Northwestern Medicine®

CORPORATE COMPLIANCE POLICY

Department/Category: **CORPORATE COMPLIANCE AND INEGRITY**	Page **1 of 19**	Policy # **CCI 04.0041**
Title: **RESEARCH PRIVACY AND CONFIDENTIALITY**	Revision of: **09/01/2021**	Effective Date: **04/27/2023**
		Next Review: **04/27/2026**

SCOPE: Applies to entities indicated below as well as their subsidiaries and affiliates

☒ **NM – Northwestern Memorial Hospital**	☒ **NM – Lake Forest Hospital**
☒ **NM – Northwestern Medical Group**	☒ **NM – Central DuPage Hospital**
☒ **NM – Regional Medical Group**	☒ **NM – Delnor Hospital**
☒ **NM – Kishwaukee Hospital**	☒ **NM – Valley West Hospital**
☒ **NM – Marianjoy Rehabilitation**	☒ **NM – Palos Community Hospital**
☒ **NM – Huntley Hospital /** ☒ **NM – McHenry Hospital /** ☒ **NM – Woodstock Hospital**	
☒ **NM – System Functions / NMHC Employees**	
☐ **NM – Other **See "Scope/Persons/Areas Affected" Section below****	

I. PURPOSE:

This Policy establishes Northwestern Memorial HealthCare ("NMHC") standards, responsibilities and behavioral expectations regarding obtaining, creating, using, and/or disclosing patients' Protected Health Information ("PHI") in accordance with applicable state and federal laws and regulations, including, but not limited to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), for Research purposes.

II. POLICY STATEMENT:

A. NMHC is committed to supporting the advancement of medical science and knowledge through Research in a manner consistent with all applicable state and federal laws and regulations, including, but not limited to HIPAA. NMHC protects the privacy and confidentiality of PHI by allowing Use and Disclosure of PHI for Research purposes only through the pathways set forth below and as further described within this Policy:

1. A HIPAA-compliant Authorization containing required elements of other applicable state and federal law;
2. Waiver of Authorization as approved by an Institutional Review Board ("IRB") or Privacy Board;
3. Uses and Disclosures not requiring Authorization or IRB waiver of Authorization:
   a. Research on Decedents
   b. Preparatory to Research
   c. De-identified data
   d. Limited Data Set with Data Use Agreement
4. Research-related purposes performed by a business associate.

B. Research participants shall also be provided certain Research rights as described further in this Policy, including the right to revoke their Authorization and to obtain an accounting of Disclosures made for Research purposes where no Authorization exists.

III. SCOPE/PERSONS/AREAS AFFECTED:

This Policy applies to all Workforce (as defined herein), as well as to any individual conducting Research at NMHC facilities or requiring NMHC information for Research ("Researcher").

IV. DEFINITIONS:

See *Appendix A: Definitions*.

V. RESPONSIBILITIES:

A. Implementation: The NMHC Office of Corporate Compliance & Integrity ("CCI") and the NMHC Office of Research shall be responsible for implementing this Policy. CCI shall be responsible for receiving and investigating privacy complaints under this Policy and pursuant to NMHC Policy CCI 01.0101, *Corporate Compliance & Integrity Compliance Investigations: Responsibilities & Procedures*.

B. Training: Feinberg School of Medicine shall train Researchers with respect to Use and Disclosure of PHI in connection with Research. CCI shall train Workforce with respect to Use and Disclosure of PHI in connection with Research.

C. Enforcement: CCI is responsible for enforcing this Policy.

VI. PROCEDURAL RESPONSIBILITIES:

A. General Rules Regarding Research

1. Prior Approval: In addition to complying with this policy, Researchers conducting Research at NMHC, or using NMHC information, must abide by the following:
   a. Researchers shall obtain IRB approval of their Research studies as required by law and NU and NMHC policies.
   b. All Research shall be conducted in accordance with the research protocol approved by the applicable IRB and only by Authorized/key personnel, or NMHC Workforce, listed on the IRB-approved protocol.
   c. If the Research has does not require review by an IRB (e.g., the Research does not qualify as human subjects research), then CCI will need to approve the Disclosure of PHI as set forth in this policy.
2. Additional Policies: Researchers conducting Research at NMHC or using NMHC information for Research must abide by all applicable NMHC policies including, but not limited to the following:
   a. NMHC Policy ADM 01.0002, *Reviewing Alleged Misconduct in Research*;
   b. NMHC Policy CCI 01.0015, *Privacy and Confidentiality: Patient Information*;
   c. NMHC Policy ADM 01.0050, *Quality Improvement and Research Approval*;
   d. NMHC ADM 01.0055, *Electronic Recruitment Through The Medical Record*;
   e. NMHC ADM 01.0054, *Visitation And Systems Access By Representatives Of Research Sponsors*; and
   f. Other applicable policies as promulgated by NMHC from time-to-time and of which Researchers are notified.

3. Data Steward: All releases of information for Research purposes from NMHC's Enterprise Data Warehouse (EDW) or releases of images for Research are subject to NMHC Data Steward approval processes.

4. Non-Feinberg NU Researchers: Researchers from Northwestern University, not affiliated with the Feinberg School of Medicine (Feinberg), must comply with Feinberg policies governing the conduct of Research, including those relating to privacy and security. Researchers must also complete required trainings. Applicable polices include, but are not limited to, Physical Device Security, Research Use of Electronic Medical Record Data, Data Security Plans for Information Used in Clinical Research, and the Security Training Policy.

5. Obtaining Information:

    a. Unless an exception is granted, in accordance with Feinberg policy, *FSM Research Use of Electronic Medical Record Data*, all Researchers must obtain information needed for Research from the EDW unless an exception is granted.

    b. The EDW staff shall provide the minimal information pursuant to the approved protocol needed to contact the patient and to assess eligibility for the research study. Researchers may contact the EDW directly for report or exception requests at nmedw@northwestern.edu.

    c. NMHC may grant a Researcher direct access to NMHC's electronic medical record(s) *only if* NMHC has received from the EDW a written exception confirming that direct access is necessary and that information required for recruitment is not available through the EDW.

    d. NU Researchers, who do not otherwise have access to NMHC systems (e.g. NMG physician), and are granted an exception to access the medical record directly, must gain access through the NMHC Office of Research Access Program process.

    e. Because of the additional requirements for confidentiality under Illinois state law and/or federal law for Sensitive Information, all Research studies and activities involving Sensitive Information must first be presented to the EDW.

6. Requirements for Maintaining the Research Record within Epic:

    a. Researchers shall record research information in Study Tracker as required by the FSM Clinical Research Participant and Study Information Tracking Policy. Data entered into Study Tracker is transferred to Epic to create research records.

    b. Researchers shall document clinically relevant research information in Epic.

    c. Northwestern University shall inform Researchers regarding appropriate content to place in Epic.

    d. The research record shall be included in NMHC's designated record set. See NMHC Policy CCI 01.0015*, Privacy and Confidentiality: Patient Information*.

7. Conversion to Research Information:

    a. Except where a Researcher is acting as a Business Associate to NMHC (e.g., recruitment, creating of a limited data set, de-identification), once PHI is provided to a Researcher in accordance with applicable law and this policy, the PHI ceases to be PHI and becomes research information, which may also be Personal Identifiable Information ("PII").

    b. The protection of research information and PII is the responsibility of the Researcher and the Researcher assumes liability for any unauthorized use or disclosure.

8. Supplemental Documents:

    a. Supplemental materials, consistent with this policy, may be developed from time-to-time to assist with implementation and ongoing administration of this policy. Such

materials may include, but are not limited to, training documents and Frequently Asked Questions.

B. Requirements For the Use or Disclosure of Protected Health Information for Research

1. Use or Disclosure Pursuant to an Authorization:

a. As a general rule, a HIPAA-compliant Authorization must be obtained from all Research participants prior to the Use or Disclosure of PHI for any Research-related purpose that is not otherwise permitted under this Policy. The HIPAA-required elements of an Authorization are listed in Appendix B. The HIPAA-compliant authorization may be incorporated in the research consent.

i. Northwestern University Principal Investigators must use HIPAA *Authorization Templates* available at the Consent Templates & HIPAA Requirements: Institutional Review Board (IRB) Office - Northwestern University.

ii. If the Research involves Sensitive Information, the Authorization form must be amended to reflect additional requirements set forth in *Appendix B*.

iii. If an Authorization is defective, then the Principal Investigator shall take steps to correct the Authorization and obtain a new Authorization from study participants. Notwithstanding the foregoing, NMHC, in its sole discretion, may waive the requirement or allow alternative methods to ensure that study participants are informed of required authorization elements.

b. Individuals authorized to sign an informed consent for Research may also sign the Authorization.

c. An Authorization is not required for creation, collection, Use or Disclosure by Researchers of information obtained directly from an individual (e.g., from an individual who contacts a Researcher directly in response to a general advertisement for a Research study) as opposed to NMHC.

d. The Principal Investigator must complete the Authorization template prior to enrolling any participants. The Principal Investigator will also be responsible for obtaining signed Authorizations from the individuals participating in a Research study.

e. The Principal Investigator must provide a copy of the signed Authorization to study participants (or their authorized representatives).

f. The Principal Investigator must ensure that a copy of each executed authorization is maintained in Study Tracker and can also be maintained in the Research participant's NMHC electronic medical record under the media tab.

g. Study participants may revoke their authorizations. See *Appendix F*.

h. An Authorization is generally required for a Case Report. The signed Authorization should be scanned into the patient's record.

2. Use or Disclosure Pursuant to a Waiver of Authorization:

a. NMHC may Use or Disclose PHI for Research purposes if an IRB or Privacy Board has waived the need for such Authorization in accordance with applicable law, including without limitation *45 CFR 164.512(i)*. There may be cases where NMHC will require an IRB or Privacy Board to issue a waiver of the HIPAA Authorization requirements. For example, a Researcher may require a list of NMHC patients meeting specified criteria, along with their contact information, so that the Researcher can send a survey to the patients as part of a research study. The only activity involving the patient is completion of the survey, and, other than the initial contact information, the Researcher will not require NMHC patient information to provide further PHI for purpose of the study. Study participants will not complete a HIPAA authorization. In this case, the applicable IRB or Privacy Board will need to issue a waiver of authorization in order for NMHC to provide the list of patients and their contact

information to the Researcher. The IRB or Privacy Board may grant a waiver provided that various privacy safeguards are put in place.

b. The applicable IRB or Privacy Board may waive, in whole or in part, the Authorization otherwise required under this policy for the Use or Disclosure of information for a Research study if the Principal Investigator provides the IRB or Privacy Board with documentation demonstrating that such Use or Disclosure satisfies the criteria set forth in *Appendix C*.

c. The Principal Investigator must complete a request for waiver of Authorization with the IRB or Privacy Board and submit the request to the IRB or Privacy Board for review and approval prior to conducting Research.

d. The Principal Investigator must provide documentation of the waiver approval when making a request for information from the NMHC Data Steward. NMHC will not approve any disclosure without such documentation.

e. Uses or Disclosures of PHI made pursuant to a waiver are subject to the minimum necessary requirements outlined in the approved protocol and HIPAA. When requesting PHI from NMHC, reasonable efforts must be made to limit PHI to the minimum amount of PHI necessary to accomplish the intended purpose of the Research.

f. Sensitive Information cannot be Used or Disclosed for Research pursuant to a waiver of Authorization without prior approval of the Data Steward.

3. Use or Disclosure of Decedent's Information:

   a. NMHC may, in accordance with *45 CFR 164.512(i)*, Disclose a decedent's PHI for Research without an Authorization if the Researcher provides the following information:

      i. Representation that the Use or Disclosure sought is solely for Research on the PHI of a decedent;

      ii. Documentation, at the request of NMHC, of the death of the individual about whom PHI is being sought; and

      iii. Representation that the PHI sought is necessary for the purposes of the Research.

   b. Uses or Disclosures of a decedent's PHI for Research purposes are subject to the Minimum Necessary requirements outlined in the approved protocol and HIPAA. When requesting PHI from NMHC, reasonable efforts must be made to limit Information to the minimum amount necessary to accomplish the intended purpose of the Research.

   c. Sensitive Information cannot be Used or Disclosed for decedent Research without prior approval of the Data Steward.

4. Use or Disclosure of Information Preparatory to Research:

   a. NMHC may, in accordance with *45 CFR 164.512(i)*, Use or Disclose PHI for Research without an Authorization provided that the Researcher makes the following representations:

      i. The Use or Disclosure of PHI sought is solely to prepare a Research protocol (including, without limitation, designing a study, assessing the feasibility of conducting a study, assessment of whether a sufficient and appropriate subject pool exists to support the study);

      ii. The Researcher shall not record (e.g., print) or remove (e.g., NU email address or NU server) PHI from NMHC; and

      iii. The PHI sought is necessary for the purpose of the Research.

b. Uses or Disclosures of Information Preparatory to Research are subject to the minimum necessary requirements outlined in HIPAA. When requesting PHI from NMHC, reasonable efforts must be made to limit PHI to the minimum necessary to accomplish the intended purpose of Research.

c. Sensitive Information cannot be Used or Disclosed for Preparatory to Research activities without prior approval of the Data Steward.

5. Use or Disclosure of "De-Identified" Health Information:

a. De-identified health information is not subject to HIPAA and may be Used or Disclosed for Research purposes in accordance with the standards set forth in *Appendix D* attached to this Policy.

b. The de-identified information may be assigned a "re-identification code" that can be affixed to the Research record that will permit the information to be re-identified, if necessary, provided that the key to such a code is not accessible to Researchers requesting to Use or Disclose the de-identified health information.

6. Use or Disclosure of a Limited Data Set:

a. NMHC may, in accordance with *45 CFR 514(e)*, Use and Disclose to Researchers a Limited Data Set for Research purposes.

b. A "Limited Data Set" may include any of the following direct identifiers:

i. Town, city, state and zip code; and

ii. All elements of dates directly related to an individual, including birth date, admission date, discharge date, and date of death.

c. A Limited Data Set must exclude all of the direct identifiers of the individual or of the relatives, employers, or household members of the individual as set forth in *Appendix E.*

d. Researchers may use an approved Limited Data Set only pursuant to an executed Data Use Agreement, which must be created and negotiated by the NMHC Office of General Counsel.

e. Limited Data Sets containing Sensitive Information cannot be Used or Disclosed to Researchers without prior approval of the Data Steward.

7. Recruitment:

a. Health Care Operations: Obtaining Authorizations as described in Section VI.B.1. above during Study Recruitment is considered a health care operation of NMHC, and Researchers, acting as either "Workforce" (if employed by NMHC) or a "business associate," conduct Recruitment on behalf of NMHC.

b. Recruiting Individuals as Part of Treatment: Treating Health Care Professionals at NMHC may discuss with their patient's treatment alternatives, which may include participating in a clinical trial. These treating Health Care Professionals and their research coordinators may obtain patient contact information directly from NMHC's electronic medical record and may communicate with patients face-to-face or by phone, letter or email.

c. Recruiting Individuals Where no Treatment Relationship Exists: NMHC Health Care Professionals or NU employed Researchers who are recruiting patients where no treatment relationship exists may recruit NMHC patients as follows:

i. Prior Permission to Recruit: Researchers do not need to obtain permission from an individual's treating provider prior to recruiting the individual.

ii. Face-to-Face: Face-to-face contact is allowed within NMHC facilities. For this purpose, a Researcher may receive names of potential study participants from the

EDW. Where necessary, direct access to NMHC's electronic medical records may also allowed where real-time data is required (e.g., checking patient schedules).

iii. Cold-Calling: Researchers who do not have a treatment relationship with an individual may contact that individual (i.e. as a potential study subject) by phone, email, or letter. Contact information for such "cold-contact" activity must be obtained from the EDW to ensure that patients who have indicated that they do not want to receive Recruitment emails, letters or phone calls are not contacted.

iv. Sensitive Information cannot be Used or Disclosed for Recruitment activities where no treatment relationship exists without prior approval of the Data Steward.

d. Patient Request Not to be Contacted:

i. If a patient indicates that he or she does not want to be contacted for Recruitment purposes, the patient should be instructed to call the NMHC Office of Research at

630-933-6528

ii. If a patient has indicated that he or she does not want to be contacted by Researchers, the NMHC Office of Research will set the "do not contact" flag in the electronic medical record, and the EDW staff will not release the patient's name to Researchers who wish to contact the patient for recruitment purposes by phone, email, or letter.

e. Research Communications: Researchers may create and send a letter to potential participants in accordance with the following procedures.

i. For paper letters, Researchers shall use NMHC letterhead compliant with NMHC branding standards.

ii. If email is used, the email shall be sent from an nm.org email address.

iii. The communication must state that the patient is being contacted "on behalf" of an NM clinical entity (e.g., Northwestern Memorial Hospital, Northwestern Memorial Regional Medical Group, Northwestern Medical Group, etc.). The purpose of this communication is to inform the recipient about a study and ask him or her to contact the Researcher for purposes of securing a HIPAA-compliant Authorization and research informed consent.

C. Individuals' Rights With Regard to Their Information:

1. Revocation of Authorization

a. As a general rule, a study participant may revoke his or her Authorization in writing to the Principal Investigator at any time. Upon receipt of revocation, NMHC shall cease to provide the study participant's PHI to Researchers involved in the affected study. However, Researchers may continue to use and disclose, for Research integrity and reporting purposes, any PHI collected about the study participant pursuant to a valid Authorization before it was revoked.

b. The revocation will be applicable to the protocol or protocols specified by the study participant.

c. The Principal Investigator shall forward a copy of the written revocation to the NMHC Office of Research; keep copies of all revocations of Authorizations for a specific protocol for at least six (6) years; and provide a copy to NMHC's Privacy Official upon request.

2. Access to PHI:

a. As a general rule, individuals who participate in Research have a right of access to their own PHI that is maintained by NMHC (or a third party that NMHC retains to provide services to or perform functions for NMHC).

b. However, individuals participating in a Research study that includes treatment (i.e. clinical trials) may be denied access to PHI in their medical records resulting from treatment provided as part of a Research study, provided that:

i. The information was obtained in the course of the Research;

ii. The individual agreed to the denial of access in the applicable Authorization;

iii. The Research study has not been completed; and

iv. The individual's rights to access such information is reinstated once the Research study has ended and the Research Authorization has expired.

c. In addition, information generated in the course of the Research that is not included in the medical record is not subject to the access requirement.

d. Individuals seeking access to their PHI should be directed to NMHC's Health Information Management Department or Patient Relations.

3. Accounting of Disclosures:

a. As a general rule, an individual must be provided with an accounting of all Disclosures of the individual's information used for Research purposes, unless such Disclosure was made pursuant to an Authorization, or is part of De-Identified Information or a Limited Data Set used pursuant to a Data Use Agreement.

b. Individuals seeking an accounting should be directed to NMHC's Health Information Management Department or Patient Relations.

VII. POLICY UPDATE SCHEDULE:

This policy is reviewed or updated every three (3) years or more often as appropriate.

VIII. REFERENCES:

A. NMHC Policy CCI 01.0015, *Privacy and Confidentiality: Patient Information*

B. NMHC Policy ADM 01.0002, *Reviewing Alleged Misconduct in Research*

C. Health Insurance Portability and Accountability Act Of 1996 (HIPAA)

D. Northwestern Medicine Feinberg School of Medicine, Information Security: *Research Use of Electronic Medical Record Data*

IX. APPENDICES:

A. Appendix A: Definitions

B. Appendix B: HIPAA Required Elements of an Authorization

C. Appendix C: Criteria for Waiver of HIPAA Authorization and Documentation of Waiver

D. Appendix D: De-identification Standards

E. Appendix E: Limited Data Set Standards

X. APPROVAL:

Responsible Party:	Kristin Kurczewski Director, Corporate Compliance and Integrity
Reviewers:	Office of General Counsel Office of Research Northwestern University, Feinberg School of Medicine Dean's Office
Committee:	N/A
Approval Party:	Jennifer Wooten Ierardi Vice President, Integrity Electronic Approval: 04/26/2023

XI. REVIEW HISTORY:

Written: 11/01/2019

Reviewed/Revised: 09/01/2021 – Palos Inclusion
11/01/2022
04/27/2023

APPENDIX A – RESEARCH PRIVACY POLICY DEFINITIONS

NOTE: Capitalized terms used throughout the policy shall be as defined below. If a term is not found below, the term shall be as defined under HIPAA.

A. **Authorization** is the written confirmation that a Research participant has voluntarily agreed, pursuant to an Authorization in the form required by this policy, to permit the use, sharing, copying and release of his or her current and future health information related to a particular Research study, after having been apprised of the types of persons permitted to make such uses and releases of health information, their rights in connection with that information, and the potential risks relevant to the participant's decision to permit use and release of health information.

B. **Authorized/Key Personnel** is anyone who engages in research with human subjects or their identifiable personal health information for the purposes of research as delegated by the PI. Engaging in research includes, but is not limited to; enrolling subjects in research, obtaining informed consent for research, intervening or interacting with research subjects (either invasively or non-invasively) as directed by a research protocol that deviates from their normal responsibilities of employment, and/or collecting identifiable private information directly from research subjects or their medical record.

C. **Case Report** means an unsystematic clinical observation that states the outcome or response of a single patient to a diagnostic strategy or treatment that is not subject to the Common Rule and therefore may not be subject to IRB review. However, since case reports describe unique or rare circumstances, there is a likelihood that a patient can be identified despite best efforts to remove identifiers from the report or publication.

D. **Data Steward** means the individual or that individual's designee responsible for approving releases of NMHC data from the EDW to Researchers in accordance with this Policy.

E. **Disclosure** means the release, transfer, provision of access to, or divulging/sharing of information outside of NMHC.

F. **Healthcare Professional** means a physician, nurse, nutritionist, therapist or other individual who is both trained in a particular area of health care delivery and directly involved in the delivery of clinical care to patients.

G. **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** is a federal regulation that, among other provisions, requires that patient information be kept private and secure.

H. **House Staff** are Residents and fellows at any NMHC location. Residents and fellows are generally not directly employed by NMHC, but they are included in the definition of NMHC Workforce in connection with their activities on NMHC premises and/or access to NMHC patient information.

I. **Institutional Review Board ("IRB")** shall include a board, committee, or other group formally designated by an institution to review Research involving humans as subjects. IRBs have authority to approve, require modification to, or disapprove all Research activities covered by the HHS and FDA Protection of Human Subjects Regulations.

J. **Medical Staff** are NMHC hospital medical staff members who are not employed by NMHC, but they are included in the definition of NMHC Workforce in connection to their activities on NMHC premises and/or access to NMHC patient information.

K. **Northwestern University** shall include all operations of Northwestern University, including, without limitation, all Northwestern University controlled Research centers and institutes.

L. **NMHC** includes Northwestern Memorial HealthCare and its current and future subsidiaries and affiliates.

M. **NMHC Workforce** includes NMHC: employees; volunteers; corporate officers; directors; board committee members; student trainees; temporary agency staff or leased employees;

House Staff and/or Medical Staff who: (a) hold a paid or unpaid medical administrative position (e.g., clinical Department Chairs, Section and Division Chiefs, or special care unit directors), (b) have procurement responsibility or the authority to recommend such procurement, or (c) participate on boards or board committees; and such other persons whose conduct is under the direct control of NMHC.

N. **Workforce** means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate. See 45 CFR § 160.103

O. **Preparatory to Research** means representations from the researcher, either in writing or orally, that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any protected health information from the covered entity, and representation that protected health information for which access is sought is necessary for the research purpose.

P. **Privacy Board** is a review body established to act upon requests for a waiver or an alteration of the HIPAA Authorization requirement under the HIPAA Privacy Rule for uses and disclosures of Protected Health Information (PHI) for a particular research study.

Q. **Protected Health Information ("PHI")** is broadly defined and includes any health information, including demographic information, that can be used to identify the individual, or there is a reasonable basis to believe that the information can be used to identify the individual, and is created or received by a healthcare provider, and relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future Payment for the provision of healthcare to an individual.

R. **Psychotherapy Notes** means notes recorded (in any medium) by a healthcare provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the of the individual's medical record. The definition of psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of Treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the Treatment plan, symptoms, prognosis, and progress to date.

S. **Recruitment** of subjects for a Research study includes (1) review of PHI for the purpose of identifying specific individuals to enroll as study participants, and (2) contacting such individuals for purposes of enrolling them in the study and obtaining the individual's written Authorization. Recruitment does not include review of PHI for purposes of ascertaining whether or not sufficient and appropriate pool of subjects exists to support the Research Study.

T. **Research** means a systematic investigation, including Research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

U. **Researcher** means individuals, including students, conducting Research at NMHC facilities involving NMHC patients or utilizing NMHC patient information.

V. **Sensitive Information** includes PHI relating to HIV/AIDS, behavioral or mental health, developmental disabilities, treatment for substance (alcohol and/or drugs) use disorder, genetic testing, or genetic counseling. For minors, sensitive information also includes PHI relating to treatment or services that the minor can legally consent to without a parent or guardian. See NMHC Policy HIM 01.3006, *Responding to a Request for the Patient Medical Record* for more information.

W. **Study Tracker** is a research subject tracking tool. All clinical studies overseen by the Northwestern University Institutional Review Board involving Feinberg faculty are required to record participants in this tool.

X. **Use** means the sharing, employment, application, utilization, examination, or analysis of identifiable health information.

APPENDIX A:
Research Privacy and Confidentiality Policy Definitions

Kristin Kurczewski
Director, Corporate Compliance and Integrity

Effective Date: 04/27/2023

REVIEW HISTORY

Written: 11/01/2019
Reviewed/Revised: 09/01/2021 – Palos Inclusion
11/01/2022
04/27/2023

APPENDIX B – HIPAA AUTHORIZATION

I. HIPAA-Required Elements of an Authorization

A. Under HIPAA, the following core elements and statements must be included in the Authorization document.

1. A description of the PHI to be Used or Disclosed in a specific and meaningful fashion (e.g., list the types of data to be collected from the medical record);
2. The name of the person(s) or class of persons to whom NMHC may make the requested Use or Disclosure (i.e. Researchers must list all of the entities [by name or by class] that might have access to the study's PHI such as the IRB, NU representatives, sponsors, Food and Drug Administration, study monitors, data safety and monitoring board or any others given authority by law);
3. A description for each purpose of the requested Use or Disclosure (e.g., to be able to conduct the Research and to ensure that the Research meets legal, institutional, or accreditation requirements);
4. An expiration date or an expiration event that relates to the Use or Disclosure (i.e. length of time Researchers plan to maintain the data). The statement "end of Research study," "none," or similar language is sufficient;
5. A description of how the individual may revoke the Authorization and the exceptions to the revocation. The study participants must be told how they can withdraw. Any request for revocation must be in writing. Also, the study participants should be told that if they do revoke, they can no longer participate in Research, but Researchers may use the information already obtained to maintain the integrity of the study;
6. A statement that a study participant's treatment, payment or enrollment in any health plan or their eligibility for benefits will not be affected if the study participant refuses to sign the Authorization;
7. A statement that the study participant may not participate in a Research study if the study participant refuses to sign the Authorization; and
8. An explanation that PHI Disclosed pursuant to the Authorization may no longer be protected when re-disclosed by the recipient (i.e. if the Researchers disclose the information collected to a third party, then the HIPAA protections may no longer be in place);
9. A signature of the individual and date. If a personal representative signs the Authorization, a description of the representative's authority must be provided.

B. The Authorization must be written in plain language.

C. The study participant must be given a copy of the signed Authorization.

D. Optional item: Under HIPAA, subjects have the right to access their PHI. In Research, this right can be suspended while the Research is in progress. However, subjects must be told in the Authorization that this right has been suspended and the conditions of the suspension must be listed. The subjects should also be informed that their right to access the PHI will be reinstated at the conclusion of the Research study.

II. Sensitive Information

A. If the Research study involves the Use and/or Disclosure of Sensitive Information, then the Authorization must expressly reference the type of Sensitive Information (e.g., mental health, genetic counseling, etc.).

B. If the Research study involves the Use and/or Disclosure of mental health, developmental disabilities, or genetic counseling information, then the HIPAA Authorization must also contain the following:

1. An expiration date based on an actual date (i.e. day, month, year);
2. A statement that the study participant has the right to inspect and copy the PHI Disclosed by NMHC; and
3. A signature by a witness.

APPENDIX B:
HIPAA Authorization

Kristin Kurczewski
Director, Corporate Compliance and Integrity

Effective Date: 04/27/2023

REVIEW HISTORY

Written: 11/01/2019
Reviewed/Revised: 09/01/2021 – Palos Inclusion
11/01/2022
04/27/2023

APPENDIX C –CRITERIA FOR WAIVER OF AUTHORIZATION AND DOCUMENTATION

I. Criteria for Waiver of HIPAA Authorization

A. The Use or Disclosure of information involves no more than a minimal risk to the privacy of individuals, based on the presence of at least the following elements:

1. An adequate plan to protect the identifiers from improper Use and Disclosure;
2. 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; and
3. Adequate written assurances that the 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 information would be permitted by this Policy;

B. The Research could not practicably be conducted without the waiver; and

C. The Research could not practicably be conducted without access to and use of the information.

II. Criteria for Documentation of the Waiver of Authorization

A. A statement identifying the IRB or Privacy Board and the date on which the waiver request was approved;

B. A statement that the IRB or Privacy Board determined that the waiver request satisfied the criteria for the waiver;

C. A statement that the waiver has been reviewed and approved under either normal or expedited review procedures; and

D. The documentation is signed by the IRB or Privacy Board chair or their designee.

APPENDIX C:
Criteria for Waiver

Kristin Kurczewski
Director, Corporate Compliance and Integrity

Effective Date: 04/27/2023

REVIEW HISTORY

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APPENDIX D – DE-IDENTIFICATION STANDARDS

De-identified PHI neither identifies nor provides a reasonable basis to identify an individual. As discussed below, the Privacy Rule provides two de-identification methods: 1) a formal determination by a qualified expert; or 2) the removal of specified individual identifiers as well as absence of actual knowledge by NMHC that the remaining information could be used alone or in combination with other information to identify the individual. Although there is still a very small risk of identification based on both methods, the Privacy Rule does not restrict the Use or Disclosure of de-identified health information, as it is no longer considered protected health information.

A. The 18 elements of individually identifiable health information are:

1. Names;
2. Geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and equivalent geo-codes, except for the initial three digits of a zip code to 000;
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locator (URL);
15. Biometric identifiers, including finger or voice prints;
16. Full face photographic images and any comparable images;
17. Internet Protocol address numbers; and
18. Any other unique identifying number characteristic or code

B. PHI can be de-identified if:

1. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

    a. Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

    b. Documents the methods and results of the analysis that justify such determination.

2. All 18 elements of individually identifiable health information are removed and if the Covered Entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

APPENDIX D:
De-Identification Standards

Kristin Kurczewski
Director, Corporate Compliance and Integrity

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APPENDIX E – LIMITED DATA SET

A. Limited Data Set: NMHC can Disclose PHI for purposes of Research, Public Health or Healthcare Operations if (1) the PHI has been stripped of all identifiers listed in the definition of Limited Data Set as listed in par. F below; and (2) NMHC obtains a Data Use Agreement from the person who is requesting the limited data set. A Limited Data Set is still considered to contain PHI, so the same prohibitions on the sale of PHI apply to a Limited Data Set.

B. Data Use Agreement: The Data Use Agreement shall be approved by the Office of General Counsel and must contain the following elements:

1. A description of the permitted Uses and Disclosures of the Limited Data Set, which must be limited to and consistent with Public Health, Research or Healthcare Operations purposes;
2. A description of those persons who are permitted to use or receive the Limited Data Set;
3. A statement requiring that the Limited Data Set recipient shall:
   a. Not Use or further Disclose the information other than as permitted in the Data Use Agreement or as required by law;
   b. Use appropriate safeguards to prevent the Use or Disclosure of the information other than as permitted in the Data Use Agreement;
   c. Report to NMHC any Use or Disclosure of the information that is not permitted by the Data Use Agreement of which it becomes aware;
   d. Ensure that any of its agents or subcontractors to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply to the Limited Data Set recipient; and
   e. Not identify the information or contact the Individuals who are the subject of the information.

C. Who May Create Limited Data Set

Individuals who have a need to create a limited data set should contact CCI or OGC for guidance.

D. Non-Compliant Limited Data Set Recipients

If at any time NMHC becomes aware that a recipient of a Limited Data Set has violated his/her/its Data Use Agreement, then NMHC shall:

1. Take reasonable steps to end the breach of the agreement or cause the breach to be cured; or
2. If the breach cannot be ended or cured, then stop Disclosing the Limited Data Set or other PHI to the recipient and report the problem to the Secretary of Health and Human Services.

E. Applicability of Minimum Necessary and Accounting Rules

1. Because the Limited Data Set that is released is already limited in nature, the HIPAA Minimum Necessary Rule, which requires the Use or Disclosure of only the minimum necessary PHI necessary to accomplish the purpose for which the Use or Disclosure is made, is not applicable, however the amount of PHI disclosed should be limited to the amount that is reasonably necessary to accomplish the purpose.
2. Limited Data Set Disclosures do not need to be included in an accounting of Disclosures.

F. NMHC may disclose PHI for purposes of Research, public health, or healthcare operations if the PHI has been stripped of identifiers according to the definition of Limited Data Set below, and if NMHC obtains a Data Use Agreement from the person or entity requesting the PHI.

1. Limited Data Set: To create a Limited Data Set, the PHI must be stripped of all identifiers of the individual or relatives, employers, or household members of the individual:

   a. Names;

b. Postal address information, other than town or city, state, and zip code;
c. Telephone numbers;
d. Electronic mail addresses;
e. Social Security numbers;
f. Medical record numbers;
g. Health plan beneficiary numbers;
h. Account numbers;
i. Certificate/license numbers;
j. Vehicle identifiers and serial numbers, including license plate numbers;
k. Device identifiers and serial numbers;
l. Web Universal Resource Locations (URLs);
m. Internet Protocol (IP) address numbers;
n. Biometric identifiers, including finger and voice prints; and
o. Full face photographic images and any comparable images.

APPENDIX E:
Limited Data Set

Kristin Kurczewski
Director, Corporate Compliance and Integrity

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