

Guidance for Creating a Screening Survey & Using a Waiver or Alteration of Informed Consent

1. Minimal Risk Requirement

The screening survey must involve no more than minimal risk to participants.

2. Impracticability Requirement

The research could not practicably be carried out without the waiver or alteration of consent.

3. Protection of Rights and Welfare

The waiver or alteration must not adversely affect the rights and welfare of participants.

4. Post-Participation Information

When appropriate, participants should be provided with additional pertinent information after participation.

5. Identifiability Considerations

If identifiable information is collected, the research must demonstrate that it cannot be conducted without such data in identifiable form.

6. Document Format

It is suggested that the screening questions are ordered in such a way that the exclusion criteria questions are answered before any personally identifiable information is supplied by the potential participant.

7. Compliance with General Consent Requirements

Even with an alteration, general informed consent protections must be maintained, including clarity, voluntariness, and minimizing undue influence.

8. Documentation Waiver Justification

If documentation of consent is also waived, justification must be provided (e.g., confidentiality risks or minimal-risk procedures not requiring written consent outside research).

Definition of Impracticability (Fed. Context)

In federal regulatory and procedural contexts, *impracticability* generally refers to a condition where an action **cannot be accomplished without undue difficulty or extreme inconvenience**, even though it is not literally impossible.