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Guidance: What You Must Include in a Screening Survey Protocol

When designing the screening instrument *and* IRB submission, you should clearly address:

A. Description of the Screening Activity

- Purpose of screening
- Type of questions and data collected
- Whether identifiable information is involved

B. Justification for Waiver/Alteration

- Statement that the survey is **minimal risk**
- Clear explanation of the **impracticability** of obtaining full consent
- Demonstration that the waiver **does not affect rights/welfare**

C. Participant Information (If Alteration vs. Full Waiver)

If using an alteration, provide **abbreviated or modified information** such as:

- Purpose of the screening
- Voluntariness
- Risks (if any)
- Contact information for questions
  (This can often be included in a short intro text at the beginning of the survey.)

D. Privacy and Data Protections

- How data will be stored and protected
- Whether identifiers are collected or removed

E. Post-Participation Plan

- If applicable, how participants will receive additional information afterward

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Summary

To create a screening survey using a waiver or alteration of informed consent, you must demonstrate compliance with 45 CFR 46.116 by ensuring:

1. **Minimal risk**
2. **Impracticability** of obtaining full consent
3. No adverse effect on **rights and welfare**
4. Providing **additional information** later when appropriate
5. Justification for using **identifiable information** (if applicable)
6. Compliance with **general consent protections**
7. Justification for **waiver of documentation** (if needed)

These elements must be articulated in your IRB application and reflected in how your screening survey is designed and administered.

Definition of Impracticability (Federal 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.