REGISTRIES AND DATA REPOSITORIES

AN EXAMINATION OF THE REGULATORY AND NU REQUIREMENTS AS WELL AS CURRENT BEST PRACTICES.

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MANAGER, COMPLIANCE
OBJECTIVES

- Define the Responsibilities of;
  - The Investigator
  - The IRB
  - Honest Broker or Repository Manager
- Address the risks associated with the registries
- When is IRB review needed?
- Other considerations
"Actually, we’re only taking tissue samples."

http://imgc-cn.artprintimages.com/images/P-473-488-90/60/6066/TGZD1002/posters/j-p-rini-actually-we-re-only-taking-tissue-samples-new-yorker-cartoon.jpg
DATA REPOSITORY VS. REGISTRY

- **Data Repository** - A collection of identifiable or de-identified biological specimens and/or data that support research-related activities.

- **Registry** - A list or database of participants, which may be used to grant access to that list to multiple Investigators.

- ✔ Both need to be submitted to the IRB for review
- ✔ Both require oversight by the Investigator or Manager and the IRB
TYPES OF REPOSITORIES AND REGISTRIES

✓ Tissue
✓ Blood, Urine, other fluids
✓ Medical Record data
✓ Subject Recruitment
✓ Disease or condition specific Registry information
INVESTIGATOR RESPONSIBILITIES

• Oversight
• Submission of a protocol to the IRB
• Security
• Maintenance and Storage
• Recruitment
• Consent
HONEST BROKER AND THE REGISTRY MANAGER

• An honest broker maintains private or confidential data on behalf of an Institution or department, but is authorized to distribute parts of the data to other researchers who do not have access to the entire set of data.

• Registry Manager manages access to the information and contents of the registry.

IRB RESPONSIBILITIES

- Adhere to Regulatory guidance found at:
  - Office for the Protection of Human Subjects (OHRP)
    - 45CFR46.102(d, f)- addresses identifiable private data and criteria for when research does not involve living subjects.
  - Food and Drug Administration (FDA)
  - Health Insurance Portability and Accountability Act (HIPAA)
    - 45CFR160 and 164- addresses when an authorization is required and when it is not required
  - Finally, as with all IRB approved studies there is a requirement for continuing review and monitoring!
RISKS

• Security
  • Inappropriate access to the information

• Confidentiality
  • Subject no longer wants to be part of registry

• Misuse of data
  • Depends on terms of the agreement
WHEN IS IRB APPROVAL NEEDED?

• IRB Approval and consent is needed if:
  • There is planned collection of additional tissue beyond what is needed for the clinical procedure.
  • Discarded tissue is obtained with identifiable information for analysis.

Note: Secondary analysis of de-identified specimens does NOT require IRB review and approval. However, federally funded studies may need some documentation of an IRB determination.
Issues to Consider in the Research Use of Stored Data or Tissues

- **Human Tissue Repositories** collect, store, and distribute human tissue materials for research purposes. Repository activities involve three components: (i) the **collectors** of tissue samples; (ii) the **repository** storage and data management center; and (iii) the **recipient** investigators.

- If supported by the Department of Health and Human Services (HHS), each component must satisfy certain **regulatory** requirements.

  ![Diagram]

  - Tissue Collector ➔ Repository Storage ➔ Recipient Investigator
  - Tissue Collector ➔ Data Management Center ➔ Recipient Investigator
  - Tissue Collector ➔ IRB Review ➔ Recipient Agreement
  - IRB Review ➔ Informed Consent ➔ Local Policies
  - IRB Review ➔ Submittal Agreement ➔ Sample Informed Consent ➔ Certificate of Confidentiality
  - Assurance of Compliance ➔ Assurance of Compliance

- Operation of the Repository and its data management center should be subject to **oversight by an Institutional Review Board (IRB)**. The IRB should review and approve a protocol specifying the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. The IRB should also review and approve a sample collection protocol and informed consent document for distribution to tissue collectors and their local IRBs. A **Certificate of Confidentiality** should be obtained to protect confidentiality of repository specimens and data.

- **Source**: OHRP Guidance-Repositories and Tissue Banks: [http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm)
A researcher obtains IRB approval for collection of blood and surveys from her patient population for a study looking at genetic variances in Parkinson’s patients. Consent is obtained from the individual and the risks of the blood sample and confidentiality are addressed.

A coded sample collected by the researcher is provided to a second Researcher who sequences the DNA, but is not given any additional information and he will not have access to the information. He publishes the DNA sequence on a public web-site.

A third Researcher is also interested in studying a specific genetic marker associated with Parkinson’s Disease and accesses the public web-site to analyze the published DNA sequence.

Source: no longer de-identified, McGuire, A.L., Science 2006
BEST PRACTICES

• Describe the Security
  • Obtain a Certificate of Confidentiality
• Describe how the registry will be maintained
• Consent Process for participation
• Develop a training plan for the personnel involved in the repository or registry
• When it comes to the Protocol - sweat the details!
CASE STUDY

Dr. Spore maintains a recruitment registry for families that have children with diabetes-type 1. These families are interested in participating in research and agree to be contacted per the consent form they signed. However, one family in the registry contacts Dr. Spore and expresses concern regarding the number of phone calls that they are receiving from Dr. Que, a colleague who is also using the registry for her research regarding chronic illnesses.

- What should be the Researchers initial first steps?
- What could have been done to prevent this from happening?

http://multimedia.journalism.berkeley.edu/media/upload/blog/data-image.jpeg
OTHER CONSIDERATIONS

• Data use agreements
  • A written contract that governs the sharing of data between research collaborators at different institutions
    • I.e., universities, government agencies, other non-profits, for-profit companies

Source: Ann Grace, OSR 10/18/2013 IRB Retreat
THANK YOU!

Still have questions? Contact the IRB!

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http://www.adkmuseum.org/resources/images/P049587.jpg