

# §46.111 Criteria for IRB approval of research

In order to approve research the IRB must determine that very specific requirements are satisfied.

One of those criteria is:

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.



# What's the difference between privacy and confidentiality?

- **Confidentiality pertains to data.** Confidentiality means making sure others don't have more access **to information about you** than you want them to have.
- **Privacy pertains to people.** Privacy means making sure others don't have more access **to you** than you want them to have.

# What are some ways to maintain confidentiality in research?

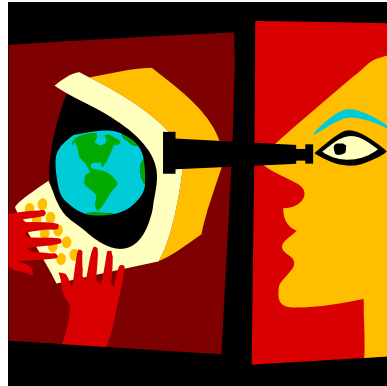
- Provide accurate information in the consent process about who will have access to the records.
- If appropriate, substitute codes for identifiers and keep the key code in a secure, separate location. For example, a participant number or some other type of code could be used instead of using identifiers such as names or social security numbers.
- Keep data in locked files.
- Ensure that all involved staff know the importance of confidentiality.

# What are some ways to maintain confidentiality in research?

- Ensure that any electronic storage is secure.
- When planning the research study, consider using collection or analysis procedures that provide anonymity.
- Prevent the possibility of deductive identification by using broader categories or other data presentation methods. Be careful that it is not possible to make someone identifiable by the information you ask. For example, if race, gender and age are asked in a small group, some members would be identifiable even if no names were collected. To prevent this, use broader categories (i.e., age ranges rather than birthdate) or ask fewer questions.

# How is privacy different than confidentiality?

- Privacy is about people and their desire to be in control of how much access they want to give others.



## What are some ways to maintain privacy in research?

- Ensure that the informed consent provides potential participants adequate information about what they will be asked and what they may experience.
- Consider the ages of participants. Expectations of privacy vary with age. For example, a young child will want the presence of his/her parents. A teenager would be embarrassed to be asked personal questions in the presence of his/her parents.

## What are some ways to maintain privacy in research?

- Consider the participant's culture and its impact on their expectations of privacy. Community consultation, focus groups, etc. may provide insight into cultural perspectives.
- Include ways to protect privacy in the participant's environment. For example, provide a private environment for the participant to read the informed consent.

## What are some ways to maintain privacy in research?

- Explain the study to the person in a private setting.
- Provide a private setting for the participant to complete study related procedures.

Remember, the IRB can not approve a study unless...

**there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**



# Sources:

45 CFR 46.111

Sieber J., Procedures to Protect Privacy and Maintain Confidentiality,  
California State University

