Privacy and Confidentiality

The Common Rule specifies that *when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data* (45CFR46.111).

Privacy vs. Confidentiality

Generally speaking privacy, applies to the person and confidentiality applies to the data.

Privacy protections

Careful consideration should be given to how potential participants are approached, the setting for approaching subjects, and the level of privacy needed to conduct the discussion about participation.

Some of the issues that should be taken into consideration when ensuring subjects' privacy include:

- the methods used to identify and contact potential participants
- consent discussions and study visits (the subject may not want others to know that they are in a study);
- the settings in which an individual will be interacting with an investigator. For example, persons may not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the front of the building
- the appropriateness of all personnel present for research activities
- information that is obtained about individuals other than the potential participants, and whether such individuals meet the regulatory definition of "human subject" (e.g., a subject provides information about a family member for a survey)
- telephone calls to the subject's house (not all members of the household might be aware that the subject is participating)
- letters sent to the subject's house containing private information
- emails and text messages that might be seen by others (e.g. children may not have complete control of their phones and email)
- Facebook or other social media groups
- how to access the minimum amount of information necessary to conduct the study

Confidentiality

The level of protections needed to ensure the confidentiality of subjects' private information will vary from study to study. Participants should be informed in the consent process that although

strict measures will be in place to protect their data, absolute confidentiality cannot be guaranteed.

Investigators have an obligation to inform research participants:

- how their data will be used
- who will have access to their data
- what procedures will be put in place to ensure that only authorized individuals will have access to the information, and
- the limitations (if any) to these confidentiality procedures

Researchers should give consideration to:

- Information obtained preparatory to research. Information obtained about individuals who were not recruited or who refused participation should be destroyed in a confidential manner.
- Methods to shield participants' identity to adequately protect participant privacy (e.g., encryption of data files, Certificate of Confidentiality).
- Whether there is a long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.
- Whether the consenting process adequately describes confidentiality risks
- Whether the informed consent process and the informed consent document, and if applicable the HIPAA Authorization Form, clearly delineates who will have access to the subject’s information (i.e., regulatory agencies, sponsors).

Studies that require a higher than usual level of protection for subjects' confidential information should obtain a Certificate of Confidentiality issued by the Department of Health and Human Services (HHS) or the Food and Drug Administration (FDA). Please refer to the Certificates of Confidentiality policy for more information.