to clients upon their request:

- Disclosures pursuant to an IRB or Privacy Board alteration or waiver of authorization
- Disclosures used in preparation of a research protocol or
- Disclosure of a decedent's individually identifying health information used for research.

Refer to the DPH Privacy Policy [Use and Disclosure Policies, Accounting of Disclosures](#) for more information about accounting for disclosures of individually identifying health information made for research purposes.

## Client Access to Research Information

Client health records that are designated record sets may contain research data to which a client has the right to request access. Clients also have a right to request access to separate research records that have been identified as designated record sets.

Clients receiving treatment in research protocols may be temporarily denied access to their research records in accordance with the DPH Privacy Policy [Client Rights Policies, Client Privacy Rights](#) provided that:

- The individually identifying health information was obtained in the course of the research
- The client agreed to the denial of access via the signed research authorization
- The research remains in process and
- The client's right to access such individually identifying health information is re-instated once the research study has concluded.

Refer to the DPH Privacy Policies Client Rights Policies, [Designated Record Sets](#) and [Rights of Clients](#) for more information about designated record sets and clients' right to request access to their health information.

**Relevant Forms:**

[DHHS Authorization to Disclose Health Information for Research](#)  
[DHHS Request for Access to Health Information for Research Template](#)  
[DHHS Application for Waiver/Limited Waiver of Authorization for Research](#)  
[DPH Data Use Agreement Template](#)

These documents can be accessed on the DPH HIPAA website at <http://www.schs.state.nc.us/hipaa/>.

**References:** DHHS Directive Number III-11; DHHS Policy and Procedure Manual, Section VIII, Security and Privacy, DPH HIPAA Compliance Statement, 45 CFR 164.514, NC General Statutes 130A-131.17, NC General Statutes 130A-143, NC General Statutes 130A-374, NC General Statutes 130A-9310A, NC General Statutes-130A-212, 10A NCAC 46C.0102, 10A NCAC 41A.0104, 10A NCAC 47A.0106, 10A NCAC 41H0702, 10A NCAC 47B.0106, 10A NCAC 43G.0409

For questions or clarification on any of the information contained in this policy, please contact the DPH Privacy Office at <mailto:HIPAA.DPH@ncmail.net>.