

Consent Waivers: What's available and what do they mean?

Usually, the principle of respect for persons dictates that every subject be fully informed about a study and personally consent to participate prior to any study activities being done on a particular subject, their specimens, or their data. However, the IRB and the regulations in this area recognize that while this is the preferred way research would be conducted, doing so is not always practicable. This document outlines the waiver allowed under the Common Rule, the criteria required to be met for a particular waiver to be granted, and the comparison between an allowable waiver and a common colloquial misinterpretation.

Full Waivers of Consent

In some cases, it is possible for the IRB to fully waive the requirement for informed consent when a study is otherwise subject to the Common Rule. This is common for studies involving a secondary use of previously collected data (e.g. chart review studies) or other studies in which there may not be an interaction with the subjects. This full waiver of the consent process means that subjects will not be informed they're in a research study, will not be given the option to opt out of the research, and won't be given any of the other information commonly provided via a consent document.

Given the conflict with the principle of Respect for Persons that a full consent waiver raises, the Common Rule provides five criteria that all must be met in order for consent to be fully waived by an IRB:

1. The research involves no more than minimal risk to the subjects
2. The research could not practicably be carried out without the requested waiver or alteration
3. If identifiable private information and/or identifiable biospecimens will be used, the research could not practicably be carried out without using such information and/or biospecimens in an identifiable format
4. The waiver will not adversely affect the rights and welfare of the subjects
5. When appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

It is important to note that the Common Rule is not the sole voice on the matter. The FDA regulations at 21 CFR 50 and 56 along with FDA guidance also provide options for waivers of consent. FDA guidance allows for a waiver of consent when criteria 1, 2, 4, and 5 from the above are met. This guidance was developed before the Revised Common Rule was finalized and may be updated in the future to include criterion 3 above.

In addition, California law requires that any research which involves a "[medical experiment](#)" be conducted only after full documented informed consent is obtained from the subject or their legally authorized representative. Research procedures which fall into the classification of "medical experiment" are those that involve: severance or penetration or damaging of human tissues (e.g. blood draws), the use of a drug or device, use of electromagnetic radiation, use of heat or cold, use of a biological substance or organism.

Because the California law is more restrictive than either the Common Rule or FDA requirements, some studies may qualify for a full consent waiver under the Common Rule but cannot have one granted due to the California legal requirements.

Waiver of Documented Informed Consent

In some instances, it is advantageous for a study to have a consent process but not require that the subjects sign a consent form. This could be for cultural reasons, concerns for confidentiality, or simply practicality. This waiver of documented informed consent does still require that the research team present every subject with a written document explaining what will happen to them in the study embodying all the elements of consent, go over that document with subjects, and obtain their consent to participate orally before beginning any study procedures. For that reason, studies employing such a waiver may be said to use an oral or verbal consent process.

The roots of this waiver seek to strike an appropriate balance between all three of the Belmont Principles, and so the Common Rule lays out three scenarios in which documented informed consent can be waived. Notably, all the criteria in a given scenario must be met for a waiver of documented informed consent to be able to be granted:

1. The only record linking the subject and the research would be the informed consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
2. 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.
3. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing documents is not the norm, the research presents no more than minimal risk of harm to subjects and there is an alternative mechanism for documenting that informed consent was obtained.

Like with full waivers of consent, the Common Rule is not the only regulation that requires consideration. The FDA only allows a waiver of documented informed consent when scenario number 2 above is satisfied. The other two scenarios do not qualify for waivers under FDA regulation.

Additionally, California law does not allow waivers of documented informed consent for studies which involve a "medical experiment" regardless of whether any of the Common Rule scenarios apply. In practice, this generally means that FDA-regulated studies will not qualify for a waiver of documented informed consent.

Partial Waivers

Sometimes a waiver (either of consent or of documentation) is required not for all of the study procedures envisioned but only for a subset. For example, some initial data collection or procedures might need to be conducted before it would be practicable to obtain or document consent. When a study requires such a waiver, the IRB can grant a partial waiver for just the subset of procedures for

which a waiver is required. The Common Rule criteria (either for waiving consent or waiving documentation) must be met for all the procedures to be waived.

Some examples for when a partial waiver of consent would be necessary include studies that have both a retrospective and prospective cohort. In such cases, it may be appropriate for consent to be waived for the retrospective cohort, but not for the prospective cohort. Thus, a partial consent waiver would be appropriate. Additionally, it may be appropriate to issue a partial documentation waiver for some studies. One example might be a study that involves a survey with an optional imaging component. The IRB could waive the requirement for documentation of consent on the survey but would have to require consent for the imaging procedure.

FDA guidance also allows for partial consent waivers when the study as a whole is minimal risk and the previously noted criteria are met. The FDA also allows for an [Exception From Informed Consent](#) (EFIC) process to allow for the initial enrollment of subjects and intervention; however, this is a more involved process that involves approval from the FDA in the form of an IND or IDE, community consultation, public disclosure, and a very narrow range of study procedures. Notably, this also requires that consent be obtained as soon as possible and many of the less immediate study procedures will not be allowed until consent is obtained from the subject or their legally authorized representative.

In addition, California law only allows a partial consent waiver for procedures which do not constitute a “medical experiment,” unless the EFIC process described above is used.

Delayed/Deferred Consent vs. Partial Consent Waiver

The IRB sometimes receives requests for “delayed consent” or “deferred consent.” These terms are synonymous and for the purposes of further explanation this document will use only “delayed consent” to refer to both processes. These requests vary in what they are specifically asking for; however, the end result is usually a request for a partial consent waiver. It is important to note that neither “delayed consent” nor “deferred consent” are regulatory terms and these processes are not discussed anywhere in the relevant human subjects research regulations.

A typical “delayed consent” request generally seeks to perform some aspect(s) of the research study prior to receiving informed consent (documented or oral) from the subject or their legally authorized representative. Then, at some point in the future, the researcher would seek out both prospective and retrospective consent both for additional procedures to be done as well as for the procedures already performed.

One example the IRB commonly sees of studies attempting to use this process is where a subject has recently been involved in a trauma. Their injuries may make it hard or impossible for a subject to provide legally effective informed consent and a legally authorized representative is rarely available. In such cases, it may even be possible to discuss the study briefly with the subject, but not in any depth that would be considered legally effective informed consent.

This concept of “delayed consent” is problematic because an individual really can’t consent to something that has happened or been done to them in the past. Furthermore, the ethical principles and regulations surrounding human subjects research only discuss prospective informed consent. As such, “delayed consent” is not something that can be approved by an IRB.

So what should researchers do instead? As discussed above, sometimes the IRB can approved a partial waiver to allow some procedures to be conducted prior to obtaining consent or documentation from some or all subjects or their legally authorized representatives. When a study seeks to enroll subjects prior to obtaining consent or documentation, a partial consent waiver should be sought from the IRB. The IRB will evaluate the request and reasoning and determine whether the criteria for approving the waiver have been met. The IRB will only be able to grant a partial waiver of consent or documentation for specific research procedures if the application provides enough information to demonstrate that the criteria of the waiver (as described earlier) have been met.

[OIA is Here to Help](#)

Not sure if you need a waiver? Unsure if a study qualifies? Contact us!

If you have determined that your study requires a full or partial waiver of consent or documentation, it is strongly advised that you contact OIA to assess and discuss your study's details prior to submission in order minimize delays in the review process.