Guidance for Research That Involves Use of Protected Mental Health and/or Developmental Disabilities Information

Overview:

The purpose of this guidance is to highlight considerations for the use of protected health information covered by the Illinois Mental Health & Developmental Disabilities Confidentiality Act (MHDDCA), for research-related purposes. This guidance applies to research protocols that are limited to secondary data analysis and studies that involve in-person interactions/interventions.

MHDDCA citations referenced within this guidance originate from the following Illinois General Assembly web source: http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2043&ChapterID=57

Definitions: The following section of this guidance includes a list of terms most relevant to research-related activities. See Section 2 of the MHDDCA for the comprehensive list of related terms.

*"**Confidential Communication**" or "communication" means any communication made by a recipient or other person to a therapist or to/in presence of other persons during or in connection with providing mental health or developmental disability services to a recipient. Communication includes information which indicates a person is a recipient.* *Note: "Communication" does not include information that has been de-identified in accordance with HIPAA, as specified in 45 CFR 164.514
***"Covered Entity"** has the meaning ascribed to it under HIPAA, as specified in 45CFR 160.103.*
*"**HIPAA**" means the Health Insurance Portability and Accountability Act.* Note: the HIPAA Authorization Worksheet (HRP-330) provides more details about Waivers of HIPAA Authorization, and when they are valid. The following excerpt about HIPAA, also referred to as the Privacy Rule, is from the US Department of Health and Human Services (HHS): *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 provisions that are similar to, but separate from, the Privacy Rule's provisions for research. These human subject protection regulations, which apply to most Federally-funded and to some privately funded research, include protections to help ensure the privacy of subjects and the confidentiality of information. The Privacy Rule builds upon these existing Federal protections. More importantly, the Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.*
*"**Mental health or developmental disabilities services**" includes, but is not limited to: examination, diagnosis, evaluation, treatment, training, pharmaceuticals, aftercare, habilitation or rehabilitation.*

"Recipient" *means a person who is receiving or has received mental health or developmental disabilities services.*
*"**Record**" means any record kept by a therapist or by an agency in the course of providing mental health or developmental disabilities service to a recipient concerning the recipient and the services provided.* Note: "Record" does not include information that has been de-identified in accordance with HIPAA, as specified in 45 CFR 164.514. "Record" also does not include a reference to the receipt of mental health or developmental disabilities services noted during a patient history by a physician or other summary of care.
"***Therapist***" *means a psychiatrist, physician, psychologist, social worker, or nurse providing mental health or developmental disabilities services or any other person not prohibited by law from providing such services or from holding himself out as a therapist if the recipient reasonably believes that such person is permitted to do so. Therapist includes any successor of the therapist.* Note: Genetic Counselors and Primary Care Physicians would also be persons to whom this law applies.

Consent Requirements:

Section 4 of the MHDDCA explicitly details a list of persons who are entitled, upon request, to inspect and copy a recipient's record. When considering the use of mental health and/or developmental disabilities data for research purposes, the IRB requires that all required processes are in place to properly document consent (or parent permission with assent, or legally authorized representative (LAR) if applicable).

[**Except as provided in Sections 6 through 12.2 of the Act] Records and communications may be disclosed to someone other than those persons listed in Section 4 of the Act only with the written consent of those persons who are entitled to inspect and copy a recipient's record.

Key elements required by MHDDCA relevant to research:

Every consent form shall be in writing and shall specify the following:

(1) the person or agency to whom disclosure is to be made;

(2) the purpose for which disclosure is to be made;

(3) the nature of the information to be disclosed;

(4) the right to inspect and copy the information to be disclosed;

(5) the consequences of a refusal to consent, if any; and

(6) the calendar date on which the consent expires (provided that if no calendar date is stated, information may be released only on the day the consent form is received by the therapist;) and

(7) the right to revoke the consent at any time.

The consent form shall be signed by the person entitled to give consent, and the signature shall be *witnessed by a person who can attest to the identity of the person so entitled* (note that the 'witness' signature on the NU IRB consent template may or may not be the same as the study team member who signs to 'obtain' consent, depending on the pre-existing relationship and/or established processes in place that can confirm identity). The *witness must see the participant actually sign the consent form*.

A copy of the consent and a notation as to any action taken thereon must be entered in the recipient's record. Any revocation of consent must be in writing, signed by the person who gave the consent, and the signature shall be witnessed by a person who can attest to the identity of the person so entitled.

Further, only information relevant to the purpose for which disclosure is sought may be disclosed. Blanket consent to the disclosure of unspecified information shall not be valid. Advance consent may be valid only if the nature of the information to be disclosed is specified in detail and the duration of the consent is indicated. Consent may be revoked in writing at any time, and any such revocation shall have no effect on disclosures made prior thereto.

**The following are provisions for the use of the recipient's record that are most common in NU research.

- Section 7 of the Act details provisions for the review of a therapist or agency:

  When a therapist or agency which provides services is being reviewed for purposes of licensure, statistical compilation, research, evaluation, or other similar purpose, a recipient's record may be used by the person conducting the review to the extent that this is necessary to accomplish the purpose of the review, provided that personally identifiable data is removed from the record before use.

- Section 9 of the Act details provisions for when protected information may be shared with the Institute for Juvenile Research and the Institute for the Study of Developmental Disabilities.

Application: The following section of this guidance provides examples of common research protocols that involve accessing mental health and/or developmental disability information.

Research Protocols Limited to Secondary Data Analysis:

Data sets that include identifiable mental health and/or developmental disabilities information are subject to the requirements for disclosure of records and communication detailed above.

If information is de-identified in accordance with HIPAA (e.g., provided to the research team with all identifiers already removed), consent is not required.

If protected health is coming from NMHC, policies governing the Electronic Data Warehouse (EDW) must be followed to comply with MHDDCA. EDW will ensure that the data provided will comply with the laws

stated above. If an EDW waiver will be requested, you must provide details of how you will ensure you will comply with the above-mentioned law.

More information about NMHC and Feinberg School of Medicine's requirements for the use of the EDW and related policies can be found here: https://www.feinberg.northwestern.edu/it/policies/research-use-of-edw-data.html

Otherwise, if private, identifiable mental health and/or developmental disabilities information is accessed from a covered entity other than NMHC, it is the IRB's expectation that all of the MHDDCA consent requirements detailed above are met. Additionally, any site-specific policies and procedures should be clearly detailed within the application to facilitate IRB review of any potential local context considerations.

Research Procedures that include interactions and/or interventions with participants in conjunction with accessing protected identifiable mental health and/or developmental disabilities information:

It is expected that written documentation of consent from those persons entitled to inspect and copy a recipient's record be obtained before any research activities occur. All of the identified MHDDCA requirements for consent must also be included in the consent template.

If NMHC is providing the protected health information, then the HIPAA Authorization language included in NU IRB-approved informed consent form templates must be used (Social Behavioral Consent Document w/HIPAA HRP-1721 OR Biomedical Consent Document, HRP-592). All sections applicable to mental health and developmental disabilities information must be included (e.g., statement about the right to copy/inspect records, expiration date, documentation of witness signature). See the Biomedical & Social Behavioral Consent Templates Page.

If protected health information will be obtained from a covered entity other than NMHC, the PI will need to include the site-specific HIPAA Authorization and any other local context information in the application for IRB review.