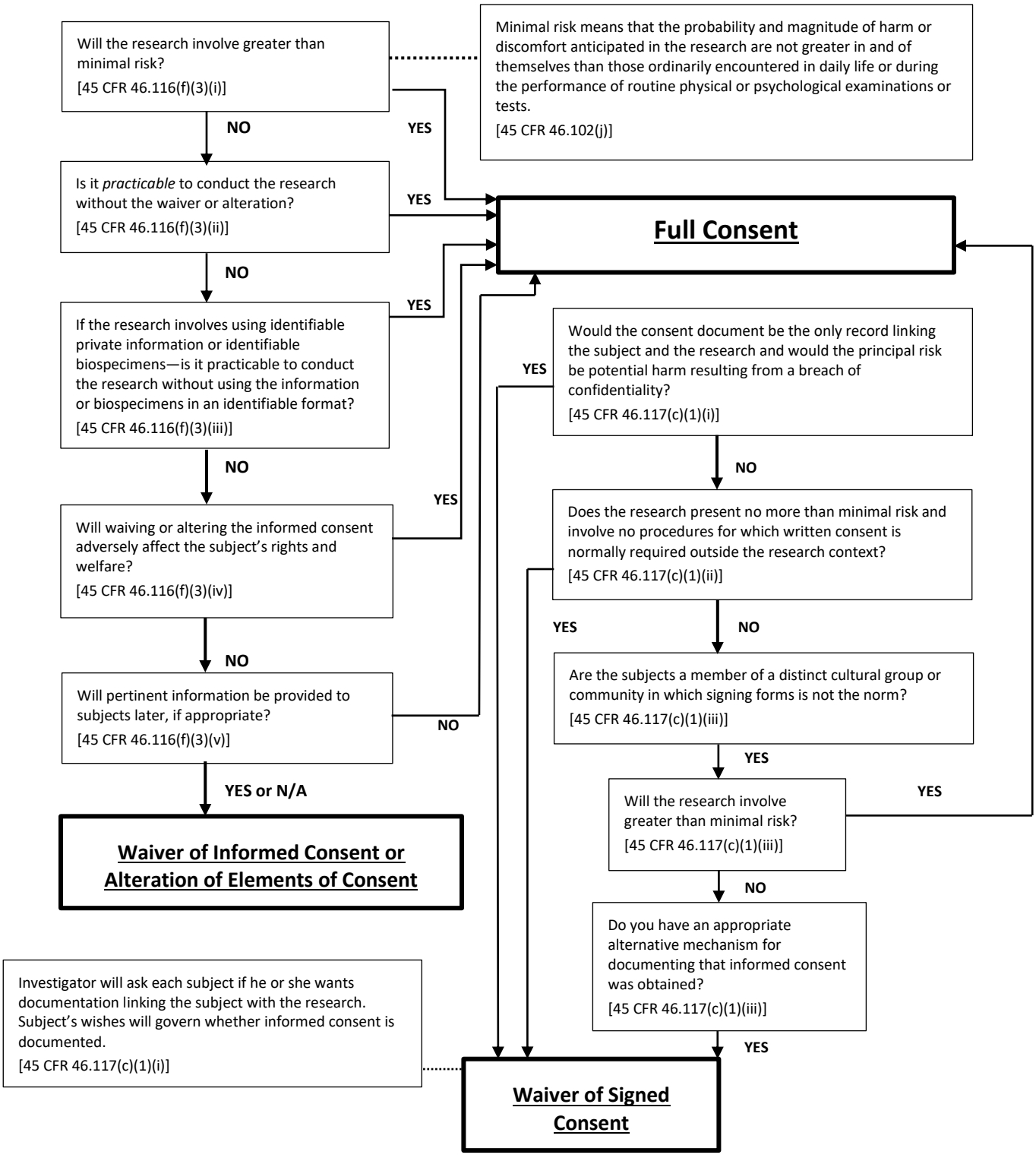
Benaroya Research Institute
Virginia Mason

Guidance on When Researchers Can Request Waivers of Consent, Alteration of Elements of Consent, or Waivers of Documentation of Consent

Introduction

Investigators are required to obtain the legally effective informed consent of each participant or their legally-authorized representative, unless the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent.



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Waiver of Signed Consent (Oral Consent)

The IRB will often require Investigators to provide an information sheet/oral consent to participants. When an information sheet/oral consent is not required, the IRB requires an oral script or outline of the planned consent process. Another alternative is the use of an introductory paragraph at the top of the study instrument (e.g., questionnaire) or an introductory letter attached to the study instrument, which includes a statement that return of the questionnaire represents consent to participate in the project.

Investigators may request a waiver for documenting signed informed consent for minimal risk studies in three situations:

Situation 1:

- The research presents no more than minimal risk of harm to participants, and
- The research involves no procedures for which written consent is normally required outside of the research context.

Situation 2:

- The only record linking the participant and the research would be the consent document;
- The principal risk would be potential harm resulting from a breach of confidentiality;
- Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; and
- The research is not a clinical investigation subject to FDA regulations.

Situation 3:

- The research presents no more than minimal risk of harm to participants, and
- The participants are members of a distinct cultural group or community in which signing forms is not the norm, and
- There is an appropriate alternative mechanism for documenting that informed consent was obtained.

Complete or Partial Waiver of Informed Consent

Investigators may request a complete waiver for obtaining consent (or an alteration of some or all of the elements of informed consent) in two situations:

Situation 1 (Commonly Used): Waiver for Minimal Risk Research

- The research involves no more than minimal risk to the participants; and
- The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- The research could not practicably be carried out without the waiver or alteration; and
- 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; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- If your research is a clinical investigation subject to FDA regulations, and fits the above criteria, please contact the Research Protections Department for confirmation that your study qualifies for a complete or partial waiver.

Situation 2 (Rarely Used): Waiver for Research Activities Designed to Study Certain Aspects of Public Benefit or Service Programs

- 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:
    - Public benefit or service programs;

  - Procedures for obtaining benefits or services under those programs;
  - Possible changes in or alternatives to those programs or procedures; or
  - Possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.

Exceptions from Informed Consent Requirements

Emergency Use of a Test Article (Drug/Device):

Emergency use of an investigational drug/device for patient care requires the treating physician to obtain the informed consent of the patient or a legally-authorized representative, *unless* the criteria in 21 CFR 50.23(a) are met. Because there is no equivalent provision in DHHS regulations, this exception may only be used for the emergency use of a test article for purposes of patient care, which is not "research". For more information, see FDA Information Sheet: Emergency Use of an Investigational Drug or Biologic and the "Emergency Use" section of Expanded Access for Medical Devices .

Planned Emergency Research:

Conducting planned research in life-threatening situations may allow for exception from informed consent requirements as provided for in 21 CFR 50.24 (and in a corresponding waiver from the Secretary of HHS for research not regulated by the FDA). See Informed Consent Requirements in Emergency Research.