I. Description
Requirements for safeguarding the privacy of patient information (PHI)

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II. Rationale
The University of North Carolina Health Care System (UNC HCS) recognizes its obligation to safeguard individually identifiable health information (Protected Health Information or PHI) against disclosure or use by unauthorized individuals. The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 and its accompanying regulations (HIPAA) have specific requirements regarding policies and procedures relating to patients’ rights with respect to their PHI. This policy describes these requirements and references relevant entity and departmental policies and procedures.

Except for certain specified exceptions, authorization of the patient or the patient’s legal representative is required for use or disclosure of PHI. Original records of PHI may be removed from UNC HCS’s jurisdiction and safekeeping only in accordance with a court order, subpoena, or statute.
This policy applies to all entities which comprise the University of North Carolina Health Care System, including UNC Hospitals, UNC Physicians & Associates, Rex Healthcare, and the clinical activities of the UNC School of Medicine. These entities have designated themselves as a single “affiliated covered entity” for HIPAA purposes (as defined below).

III. Policy

A. Definitions

Protected Health Information (PHI)

PHI is health information, including demographic information, created or received by UNC HCS entities which relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual and that identifies or can be used to identify the individual. PHI does not include de-identified PHI as defined in V. below. Other exclusions may be applicable as authorized by the appropriate UNC HCS Privacy Officer.

Consent

A consent for purposes of this policy is written permission for use and/or disclosure of an individual’s PHI for treatment, payment, and health care operations.

Authorization

An authorization is a specialized written permission for use and/or disclosure of an individual’s PHI for purposes other than treatment, payment and healthcare operations, as discussed below. An authorization must contain specific elements and must be approved by the Medical Information Management Department.

Business Associate

A business associate is a person or entity which performs certain functions, activities or services for or to UNC HCS involving the use and/or disclosure of PHI, and such person or entity is not a part of UNC HCS or its workforce.

De-identified PHI:

De-identified PHI is health information that is not individually identifiable because it meets the HIPAA criteria for anonymity (as defined in the Medical Information Management release of information policies).

Affiliated Covered Entities

Legally separate, but affiliated, covered entities which choose to designate themselves as a single covered entity for purposes of HIPAA.

Minimum Necessary

Minimum necessary standard applies when using or disclosing PHI or when requesting PHI from another covered entity. A covered entity must make reasonable efforts to limit access to PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. The minimum necessary standard does not apply to (1) disclosures to or requests by a provider for treatment; (2) uses or disclosures made to the individual who is the subject of the information; (3) uses or disclosures made pursuant to a valid authorization signed by the individual who is the subject of the information; or (4) uses or disclosures required by law or for compliance with applicable laws and regulations. Other exclusions
may be applicable as authorized by the appropriate UNC HCS Privacy Officer. (See the UNC HCS Minimum Necessary Policy.)

**Disclosure**

Disclosure is the release of, transfer of, or provision of access to information, or the divulging of information in any other manner.

**Research**

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. UNC HCS quality assessment and improvement studies for outcomes evaluation and development of clinical guidelines are healthcare operations studies rather than research when they are used only internally to evaluate and assess UNC HCS health care operations. Such health care operations studies are included in activities covered in consent for treatment, payment and health care operations and do not require authorization or waiver of authorization. All other types of studies may constitute research and the researcher should seek guidance from the UNC HCS IRB. (See the UNC HCS Release of PHI for Research Purposes Policy.)

**Marketing**

Marketing is communication intended to encourage the purchase or use of products or services. Per HIPAA, marketing does not include communications to the individual: (1) to describe entities that participate in health care provider networks or health plans; (2) to describe products or services offered by a provider or included in a plan of benefits; (3) relating to the individual's own treatment; or (4) relating to the case management or care coordination or to direct or recommend alternative treatments, therapies, healthcare providers, or settings of care to that individual.

**B. Procedure**

Except as authorized in this policy or other applicable UNC HCS entities’ policies, all disclosures of PHI (1) outside of UNC HCS and (2) within UNC HCS, other than for treatment, payment, or health care operations, must be processed through the Medical Information Management Department. In certain circumstances, the Medical Information Management Department policies may specifically delegate the disclosure process to other departments. All uses and disclosures of PHI of any nature are subject to the provisions of HIPAA, this policy and other related UNC HCS policies.

**Notice of Privacy Practices**

UNC HCS entities shall provide to each patient no later than the date of the first service delivery, including service delivered electronically, a Notice of Privacy Practices containing a description of the uses and disclosures of PHI that may be made by UNC HCS, UNC HCS’ duties with respect to PHI, and the rights afforded to patients. The Notice of Privacy Practices must also be posted by each entity as determined by the appropriate UNC HCS Privacy Officer and copies must be made available to patients upon request.

**Consent**

If possible, prior to providing care, UNC HCS entities shall obtain and retain, from each patient or authorized representative a signed and dated general consent to use or disclose PHI to carry out treatment, payment and healthcare operations. (See the UNC HCS General Consent for Treatment Policy.)
Authorization

To use or disclose PHI for any purpose other than treatment, payment and healthcare operations, UNC HCS entities shall obtain a signed and dated specific authorization, using the UNC HCS Authorization Form MIM #710-S or another HIPAA-compliant form, from the patient or authorized representative, unless authorization is waived or not required as further described in the Medical Information Management release of information policy. (See UNC HCS Use and Disclosure of PHI Based on Patient Authorization Policy.)

Other uses and disclosures

a. De-identified PHI

De-identified PHI as defined above may be used or disclosed as defined in the Medical Information Management release of information policies.

b. Marketing

Marketing conducted by a face-to-face communication with an individual is allowed under HIPAA; however, other types of marketing activities using PHI require an authorization. The applicable entity’s marketing department must approve marketing activities in advance. (See the UNC HCS Marketing Policy.)

c. Fundraising

UNC HCS may use, without an authorization, demographic and date-of-service PHI in fundraising activities; however, all fundraising activities must be conducted through the applicable entity’s fundraising organization(s). (See the UNC HCS Fundraising Policy.)

d. Business Associates

PHI may be used by and disclosed to a business associate of UNC HCS under the procedures set forth under the UNC HCS entity’s business associate policy, including signing and complying with a Business Associate Agreement in a form approved by UNC HCS. (See the UNC HCS Business Associates Policy and Procedure.)

e. Affiliated Covered Entities

UNC Hospitals, UNC Physicians & Associates, Rex Healthcare, and the clinical activities of the UNC School of Medicine have designated themselves as an “affiliated covered entity” for purposes of HIPAA compliance. Because these entities have designated themselves as an “affiliated covered entity”, PHI may be used and disclosed within UNC HCS in the same way as it could be disclosed within one single entity.

f. Research

With authorization: Use and disclosure of PHI for research purposes generally requires the permission of the individual whose PHI will be used in research. Such permission must be in the form of a HIPAA-compliant authorization for research approved by the UNC HCS IRB. Without authorization: PHI may be used in research without an individual’s authorization if the UNC HCS IRB grants a waiver of the requirement for authorization, or if there is an informed consent signed before April 14, 2003, or an IRB waiver of informed consent approved before April 14, 2003. There are also four general research scenarios that may require neither authorization nor waiver of authorization: (1) reviews preparatory to research (2) research on decedent’s information, (3) research use of a “limited data set” under a data use agreement, and (4) research use of de-identified data. These general scenarios require compliance with specific HIPAA requirements. For more complete information refer to the UNC HCS Release of PHI for Research Purposes policy.
Opt Out

PHI may be used or disclosed for the following purposes if the patient is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit, or restrict, the use or disclosure:

a. Facility Directories (Patient List).

UNC HCS maintains a list of patients currently in the hospital to provide the following “patient list” information to people who request it, unless the patient objects:

i. The patient’s location in UNC HCS and

ii. The patient’s condition described in general terms that do not give specific medical information about the patient (“good”, “fair”, “serious”, “critical”, or “deceased”).

The above “patient list” information including religious affiliation, is included on a community clergy list and will be provided to those clergy when requested. If the patient objects to having his/her religious affiliation released to clergy then their information will not be included on the community clergy list. Chaplains employed by UNC HCS are not considered community clergy, and will receive patient information to perform their patient care responsibilities.

b. Family Members/Friends.

When the requirements of subsections i and ii below are met, UNC HCS may (i) use or disclose to a family member, other relative, or a close personal friend of the patient, or any other person identified by the patient, PHI directly relevant to such person’s involvement with the patient’s care or payment related to the patient's care; and (ii) use or disclose PHI to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the patient, or another person responsible for the care of the patient, of the patient’s location, general condition, or death.

i. If the patient is present at the time of or prior to the use or disclosure and has the capacity to make decisions, the use or disclosure may be made if (i) the patient’s consent is obtained; (ii) the patient is provided with an opportunity to object and the patient does not object; or (iii) it is reasonably inferred from the circumstances, using professional judgment, that the individual does not object to the disclosure.

ii. If the patient is not present at the time of or prior to the use or disclosure or the opportunity to object to the use or disclosure cannot practicably be provided due to the patient’s incapacity or in an emergency, the use or disclosure may be made if the disclosure is in the best interest of the patient, using professional judgment, and, if so, only the PHI which is directly relevant to the person’s involvement with the patient’s health care may be disclosed. UNC HCS may use professional judgment and experience with common practice to make reasonable inferences regarding the patient’s best interest in allowing a person to act on behalf of the patient to pick up filled prescriptions, medical supplies, x-rays, or other similar forms of PHI.

At the first point of contact with the patient or the legal representative, he/she must be informed of the proposed use and disclosure of this information, and of his/her right to prohibit or to restrict any of these uses or disclosures. If the opportunity to prohibit or restrict any of these uses or disclosures cannot be provided to a patient due to incapacity or emergency, the information may be used or disclosed if the disclosure is consistent with a prior expressed preference by the patient, if any, that is known to UNC HCS, and the disclosure is determined, in the exercise of professional judgment, to be in the best interest of the patient. Under such circumstances, the patient must be informed and then allowed to prohibit or restrict such uses and disclosures when it becomes practicable to do so.
If a patient “opts out” regarding his or her family and friends, as long as the patient is not deceased or incapacitated, UNC HCS will honor the “opt out”.

If a patient who has “opted out” later becomes incapacitated or dies, the care providers will determine the individual who serves as the patient’s authorized representative. (See UNC HCS Policy ADMIN 0019, “Authorized Representatives of Patients”.) After making this determination, the care providers will provide to the authorized representative all PHI necessary to permit the authorized representative to make decisions on behalf of the patient.

c. Disaster Relief. UNC HCS may use or disclose PHI to a public or private entity authorized by law or its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted above. The requirements listed above apply to the extent that it is determined, using professional judgment that the requirements do not interfere with the ability to respond to the emergency circumstances.

Consent, Authorization, Agreement Not Required

The following is a list of the types of uses and disclosures which do not require a consent or an authorization or the opportunity to opt out. In each case, reference should be made to the Medical Information Management Release of PHI policy regarding the specific situations.

a. Disclosure required by law

PHI may be used or disclosed if and to the extent required by law.

b. Public health activities

PHI may be used or disclosed to a public health authority that is authorized by law to collect or receive such information for preventing or controlling disease, injury or disability, including public health issues, vital records, child or adult abuse or neglect; adverse food or drug events, and investigations of work-related illnesses or injuries as required under law.

c. Victims of abuse, neglect, or domestic violence

PHI may be used or disclosed to a government authority, including a social service or protective service agency, which is investigating a report of abuse, neglect or domestic violence to the extent the disclosure is required or permitted by law.

d. Health oversight activities

With certain exceptions, as outlined in the UNC HCS Release of PHI policy, PHI may be used or disclosed to a health oversight agency for oversight activities authorized by law, including audits, civil, administrative or criminal investigations or proceedings, inspections, licensure or disciplinary actions, or other activities for oversight of UNC HCS or other government benefit or regulatory programs (e.g., JCAHO).

e. Judicial and Administrative Proceedings

PHI may be disclosed in the course of a judicial or administrative proceeding in response to an order of a court or administrative tribunal, a subpoena, discovery request or other lawful process with certain assurances, as addressed in the Medical Information Management Release of PHI policy.

f. Law Enforcement Purposes
PHI may be disclosed for law enforcement purposes to a law enforcement official under certain conditions, as addressed in the UNC HCS Releases of PHI to Law Enforcement Officers policy.

g. Decedents.
PHI regarding decedents may be disclosed to coroners, medical examiners and funeral directors if necessary to carry out the duties of their positions.

h. Cadaveric organ, eye, or tissue donation.
PHI may be disclosed to organ procurement, banking or transplantation organizations to facilitate organ, eye or tissue donation and transplantation.

i. Research.
Without authorization: PHI may be used in research without an individual's authorization if an IRB grants a waiver of the requirement for authorization, or if there is an informed consent signed before April 14, 2003, or an IRB waiver of informed consent approved before April 14, 2003. There are also four research scenarios that require neither authorization nor waiver of authorization: (1) reviews preparatory to research, (2) research on decedent's information, (3) research use of a "limited data set" under a data use agreement, and (4) research use of de-identified data. For more complete information refer to the UNC HCS Release of PHI for Research Purposes policy.

j. Threats to Health or Safety.
PHI may be used or disclosed under certain circumstances if UNC HCS believes in good faith that the use or disclosure is necessary to protect a person or the public.

k. Specialized Government Functions.
PHI may be used or disclosed for specialized government functions such as military and veterans activities, security and intelligence activities, protective services for officials, medical suitability, and correctional institutions.

l. Workers’ Compensation.
PHI may be used or disclosed to the extent required to comply with workers’ compensation and similar programs.

Specific Patient Rights

a. Right to accounting of disclosures
A patient has the right to receive an accounting of the disclosures of PHI made by UNC HCS entities in the 6 years prior to the request except for disclosures: (1) for payment, treatment and health care operations, (2) to the individual patient, (3) incident to a use or disclosure otherwise permitted by HIPAA, (4) pursuant to an authorization, (5) for the entity’s directory or to persons involved in the individual’s care as allowed in Section V above, (6) for national security or intelligence purposes, (7) to correctional institutions or law enforcement officials, (8) made as part of a “limited data set”, as defined in the applicable entity's research policies, or (9) made prior to the compliance date. Documentation including titles or departments responsible for providing accountings of disclosure must be retained for no less than 6 years. Requests for accounting of disclosures should be referred to the appropriate UNC HCS Privacy Officer.

b. Right to amendment of PHI
d. The patient has the right to have UNC HCS amend his/her PHI for as long as UNC HCS maintains the information. Requests for amendments should be referred to the Medical Information Management Department.

e. Right of access to PHI

f. The patient has a right to inspect and receive a copy of his/her PHI that is used, in whole or in part, to make decisions about the patient, for as long as UNC HCS maintains the information. However, the patient/authorized representative does not have an automatic right to access: (1) psychotherapy notes; (2) information compiled in anticipation of a criminal, civil or administrative action or proceeding; or (3) PHI that is maintained by an entity that is subject to Clinical Laboratory Improvement Amendments (CLIA), to the extent provision of access would be prohibited by law, or exempted from CLIA. Requests for access to PHI should be referred to the Medical Information Management Department, with certain exceptions noted in the UNC HCS Policy ADMIN 0034, "Patient Right to Access, Inspect and/or Obtain a Copy of Protected Health Information (PHI)."

g. Right to request additional privacy protection

h. A patient has the right to request that UNC HCS restrict: (1) uses and disclosures for treatment, payment and health care operations; and (2) disclosures permitted for involvement in the patient's care and for notification purposes. UNC HCS is not required to agree to the restriction; however, if UNC HCS agrees to the restriction, it must abide by it except in emergencies. The restriction must be properly documented and maintained for 6 years. The restriction may be terminated by: (1) written agreement or request of the individual; (2) written documentation of an oral agreement or request of the individual; or (3) written documentation of notification to the individual by UNC HCS that it is terminating its agreement to the restriction, provided that the termination is only effective for PHI created or received after such written notification. Requests for restrictions on uses and disclosures of PHI should be referred to the appropriate UNC HCS Privacy Officer for further research and coordination with the involved entity.

i. Right to Complain about Privacy and Security Policies and Procedures

j. Patients have a right to complain about UNC HCS policies and procedures regarding privacy and security of their PHI. Patients may complain to the appropriate UNC HCS Privacy Officer for the involved entity. The appropriate UNC HCS Privacy Officer will develop and maintain procedures regarding coordination, documentation and resolution of any such patient complaints.

k. Refraining from Intimidating or Retaliatory Acts

l. Neither UNC HCS nor any of its employees or contractors may intimidate, threaten, coerce, discriminate against, or take any other retaliatory action against (1) any individual (including patients and employees) for exercising his/her rights under this policy or HIPAA, or participating in any process established by this policy or HIPAA, including filing a complaint; or (2) any individual (including patients and employees) or entity for (i) filing a complaint with the Secretary of DHHS under HIPAA, (ii) testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under any section of HIPAA (Part C of Title XI of the Social Security Act), or (iii) opposing any act or practice which is unlawful under HIPAA, as long as the individual or entity has a good faith belief that the practice is unlawful, and the manner of opposition is reasonable and does not involve a disclosure of PHI in violation of HIPAA.

m. Waiver of Rights
n. UNC HCS may not require an individual to waive his/her rights under this policy or HIPAA as a condition of treatment, payment, enrollment in a health plan, or eligibility for benefits.

Physical and Electronic Security of PHI

HIPAA and other legislation require physical and electronic security to maintain the privacy of PHI. This includes physical and electronic access to PHI through all forms such as written, spoken, pictorial, recorded electronically, or printed. See security requirements contained in the UNC HCS Information Security policies.

Breaches of Privacy or Security

If any UNC HCS employee or contractor becomes aware of a breach of this policy or any related departmental policies, or any other breach of privacy or security of PHI, the employee or contractor is required to report the breach to the appropriate UNC HCS Privacy Officer or the involved entity’s Privacy or Security Officer. UNC HCS will mitigate, to the extent practicable, any known harmful effect of a use or disclosure of PHI in violation of this or any similar policies and procedures, or the requirements of HIPAA. Any UNC HCS employee or contractor who is found to be in violation of any part of this policy is subject to disciplinary action up to and including dismissal (refer to the applicable entity’s Human Resources policies).

Penalties

UNC HCS and its employees or contractors who violate HIPAA may be subject to both civil and criminal penalties under HIPAA regulations. Civil money penalties are $100 per incident, up to $25,000 per person, per year, per standard. Federal criminal penalties range from $50,000 to $250,000 in fines and up to 10 years in prison.

Documentation

UNC HCS shall maintain all versions of its policies and procedures relating to HIPAA, required communications, activities and designations for a period of six years from the date of creation or the date when it last was in effect, whichever is later.