

Confidentiality in Research

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Outline

- Definition of Terms
- Confidentiality of Data
- Duty of Confidentiality
- Maintaining Confidentiality in Research
- Breaking Confidentiality

Privacy

- The right to be left alone
- The right of an individual to withhold himself and his property from public scrutiny
- Derives from the concepts of individual freedom and autonomy and involves the ability of an individual to control the release or dissemination of information that relates to him/herself (Sacks, 1997)
- Refers to the person—consider where you will speak with the person, consider what you will say, how you will address their concerns (HIPPA)

Confidentiality

- The right to rely on the trust or discretion of another
- The right of an individual to control access to and disclosure of private information entrusted to another
- Derives from a relationship when an individual gives private information to another, on the condition or with the understanding that the other will not disclose it, or will disclose it to the extent that the individual directs (Sacks, 1997)
- Refers to the data of the person—how you will keep it secure, who will have access to it or who you may share it with, what you will do with it once the project is complete (HIPPA)

Anonymity

- Defined as 'of unknown name, of unknown authorship' (Concise Oxford Dictionary)
- De-identify
- The extent to which anonymisation is successful varies according to the research context

Duty of Confidentiality

- A duty of confidentiality can be established in situations where information is passed, in confidence, to the confidant (the receiver of the information)
- Research participants should be informed about how far they will be afforded anonymity and confidentiality
- Guarantees of confidentiality and anonymity given to research participants must be honoured, unless there are clear and overriding reasons to do otherwise
- Researchers should not breach the 'duty of confidentiality' and not pass on identifiable data to third parties without participants' consent
- However, research data given in confidence may not enjoy full legal privilege and may be liable to subpoena by a court. In relevant circumstances research participants should be made aware of this fact

Importance of Confidentiality in Biomedical Research

- Research involving human participants may involve the collection and storage of information, which if disclosed to a third party could **cause harm or distress** to the participants (CIOMS, 2002)
- The nature of the harm may be **emotional/psychological, physical, social, legal**
- Every person is entitled to privacy with regard to his/her most personal physical and psychological secrets
- Confidentiality is an important component of **respect for persons**, one of the principles of research ethics

Importance of Confidentiality (2)

- Confidentiality is **the basis of trust** between the investigator & the research participants
- Participants must trust that investigators will keep secret the information they disclose during research
- Researchers must trust that participants will provide truthful information
- Investigators cannot draw reliable conclusions from research based on lies (Beauchamp & Childress, 2001).
- **It is this trust that makes research enterprise flourish**

Confidentiality of Data



- Maintaining confidentiality of data/records
 - ensuring the separation of data from identifiable individuals
 - storing the code linking data to individuals securely
- Ensuring those who have access to the data maintain confidentiality
 - e.g. - not discussing the issues arising from an individual interview with others in ways that might identify an individual
 - not disclosing what an individual has said in an interview
- Anonymising individuals and/or places in the dissemination of the study to protect their identity

Guidelines for Maintaining Confidentiality

- At the beginning of a relationship or conversation, establish the expectations of confidentiality
- Re-establish boundaries at the end of the conversation
- Confidentiality must be protected in all forms of communication: written, spoken, and electronic. Pay attention to person, place, and time when personal information is involved
- Secure the environment in which confidential information is kept
- Determine “need to know” before you share information

Precautions to Protect Data Confidentiality

- Face sheets containing are removed from completed survey instruments
- Access to master code lists or key codes is limited
- Master lists are stored separately from the data and destroyed as soon as reasonably possible.
- Contact lists, recruitment records, or other documents are destroyed when no longer required
- Files containing electronic data are password-protected and encrypted
- Research data/specimens are stored securely in locked cabinets or rooms
- Coding of data/specimens
- Electronic data are stored in password-protected computers or files
- Files containing electronic data are closed when computers will be left unattended
- Consent and HIPAA authorization forms are stored securely in locked cabinets or rooms separately from the research data.
- Research staff are trained in the IRB-approved methods for managing and storing research data/specimens

Further Considerations in Confidentiality in Research

- Biometric or genetic testing
- Linking multiple data sets
- Re-contacting participants
- Internet research
- Use of interpreters/translators
- Placement of data in repositories
- Secondary or incidental findings
- Materials Transfer Agreements
- HREC review of confidentiality protections

Breaking Confidentiality

- The law requires researchers (and others) to break the confidence of a participant if they disclose having committed or being about to commit a crime
- A moral duty (although no legal obligation) to disclose information if a study participant reports being a victim of crime or if a researcher feels a study participant is at risk of harm
- Think through the circumstances and alert participants as part of the consent process
- Consider participants' safety and well-being and various legal, regulatory and professional frameworks to which you are subject

Valid Consent for Releasing Confidential Information

- A person's name and identifying information
- Address of the entity directed to release the information
- Description of the information to be released
- Identity of the party to be furnished the information
- Language authorizing release of information
- Signature of person or authorized individual
- Time period for which release remains valid

Resources

- Wiles R, Crow G, Heath S, Charles V. Anonymity and confidentiality. 2006. ESRC National Centre for Research Methods NCRM Working Paper Series
- Henderson L. Confidentiality in Research: Tips and resources for researchers. Vanderbilt Kennedy Research Ethics Center
- Health Insurance Portability and Accountability Act (HIPAA). Medical Privacy - National Standards to Protect the Privacy of Personal Health Information <http://www.hhs.gov/ocr/hipaa/>
- Maintaining data confidentiality. University of Nevada, Reno
- Ajuwon J. Confidentiality in Biomedical Research. 2016 MEPIN Workshop
- Duty of confidentiality for research participants. Oxford Brookes University