

Sometimes there are reasons to forego some parts or elements of the process of consent or the elements of consent.

The rules of the FDA and the Common Rule are different in this area because the types of studies they govern are quite different.

WAIVER OF THE SIGNED CONSENT DOCUMENT

Fully informed consent can be gained without a document. It is just more difficult to prove.

Common Rule 45 CFR	FDA 21 CFR
§46.117 Documentation of informed consent	§. 56.109 IRB review of research.
(c) An IRB may waive the requirement for the investigator to obtain a <i>signed consent form</i> for some or all subjects if it finds either: <ol style="list-style-type: none"> (1) That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (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. 	(c) An IRB shall require documentation of informed consent in accordance with Sec. 50.27 of this chapter, except as follows: <ol style="list-style-type: none"> (1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, <i>sign a written consent form</i> if it finds 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 the research context; or (2) The IRB may, for some or all subjects, find that the requirements in Sec. 50.24 of this chapter for an exception from informed consent for emergency research are met.
In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.	(d) In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

WAIVER OF SOME OR ALL ELEMENTS FROM CONSENT DOCUMENT

This is a section found only in the Common Rule.

Common Rule 45 CFR	FDA 21 CFR
§46.116 General requirements for informed consent.	§. 56.109 IRB review of research.
(c) An IRB may approve a <i>consent procedure which does not include, or which alters, some or all of the elements</i>	

<p><u>not include, or which alters, some or all of the elements</u> of informed consent set forth above, or ... provided the IRB finds and documents that:</p> <p>(1) the research or demonstration 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</p> <p>(2) the research could not practicably be carried out without the waiver or alteration.</p>	
<p>(d) An IRB may approve <u>a consent procedure which does not include, or which alters, some or all of the elements</u> of informed consent set forth in this section, or ... provided the IRB finds and documents that:</p> <p>(1) the research involves no more than minimal risk to the subjects;</p> <p>(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;</p> <p>(3) the research could not practicably be carried out without the waiver or alteration; and</p> <p>(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.</p> <p>(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.</p> <p>(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.</p>	

WAIVER OF THE CONSENT PROCESS (eg., NO CONSENT)

No consent process is done at all. To breach a person's rights so greatly, a heavy standard must be met.

<p>Common Rule 45 CFR 46.116 General requirements for informed consent.</p>	<p>FDA 21 CFR § 50.23 Exception from general requirements</p>
<p>(c) An IRB may approve a <i>consent procedure</i> ..., <u>or waive the requirement to obtain informed consent</u> provided the IRB finds</p>	<p>(a) The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph</p>

<p>and documents that:</p> <p>(1) the research or demonstration 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</p> <p>(2) the research could not practicably be carried out without the waiver or alteration.</p>	<p>(b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:</p> <ol style="list-style-type: none"> 1. The human subject is confronted by a life-threatening situation necessitating the use of the test article. 2. Informed consent cannot be obtained from the subject because of an inability to communicate with or obtain legally effective consent from the subject. 3. Time is not sufficient to obtain consent from the subject's legal representative 4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.
<p>(d) An IRB may approve ..., <u>or waive the requirements to obtain informed consent</u> provided the IRB finds and documents that:</p> <ol style="list-style-type: none"> (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. <p>(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.</p> <p>(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.</p>	<p>§ 50.24 Exception from informed consent requirements for emergency research_ (Final 11/1/96)</p> <ol style="list-style-type: none"> (2) The IRB may, for some or all subjects, find that the requirements in Sec. 50.24 of this chapter for an exception from informed consent for emergency research are met.

