

*Privacy/Confidentiality –  
Principles and Regulations  
in the  
Social Sciences and  
Behavioral Research*

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**Potential breach of confidentiality  
most common risk in SSBR:**

- (1) those chances that specific individuals are willing to undertake for some desired goal; or
- (2) the conditions that make a situation dangerous *per se*.
  - The IRB is responsible for evaluating risk only in the second sense.
  - It must then judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies inviting any person to undertake the risks.

[http://ohrp.osophs.dhhs.gov/irb/irb\\_chapter3.htm#e1](http://ohrp.osophs.dhhs.gov/irb/irb_chapter3.htm#e1)

**Problems with Privacy and  
Confidentiality**

- Regulations set an ill defined standard
- Risk is in the eye of the beholder
- Modern technology allows greater protection and greater access to information
- IRB standard setting is insufficient to the task of protection
- Need to shift thinking and set universal standards



**Regulations set an ill defined  
standard**

“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data”  
45 CFR 46.111(a)(7)

*The Common Rule does not define:*

- “adequate”
- “confidentiality ”

**Confidentiality and Privacy:**

The need for confidentiality exists in virtually all studies in which data are collected about identified subjects.

It is in the interest of researchers and essential to the conduct of research on sensitive topics that researchers be able to offer subjects some assurance of confidentiality.

These assurances should be given honestly, which sometimes requires the researcher and the IRB to make explicit provisions for preventing breaches of confidentiality.

OPRR Guidebook 1993

**Risk is in the eye of the beholder**

- IRB ethnocentric notion of privacy and confidentiality—“class issues”
- Temporal changes in concern for privacy
  - Age: child, adolescent, adult, elder
  - Profession
  - Political/economic/social situations
- Public perception:
  - “do not call list”
  - bank scandals
  - HIPAA
- Legal changes--Patriot act
- Technology impact—advances in controls and access



## RISK

The probability of harm or injury (physical, psychological, social, economic, or legal) occurring as a result of participation in a research study.

Both the probability and magnitude of possible harm may vary from minimal to significant.

Federal regulations define only "minimal risk."

- **Minimal Risk:** A risk is minimal where the probability and magnitude of **harm or discomfort** anticipated in the proposed research are not greater, in and of themselves, than those **ordinarily encountered in daily life** or during the performance of **routine** physical or psychological examinations or tests. 45 CFR 46.102(i)].

- **Minimal Risk** is the probability and magnitude of **physical or psychological** harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of **healthy persons**. 45 CFR 46.303 (d)

IRB is specifically cautioned to think of risk of

- criminal/civil liability,
  - financial risk,
  - employment risk,
  - stigmatization,
  - insurability,
  - embarrassment
- in deciding if risk is truly minimal.

Modern technology allows for greater protection and also greater access to information

Computer technology allows for encryption and sophisticated methods for securing information

CONVERSELY:

- Loopholes abound for potential breach of privacy
- Hacking/cracking
  - Theft

IRB standard setting is insufficient to the task of protection

- "Locked file" as standard is antiquated
- Encryption and coding formula are unintelligible to most IRB members
- Technology outpaces standards for security
- Reliance on vendor assurances is inadequate



Shift thinking and set universal standards

- IRBs should require investigators to establish ahead of time what information will be revealed to whom and under what circumstances, and to communicate these conditions to subjects in clear language.
- Data must be stored in such a manner that does not directly identify individuals.

[http://ohrp.osophs.dhhs.gov/irb/irb\\_chapter5ii.htm](http://ohrp.osophs.dhhs.gov/irb/irb_chapter5ii.htm)

IRBs and Researchers should consider confidentiality protection issues as continuous and necessary at all phases of research:

- Planning
- Implementation
- Storage of data
- Publication
- Data sharing



### NHRPAC Recommendations July 30-31, 2002

- (1) Degree of confidentiality protection should be commensurate with risk, and data protection plan can reduce risk
  - (2) OHRP should clarify what confidentiality certifications are available
  - (3) OHRP should conduct a review of statutes and regulations on the topic and identify gaps
  - (4) A clearinghouse linking information on all federal and state protections should be established
  - (5) Guidance should be developed for describing confidentiality protections in the consent process, including when confidentiality cannot be maintained
  - (6) Research institutions should actively support the investigator's efforts
  - (7) Guidance should be developed to ensure confidentiality protections are transferred when data are shared among investigators
- (summary thanks to Felice Levine)*

### IRBs should:

- Exercise authority for waiver of consent elements and consent documentation more frequently and consistently across institutions
- Secure Certificates of Confidentiality
- Consider long term implications for individuals and communities
- Gather data on unanticipated problems (inadvertent disclosure) and measure probability and magnitude of risk
- Encourage regulatory agencies for more guidance

### IRB Questions to ask now:

- Is the information sought, essential to addressing the research question ?
- Are there adequate provisions for controlling access to that information ?
- Are there acceptable means of communicating this control to subjects ?
- What should the IRB watch for in continuing review to keep pace with changes ?