

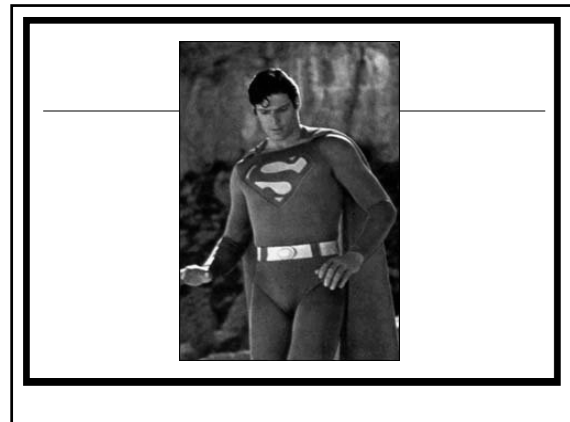
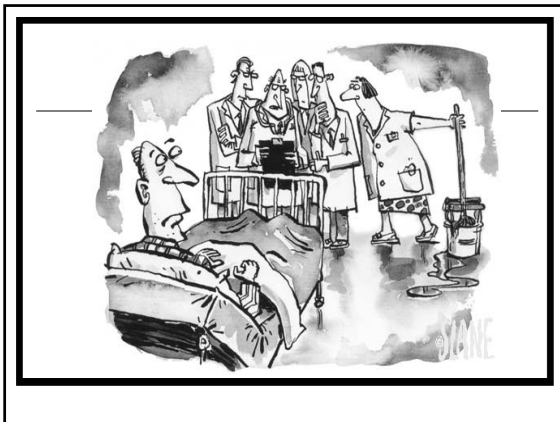
Privacy Concerns in Research Involving Third Parties

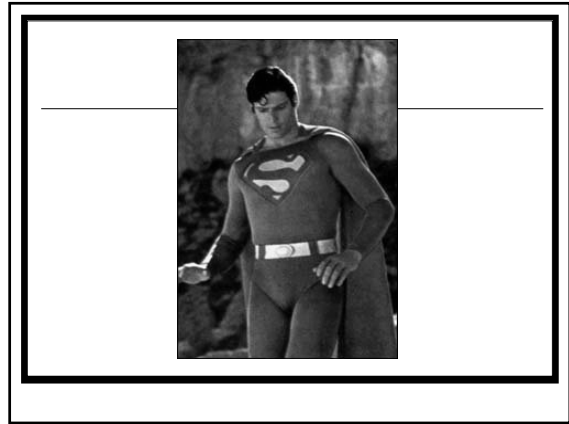
- PRIM&R
- May 4
- Hyatt Harborside Hotel
- Boston, MA



The Wanton Indiscretion

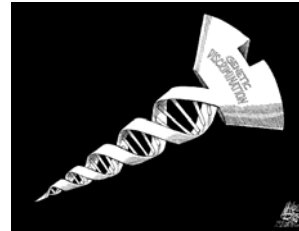
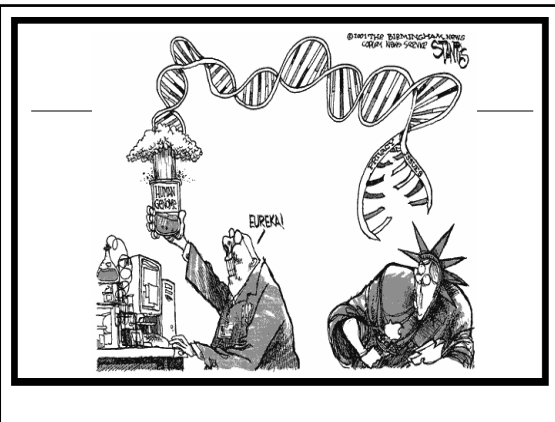
- Mark Seigler, "Confidentiality in Medicine A Decrepit Concept." *New England Journal of Medicine* (December 9, 1982, p. 1582)





The Wanton Indiscretion

- Mark Seigler, "Confidentiality in Medicine A Decrepit Concept." *New England Journal of Medicine* (December 9, 1982, p. 1582)





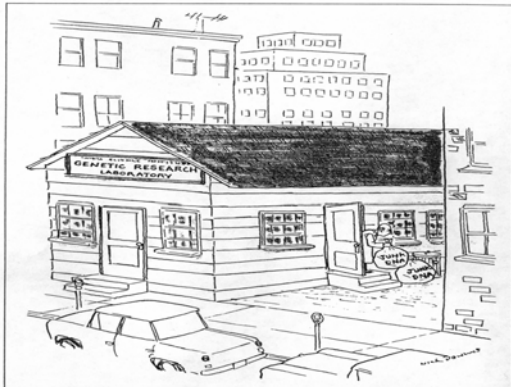
- Richard Curtin with his twins, Allison and Kevin, objected to having his medical history become part of a research project Allison was involved in.

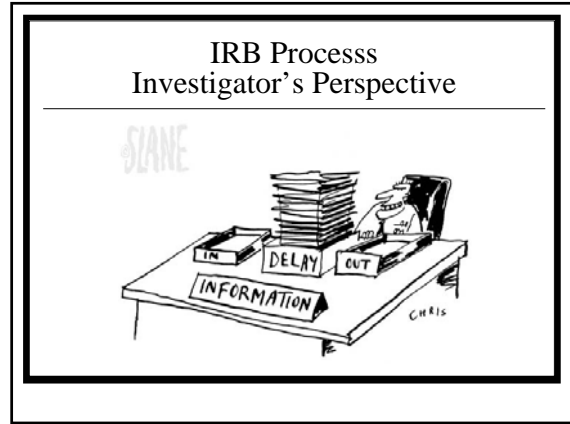
04/08/2001
Whose medical history is it, anyway?
By Rita Rubin, USA TODAY

- At a meeting this afternoon, members of the National Human Research Protections Advisory Committee, established by former Health and Human Services secretary Donna Shalala, will enter the fray.

USA Today

- "I hope Monday will be a big step forward," says Francis Collins, director of human genome research at the National Institutes of Health. Collins will moderate a panel about relatives in research at the meeting, being held near the NIH campus in Bethesda, Md.





NHRPAC REPORT ON THIRD PARTIES

- April 24, 2002
- Clarification of the Status of Third Parties When Referenced by Human Subjects in Research

Genetics Workgroup

- Mary Kay Pelias, Chairperson
- Terri Sargent: Alpha 1 Association
- Margaret Borwhat: Women's Cancer Advocacy Network
- Francis Collins

Risks and Protections: Commensurability

- As the risk of harm incurred by disclosure increases, so should the level of protection from such harm.

What Protections Allow

- Minimize subject's concerns over use/misuse of data
- Subjects provide more accurate information to investigators thus improve quality of research

What Protections Allow

- Researchers are able to conduct difficult research on important social problems such as substance abuse, violence, high risk sexual behaviors, and genetic predispositions

Assessing Risk

- Some studies are inaccurately perceived as conveying minimal risk
- Disclosure of identifiable data may present significant risk to the subject
- Sensitive nature of the topic
- Protecting data is the key element in minimizing risk

Third Parties Report

- Issues specifically dealing with information provided by a human subject about someone else
- NOT: information about a research subject gathered through indirect means (chart review) = existing regulation

Interested Parties

- Investigators or their agents
- Human subjects who interact personally with investigators
- Third parties about whom researchers obtain information from human subjects but who themselves have no interaction with investigators or their agents

Who Decides?

- The determination of who is and is not a human subject rests with the IRB
- The requirement of informed consent, or waiver of consent, pertains only to those deemed to be human subjects by IRBs

Who Decides?

- Whether through interaction, intervention, or identifiable private information, persons are human subjects when they provide personal or contextual information about their own lives, circumstances, perceptions, or histories even when they make reference to others

Reference to a Third Party?

- Neither reference to a third party in a research design, nor the recording of information about a third party in research records suggests that a third party must be regarded as a research subject

Other Persons

- Investigators, in designing and proposing research projects and IRBs, in considering and reviewing research projects and in conducting continuing review, should consider how the research design might focus not only on the identified human subjects, but on other persons.

Factors in Research Design and Review

- Factors to consider in determining whether information is private and whether the third party is identifiable (and thus, by definition, a human subject)

Factors to Consider

- 1. The quantity of information collected about the third party
- 2. The nature of the information collected, including the sensitivity of the information and the possibility that it might cause harm to the third party

Factors to Consider

- 3. The ability of investigators to record information on third parties in a manner that protects the identity of those parties

Factors to Consider

- The possibility that classification of a third party as a human subject may have an impact on the rights or welfare of the originally designated human subject

Factors to Consider

- This requires the IRB to protect the interests of both the original human subject and the third party

Confidentiality and Data Protections

- Recommendations on Confidentiality and Research Data Protections
- July 30-31, 2002

Recommendations

- Host research institutions should recognize and fulfill their obligations to actively support the investigator in protecting all confidential information from compelled disclosure or as otherwise agreed to in the data protection plan

Recommendations

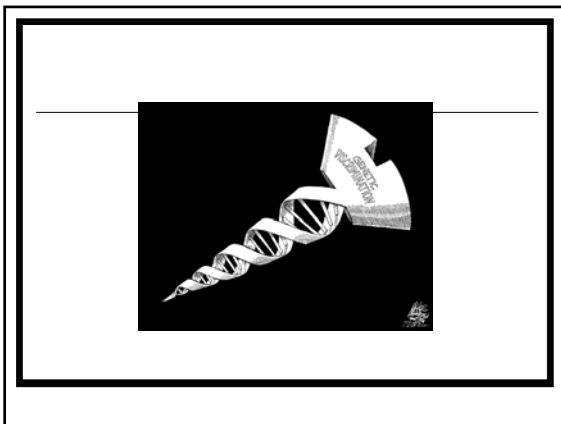
- OHRP should issue guidance to IRBs and the research community indicating that the degree of confidentiality protection required in research protocols be commensurate with the degree of risk of harm associated with the type of data collected

Recommendations

- This guidance should emphasize that a good DATA PROTECTION PLAN can reduce or ameliorate the degree of risk of harm

Recommendations

- To this end, OHRP should require this institutional responsibility as a term and condition of the assurance, and any future accrediting bodies should establish requirements in this area



Rudolph Virchow

- The physicians are the natural attorneys for the poor, and social problems should largely be solved by them
- Medical education does not exist to provide students with a way of making a living, but to ensure the health of the community

Rudolf Virchow

- The task of science is to stake out the limits of the knowable, and to center consciousness within them.



