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)*

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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.

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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.

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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

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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).
- Testing for HIV? Give HIV info sheet as well.

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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.

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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.

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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

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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.

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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.

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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

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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.

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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!

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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

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De-Identification of Data – Common Areas of Confusion

Exempt 2 vs. Expedited 7

Exempt 2

Anonymous survey or similar activities

Or

Identifiable survey or similar but no PHI or information that could be potentially damaging if accidentally released

Expedited 7

Identifiable survey or similar with PHI or other information that could be potentially damaging if released

Pay attention to how you set up your SurveyMonkey survey! You can link email addresses.

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De-Identification of Data - Repositories

- 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?

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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!***

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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

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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.

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Data Security – Best Practices

- John Rasmussen, Chief Information Security Officer
- Information Privacy and Security Website

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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)
  - December 13: ***Recruitment and Consent Discussions*** (Trish Lindstrom and Triana Nagel)
- IRB Training (Melinda Allie and Kaija Maggard)
  - Intro to IRB: October 18
  - eIRB Basics: November 1
  - eIRB Intermediate: November 15

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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

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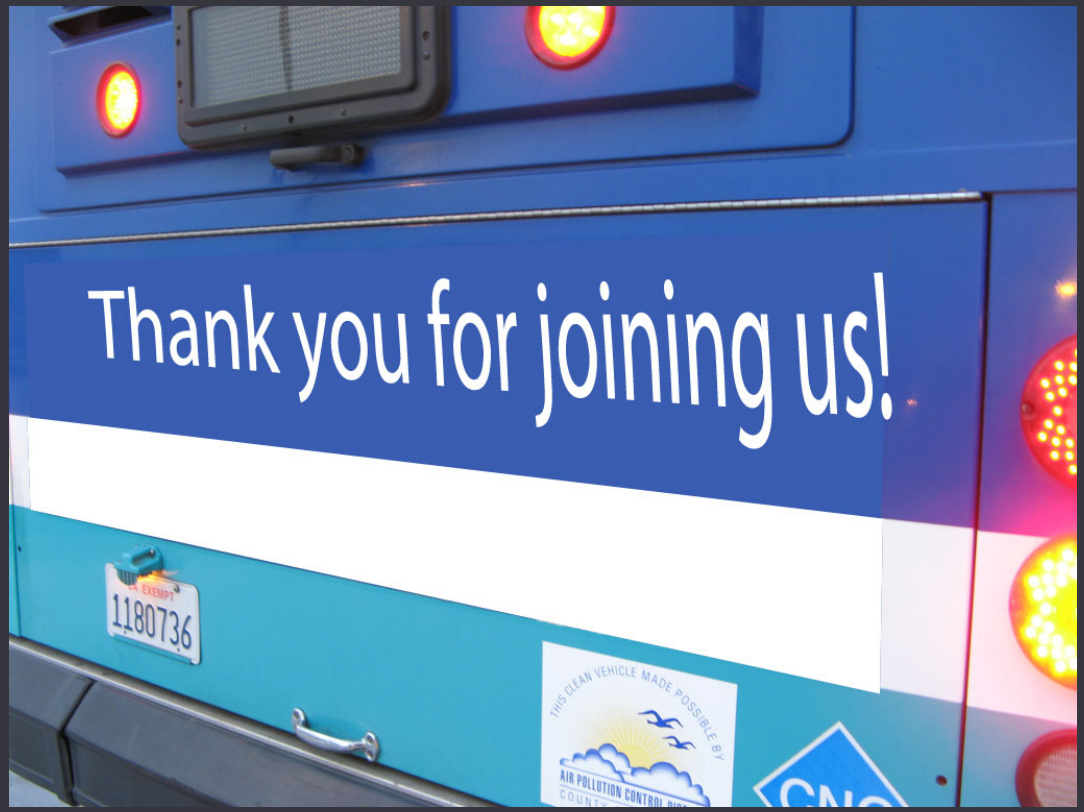

Mark your calendars!

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:
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