

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria.

1.0 Waiver or alteration of some or all elements of informed consent.

Some types of research projects would be impracticable to conduct if prospective informed consent is required from participants. The regulations allow the IRB to approve an alternate consent procedure (i.e., selected information is temporarily withheld from participants), or eliminate the requirement for informed consent for such projects under certain specific conditions. Research subject to FDA regulations (e.g., clinical investigations of drugs, biologics, devices, or other test articles) does not qualify for a waiver of informed consent.

1.1 Applications.

1.1.1 Observation.

Research involving study of individuals' natural behavior may require that participants be unaware that research is taking place. Because participants may behave differently if they knew they were being observed researchers may request that the IRB waive the requirement for consent. Participants would not be notified of the research prior to being observed or having their behavior recorded, and therefore would not have any opportunity to provide their consent. Several examples may include studies of the behavior of passersby to staged emergencies, or the interaction between patients and staff in mental hospitals. Such research poses ethical considerations that would require careful deliberation regarding the rights and welfare of participants. The IRB may, for example, require notice to participants after the research, and/or an alternate notice.

1.1.2 Incomplete disclosure or deception.

For other projects, investigators may plan to withhold certain information about the research (e.g., the true purpose, or other aspects about the project), or provide false information so that participants' responses are not biased. This would mean that a participant would receive most of the required information, but would not be fully informed prior to agreeing to participate in research. Such a procedure would require the investigator to request the IRB waive some of the elements of informed consent. Typically, participants would be provided with the full information only after participation, i.e., during a debriefing session. Such research poses ethical considerations, and the IRB would consider, among other things, whether or not the information withheld would materially affect a decision to participate.

1.1.3 Existing records.

Research involving the use of pre-existing records may also be impracticable to conduct if informed consent were required from each of the individuals whose records are being utilized. Obtaining informed consent may be impracticable either because a database may contain thousands of records, and/or may not contain any identifying information in order to contact the individuals. Use of such records for research would require the investigator to request that the IRB waive the entire consent process. When such records are subject to HIPAA regulations (due to use of protected health information),

additional considerations for a waiver of authorization are required; refer to *11.1 Use of Confidential Records* for more information.

1.1.4 'Passive' consent.

Researchers may utilize a consent process whereby participants are provided with all required information about research, and automatically enrolled unless they 'opt-out' by notifying the investigator. This process is sometimes termed 'passive' consent, because subjects are not required to take any positive action (e.g., sign a consent form, return a survey, answer questions, etc.) to indicate their agreement to participate in research. However, this process does not constitute legally authorized informed consent and its use requires that the IRB approve a waiver or alteration of informed consent requirements, as described in 1.2 below. When the 'passive' process is used in lieu of obtaining parental permission for a child/guardian to take part in research, IRB approval of a waiver or alteration of parent/guardian permission would also be required. Refer to *9.4 Children as Research Participants*.

1.2 Criteria for IRB approval.

The IRB may approve a waiver or alteration of informed consent requirements under either of following conditions:

1.2.1 Public benefit or service programs (§ ____ .116(e)(1-3)).

The IRB may approve a consent procedure that does not include, or which alters, some or all the elements of informed consent, or waive the requirement to obtain informed consent, provided that the IRB finds and documents that:

- (i) 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:
 - (A) Public benefit or service programs;
 - (B) Procedures for obtaining benefits or services under those programs;
 - (C) Possible changes in or alternatives to those programs or procedures;or
 - (D) Possible changes in methods or levels of payment for benefits or services under those programs;
- AND
- (ii) The research could not practicably be carried out without the waiver or alteration.

If an individual were asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at § ____ .46.116(d), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

1.2.2 Minimal risk research (§ ____ .116(f)).

The IRB may approve a consent procedure that does not include, or which alters, some or all the elements of informed consent, or waive the requirement to obtain informed consent, provided that the IRB finds and documents all the following:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) 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;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

2.0 Waiver of the requirement for documentation of informed consent (§ ____ .117 (c))

Under certain circumstances, the IRB may waive the requirement to obtain a signature on the consent document. This process may be termed 'implied' consent, where research information is provided to participants, and they indicate agreement by taking an action (e.g., returning a survey, answering a question, etc.), but are not required to sign a consent document.

2.1 Applications.

This waiver provision may be utilized where it is not feasible to obtain a signature (e.g., research performed entirely online, or over the phone or mail surveys), when a signature is not necessary, or would pose confidentiality concerns. The signature requirement may be waived for many social and behavioral research projects that involve no more than minimal risk.

2.2 Criteria for IRB approval.

The IRB may waive the requirement to obtain a signed consent form for some or all research participants under either of the following conditions:

2.2.1 Protection of confidentiality (§ ____ .117(c)(1)(i)).

The only record linking the subject and the research would be the informed consent form 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;

2.2.2 Minimal risk research (§ ____ .117(c)(1)(ii), (21 CFR 56.109(c)(1)).

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; or

2.2.3 Cultural Considerations.

If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

When the requirement for signed consent is waived, participants should still be provided with a written statement regarding the research, where applicable, or required by the IRB. Research subject to FDA regulations (i.e., clinical investigations of drugs, biologics, and devices) may only qualify for a waiver of the signature requirement under 2.2.2 (21 CFR 56.109(c)(1)).

3.0 Waiver of Informed Consent Requirements for Emergency Research.

The IRB may approve research that will be performed in emergency settings without requiring informed consent from participants, under certain circumstances. Such research would involve participants in need of emergency treatment, and because of their medical condition and/or unavailability of legal representatives, it would not be possible to obtain legally effective informed consent. This exception may also be used for research subject to FDA regulations. Refer to *11.7 Review of Planned Emergency Research* for more information.

DEFINITIONS:

Informed consent: the voluntary agreement of a participant, or their legally authorized representative, to take part in research after being provided with sufficient information about the study, in a language and terminology understandable to them, and sufficient opportunity to consider their decision.

Legally authorized representative (LAR): an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing the issue, LAR means an individual recognized by **institutional policy** as acceptable for providing consent in the non-research context. (§___.102(i)) Examples of LARs may include: a health care agent (named as a durable power for health care decision maker while the subject had competency), or a court-appointed guardian.

Minimal risk: 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.

REFERENCES:

§___.116 General requirements for informed consent

§___.117 Documentation of informed consent

§___.111 and [21 CFR 56.111](#) Criteria for IRB approval of research

§___.109 and [21 CFR 56.109](#) IRB review of research

[21 CFR 50, Subpart B](#) Informed Consent of Human Subjects

OHRP guidance on Written Procedures

OHRP FAQs: [Informed Consent](#)

FDA Information Sheet, [A Guide to Informed Consent](#)

FDA Information Sheet, [Exception from Informed Consent for Studies performed in Emergency Settings](#)

OHRP Guidance, Informed Consent Requirements in Emergency Research

RELATED FORMS:

IRB Protocol Form
Informed Consent Waiver or Alteration Request
Informed Consent templates
Children in Research Attachment

RELATED HRPP SECTIONS:

9.1 Consent Process
9.2 Documentation of Informed Consent
9.4 Children as Research Participants
11.1 Use of Confidential Records
11.7 Review of Planned Emergency Research