Northwestern | OFFICE FOR RESEARCH

Considerations for Research that Involves Use of Mental Health and/or Developmental Disabilities Information

Beth Irwin, MA, LPC
Senior IRB Analyst
Institutional Review Board Office

Trust is the highest honor and obligation in research

Objectives

- Review the Illinois Mental Health & Developmental Disabilities Confidentiality Act (MHDDCA)
  - Terms most relevant to research-related purposes
- Identify considerations for use of protected mental health information covered by MHDDCA
  - Protocols that include secondary data analysis
  - Consent Requirements
- Apply knowledge to examples of common research protocols that involve accessing mental health and/or developmental disability information.
  - NMHC compared to other covered entities
- Discuss ethical considerations pertaining to mental health information
  - Self-reports and assessments of SI/SA and trauma-related information

Regulatory: IL State Law

MHDDCA

- Illinois General Assembly web source: http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2043&ChapterID=57

- Pertains to all confidential records and communications made or created in the course of providing mental health or developmental disability services in the State of IL.
  - Protects records from disclosure, regardless of whether they are made or created in the therapeutic relationship

Relevant Terms

Confidential Communication	***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.*** ***Does not include information that has been de-identified in accordance with HIPAA, as specified in 45 CFR 164.514**
Mental health or developmental disabilities services	***Includes, but is not limited to examination, diagnosis, evaluation, treatment, training, pharmaceuticals, aftercare, habilitation or rehabilitation.***
Recipient	***A person who is receiving or has received mental health or developmental disabilities services.***
Record	***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.*** **"Record" 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	***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. Also includes any successor of the therapist.***

Research Considerations

- Secondary-Data Analysis
  - If information has been de-identified in accordance with HIPAA (specified in 45 CFR 164.514) then consent is not required.
  - Waivers **cannot** be applied when MHDDCA protected information is accessed if consent is not in place.

- Required processes to properly document consent (or parent permission with assent, or legally authorized representative (LAR) if applicable) must be in place and **witnessed** by a person who can attest to the identity of the person so entitled.
  - *Except as provided in Sections 6 through 12.2 of the Act

Consent Requirements

Consent Requirements

Every consent form shall be in writing and 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.

Consent Considerations

- The signature *shall be witnessed by a person who can attest to the identity of the person so entitled*
- Copy of the consent document must be placed in the confidential record
- Any revocation of consent must be in writing
- Only information relevant to the purpose for which disclosure is sought may be disclosed. *Blanket consent* to the disclosure of unspecified information is invalid.
- There are some instances where minors may 'consent' without parent permission:
  - Based on legal status (e.g. Emancipated minors with court order, Pregnant or married minors)
  - Minors 12+ years may receive services/counseling related to diagnosis & treatment of STDs, drug use or alcohol consumption, outpatient mental health services (12-16 yrs, eight 90 min sessions)
    - Providers may not inform parents without minors consent unless deemed necessary to protect safety
    - Just because a provider need not obtain consent for services does NOT meant the criteria for a wavier of parent permission for the minor to participate in research is automatically granted.

NU Protocols

Common Research at NU

- Limited to Secondary Data-Analysis
  - Accessing Medical Record Information
  - Treatment plan review
- Interactions and/or Interventions
  - Interviews
  - Surveys
  - Behavioral Interventions

NMHC vs Other Covered Entities

- If protected health is coming from NMHC, than policies governing use of the Electronic Data Warehouse (EDW) must be followed in order to comply with MHDDCA.
  - Protocols must reflect that EDW will be utilized to access health information
- 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 into the application for IRB review.
  - The Family Institute
  - Locations outside of IL

Ethical Considerations

Ethical Considerations

What is 'sensitive information'? Who is qualified to assess? Impacts of remote procedures?

- Direct Assessments related to Suicidal Ideation (SI) and/or plans for Suicidal Attempts (SA) should have an explicitly detailed data management plan within the protocol and expressly clarified within the consent.
  - Patient Health Questionnaire (PHQ-9) and Beck Depression Inventory (BDI) (Q9 on both)
  - "Calling 911" alone is insufficient.

- Qualifications of Study Team members are of the utmost importance. Direct interventions can only be made by appropriate licensed professionals
  - Illinois Department of Financial & Professional Regulations https://ilesonline.idfpr.illinois.gov/DFPR/Lookup/LicenseLookup.aspx

Ethical Consideration

- Assessments specifically related to traumatic experiences and/or asking participants to potentially relive a traumatic event, need to be appropriately managed
  - E.g. Do you consider COVID-19 to be a traumatic experience? **Vs.** Tell me about the most traumatic experience in your life; Did it include any of the following…;

- Need to be mindful about the impact of remote procedures
  - Don't ask questions the study team is not able/prepared to appropriately manage
  - How best to provide support/resources?
  - Ensure the participant is in a private location prior to the interview/survey/focus group
  - How to obtain written documentation of consent w/witness signature, if necessary

Check out the new NU *Guidance for Research that Involves Use of Protected Mental Health and Developmental Disabilities* Information on the IRB website!

Email the Social Behavioral Team to request an appointment for weekly remote drop-in hours!
sbsirb@northwestern.edu
Wednesdays 2:30-3:30pm

Questions? Thoughts? Wonders?