

Waivers: Authorization

Waiver of Consent versus Waiver of Authorization

- Waiver of Consent - for study participation
- Waiver of Authorization – for use and disclosure of confidential personal records/PHI (Pre-HIPAA – authorization forms were commonly called “medical record release forms”)
- Consent and authorization are two different things; sometimes combined in one study (e.g., consent for a research procedure and authorization for use of medical records), but often not.
- Regulations REQUIRE consent and authorization. Waivers come into play when a researcher argues it’s not possible to meet the default regulatory requirements to obtain consent and/or authorization.
- Waivers of consent will be covered in another session – today, I want to focus on waivers of authorization.

Ethical Principle: Respect for Persons

Individuals should be treated as autonomous agents, able to make decisions about issues that affect them. Central to the consideration of waivers are the principles of privacy and confidentiality.

- **Privacy** – having control over the extent, timing, and circumstances of sharing oneself or one’s personal information, with others (*i.e., the right to determine what will be known about oneself*).
- **Confidentiality** – treatment of personal information disclosed in 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 permission (*i.e., personal information will not be disclosed without permission*).
- Per these definitions, any disclosure of personal information for research without the person’s permission (regardless of how worthy the research) violates a right to privacy and confidentiality. (Note, however, that information must be identified, or at least identifiable, to be considered personal information or PHI.)

Historical Context

- While it’s easy to require that use of personal information for research must be authorized by the individual, there are some situations in which it’s probably unfeasible if not impossible to obtain signed authorizations.

- The clearest example might be epidemiological research using thousands of individual records stored in electronic information systems. The numbers are too large, and the contact information may be too out-of-date, to be able to contact these individuals and ask for their permission.
- Without the waivers, worthwhile and important research that could benefit society, and the class of individuals whose records would be used, could not be conducted.
- Under these circumstances, if the risks can be minimized by strong measures to protect the security and confidentiality of the personal information, it is reasonable to ask whether waiver of authorization is ethically justified.
- Privacy Protection Study Commission (1977) concluded that medical records can be used for research without authorization provided certain criteria are met.
- The National Commission for the Protection of Human Subjects (1979) endorsed this position "if the subjects interests are adequately protected and the importance of the research justifies the invasion of privacy."
- In the ensuing years, various criteria for waiver of authorization have been codified in statute and regulation. To approve a waiver, the IRB must document that these criteria have been met.
- It is the researcher's responsibility to make the case that the waiver criteria have been met, and the IRB's responsibility to determine if the researcher has successfully made the case.

Statutes and Regulations

- **45 CFR 46.116(d)(2)** – This is the provision in the federal human subject protection regulation (1978) for the waiver of consent. If the research is subject to this regulation, this section also pertains to waiver of authorization. This causes some problems, as the waiver of consent criteria were not written for the use or disclosure of personal information, but rather for study participation.
- **RCW 42.48** – Until this state statute was enacted in 1986, 45 CFR defined the only criteria in statute or regulation that must be satisfied for the IRB to approve waiver of authorization. This statute applies to the research use and disclosure of all personal record information held by Washington State Agencies (DSHS, DOH, DOC, DEL, and institutions of higher education).
- **RCW 70.02** – This is the state medical records / health care information access and disclosure law enacted in 1991. The statute applies to "health care information" defined as "information that identifies or can readily be associated with the identity of the patient and directly relates to the patient's health care." It allows waivers if certain conditions are met.
- **45 CFR 164.512(i)** – The HIPAA Privacy Rule (2003) applies broadly to all health care information created or received by a health care provider, health plan, or health care clearinghouse. It allows waivers under specified circumstances.

Waiver Criteria

The applicability of these four statutes and regulations varies, and their waiver criteria overlap but are not identical. Rather than try to micromanage waivers of authorization, WSIRB has developed an unduplicated list of waiver criteria as a general set of conditions the researcher must satisfy for a waiver or authorization request to be approved. (See Research Application, Appendix I, Section 4)

1. The research involves no more than minimal risk. (CFR 46.116(d); RCW 42.48; CFR 164.512(i))
2. The waiver won't adversely affect the rights and welfare of the subjects. (CFR 46.116(d))
(Doesn't really apply to record disclosures; if taken literally, would never be met)
3. It is not practicable to obtain signed authorization for the disclosure. (CFR 46.116(d); RCW 42.48; CFR 164.512(i))
4. It is not practicable to conduct the research without use or disclosure of identifiable records. (RCW 42.48; RCW 70.02; CFR 164.512(i))
5. Identifiable information used or disclosed for the research will be protected from improper uses or disclosures. (RCW 42.48; RCW 70.02; CFR 164.512(i))
6. The research is of sufficient importance to outweigh the intrusion into the privacy of subjects resulting from the uses or disclosures. (RCW 70.02)
7. When appropriate, the subjects will be provided with additional information about participation. (CFR 46.116(d)) **(Doesn't really apply to record disclosures)**
8. Specify when and how identifiable information will be destroyed. (RCW 42.48; RCW 70.02; CFR 164.512(I))
9. Provide written assurance that identifiable information will not be reused for other purposes or disclosed to any other person or entity. (RCW 42.48; CFR 164.512(i))
10. Provide written assurance that no individual whose identifiable information has been used will be identified in any written report resulting from the research. (RCW 42.48; RCW 70.02)

Other Factors to Consider

- Transparency: Notify individuals about the uses of their identifiable information. Many custodians of the personal records provide information to individuals that their information can be used for research purposes (e.g. WSCR; DSHS client consent form). Note this is not the same as an authorization – it's a notification, but it tips the ethical balance back to a more favorable position.

- In this age of electronic data, direct examination of hard copies of medical or social services records are occurring less frequently. One could argue that direct examination poses more risks (e.g., of discovering anecdotal information in a medical chart that's not related to the research question) than extracting and linking information across electronic systems.
- On the other hand, the construction of large linked datasets drawing from multiple sources may increase the potential harm to the individual if security is breached and the information disclosed to unauthorized persons.
- Unless obtaining information for study recruitment, researchers generally are not interested in knowing the identities of subjects beyond the need to link information from different sources.
- Records from large datasets are generally linked using automated routines with little if any manual inspection.
- All direct identifiers will be destroyed when they are no longer needed. If they need to be retained, they will be removed from analytic files and replaced with a code number. The link between identifiers and code numbers is locked.
- Often direct identifiers are not disclosed, and linked datasets are created "in-house" and disclosed by the custodian in the form of "limited datasets." This is consistent with the "minimum necessary" requirements in the Privacy Rule.
- Finally, all disclosures for research without authorization must be reviewed and approved by the IRB,
 - must meet the criteria for waiver of authorization;
 - must be disclosed to researchers under terms or written agreements that have legal penalties for violations;
 - and must have stringent procedures in place for the protection of confidentiality and the security of the data (e.g., encryption; secure file transfer).

So, I leave you with this thought:

Have we violated an immutable ethical standard when we waive authorization?

Or is the waiver ethically justified on grounds we are facilitating research that benefits us all?