

INFORMED CONSENT

Key Considerations:

- Does the consent process address Who, What, When, Where, and How?
- Is the form written in language that is understandable to the subject population?
- Are investigators assessing comprehension of the information/document?
- If there are non-English speakers, are translated consent documents required/provided?
- Does the consent process match with the study procedures? (i.e. collecting signatures for minimal risk online survey or phone interview)

Required elements of consent

- 1) Purpose
- 2) Activities
- 3) Expected Duration
- 4) Risks or Discomforts
- 5) Benefits
- 6) Confidentiality*
- 7) Voluntariness
- 8) Contact information
- 9) Alternatives, if applicable
- 10) Injury Compensation, if applicable

Additional Elements, if applicable

- 1) Unforeseeable risks
- 2) Participation terminated by PI
- 3) Costs to subjects
- 4) Consequences of withdrawal
- 5) Significant new findings
- 6) Number of subjects
- 7) Funding Source

*For FDA-regulated research, this element should also include a statement that the FDA may inspect records.

Respect for Persons: Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.

Informed Consent: Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied...There is widespread agreement that the consent process can be analyzed as containing three elements: **information, comprehension** and **voluntariness**. - The Belmont Report

Waiver of One or More Elements of Informed Consent: §46.116(d)

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

- The research involves **no more than minimal risk** to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; **AND**
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

For FDA-regulated research, consent cannot be waived under the criteria noted above. It may only be waived under limited circumstances involving life-threatening situations, military operations, or public health emergencies and for emergency research [21 CFR 50.23 & 50.24].

Waiver of Documentation of Informed Consent: §46.117(c)

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern (Not applicable to FDA-regulated research); **OR**
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. NOTE: for greater than minimal risk research, some minimal risk activities may still qualify for this waiver, i.e. minimal risk telephone eligibility screening. Written consent would then be required for the greater than minimal risk activities.

Parental Permission:

Parental consent may be waived*:

- If it meets the criteria for waiving one or more elements of informed consent (§46.116(d)) **OR**
- in circumstances where the research is designed with a condition or for a subject population for which parental permission is not a reasonable requirement to protect subjects (i.e. neglected/abused children, 17 year olds in college classes) (§46.408).

*Waiver of Parental Permission—FLEX

Parental permission for FLEX-eligible studies may also be waived if it is justified by the PI and is consistent with the requirements of the research site and/or FERPA and PPRA. When appropriate, parental notification with a reasonable opt-out period should be utilized.



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