



***Research on the Internet:  
A Brief Guide***



# IRB Issues

- **The Internet will be used more and more in conducting human subjects research.**
- **Research on the Internet presents new concerns to the traditional IRB issues of:**
  - Risk/Benefit
  - Consent
  - Participation by minors
  - Confidentiality.



# Risk

## **Two sources of harm:**

- **participation in the research**

- No direct contact with subjects
- Can't deal with individual reactions (intervention or debriefing)

- **breach of confidentiality**

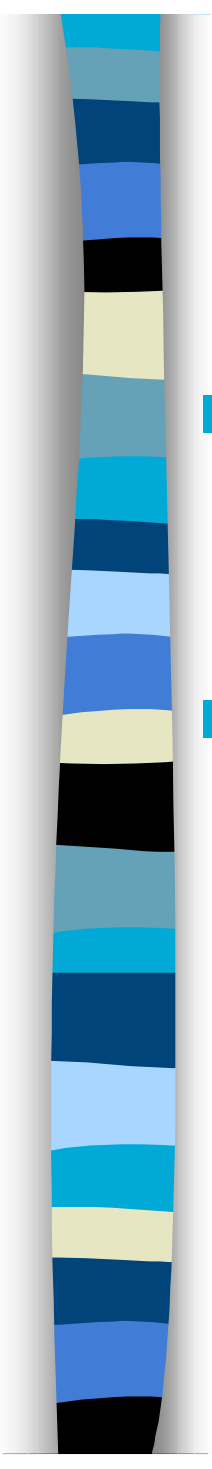
- Primary source of harm in most internet research



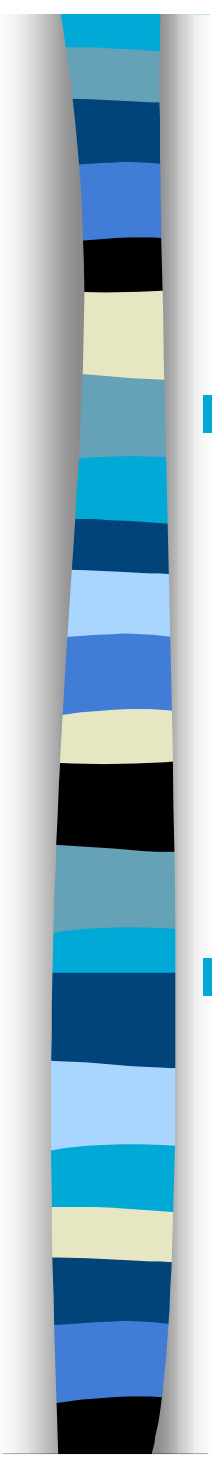
# Benefits

- **Conducting research on the Internet raises concerns about the reliability and validity of the data.**
  - skewed subject populations
  - ease with which subjects can mislead investigators
  - difficulty in preventing multiple submissions
- **Invalid research can have no benefit.**
  - inappropriate when there is risk to subjects

# Consent

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- **IRBs can waive the requirement for consent where appropriate [45CFR46.116(d)].**
  - **If consent is required, IRBs can waive the requirement for documentation of consent where appropriate [45CFR46.117(c)].**

# Consent

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- **Where consent required but documentation is waived, a “portal” can be used to provide consent information.**
    - **Subjects must click on Consent page to get to next page.**
  - **Where written consent required, it is currently not possible to get a signed consent form over the Internet.**
    - **Can have subjects submit signed consent form and get password for access to web site.**



# Participation by Minors

- **Where research qualifies for waiver of parental permission, no additional safeguards are required.**
  - **Either minors can participate without permission or a simple statement in consent that participant is over 18 is sufficient**
- **Where parental permission required, see previous options for consent.**



# Participation by Minors

**To screen out minors:**

- **use Internet Monitoring software (SafeSurf and RSACi ratings)**
- **use Adult Check systems**
- **None of these are foolproof.**

**Since there is no guarantee that minors won't access research, some research may not be appropriate for the Internet.**





# Confidentiality

**Two potential sources of breach of confidentiality**

■ **inadvertent disclosure**

– [examples]

■ **deliberate attempts to gain access**

– [examples]

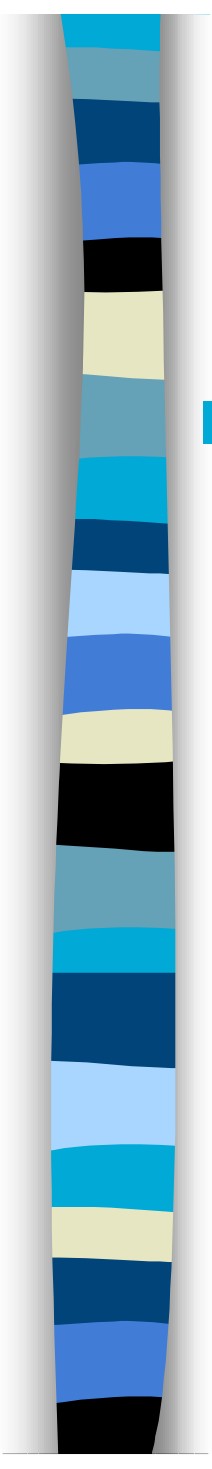
**Technology can provide reasonable security  
but cannot guarantee absolute security**



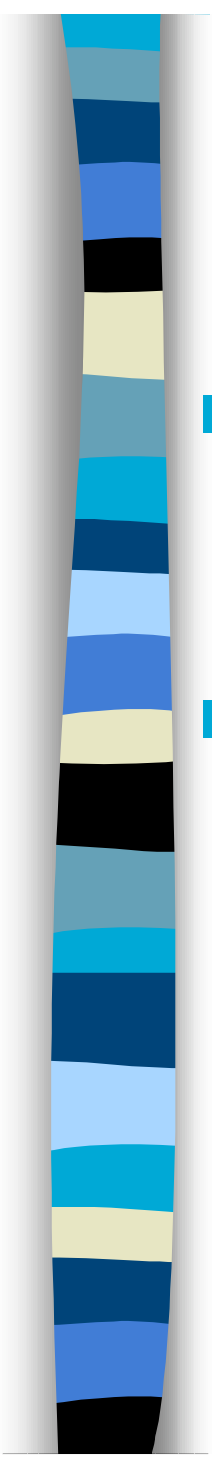
# Confidentiality

- **Data transmitted via e-mail cannot be anonymous without the use of additional steps. Almost all forms of e-mail contain the sender's e-mail address.**
  - use an "anonymizer" - a third party site that strips off the sender's e-mail address
- **Web servers automatically store a great deal of personal information about visitors to a web site and that information can be accessed by others.**

# Confidentiality

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- **Web sites can leave “Cookies”, a small file left on the user’s hard drive that is sent back to the web site each time the browser requests a page from that site. Cookies can record which computer the user is coming from, what software and hardware is being used, details of the links clicked on, and possibly even email addresses, if provided by the user.**

# Confidentiality

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- **Degree of concern over confidentiality depends on sensitivity of the information**
  - **Since it is impossible to guarantee absolute data security over the Internet, some extremely sensitive research may not be appropriate for the Internet**



# IRB Requirements

- **Investigators are going to have to provide technical information on how they will deal these issues.**
- **IRBs need to have sufficient expertise on the technical aspects of the Internet in order to ask the right questions and evaluate the information provided.**
- **IRBs that review Internet research without sufficient expertise are not in compliance with the regulations!**



# Types of Research

## **Recruiting Subjects Over the Internet**

- **Similar issues as with any other recruiting tool: IRB needs to review information presented to subjects (see FDA Information Sheets)**
- **Examples: Recruiting rape victims from discussion groups, using diabetes Web site to recruit subjects.**
- **Need to determine that subjects are who they say they are, especially minors.**



# Types of Research

## **Observation of Internet Activity**

- **Gathering information about the use of the Internet, recording user information or users' comments**
- **Example: Participant observation of grieving discussion group, using “cookies” to track sites visited**
- **IRB issues: consent/disclosure, public vs. private behavior**



# Types of Research

## **Gathering data over the Internet**

- **Having subjects submit data, e.g., survey data, over the Internet**
- **Example: survey on the use of WWW by college students; internet study of relationship issues**
- **IRB issues: consent, confidentiality and participation by minors**





# Resources

- AAAS Report on Internet Research  
<http://www.aaas.org/spp/dspp/sfrr/projects/intres/main.htm>
- FDA Information Sheet on Subject Recruitment