Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

Waiver of Informed Consent Guidance[1]

Waiver of Alteration of Consent

Common Rule

46.116(f)(3)

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section,or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. the research involves no more than minimal risk to the subjects;
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; and
5. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

FDA

21 CFR 50.23 and 21 CFR 50.24

The FDA's IRB regulations do not permit waiver of consent for FDA-regulated research with the narrow exception of emergency research meeting the requirements of 21 CFR 50.23 and 21 CFR 50.24.

Although the FDA's regulations to do not permit waiver of consent, in July 2017 the FDA released a new guidance entitled IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects. This guidance allows IRBs to waive or alter the informed consent requirements using the Common Rule criteria (above) until the FDA is able to harmonize its regulations with those of the Common Rule for waiver of consent.

"Practicable"

Regarding the criterion under HHS regulations at 45 CFR 46.116(f)(3)(ii) for IRB approval of a waiver or alteration of informed consent requirements, IRBs should consider the following points when determining whether research could not practicably be carried out without the waiver or alteration:

- The commonly accepted definitions of the term "practicable" are (a) feasible; (b) capable of being effected, done or put into practice; and (c) that may be practiced or performed; capable of being done or accomplished with available means or resources.

It should be noted that this criterion states that the research could not practicably be carried out without the waiver or alteration. Put another way, it would not be practicable to perform the research (as it has been defined in the protocol by its specific aims and objectives) if consent was required. The emphasis being that it is impracticable to perform the research, and not just impracticable to obtain consent. The following concepts may help an IRB determine whether the research could not be practicably carried out without the waiver of consent:

- Scientific validity would be compromised if consent was required.
- Ethical concerns would be raised if consent were required.
- There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.
- Practicability should not be determined solely by considerations of convenience, cost, or speed.

1. Adapted from CHOP Research Institute (https://irb.research.chop.edu/waiver-or-alteration-consent)

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Research Limited to Use of Existing Records or Specimens

The IRB's most frequent request for waivers is for research involving existing medical records or specimens. The investigator must request a Waiver of Consent and a Waiver of HIPAA Authorization. If children are subjects, Waiver of Assent. The criteria for waiver of assent and consent are the same.

The basis for both waivers (consent and HIPAA) include the requirements for the research to be no greater than minimal risk and that it not be practicable to conduct the research without the waiver.

What are existing records or biospecimens?

The terms existing, retrospective and prospective are frequently misused by investigators. This confusion leads to the potential for research non-compliance.

- **Existing** means that the records/biospecimens are already available as of the *date of submission to the IRB.*
- **Retrospective** means reviewing records or using specimens that are existing.
- **Prospective** means that the records or specimens don't exist yet as of the date of IRB submission. Reviewing data from medical charts after the information has been recorded is still prospective review from the IRB's perspective.

Common reasons for it to be impracticable to obtain consent and authorization

- Subjects are no longer seen in clinic or have moved;
- There are too many subjects to contact all;
- It is not possible to contact all of the subjects and the validity of the research depends on inclusion of all subjects.

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Waiver or Alteration of HIPAA Guidance[2]

Waiver or Alteration of HIPAA

The IRB may approve an alteration of the requirements of written HIPAA Authorization provided the research meets the criteria for waiver or alteration. The most frequent alteration is for verbal HIPAA Authorization when the IRB has also waived the requirement for written consent under 45 CFR 46.117(c)(1)(ii). Another alteration to obtain verbal HIPAA Authorization is issued when consent is not required for screening procedures limited to:

(a) obtaining information through oral or written communication with the prospective subject or legally authorized representative, or (b) obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. Demonstrating that the "research could not practicably be conducted without the waiver or alteration" is the main obstacle to approving an alteration. If the subject is physically present, it is usually practicable to obtain written HIPAA Authorization.

45 CFR 164.512(i)(2)(ii): Criteria for Waiver or Alteration of HIPAA:
A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

A. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   1. an adequate plan to protect the identifiers from improper use and disclosure;
   2. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   3. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

B. The research could not practicably be conducted without the waiver or alteration; and

C. The research could not practicably be conducted without access to and use of the protected health information.

See section "(i)" of 45 CFR 164.512(i) Uses and disclosures for which an authorization or opportunity to agree or object is not required for the HIPAA regulations related to waivers by the IRB or privacy board.

2. Adapted from CHOP Research Institute (https://irb.research.chop.edu/waiver-or-alteration-hipaa)