Consent Waiver Documentation Flow Chart

Consent Process Decision Tree 2: When Is IRB Approval for a Waiver Documentation Consent Required?

Federal regulations specify that for the IRB to approve non-exempt research, informed consent covering specific elements must be obtained from all research subjects prior to their participation unless (1) the IRB approves a waiver or alteration* of informed consent; or (2) the IRB-Flexibility Policy applies for certain minimal risk research. Use this decision tree to determine if IRB approval of a waiver or alteration of consent is required.

Is the research conducted or supported by a federal agency, or does it involve deception, incomplete disclosure, or prisoners? University IRB-Flexibility Policy

- No

IRB approval to waive the requirement for documentation of consent (participants’ signatures on the consent document) is not required. You may use a simple consent information script or sheet to inform participants about the research.

45 CFR 46.117(d)(2)

- Yes

Will the consent document be the only record linking participants to the research AND is the principal risk of the research breach of confidentiality? 45 CFR 46.117(c)(1)

- No

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside of the research context? 45 CFR 46.117(c)(2)

- Yes

The IRB may approve a waiver of documentation of consent. Complete the Consent Waiver Request Form and submit the completed Checklist with the study information script or sheet for IRB review and approval.

- No

Federal regulations require a consent process, including a written, signed informed consent document. You must obtain signed consent for all participants.