



## IRBMED QUICK GUIDE: WAIVER OR ALTERATION OF WRITTEN INFORMED CONSENT UNDER OHRP, FDA AND HIPAA REGULATIONS

In most cases, a potential research subject (or his or her legally authorized representative) must be given a full explanation of the IRB-approved protocol, including a description of its risks, benefits and alternatives, and be given the voluntary and uncoerced choice to participate or not. An individual's agreement to participate generally must be documented on an IRB-approved consent form. The Department of Health and Human Services has, however, developed special rules permitting an IRB to approve, under limited circumstances, a waiver of consent, an alternative form of consent, or a waiver of documentation of consent. These are described below.

### Waiver or Alteration of Consent

Under the Common Rule for non-FDA regulated research,<sup>1</sup> an IRB may (1) approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent otherwise required by federal regulations, or (2) waive the requirements to obtain informed consent altogether, *only* if the IRB finds and documents that:

- the research involves no more than **minimal risk** to the subjects (i.e., the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests);
- the waiver or alteration will not adversely affect the **rights and welfare of the subjects**;
- the research could not **practicably**<sup>2</sup> be carried out without the waiver or alteration; *and*
- whenever appropriate, the subjects (including their physicians, as applicable) are provided with **additional pertinent information** after participation.

In addition, HIPAA requires that the IRB or a Privacy Board find and document the following, when a waiver will result in use or disclosure of *protected health information* ("PHI") in connection with the research project:

- Any use or disclose of PHI in connection with the research project involves no more than a **minimal risk** to the privacy of individuals, as demonstrated by the following:
  - there is an adequate plan to **protect any identifiers** from improper use or disclosure (*e.g., they are kept in a locked cabinet only available to the researchers, or they are maintained in a password-protected database and only the researchers have access to the password*);
  - there is an adequate plan to **destroy the identifiers** at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, or retention is otherwise required by law (*e.g., there is a plan to break any links to identifiable information, unless the links need to be maintained, in which case a reason should be given*); and

<sup>1</sup> The Food and Drug Administration has recognized an extremely limited emergency exception to standard informed consent requirements, applicable only in certain emergency life-threatening situations where standard therapies are unproven or unsatisfactory and significant administrative burdens are met by the relevant investigators and IRB. As a matter of policy, IRBMED currently does *not* permit waiver of consent in emergency situations. An explanation and discussion of this policy is available at: <http://www.med.umich.edu/irbmed/InformationalDocuments/emergency.html>.

<sup>2</sup> Federal regulations do not define the word **practicably**. *Black's Law Dictionary*, on which courts sometimes rely in interpreting legislative or administrative agency intent, defines the term as: "reasonably capable of being accomplished; feasible."



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- there are adequate written assurances that the PHI will **not be reused or disclosed** to any other person or entity, except as require by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA (e.g., “*the information will not be used or disclosed for any purpose other than this specific research project*”); **and**
- The research could not **practicably** be carried out without access to and use of the PHI.

When waiver of consent is not appropriate, an IRB sometimes may approve a process that does not incorporate standard documentation requirements otherwise applicable to human subjects research. The criteria for such “waivers of documentation” are described below.

### Waiver of Standard Documentation Requirements and Special Rules for “Telephonic” Consent

1. In non-FDA regulated research, an IRB may require the process of consent but waive the requirement for the investigator to obtain a signed consent form for some or all subjects **only** if the IRB finds and documents 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 (in this case, each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes must govern); **or**
  - The research presents (i) no more than minimal risk of harm to subjects (i.e., the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests); and (ii) involves no procedures for which written consent is normally required outside of the research context.

The second exception (for minimal risk research where consent is not normally required) is also applicable to FDA-regulated research. When the consent documentation requirement is waived in this circumstance, the IRB may require the investigator to provide the research subject with a written statement concerning the research.

2. The IRB may approve a telephonic consent procedure under which the subject’s legally authorized representative (“LAR”) is sent a faxed version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process.
3. The IRB may approve a “short form” written consent document under limited circumstances. Its use generally is discouraged.

**QUESTIONS? Contact the Health System Legal Office at 734-764-2178**