

Privacy and Confidentiality in Research

Recent examples of privacy and confidentiality concerns:

- U.S. Census
- Credit reports
- Electronic medical records
- Health care reform
- Biobanking
- Voter initiatives

How do privacy and confidentiality relate to the Belmont Report?

BELMONT PRINCIPLE	APPLICATION
Respect for persons	Promise made by researcher to study participants that personal information will be protected. Also relevant for records research.
Autonomy	Individuals decide what and with whom to share personal information
Justice	Protecting information collected in a research context from unauthorized disclosure; safeguards to minimize disclosure risks; ensuring privacy for study subjects during data collection

But aren't "privacy" and "confidentiality" the same thing? Although often used interchangeably in common discourse, they are two different concepts, one related to the *person*, and the other related to *information*:

“Privacy”

Having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Private information must be identifiable in order for the collection of such information to constitute research.

“Confidential”

The treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without the individual's permission.

What do the federal regulations say?

The federal regulations for protection of human research subjects require IRBs to consider, "...when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data" (45 CFR 46.111(a)(7)). Food and Drug Administration regulations include a similar requirement. In making an assessment of privacy and confidentiality protections, IRB members should first consider how "private" the information to be collected is, which may involve considerations of: a) the study population; b) community norms; c) any legal restrictions on the information; d) what is private to one person may not be to another; and e) the definition of "minimal risk" in the regulations.

In addition, required elements of informed consent listed in 45 CFR 46.116 specify that subjects be informed of "...the extent, if any, to which confidentiality of records identifying the subject will be maintained". In addition, consent documents must include explanation of the "reasonably foreseeable risks" of research participation--which may have implications for privacy of subjects and confidentiality of the information to be collected in the course of the research.

Certificates of Confidentiality

Certificates of Confidentiality are granted by Department of Health and Human Services agencies in order to provide protection against compelled disclosure of identifying information about subjects enrolled in research. Typically, Certificates are granted when the research involves collection of sensitive information or involves subjects whose behaviors put them at risk, such as injection drug users or persons involved in illegal behaviors. This protection is *not* limited to federally supported research. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. Certificates help to minimize risks to subjects by adding an additional level of protection for the confidentiality of private information.

Certificates of Confidentiality do not prevent the voluntary disclosure of identifying information regarding research subjects or others. Abuse or neglect of children and reportable communicable diseases are examples of disclosures that a Certificate does not protect, as researchers are required by law, institutional policy, and/or professional ethics to disclose in such cases.

U.S. Department of Justice regulations (28 CFR §22.23) require that a Privacy Certificate be submitted as part of any grant application in which information identifiable to a private person will be collected for research. Individuals seeking DOJ grant funds are required to certify that data identifiable to a private person will not be used for other purposes or revealed, unless the subject has given consent or has been informed that study findings cannot, by virtue of sample size, or uniqueness of subject, be expected to totally conceal subject identity.

Privacy and confidentiality are central to human subjects review at all phases of research:

➤ **Identification and selection of potential study subjects**

Medical records
Registries/databases
Schools
Inpatient settings

Self-identification
Screening for eligibility
Ineligibles
“Opt out” provisions

➤ **Recruitment**

Public areas, on the street
Hospitals/clinics
Mailings
RDD
Internet/web sites/chat rooms

Recruitment of minors
Jail/prison
Drug/alcohol treatment centers
Use of intermediaries/gatekeepers
Telephone systems/voice mail

➤ **Consent Procedures**

Setting
Presence of other individuals or
observers
Internet-based
Waiver of documentation of consent

Copies of consent forms in
clinical/program records
Focus groups
Promise made to study participants

➤ **Data Collection**

In-person interviews
Internet/Email
Record abstraction
Using clinical/program records for
research
Electronic records

Group settings (schools, jail, clinics,
treatment centers)
Focus groups
Field procedures
Recontact/use of collaterals
Biological specimen collection
Genetic testing

➤ **Data storage**

Who has access?
How is security maintained?
What identifiers are *essential* to
maintain?

How long are identifiers kept?
When will identifiers be destroyed?
Is the dataset truly “deidentified”?

Special issues: Audio and video recordings
 Biological specimens

➤ **Data Analysis and Presentation**

Small cell sizes
Discrete variables
Redaction

Anonymous aggregate data
Geocoding/mapping

➤ **Other Issues**

Cultural
Use of translators and interpreters
Retention of research data in
clinical/program records

Unvalidated instruments, screening
tools, or diagnostic tests
Genetic test results

Privacy and confidentiality also intersect with other ethical issues and legal requirements:

- Limits to confidentiality (abuse reporting, infectious disease reporting, handling threats of harm)
- State statutes or federal regulations regarding certain study populations (substance abusers, people with HIV infection)
- Institutional policy (e.g., prior notification/opt out for agency clients)
- Disclosure of records for research purposes and prohibitions on redisclosure
- Protection of research data (Certificate of Confidentiality, security procedures, etc.)
- Redisclosure of research or administrative data for other purposes or to other researchers

Some examples of research which prompted discussion about privacy and/or confidentiality:

- ❖ Researcher develops rigorous procedures to protect confidentiality of study data and identity of subjects. *But...* the script for leaving telephone messages for study subjects refers to a study of welfare recipients.
- ❖ Researcher plans to keep in touch with study participants through postcard mailings. Postcard refers to “Medicaid recipients”.
- ❖ Researcher submits with an adverse event report a copy of a letter sent to a potential study participant. The letter included the subject name, child name, address, and the condition which was the focus of the research.

- ❖ Researcher reports to IRB A the name of study subjects participating in an intervention. *But...* IRB A is not reviewing that component of the study, and the focus of the research is in an area which has special federal protections.
- ❖ Researcher obtains thousands of directly identifiable confidential records, prior to IRB review and approval and with no legal authority in place for access to the records.
- ❖ Researcher proposes unrestricted access to “live” database regarding child abuse/neglect referrals.
- ❖ Researcher proposes web-based survey, ensuring confidentiality of the information. *But...* the institution collects and retains all identifiable information voluntarily disclosed by persons accessing its web pages.
- ❖ Researcher proposes hospital-based survey of ward staff regarding their treatment of patients and beliefs about treatment of the mentally ill. The survey proposes to collect information on age, job title, education, years at current job, detailed information regarding race/ethnicity....
- ❖ Researcher proposes to review STD clinic records and appointment books to find eligible subjects.
- ❖ Researcher proposes to obtain records for investigation of child mortality. *But...* records may only be disclosed in aggregate, unidentified form.
- ❖ Researcher hires former employee of Agency X to access and disclose Agency X records for the study.
- ❖ Researcher discloses subject identifiers to individuals not affiliated with the study, in violation of a data sharing agreement.
- ❖ Completed interview forms are left in a parked car overnight. Car is broken into and box of completed instruments is stolen.