

IRBs and Data Sharing

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Research Questions

- What does the federal government expect regarding the responsible dissemination and use of social science data?
- How do data distribution practices and policies fit into their expectations?
 - Ethical issues associated with the analysis of secondary data
 - Legal statutes pertaining to data dissemination and analysis
 - Designated roles of IRBs, producers, archivists, and users

NIH Data Sharing Policy

- **Purpose:** “Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data.”
- **Requirement:** Investigators submitting a research application are expected to include a plan for sharing data, or state why data sharing is not possible.
- **Applies to:** Sharing of final research data for research purposes; from basic research, clinical studies, surveys, and other types of research supported by NIH; for applicants seeking \$500,000 or more in direct costs in any year.

NIH Data Sharing Policy

- **Enactment:** If an application describes data-sharing plan, NIH expects that plan to be enacted. Information about progress to be given in annual report.
- **Timeliness:** Release and sharing of data to be no later than the acceptance for publication of the main findings from the final dataset.
- **Incentives:** Awards not contingent on the quality of data sharing plan.

NIH Data Sharing Policy

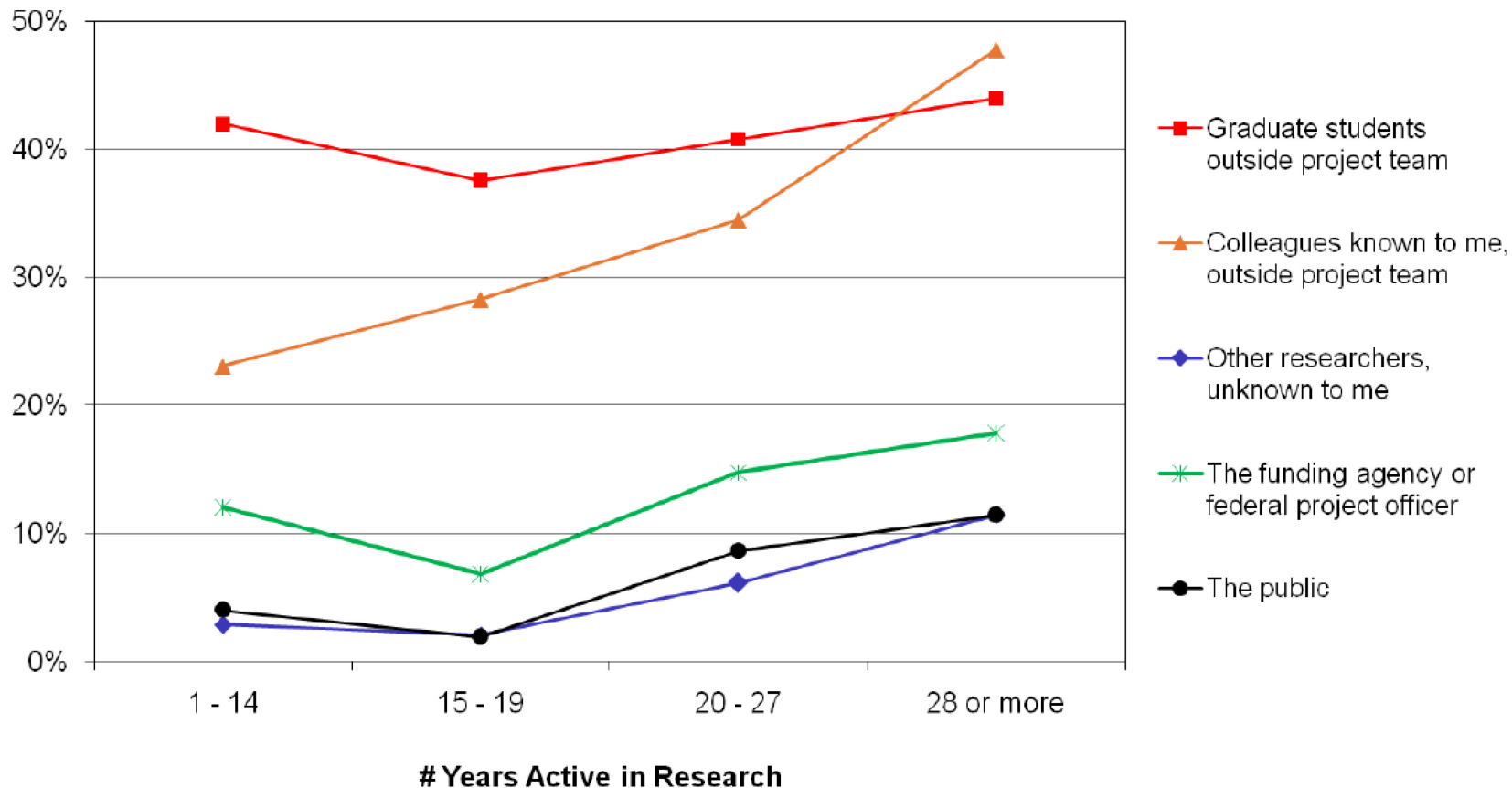
- **Standard:** “The rights and privacy of human subjects who participate in NIH-sponsored research must be protected at all times.”
- **Obligation:** “Responsibility of investigators, their IRBs, and their institution to protect the rights of subjects and the confidentiality of the data.”
- **Regulations:** “45 CFR 46”, Subpart A known as the “Common Rule”

Sharing of Microdata Files

- Have you [ever] been PI / co-PI of a study that released public-use microdata? (n=866)
 - 16% Yes
 - 81% No
 - 3% Not Sure
- Have you shared microdata from the sampled study? [Including sharing with project team, other researchers outside team, graduate students, the public] (n=813)
 - 59% Yes
 - 13% No, but I expect to
 - 28% No, and I do not plan to

O'Rourke, J. M. and M. Feldbaum. 2006. "Human Subjects Protection and Disclosure Risk Analysis, Early Results." Working Paper.

With Whom Did You Share? For Those Sharing Outside Project Team



O'Rourke, J. M. and M. Feldbaum. 2006. "Human Subjects Protection and Disclosure Risk Analysis, Early Results." Working Paper.

What Do The Experts Say?

- **Question:** NIH policy exhorts PIs to share their data, but most data are not shared. PIs often cite confidentiality concerns as reasons for not sharing data, and many use informed consent statements that specifically preclude data sharing (in violation of NIH policy).

What role should IRBs play in reviewing proposals and data sharing plans to encourage sharing and re-use of data?

OHRP Research Community Forum. Reducing Regulatory Burden: Real Strategies for Real Change. May 14, 2009.

What Do The Experts Say?

- **Answer:**



OHRP Research Community Forum. Reducing Regulatory Burden: Real Strategies for Real Change. May 14, 2009.

Ensuring the Rights and Privacy of Human Subjects



Collect



Disseminate



**Secondary
Analysis**

Data Life Cycle

Methodology

- Content analysis of materials constructed by universities, distributed via websites
- Office of Vice President for Research and their Human Research Protection Program
- Excluding links to federal government websites and associated materials

IRB's Under Study

- Arizona State University
- Pennsylvania State University
- University of California – Berkeley
- University of California – Los Angeles
- University of Chicago
- University of Michigan
- University of North Carolina – Chapel Hill
- University of Pennsylvania
- University of Texas – Austin
- University of Washington
- University of Wisconsin – Madison

Methodology

- 242 documents
- Policies, guidelines, and templates
- Excluding decision-trees and forms
- Search for 30 terms related to dissemination and secondary analysis
 - E.g., access, agreement, archive, confidential, disclosure, disseminate, harm, human subject, repository, risk, secondary, sharing, public use, . . .

Ensuring the Rights and Privacy of Human Subjects



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Disseminate



**Secondary
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Data Life Cycle

Informed Consent

- Communication process allowing individuals to make an informed choice about participation in a research study
 - Formal agreement to be study participant
 - Minimizes coercion of undue influence
 - Language understandable to subject
 - Signed by subject or legally authorized representative
- Provide 8 basic information elements about study
 - Describes extent that confidentiality will be maintained
 - May limit investigator's discretion to share data

National Institutes for Health, Office of Extramural Research; U.S. Department of Health & Human Services, Office for Human Research Protections (OHRP)

Informed Consent

- The informed consent form for my recently completed study states explicitly that **only my research team will see the data** provided and that we will not share the data. **Am I now expected to share it?**

No, but if you plan to collect additional data from those subjects under a grant with a data-sharing plan, you should revise the consent procedure to be consistent with the data-sharing plan. In preparing and submitting a data-sharing plan during the application process, **investigators should avoid developing or relying on consent processes that promise research participants not to share data with other researchers**. Such promises should not be made routinely or without adequate justification described in the data-sharing plan.

Informed Consent

- The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. **No information about you, or provided by you during the research, will be disclosed to others without your written permission**, except:
 - if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
 - if required by law

Suggested Language

- **Sample 1:** We will make our best effort to protect your statements and answers, so that no one will be able to connect them with you. These records will remain confidential. Federal or state laws may require us to show information to university or government officials [or sponsors], who are responsible for monitoring the safety of this study. **Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.**
- **Sample 2:** The information in this study will only be used in ways that will not reveal who you are. **You will not be identified in any publication from this study or in any data files shared with other researchers.** Your participation in this study is confidential. Federal or state laws may require us to show information to university or government officials [or sponsors], who are responsible for monitoring the safety of this study.

Certificate of Confidentiality

- Legal document that protects identifiable research information from forced disclosure
 - Issued by NIH
 - Investigators can refuse to disclose identifying information on research participants
 - Applies to:
 - Any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level
 - Studies collecting information that may be harmful if disclosed

Certificate of Confidentiality

- Legal document that protects identifiable research information from forced disclosure
 - Exceptions:
 - Reporting child /elder abuse, or intent to hurt oneself/others.
 - Subject has given written consent for the release of their data
 - Federal government and FDA needs data for auditing/evaluation
- Promotes participation in studies and data sharing

Acquisition and Transfer of CoC

- Original data collector granted CoC from NIH.
- All personally identifiable information maintained about project participants (from original protocol) is protected in perpetuity.
- This CoC then granted to subsequent institution.
- Via restricted use contract, subsequent institution stipulates disseminators and users as contractees.
- Contractees inherit CoC from subsequent institution.

CoC and Restricted Use Data Contracts

Research subjects who participated in STUDY NAME are protected by a certificate of confidentiality issued by the Department of Health and Human Services in accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)). Institution is considered to be a contractor or cooperating agency of SUBSEQUENT INSTITUTION under the terms of the Confidentiality Certificate; as such, Institution, Investigator, and Research Staff are authorized to protect the privacy of the individuals who are the subjects of STUDY NAME by withholding their identifying characteristics from all persons not connected with the conduct of the study. Identifying characteristics are all STUDY NAME Data Files which are defined as sensitive under the terms of this contract.

Certificate of Confidentiality and Compelled Disclosure of Data

- “The full legal effect of Certificates of Confidentiality remains unclear.” (Beskow, Dame, and Costello 2008)
- Challenged, and upheld, in a trial that sought to identify study participants reporting drug use and illegal behaviors.
- The Constitutional rights of the accused to defend themselves may outweigh societal interest in protecting research records.

Beskow, Dame, and Costello. 2008. “Certificate of Confidentiality and Compelled Disclosure of Data.” Science 322: 1054-1055.

NIH Guidance for Data Sharing

- Prior to sharing, delete all identifiers and apply effective strategies to minimize risks of unauthorized disclosure
 - Direct identifiers: name, address, dates, etc.
 - Deductive disclosure: unusual characteristics, linked datasets
 - Risk reduction methods: remove variables, delete records, statistically alter the data
- Provide access through alternative methods of data sharing
 - Public use datasets
 - Data archive, data enclave, mixed mode sharing
 - Data-sharing agreements that stipulate protection requirements

NIH Guidance for Data Sharing

- Data Use Certification Agreements
 - Co-signed by investigator and their institution
 - Requirements depend on dataset being accessed
 - 17 core elements
 - E.g., Research use, sale of data, data security, legal obligations, no distribution, destruction of data, violations/non-compliance/terminations, . . .
 - Part of Genome-Wide Association Studies (GWAS)

NIH Guidance for Data Sharing

- “Procedures adopted to share data while protecting privacy should be individually tailored to the specific dataset.”
 - “. . ., neither the precise content for the data documentation, nor the formatting, presentation, or transport mode for data is stipulated.”
 - “It would be helpful for members of multiple disciplines and their professional societies to discuss data sharing, determine what standards and best practices should be proposed, and create a social environment that supports data sharing.”
- National Institutes for Health, Office of Extramural Research*

Continuum for Dissemination and Secondary Use

High / Some Risk

Restricted-Use Data

Non-Exempt User

Low / No Risk

Public-Use Data

Exempt User

IRB

Archive

**Restricted
Access Mode**

**Restricted
Use Agreements**

**Registration of
Public-Use Data**

**Responsible
Use Statement**



Analysis of Public-Use Data

- IRB review **not** required when:
 - Project only involves secondary analysis of public use data from pre-approved public data sets and repositories
 - Since UCLA IRBs have determined that data has been stripped of identifiers and are publicly available.
 - As a result “research using these data does not meet the definition of “human subjects research”.

Analysis of Public-Use Data

- IRB review is required when:
 - Project enhances public-use datasets in such a way that subjects may be reidentified
 - Project includes additional access to non-public data or interaction with subjects
 - Terms of data use agreement requires such a review

Registration of Public-Use Data

- Investigators apply to IRB to have dataset registered as a public use dataset
- Expands the amount of research that is exempt from IRB review
- Accompanied by Responsible Use Statement:
 - By [downloading these data], you signify your agreement to [. . .] conform to widely-accepted standards of practice [. . .] that are intended to protect the confidentiality of research subjects. (e.g., ICPSR)

Registration of Public-Use Data

- For published datasets:
 - IRBs typically provide a list of pre-approved public data sets and repositories
 - Three criteria: Publicly available, gathered anonymously, formal disclosure analysis to reasonably prevent identification of subjects

Registration of Public-Use Data

- For new datasets:
 - IRB approval of original data collection procedures
 - Dataset and documentation do not contain information that can be used to identify subjects
 - Must be reviewed by IRB before being made public
 - IRB considers 6 factors in this review (as indicated by NIH guidelines for disclosure limitation methods)
 - Most IRBs do not present these details

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**Restricted
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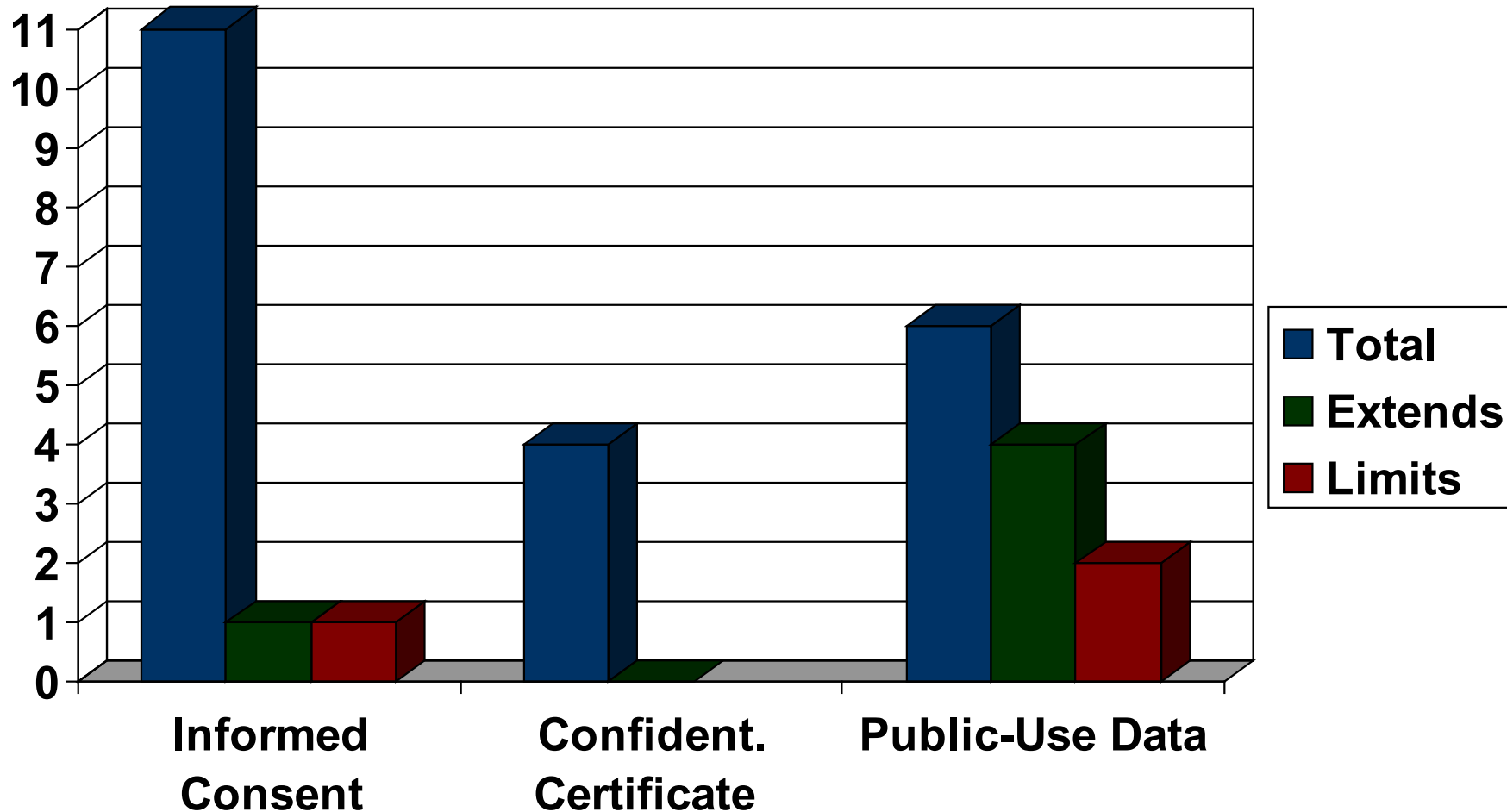
Exempt Institutions

- Archives constitute an “exempt institution”
 - “Transferring” of data does not constitute research on human subjects
 - Criteria: Services do not merit professional recognition or publication privileges; typically for non-research purposes; typically do not administer interventions.

The Role of Archives

- Archives fill a unique and important role in data sharing
 - Specialized division of labor
 - Pooling of financial resources
 - Enhanced ability to access necessary expertise

IRB Materials Supporting Data Sharing



How Can IRBs Facilitate Data Sharing?

- Follow consistent and comprehensive guidelines for creating and reviewing plans for . . .
 - Collecting research data, in light of data sharing goals
 - Disseminating research data
 - Analyzing public- and restricted-use data
- To locate helpful materials, turn to IASSIST members and your local library and archival staff

How Can IRBs Facilitate Data Sharing?

- Avoid informed consent language that needlessly limits dissemination of research data
- Create restricted use agreements to efficiently transfer confidentiality certificates
 - Promotes participation and sharing
 - Without CoC, user may be compelled to disclose copy of restricted data

How Can IRBs Facilitate Data Sharing?

- Consider design elements of data collection and sharing plans that optimally produce confidential and useful data
 - Informational content of data files and associated mode of access
 - Approach to sampling and resources needed

Thank you.

ICPSR | INTER-UNIVERSITY CONSORTIUM FOR
POLITICAL AND SOCIAL RESEARCH

A PARTNER IN SOCIAL SCIENCE RESEARCH

Additional Slides

References

- NIH Data Sharing Policy
 - National Institutes for Health, Office of Extramural Research (OER)
 - http://grants.nih.gov/grants/policy/data_sharing/
- Policy Guidance (by topics)
 - Office for Human Research Protections (OHRP)
 - <http://www.hhs.gov/ohrp/policy/index.html#human>
- Regulations and Ethical Guidelines
 - Office of Human Subjects Research (OHSR)
 - <http://ohsr.od.nih.gov/index.html>
- Informed Consent Agreements
 - Inter-University Consortium for Political and Social Research (ICPSR)
 - <http://www.icpsr.umich.edu/ICPSR/access/deposit/consent.html>

Future Research

- Extend content analysis by reviewing materials provided by
 - Collaborative Institutional Training Initiative (CITI) and their Social and Behavior Research courses
 - Professional organizations that specifically address concerns of IRB members
- Gather nuanced information about current policies, practices, and training initiatives by
 - Conducting more in-depth interviews of administrators of IRB programs and researchers who are IRB members

How Can IASSIST Help?

- Informational and training materials specifically created for different audiences of data producers, users, and IRBs.
- Research assessing the effectiveness of new policies, practices, and training.
- Research informing the creation and evaluation of dissemination plans.
- Research informing the design of studies and their data collection efforts so that confidentiality issues are addressed earlier in the research process.

Template of Informed Consent

- **Breach of Confidentiality:** “As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk.”
- **Confidentiality:** “Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.”
- **Security:** “To minimize the risks to confidentiality, we will . . .
[Explain measures to be taken, e.g., storage, coding, encryption, limited access to study records, etc.]”
- **Exceptions:** “We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, . . .”

Common Rule

- **Human subject:** Living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
- **Intervention:** Physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction:** Communication or interpersonal contact between investigator and subject.

Common Rule

- **Identifying private information:** Information which has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public; that also allows the identity of the subjects to be readily ascertained by the investigator.
- **Minimal risk:** Probability and magnitude of harm . . . anticipated in the research [is] not greater in and of [itself] than [that] ordinarily encountered in daily life . . .
- **Harm:** Which [if disclosed] can have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

*U.S. Department of Health & Human Services (HHS),
Office for Human Research Protections (OHRP)*

Exempt Research

- Involves the collection or study of **existing data . . .**, if these sources are **publicly available or** if the information is recorded by the investigator in a manner that **subjects cannot be identified**, directly or through identifiers linked to the subjects.

Exempt Research

- Involves the use of . . . **survey procedures** . . . , **unless**: (i) information obtained is recorded in a manner that **human subjects can be identified**, directly or through identifiers linked to the subjects; **and** (ii) any disclosure of the human subjects' responses outside the research could reasonably **place the subjects at risk of [harm]**.
- **Simply stated**: Collection of data must be “anonymous” and the information must be “harmless”.

Exempt Research

- **Anonymous:** Study design where it is impossible to trace data or information back to the research subject from whom it was obtained. In other words, the data **cannot** be identified to any particular research participant, not even by the researcher. There is total separation. No study design that involves the creation of a code linking the subject's identity to a pseudonym or a number can be termed an anonymous study, as the identity of the subject can be traced to the data. Additionally, when a written consent form is collected, this consent form has to be separated from the data that the subject provides.

Guidance for Defining and Minimizing Risk



Notes

Miscellaneous Notes

- Should we send our paper to the panelist from the IRB Forum for their June meeting?