Confidentiality & Privacy

Introduction

The confidentiality and privacy of study participants should be protected.

The research records identifying the participant be kept confidential to the extent permitted by applicable laws and regulations. For example, if the results of a clinical study are published, participants' identities must remain confidential.

The confidentiality of individually identifiable health information for all research participants should be protected. The records and identity of vulnerable populations, study participants receiving alcohol and drug abuse treatment should be protected as well.

What records must be kept confidential?

protections for the confidentiality of research participants as follows:

A – Basic protections of human research participants
B – Additional protections for research participants that are pregnant women, fetuses, neonates
C – Additional protections for participants that are prisoners involved biomedical and behavioral research
D – Additional protections for research participants that are children

In general, whether research related or not, all records of the identity, diagnosis, prognosis, or treatment of any person in a research must be maintained. This includes any record in connection with alcohol or drug abuse prevention, education, training, treatment, rehabilitation, or research must be kept confidential. "Identity" includes not only the participant's name but also any other information that could be readily linked to the participant. Additionally, applicable information may be in any form (e.g., paper, electronic, verbal).

With certain exceptions, an alcohol or drug abuse treatment program may not disclose to anyone outside the program that a particular person attends the program, or disclose any information that identifies a person as an alcohol or drug abuser, unless:

- the person consents to the disclosure in writing, or
- the disclosure is allowed by a court order

A breach of confidentiality is usually defined as any disclosure of protected information about a participant to a third party without either a court order or

consent of the participant. The breach of confidentiality may be oral or written and may occur by telephone, fax, or electronic means (e.g., electronic mail or other internet-based method of communication).

- law protects the confidentiality of identifiable health information for all research participants
- In general, all records of the identity, diagnosis, prognosis, or treatment of any person that are maintained in connection with alcohol or drug abuse prevention, education, training, treatment, rehabilitation, or research must be kept confidential.
- The regulations identify certain **exceptions to the confidentiality requirements**. Information in a participant's medical record can be disclosed:
  - To people performing duties related to the participant's diagnosis, treatment, or referral for treatment of alcohol or drug abuse.
  - To law enforcement officers when the participant has committed, or threatened to commit, a crime on program premises or against program staff.
  - When reporting suspected child abuse or neglect to state or local authorities.
  - To medical personnel in a medical emergency. For research purposes, with certain conditions.
  - For management audits, financial audits, or program evaluation.
  - If a participant is found to be at risk for suicide or if he or she makes a credible threat to harm another person.
  - When the participant has a communicable disease that poses a risk to public health.
  - When authorized by a court order. When required by state law

Maintaining Confidentiality of Research Participants

Recommended Routine Practices for Maintaining the Confidentiality of Research Participants

Researchers ordinarily use information that study participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. Because the relationship between researcher and study participant is based on trust, it is most important to ensure that the confidentiality of this information is maintained.

The following routine practices are recommended to ensure the confidentiality of research participants:

- Substitute codes for information that identifies the participant (e.g., use numbers instead of names to identify participants).

- Remove face sheets that contain identifiers, such as names and addresses.
- Properly dispose of all paper documents that contain identifiers. Limit access to all data that identifies participants.
- Educate research staff on the importance of maintaining confidentiality.
- Store paper records in locked cabinets.
- Assign security codes to computerized records.

Permitted Disclosures of Protected Health Information

Covered entities may use or disclose the "minimum necessary" amount of protected health information (PHI) to or among themselves, without the individual's authorization, for purposes of treatment, payment, and health care operations.

The only exceptions to the "minimum necessary" requirement are for the use and disclosure of PHI:

- To or by health care providers for treatment purposes.
- To the individual who is the subject of the protected health information.
- To the Secretary of Health and Human Services, who has authority for the Privacy Rule.
- Use or disclosure that is required by the law

Additionally, covered entities may disclose PHI for certain "public policy" purposes without the individual's authorization. However, they are required to track these disclosures for accounting purposes.

Public Policy Purposes

The Privacy Rule permits covered entities to use or disclose protected health information (PHI) without the individual's authorization for the following public policy purposes:

- When the disclosure is required by law
- For public health activities (e.g., prevention or control of disease, notification of adverse drug events).
- In cases of abuse, neglect, or domestic violence. For health care oversight activities authorized by law or regulations.
- For judicial and administrative purposes (e.g., a court order, subpoena, or warrant).
- To a law enforcement official for law enforcement purposes.
- To a coroner, medical examiner, or funeral director when the information concerns a deceased person.
- For cadaveric organ, eye, and tissue donation.

- For research purposes.
- To avert a serious threat to health or safety.
- For national security or intelligence activities.
- For workers' compensation purposes.