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Policy Area:	*HIPAA - Privacy*
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Applicability:	*UNC Medical Center*

Release of PHI for Research Purposes

I. Description

Requirements for releasing patient information for research purposes

II. Rationale

It is the policy of The University of North Carolina Health Care System (UNC HCS) to protect the rights of its patients with respect to research. Research using patient records, both paper and electronic format, or excess human tissues must be conducted by a full-time member of the Medical Attending Staff or his/her designee, with the approval of the Chair of the clinical department involved and The Committee on the Protection of the Rights of Human Subjects (IRB), and in compliance with the provisions of this policy.

III. Policy

A. Requirements for Those Conducting Research

1. General Requirements for Approval
    a. Any use of protected health information ("PHI") for research purposes, even if the investigator is the patient's treating physician, must be reviewed and approved by the IRB. Application must be made to the IRB using the approved IRB forms. Copies of the IRB application will be kept on file in the Office of Human Research Studies. In order to obtain access to PHI, the investigator must provide the Medical Information Management Department Research Section with a copy of the IRB approval document(s) for research involving review of PHI and the documents referenced in B. below.
    b. The Director of Surgical Pathology must approve requests for use of excess surgical pathology tissue and the Director of Hematopathology must approve requests for excess hematopathology tissue.
    c. In those instances where projects proposed by the Medical Allied Health Staff do not fall within the areas of concern of a member of the attending staff, the President of the Hospitals or the Chief of Staff may provide sponsorship.

All staff members who wish to conduct research using PHI or human tissue are required to follow the procedures set forth in the IRB research policy found at (http://www.unc.edu/hipaa/Research_Policy.pdf). Research policies, forms and information may be found at the UNC-CH HIPAA website (http://unc.edu/hipaa/), the School of Medicine HIPAA website (http://www.med.unc.edu/security/hipaa/), and the UNC Health Care

System HIPAA website (http://intranet.unchealthcare.org/hospitaldepartments/hipaa). IRB forms and policies, including forms for IRB review of proposed authorizations or waivers of authorization for UNC-CH research, can be found at the UNC-CH IRB web site at http://research.unc.edu/ohre/forms.php.

B. Access to and Disclosure of PHI

Research access to PHI will require the following documentation:

1. The Request for Access to Protected Health Information for Research Purposes Form (HD974), signed by the Principal Investigator listed on the IRB Approval Letter;
2. The completed Systems Access Request Form (SARF) (if applicable), signed by the Principal Investigator listed on the IRB Approval Letter;
3. IRB Approval Letter; AND
4. Authorization signed by the patient (or copy of informed consent document signed before 4/14/03). This document allows release of all PHI described in the document. A copy of the consent/authorization form should be sent to the Medical Information Management Department to be filed in the patient's medical record; OR
5. IRB Waiver of Authorization (or copy of IRB waiver of informed consent approved prior to 4/14/03). This document allows release of all PHI described in the waiver document.

Any one of the following options may be used for HIPAA-compliant disclosure of PHI from UNC HCS records for research purposes.

1. Research Eligibility Prescreening and/or Recruitment Contact: Prior to obtaining PHI, the researcher must present the written IRB waiver of authorization or IRB limited waiver of authorization to UNC HCS staff who are requested to disclose PHI for research subject eligibility prescreening and possible recruitment of patients.
2. Review Preparatory to Research Only: Access to the online clinical information system (WebCIS) will not be granted for reviews preparatory to research, thus, the SARF is not required. The researcher must present a written statement to UNC HCS staff who are requested to disclose PHI for reviews preparatory to research (Section A.3 of the HD974) that states:
    a. the researcher wants access to the PHI solely to determine whether there is sufficient data to support a specific protocol or an idea for a research study; and
    b. the researcher will not record any individually identifiable PHI; and
    c. the researcher will not remove any PHI from the records; and
    d. the access to the PHI is necessary for preparation for research; and
    e. patients will not be contacted using PHI obtained in this review preparatory to research.
    (Note: Aggregate "de-identified" data can be released directly to the researcher without additional documentation – see "De-identified Information" below.)
3. Only Decedents: The researcher must present a written statement to UNC HCS staff who are requested to disclose decedents' PHI for research purposes (Section A.4 of the HD 974) that states:
    a. the access is requested solely for research on PHI of decedents; and
    b. the PHI of these decedents is necessary for the research study; and
    c. upon request, the researcher will provide documentation of the death of the individuals whose PHI is

accessed and used.

4. Limited Data Sets: The researcher must present a Data Use Agreement to UNC HCS staff who are requested to disclose a limited data set (see definition below) prior to release of the requested information. The form HD974 incorporates a Data Use Agreement (see B. of the form HD 974) with UNC-CH researchers. For disclosure of PHI to researchers outside of UNC-CH, UNC HCS requires a Data Use Agreement executed between the external research entity and UNC HCS. Contact the UNC-CH Office of University Counsel for assistance. A limited data set may not include any of the following direct identifiers of the individual or the individual's relatives, employers or household members:

◦ Names ◦ Any geocodes that identify an **individual household**, including postal address information other than town or city, state and zip code ◦ 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 and any comparable images

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.

5. De-Identified Information: The researcher who requests "de-identified" information need not obtain IRB Approvals or present a SARF, but must present to UNC HCS Staff the HD974 form (sections C and II) and the completed Request for Record Review or Database Reports form. Data is not considered PHI if it is completely de-identified. There are 18 identifiers that must be removed to create "de-identified" information. Identifiers concerning the individual and the individual's employer, relatives and household members that must be removed include:

◦ 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	◦ Certificate/license numbers ◦ Vehicle identifiers and serial numbers, including license plate numbers ◦ Device identifiers and serial numbers ◦ Web universal resource locators (URL)

◦ Electronic mail addresses ◦ Social security numbers ◦ Medical record numbers ◦ Health plan beneficiary identifiers ◦ Account numbers	◦ Internet protocol (IP) address numbers ◦ Biometric identifiers, including finger and voice prints ◦ Full face photographic images and any comparable images ◦ Any other number, characteristic or code that could be used to identify the individual

Although a de-identified data set cannot contain a birth date, it may contain the individual's age expressed in years, 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.

C. Requirements for Records or Information Custodians

All requests for disclosure of PHI for research purposes, including both paper and electronic records (WebCIS), must be submitted first to the Medical Information Management Department. The Medical Information Management Department will send the relevant documentation to the appropriate records custodian. UNC HCS staff who are requested to disclose PHI for research purposes must ensure that the required documentation from the researcher has been obtained prior to releasing the PHI. Access to PHI must be limited to a period of time not to exceed the duration of the IRB approval for the research protocol, which is noted on the IRB approval letter. (There are exceptions which are described in the UNC-CH Research Policy.)

D. Accounting of Disclosures Requirements:

1. Authorization: UNC HCS staff who disclose PHI for research purposes pursuant to an Authorization are not required to account for these disclosures.
2. IRB Waiver of Authorization, Review Preparatory to Research, or Research on Decedents (less than 50 individuals): UNC HCS staff who disclose PHI for research purposes pursuant to an IRB Waiver of Authorization must maintain a written accounting of each individual disclosure as required by the UNC HCS Accounting of Disclosures Policy. Record custodians must enter each accounting of disclosure in the Disclosure Trac database.
3. IRB Waiver of Authorization, Review Preparatory to Research, or Research on Decedents (50 or more individuals): If UNC HCS has made disclosures for a particular research purpose for 50 or more individuals, an individual written accounting of each disclosure does not have to be maintained by the UNC HCS staff; however, UNC HCS is required to maintain a master list of protocols for which PHI of 50 or more individuals has been accessed, including all information required with respect to such protocols as specified in this policy. Upon receipt of the required documentation, the Medical Information Management Department must record the Research protocol in a database in order to generate the list of all protocols for which PHI of 50 or more individuals has been accessed.
4. Limited Data Sets (#B.4 above) or De-identified Information (#B.5 above): UNC HCS staff who disclose

"de-identified" information or "limited data sets" are not required to account for these disclosures.

E. Request to Access PHI for Non-Research Reviews (Quality Improvement, Teaching, Audit, etc.)

In order to obtain access to PHI that is NOT for Research purposes (in the form of a report or data download), but for hospital operations such as quality improvement/assurance, teaching, or audit, see the UNC HCS "Use of PHI for Teaching and Continuous Quality Improvement Purposes" policy.

Attachments:

No Attachments

Applicability

UNC Medical Center