Protecting Human Research Subjects: Confidentiality
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Agenda

• Federal and State Laws/Regulations
• Informed Consent and Authorization Forms
• Other HIPAA Mechanisms
• De-identification of Data
• Certificates of Confidentiality
• Data Security — Best Practices (*John Rasmussen, Chief Information Security Officer, Information Privacy and Security*)
Laws/Regs: General Protections

• Common Rule and FDA:
  – Breach of confidentiality as a risk
    • Risks must be minimized
    • Risks must be reasonable in relation to benefit
  – Specific requirement to protect confidentiality of data

• HIPAA:
  – Protects PHI, including mental health info
  – Restricts use and disclosure without authorization
  – Additional protection for “psychotherapy notes”

• Oregon law mirrors HIPAA for protection of PHI.
**Protections for Specific Types of Information: Substance Abuse Information**

- Obtaining Substance Abuse Information from Treatment Programs for Research Purposes
  - Federal law (42 USC 290dd-2 and 42 CFR 2, aka “Part 2”) generally requires written consent for disclosure of identifiable information obtained by a substance abuse treatment program.
  - Oregon law is more strict. It prohibits virtually all release of records from a substance abuse treatment facility operated under the rules of the Oregon Health Authority. (ORS 430.399)
  - Federal law has an exception for information disclosed for research, if the program director determines that certain criteria are satisfied.

- *If you are collecting information directly from subjects, this does not apply to you!*

- If you are collecting information from a substance abuse program, keep lines of communication open with IRB.
**Protections for Specific Types of Information: Substance Abuse Information**

- Disclosure of Substance Abuse Information
  - Researchers receiving information from a program **without written consent** of the individuals may not disclose except back to the program itself.
  - Researchers receiving information from a program **with written consent** of the individuals may not disclose unless written consent is obtained for the subsequent disclosures. This must be **specific consent** – general permission to release medical records is not enough.

- Other Things to Note
  - Mandatory state law reporting (child/elder abuse, public health) still required.
  - Protections apply to decedents. Informed consent must be obtained from someone with appropriate authority.

- **Again, if you are collecting information directly from subjects, this does not apply to you! Follow Common Rule (and HIPAA, if applicable) regarding use and disclosure of information.**
Protections for Specific Types of Information: HIV Status

• Oregon Law: No disclosure or compelled disclosure without authorization of individual unless otherwise required/permitted by law or regulation. (ORS 433.045(3))

• Requirements for authorization (OAR 333-012-0270):
  – “Specific written authorization.” General consent for release of medical records is insufficient.
  – Elements:
    • HIV status may be released
    • Purpose for release
    • Parties who may receive information
    • Time period when release may occur
    • Date of authorization and signature of individual

Consent Form

HRA Form
Protections for Specific Types of Information: HIV Status

- Recommended language for studies in which HIV status may be disclosed (even if you are not testing for it):
  
  If you are HIV positive, this information will be disclosed to [the sponsor, and list others as appropriate] along with the other health information we collect about you. The [sponsor, others] will use this information to [monitor your safety, learn more about the effects of the study drug in people with HIV, etc.].

- This language will be added to the consent form templates at the next round of updates (January 2013).

Protections for Specific Types of Information: Genetic Information

• Oregon Genetic Privacy Law
  – Obtaining/using/disclosing genetic information for research requires informed consent
  – Conducting anonymous/coded genetic research requires informed consent or opportunity to opt-out

• Informed consent means “specific informed consent for genetic research”

• Genetic language is already included in the consent templates.
Protections for Specific Types of Information: Education Records

• Federal law (FERPA) prohibits release of student records from schools without written parent or student permission.
• There are exceptions, but most research requires written permission.
• Work with the school if you are trying to access their records for research and keep lines of communication open with IRB.
Consent and Authorization Form Requirements

- Subjects must be informed about:
  - What private information will be collected
  - Who will be able to access it
  - What measures are in place to protect it

- Oregon law requires **specific permission** for the disclosure of:
  - HIV status
  - Genetic information if not for treatment, payment, or operations

  *Stating generally that all information collected in the study may be disclosed and/or used in future unspecified research is NOT ENOUGH!*

- Federal law requires **specific permission** for the disclosure of substance abuse information obtained from a treatment program

- HIPAA requires an **additional, separate authorization form** for:
  - Use/disclosure of psychotherapy notes
  - Optional uses/disclosures of PHI in a clinical trial
**HIPAA Mechanisms: Authorization**

- HIPAA Research Authorization (HRA) shows permission for use/disclosure of PHI
- Why don’t we have the separate initials lines in the HRA anymore?
  - Instead of listing this information separately in the HRA, the new HRA refers back to the consent form, where these issues can be discussed
    - Only once (less risk of inconsistency) and
    - More thoroughly.
  - This means that items requiring special permission (genetic research, certain substance abuse info, and HIV) must be discussed in the consent form.
HIPAA Mechanisms – WoA and DUA

• Waiver of Authorization
  – Allows use/disclosure of PHI without authorizations if you can show that the research is **not practicable** without the waiver and that appropriate confidentiality protections are in place so that there is only **minimal risk** to subjects.
  – Must destroy or de-identify PHI at the earliest opportunity consistent with the research.

• Data Use Agreement
  – Allows disclosure of a Limited Data Set (dates ok; no direct identifiers)
  – Not the same as a non-HIPAA Data Sharing Agreement, though may be called a DUA or contain similar language – ask us if you are not sure about something you’re asked to sign!
  – Contact Andrea Johnson if another institution wants to negotiate changes to our template DUA.
HIPAA Mechanisms – Prep to Research and Decedents

• Prep to Research
  – Allows access to PHI at OHSU for developing a protocol, recruiting, etc.
  – Can be part of a study or a separate activity (submit via request for determination)
  – Prep to Research vs. WoA:
    • WoA is more inclusive
    • WoA required if you are disclosing outside OHSU

• Decedents Representation Form
  – Allows research with decedents’ PHI
  – Appropriate confidentiality protections must be in place
  – Not limited to use at OHSU
  – Can be part of a study or separate activity
HIPAA – Accounting of Disclosures

• Required for any disclosures outside of OHSU for research purposes not covered by an authorization or a DUA.
  – Disclosures pursuant to a WoA or Decedents Representation
  – Exceptions to authorization requirement – public health reporting

• There are different procedures if you have more than 50 subjects vs. 50 or fewer, but you must account for disclosures regardless of the number of subjects in your study.

• For information on OHSU’s Accounting of Disclosures procedures and system, visit the Information Privacy & Security website.
De-Identification of Data

• The OHSU IRB uses the HIPAA standard for de-identification in all cases, including exempt and NHS determinations
  – All 18 identifiers must be removed, or
  – A statistician must certify that identification of the individuals is extremely unlikely.

• De-identification is not always preferable or even possible, and that’s usually okay!
De-Identification of Data – Common Areas of Confusion

NHS vs. Exempt 4 vs. Expedited 5

**NHS**
No identifiers and no code exists or you will not have access to the code

**Exempt 4**
Identifiers accessed but not recorded in research records

**Expedited 5**
Identifiers recorded
**Pay attention to how you set up your SurveyMonkey survey! You can link email addresses.**
We will not consider data released from a repository to be de-identified if the investigator requesting the release is also an investigator on the repository (unless no identifying code exists).

Think about this as you set up your repositories – who really has access to the code?
Certificates of Confidentiality

• Federal mechanism (NIH) that protects investigators from forced disclosure of subjects’ identifying information (e.g. subpoena)
• Does not prevent voluntary disclosure!
• Rarely tested in court
  – Can, in theory, supersede mandatory disclosures like child abuse, professional misconduct, or public health reporting, but investigators should still report unless there is a compelling reason not to report.
  – Subjects must be informed that these disclosures will still be made.
• **Call us if you are being asked to disclose subject information and you have a CoC!**
Certificates of Confidentiality

• Do you need a CoC?
  – Sensitive information
  – Repositories (per OHRP guidance)

• Can you get a CoC if your study is not federally funded?
  – YES, as long as research is within the NIH mission.
  – Embryonic stem cell research is not eligible.

• The IRB will sign your CoC application. Submit the CoC to the IRB once you have it.

• More information: NIH CoC Policy Kiosk
Certificates of Confidentiality

• Informed consent form must tell subjects that the study is covered by a CoC and explain what that means.

• **Be sure to tell subjects what investigators intend to disclose despite the CoC, such as child abuse or public health reporting.**

• Template language will be added to consent templates at next revision. In the meantime, contact the IRB if you need example language.
Data Security – Best Practices

• John Rasmussen, Chief Information Security Officer
• Information Privacy and Security Website
IRB Updates and Reminders

- Consent form templates
  - Next 6-month revision: January 2013
  - **Send us your feedback now!!**

- Brown Bags
  - October 25: *When to Submit What and Reportable Events* (Melinda Allie)

- IRB Training (Melinda Allie and Kaija Maggard)
  - Intro to IRB: October 18
  - eIRB Basics: November 1
  - eIRB Intermediate: November 15
Helpful Resources

- **IRB Forms Page**
- **IRB Policies Page**
- Don’t hesitate to contact us!
  - Andrea Johnson: regulatory questions
    Ext 4-8999 or johnandr@ohsu.edu
  - Department Analyst: general questions
  - Managing Analyst: study-specific questions
  - John Rasmussen (IPS): data security questions
  - Not sure?
    4-7887, option 1 or irbinbox@ohsu.edu
Mark your calendars!

Next Brown Bag Session is *When to Submit What and Reportable Events* with Melinda Allie October 25th in UHS 8B60.

Visit our website for more information:
www.ohsu.edu/researchintegrity