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Waiver of All Consent

In certain cases, federal regulations allow the IRB to *waive the requirement to obtain any informed consent*. Most complete waivers of consent involve studies in which there are minimal risks to subjects, but complete waivers are also possible in emergency care and other limited circumstances.

Notes: FDA regulations (21 CFR 50 and 56) differ from DHHS regulations (21 CFR 46) and are generally more restrictive. The differences are noted below.

Minimal Risk Studies

Federal regulation and recent FDA Guidance establishes five criteria for waiving consent or altering the elements of consent in minimal risk studies according to 45 CFR 46.116(f) ^[1] (Common Rule):

1. The research involves no more than minimal risk ^[2];

2. The research could not practicably be carried out without the waiver or alteration
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

When to provide additional pertinent information

There are no strict rules for deciding when it is ?appropriate? to provide additional pertinent information; but the IRB will apply some general standards in considering such requests:

- If consent is waived because it is not practicable to obtain consent from large numbers of patients for a retrospective chart review study, generally it also will not be appropriate to attempt to contact those patients to tell them about the study retrospectively.
- If consent is waived because subjects are temporarily incapacitated, it may well be appropriate to provide them with information later, and even, as noted above, to obtain consent for ongoing research.

Example of approvable waiver of consent

Study to determine whether some specific blood chemistry values change in people undergoing clinically indicated abdominal surgery, and if there is a correlation of changes with increased incidence of complications after surgery.

Involves review of medical records of all patients who have undergone abdominal surgery in the past two years (about 10,000 surgeries), collecting limited data that will be double-coded so link is known only to researchers. Results of the research will not affect clinical care of the individuals, since they will already have left the hospital.

1. **Minimal risk:** Fits definition.
2. **Would not adversely affect rights and welfare of subject:** Surgery and associated blood chemistry values are clinically indicated, therefore would be done regardless of the research. No study results would affect clinical decisions about the individual's care.
3. **Research could not be practicably carried out without the waiver:** Identifying and contacting thousands of potential subjects, while not impossible, would not be feasible for a medical record review where results would not change care the individuals already would have received. (Note: In smaller studies, it may be harder to argue that obtaining consent is not feasible, especially if subjects have not yet been treated or are still being seen.)
4. **Whenever appropriate, subject provided with additional pertinent information after participation:** Not appropriate in this case, since results of research would have no effect on the subjects. There is no anticipated benefit to subject that would change what has already occurred.

(Above example adapted from *Institutional Review Board: Management and Function*, R. Amdur and E. Bankert, Chap. 6-6, "Research without Consent or Documentation Thereof," M.

M. Elliott.)

Waiving consent versus obtaining consent from a surrogate/legally authorized representative

When prospective research participants in minimal risk studies cannot consent for themselves because they are incapacitated in some way, the researcher must decide whether to request a waiver of all consent or use of a surrogate consentor/legally authorized representative [3].

- Ethically, it is usually preferable to use a surrogate who knows the subject's wishes rather than waive consent entirely. However, these concerns are less serious for studies with minimal risks, and it might be possible to waive consent completely if the study is not practicable without the waiver.
- If surrogates will be asked to give consent, even for studies involving minimal risk, the standard procedures [3] for identifying a legally authorized representative and obtaining surrogate consent must be followed. It may not be practicable to follow this process for some minimal risk studies, in which case a waiver of all consent should be requested.
- When surrogate consent is used in a study, there are strict requirements for obtaining additional consent when the subject becomes competent, especially if there are any continuing or follow-up procedures.

Consent for continuing or follow-up procedures after an initial waiver of consent

In occasional minimal risk studies, the IRB may waive consent when subjects initially cannot consent for themselves, but require consent for later procedures when subjects recover their capacity to consent.

Examples where follow-up consent might be required: The IRB approves waiver of consent for a minimal risk blood draw from patients arriving unconscious at the emergency room. But if the researchers want any procedures (e.g., blood draws, tests, collection of information from records) to continue after subjects become competent to consent, or want the subjects to participate in follow-up procedures (e.g., interviews, office visits, or additional tests or medical record review), then the IRB would probably require that signed consent be obtained before research on that participant could continue.

Contents of follow-up consent: The consent form should clearly describe what procedures occurred without the subject's consent, why they were performed, and what additionally will be done if consent is given to continue the subject in the study. The subject must also be given the option of refusing to allow the researchers to use the data already collected.

Research in Emergency Settings ? More Than Minimal Risk

Federal regulations allow the IRB to approve a waiver of consent in planned research in an emergency setting [4] where there is more than minimal risk to participants, provided there is a prospect of direct benefit to participants and a number of other conditions are met. See the Research in Emergency Settings [4] page for more info.

This waiver applies to both FDA- and DHHS-regulated studies. Meeting all of the conditions

for waiver under these regulations is arduous, but it may be worthwhile to consider this process for research in circumstances where treatment must be provided quickly, patients are incapacitated and a legally authorized representative is not readily available (e.g. research on head trauma, spinal cord injury or gunshot wounds).

Important Note: Emergency and compassionate use of an experimental drug or device [5] is usually distinct from planned research in emergency settings.

Public Benefit or Service Program Studies

Federal regulation 45 CFR 46.116(c) [6] (Common Rule) provides for waiving consent in the following circumstances (very rare at UCSF). These provisions do not apply to FDA-regulated studies.

1. The project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

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Links

- [1] <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116>
[2] <http://irb.ucsf.edu/levels-review>
[3] <http://irb.ucsf.edu/surrogate-consent>
[4] <http://irb.ucsf.edu/research-emergency-settings>
[5] <http://irb.ucsf.edu/emergency-use-and-compassionate-use-experimental-drugs-and-devices>
[6] <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>