

Protecting people who participate in research

*CITI Training Study Guide
Privacy and Confidentiality*

Privacy & Confidentiality – IRB Obligations

- Ensure the research protocol adequately provides for protecting subjects' privacy
- Ensure effective procedures to maintain confidentiality of data

Privacy & Confidentiality - Definitions

- Privacy means having control over extent, timing and circumstances of sharing yourself with others
 - Privacy is a right that can be violated
- Confidentiality means the information you share will not be divulged to others without permission
 - Confidentiality is an agreement that can be breached

Private vs. Public Behavior

- Observation and/or recording of public behavior is not “research with human subjects”
- Private behavior occurs in a context where one can reasonably assume no observation or recording is taking place.
- Private information is information one can reasonably expect will not be made public (e.g., a school record).

Private vs. Public Behavior

- What we do on a street corner is public.
- What we do in our homes is private.
- In between.... ?
- For example, parents taking their children to a public park might consider it a violation of privacy if their children’s play was audio-taped using long-range recording devices.

Private vs. Public Behavior

“Reasonable assumptions” regarding privacy will vary from culture to culture and setting to setting.

The IRB must interpret the standard for expected privacy in the specific research setting.

Exempt Research can Honor Privacy if...

- The information is anonymous
- or
- Disclosure of the information (breach of confidentiality) is not reasonably expected to cause harm beyond that encountered in daily life.

Questions that can Guide Confidentiality Procedures

- Is it necessary to collect “identifiers” (information about who a subject is) or could data be collected anonymously?
- Can data be made anonymous by destroying identifiers after the information is collected?
- If identifiers are needed, can ID “codes” be used in data collection and analysis, keeping the “key” to the codes separate and secure?
- Can the “key” be destroyed at some point in the data analysis process?

Questions that can Guide Confidentiality Procedures

- How will data be protected from inadvertent disclosure or unauthorized access during collection, storage, and analysis?
- How will data be reported? In aggregate? Using pseudonyms? Using real names? Plans must be shared with participants so they can decide if they are comfortable participating.
- Will special permission be needed to attribute specific quotes to subjects, whether with their real names or pseudonyms?

Questions that can Guide Confidentiality Procedures

- Are there limits to the promises of confidentiality the researcher can make due to state laws requiring the reporting of suspected child abuse or neglect?
- Who else, besides the researchers, will have access to the data in the present AND in the future?
- If audio or videotapes are made, what will be done with them during and after the research? Will they be saved for future research use? Will any portion be played to anyone, such as at a scholarly conference?

Questions that can Guide Confidentiality Procedures

- If subjects were chosen for the study due to a sensitive or stigmatizing condition or participation in illegal activities, are procedures in place from the very beginning to protect identities, such as a waiver of the requirement to document consent?
- Does sensitive data need to be protected from subpoena by third parties? Should a Certificate of Confidentiality be obtained??

Certificates of Confidentiality

- May be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.
- Allows the researchers protection in legal proceedings from required disclosure of identifying information on research participants.
- Researchers apply for Certificates of Confidentiality, which are issued by the National Institutes of Health.
