Research Updates

Agenda

• Use and disclosure of “sensitive information” for research

• Current NMHC initiatives affecting research

• Questions
Use and Disclosure of “Sensitive” Information for Research Purposes
Research Updates

Sensitive Information

• HIPAA generally preempts state and other federal law provisions that are contrary to HIPAA.
• Exceptions to HIPAA preemption include contrary law that is more protective of an individual. The more protective law survives.
• As a result, HIPAA is always the floor, with more protective law “on top” of HIPAA.

Being HIPAA compliant requires abiding by HIPAA **AND** surviving state and federal law.
Research Updates

Sensitive Information

• **Mental Health**
  – Governed by Illinois Mental Health and Developmental Disabilities Confidentiality Act
  – Also governs
    • Developmental Disabilities
    • Genetic Counseling
• **Substance Abuse Treatment**
  – Governed by 42 CFR Part 2
• **Genetic Testing**
  – Governed by Illinois Genetic Information Privacy Act
• **HIV/AIDS**
  – Governed by Illinois AIDS Confidentiality Act and regulations promulgated under this law
• Additional types of information for **minors** (sexually transmitted illnesses, pregnancy, and birth control)
• **Other**
Research Updates

Sensitive Information

• NMHC’s Privacy Policy incorporates by reference Northwestern University’s HIPAA Research Policy.
• The NU policy requires that research involving sensitive information either use de-identified information or obtain consent from the patient/participant.
Research Updates
Sensitive Information

HIPAA

Non-Sensitive Information = Sensitive Information

- Law
- Patient Agreement
## Research Updates

### Sensitive Information

<table>
<thead>
<tr>
<th>Mental Health Information (amended 2013) (also applies to Developmental Disabilities and Genetic Counseling information)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is “mental health” information?</strong></td>
</tr>
</tbody>
</table>
| **What is allowed under law without written permission?** | • De-identified information  
• Limited data set  
• Recruitment performed by business associate |
| **What activities require written permission?** | • Preparatory to research  
• Decedent research  
• Waivered research |
Research Updates

Sensitive Information

<table>
<thead>
<tr>
<th>HIV/AIDS Information (amended 2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is HIV/AIDS information?</strong></td>
</tr>
<tr>
<td>HIV-related information means the identity of a person upon whom an HIV test is performed, the results of an HIV test, as well as diagnosis, treatment, and prescription information that reveals a patient is HIV-positive, including such information contained in a limited data set. &quot;HIV-related information&quot; does not include information that has been de-identified in accordance with HIPAA.</td>
</tr>
<tr>
<td><strong>What is allowed under law without consent?</strong></td>
</tr>
<tr>
<td>HIV-related information may be disclosed for research in accordance with the requirements set forth under HIPAA. Hence, one may apply HIPAA rules to the following:</td>
</tr>
<tr>
<td>• De-identified information</td>
</tr>
<tr>
<td>• Limited data set</td>
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<tr>
<td>• Preparatory to research</td>
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<tr>
<td>• Decedent research</td>
</tr>
<tr>
<td>• Waivered research</td>
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<tr>
<td>• Recruitment performed by business associate</td>
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<tr>
<td><strong>What is not allowed under law without consent?</strong></td>
</tr>
<tr>
<td>• Apply HIPAA rules</td>
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</tbody>
</table>
## Research Updates

### Sensitive Information

### Genetic Testing Information (amended 2016)

<table>
<thead>
<tr>
<th>What is HIV/AIDS information?</th>
<th>“Genetic information” is defined as under HIPAA (see handout).</th>
</tr>
</thead>
</table>
| What is allowed under law without consent? | Genetic information may be disclosed for research in accordance with the requirements set forth under HIPAA. Hence, one may apply HIPAA rules to the following  
- De-identified information  
- Limited data set  
- Preparatory to research  
- Decedent research  
- Waived research  
- Recruitment performed by business associate |
| What is not allowed under law without consent? | Apply HIPAA rules |

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Northwestern Medicine
## Alcohol and Substance Use Disorder ("SUD") Treatment Information (amended 2017)

"SUD information" includes information contained in a record held by a federally assisted "program" (i.e. a location that holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment).

(a) Information may be disclosed by the part 2 program...for the purpose of conducting scientific research if the individual...vested with authority...makes a determination that the recipient of the patient identifying information...(2) If subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), either provides documentation that the researcher is in compliance with the requirements of the HHS regulations, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.101(b) and any successor regulations...

(b) Any individual or entity conducting scientific research using patient identifying information obtained under paragraph (a) of this section:

1. Is fully bound by the regulations in this part and, if necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the regulations in this part.
2. Must not re-disclose patient identifying information except back to the individual or entity from whom that patient identifying information was obtained or as permitted under paragraph (c) of this section.
3. May include part 2 data in research reports only in aggregate form in which patient identifying information has been rendered non-identifiable such that the information cannot be re-identified and serve as an unauthorized means to identify a patient, directly or indirectly, as having or having had a substance disorder.
4. Must maintain and destroy patient identifying information in accordance with the security policies and procedures established under § 2.16.
5. Must retain records in compliance with applicable federal, state, and local record retention laws.
Research Updates

Sensitive Information

Additional uses and disclosures allowed with patient agreement:

- Currently, we are able to utilize sensitive information from NMG (starting approximately 2013) and NMH (starting approximately 2015) because patients signed a general consent allowing use of sensitive information for research purposes in the same way that HIPAA allows the use of non-sensitive information for research purposes (i.e. without consent).

<table>
<thead>
<tr>
<th>De-identified information</th>
<th>Preparatory to research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited data sets</td>
<td>Waivered research</td>
</tr>
<tr>
<td>Decedent research</td>
<td>Recruitment by business associates</td>
</tr>
</tbody>
</table>

- The Universal Consent (to be implemented by 4/30/2017) will start obtaining consent from across the NM System
Current NMHC/NU Initiatives Affecting Research
Research Updates

Current Initiatives

• Research Authorization Compliance
  – Collaborate with NU to ensure that authorizations meet all required HIPAA elements through training and technical safeguards
  – Obtain new authorization where current authorization identified as deficient

• Recruitment Processes Review
  – Initial focus on requirement that researchers obtain approval by a patient’s treating physician prior to contacting the patient for recruitment purposes
  – Patient opt-out from being contacted by NU researchers

• NMHC Research Policy Rewrite
  – Recast as an NMHC policy
  – Update portions addressing sensitive information
  – Update to reflect new processes (e.g., use of Study tracker)
  – Update to reflect EDW
  – Other
Questions?
Thank You