

Waivers: Consent and Documentation of Consent Social, Behavioral, Epidemiological Research

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 authorization were discussed in our 10/16 meeting – today, I want to focus on waivers of consent.

Two distinctly different types of waivers related to consent:

- Waiver of consent – a request for a consent procedure which **does not include, or which alters, some or all** of the elements of informed consent. (45 CFR 46.116(c) and (d))
- Waiver of **documentation** of consent – a request for a consent procedure that does not require the subject to sign the consent form. (45 CFR 46.117 (c)(1) and (c)(2))

Ethical Principle: Respect for Persons

- Individuals should be treated as autonomous agents, able to make considered decisions about issues that affect them.
- Central to the approval of waivers of consent is whether it is justified to **withhold information** needed for an individual to make a considered decision about participating in the research.

Research Examples

- **Withholding information** often arises in a subset of social/behavioral research that requires deception to obtain valid results – i.e., in situations in which complete knowledge of the purpose of the research would influence how the subject responds. (e.g., **Milgram studies of obedience to authority** – in which subjects ostensibly administered electric shocks to other subjects, who were in fact collaborators in the deception, or **Laud Humphries** research on **Tearoom Trade**).
- While Milgram’s research is generally viewed in a negative light, other studies may require withholding some information for similar purposes (e.g., **Fostering Hope Study** - assessing the effects of an engagement strategy on improving outcomes for foster children in Trauma-focused Cognitive Behavioral Therapy – telling foster parents the study is about engagement would likely bias their responses to the intervention.)
- The ethical tension about **withholding information** arises from the fact that a person can’t make a considered decision without having all the pertinent information. On the other hand, certain kinds of valuable research could not be done without **withholding information**. The waiver criteria in the regulations have resolved this tension by stipulating that waiver can be approved only for **minimal risk** research, and by requiring other criteria to be met.

What are the required elements of consent that might be waived or altered?

1. The activity involves **research**; **why the study is being done**; **what are the study procedures**; **how long will it take?**
2. What are the **risks or discomforts** involved, and how are they minimized?
3. What are the **anticipated benefits**, to the subjects, or in terms of increased knowledge?
4. What **procedures will protect confidentiality** of study information?
5. **Who to contact** if they have questions about the study or about their rights?
6. A statement that study participation is **voluntary**, and that subjects **may refuse to participate**, or stop the interview at any time, with **no penalty**.

Two additional elements (usually apply to biomedical, but usually not to social, behavioral and epidemiological research)

1. What **alternative procedures** or **courses of treatment**, **IF ANY**, are appropriate?
 2. If more than **minimal risk**, what **compensation** and/or **medical treatment** is available **if an injury occurs?**
- I have seen consent forms for social/behavioral research in which **alternative procedures** were described when the study only involved surveys or interviews. The consent form might say that the alternative procedure was “not to respond.” This is silly in my opinion, and I don’t think it’s the intent of the regulations.

- The consent requirement to disclose **alternative procedures** or **course of treatment** in the regulations presumes research **interventions** rather than research **interactions** - if there's no reasonable alternative, this element does not have to be in the consent form.
- Likewise, most social, behavioral and epidemiologic research is **minimal risk**. There is **no requirement** in minimal risk research to specify whether compensation or medical treatments will be provided if an injury occurs.

Review Criteria - Waiver of Consent:

46.116(c) is rarely used – applies to research involving experiments that provide different levels of service or benefits in government programs – have used it in DSHS research less than a half dozen times over the past 25 years.

We use 46.116(d) -

1. **The research involves no more than minimal risk.** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater ... than those (1) ordinarily encountered in daily life or (2) during the performance of routine physical or psychological examinations or tests.
2. **The waiver or alteration will not adversely affect the rights and welfare of subjects.** This is a tough standard – if you withhold any pertinent information needed for a subject to make an informed decision, haven't you violated this standard? The criterion is usually assessed in terms of minimizing adverse effects on rights and welfare.
3. **The research could not practicably be carried out without the waiver or alteration.** Generally, for research involving interventions or interactions with individuals, this criterion is assessed in terms of preserving the integrity of the design and maximizing the validity of the findings. For research involving the use of private information or PHI, it is assessed in terms of the practicality of contacting large numbers of individuals to obtain their authorization to use the PHI when they otherwise would not be contacted.
4. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.** This is generally interpreted to be a debriefing requirement when subjects have not been given all the pertinent information usually provided in an informed consent process.

Note:

- These criteria were developed primarily for social/behavioral research in which incomplete disclosure or deception is required to maximize the integrity of the study design and the validity of the findings.

- However, the criteria also must be satisfied when researchers request a waiver of authorization for use or disclosure of confidential records (PHI) for research, i.e., **records research**.
- While IRBs routinely waive **all** elements of consent for **records research** that does not otherwise involve contacting subjects, I'm not aware of an IRB waiving **all** the elements of consent for research that involves interventions or interactions with subjects.

Review Criteria – Waiver of Documentation of Consent (i.e., signed consent):

(46.117(c)(1) or (2))

1. **The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.** (e.g., interviews with a convenience sample of gay men at a venue where they hang out.)

If this criterion is used however, **each subject will be asked whether he/she wants documentation linking the subject with the research, and the subject's wishes will govern...** (Rarely will a researcher want to take this additional step, and rarely [it seems to me] would a subject want their name linked to their study data.)

So, I usually recommend the second criterion:

2. **That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.** (This would apply to most minimal risk telephone interviews, mailed surveys, and focus groups)

Note:

- This is a waiver of **documentation** of consent, not a waiver of consent.
- When documentation of consent has been approved, WSIRB will require a **consent script** (for telephone or in-person interviews) that includes all the elements of consent. After reading the consent script, the researcher will ask for **oral consent** before starting the interview.
- For mailed surveys, the elements of consent are usually included in a cover letter that accompanies the survey. Returning the survey is considered to be **implied consent** to participate.
- If waiver of signed consent is approved in a study that requires disclosure of PHI, signed authorization for the disclosure of PHI is still required.