



**REQUEST FOR WAIVER OF INFORMED CONSENT**  
(Not Required for Exempt Studies)

**Protocol ID:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_ **Faculty Sponsor:** \_\_\_\_\_

**Other Personnel:** \_\_\_\_\_

**Protocol Title:** \_\_\_\_\_

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Under federal regulations (**45 CFR 46.116 and 46.117**), investigators may request a waiver or alteration of informed consent under specific circumstances. There are three common types:

1. **Waiver or Alteration of Informed Consent** – Permitted when the research poses minimal risk, cannot be practicably carried out without the waiver, and would not adversely affect subjects’ rights or welfare. This is often used in **secondary data analysis** or when obtaining consent could harm or bias participants.
2. **Waiver of Parental Permission** – May be granted when parental consent is **not legally required** or would compromise the **privacy or safety** of minors (e.g., studies involving legally permitted behaviors like abortion or experiences with abuse).
3. **Incomplete Disclosure, Deception, or Delayed Consent with Post-Study Debriefing** – Allows researchers to request a waiver or alteration of informed consent when full disclosure of the study's purpose or procedures is not feasible prior to participation, often due to scientific necessity. In such studies, participants may not be fully informed at the outset due to:
  - Incomplete disclosure – withholding certain information about the study (e.g., specific hypotheses or conditions);
  - Deception – intentionally providing false or misleading information to participants (e.g., use of a cover story);
  - Delayed consent – obtaining participant consent only after the study has concluded (e.g., following debriefing).

All waivers require **IRB approval** and must be **justified with compelling ethical and practical reasons**.

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The Institutional Review Board determines which type of consent applies to your research, but please indicate the type that you are requesting.

**Waiver or alteration of the informed consent process.** *(Complete Section I)*

**Request for waiver of parental permission.** *(Complete Section II)*

**Request for deception with post-study consent.** *(Complete Section III)*

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**I. Request for waiver or alteration of the consent process** (Not required for Exempt studies)

I believe that this protocol is eligible for waiver or alteration of required elements of the informed consent process because the protocol meets all the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for the following:)

1. The research presents no more than “minimal risk” of harm to subjects. (Section 46.102(I))
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
5. Elements of informed consent for which a waiver or alteration is requested and the rationale for each.
6. The research does not involve non-viable neonates.
7. The research is not subject to FDA regulation:

**II. Request for waiver of parental permission** (Not required for Exempt studies)

I believe that this protocol is eligible for waiver parental permission because the protocol meets all the following criteria:  
(Provide protocol-specific supporting information for each criterion that justifies the findings for one of the following two options:)

**Option 1:**

1. The research presents no more than “minimal risk” of harm to subjects. (Section 46.102(I)).
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
5. Elements of informed consent for which a waiver or alteration is requested and the rationale for each.
6. The research does not involve non-viable neonates.
7. The research is not subject to FDA regulation.

**Option 2:**

1. The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).
2. An appropriate mechanism for protecting the children who will participate as subjects in the research will be substituted.
3. The research is not subject to FDA regulation.
4. The waiver is consistent with federal, state, and local law.

**III. Request for Incomplete Disclosure, Deception, or Delayed Consent with Post-Study Debriefing** (Not required for Exempt studies and not required when the consent process is waived).

I believe this protocol is eligible for a request for incomplete disclosure, deception, or delayed informed consent because it meets one of the following criteria: (Provide protocol-specific justification for each applicable criterion below. Your justification should explain why full disclosure is not feasible prior to participation and how the study design safeguards participants' rights and welfare.) (NOTE: Even when documentation of informed consent is waived, the investigator is required to provide participants with all necessary consent information after participation (during debriefing); clearly explain the nature and purpose of the incomplete disclosure or deception; and; obtain participants' voluntary consent post-study—either orally, in writing, or through implied consent, as appropriate—allowing them the opportunity to withdraw their data if desired).

**Option 1:**

*(Example: Conducting interviews in which the study design requires temporary withholding of the study's true purpose to reduce response bias. For example, participants will be told they are completing a general personality survey when the actual aim is to assess implicit bias in reaction to specific wording within the survey. The study poses minimal risk and does not involve physical or psychological harm. Full disclosure prior to participation would invalidate the research goals. All participants will receive a thorough debriefing immediately after completion of the study, during which they will be informed of the study's true purpose, why deception was used, and their right to withdraw their data. A written debriefing form will be provided, and participants will be given contact information for further questions or concerns).*

1. The research presents no more than “minimal risk” of harm to subjects. (Section 46.102(I)).
  
2. Full disclosure of the study's purpose or procedures before the study begins would invalidate the study (i.e., knowledge of the true purpose significantly bias participants' behavior or responses).
  
3. There is a plan to inform participants of the deception *as soon as possible* after their participation. A debriefing script or plan will be provided that explains the study's true nature and purpose.
  
4. Participants will have the option to withdraw their data after learning about the deception.
  
5. There are no equally effective, non-deceptive alternatives available. Therefore, the research question only be answered if deception is used.
  
6. The research is not subject to FDA regulation.

**Option 2:**

*(Example: Conducting interviews with street gang members about illegal gang activities. The only record of the name or other identifying information of the subject would be the signed consent form and knowledge of an individual's participation or information provided could lead to potential legal, social, or physical harm).*

1. The only record linking the subject and the research would be the consent document.
  
2. The principal risk would be potential harm resulting from breach of confidentiality.
  
3. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
  
4. The research is not subject to FDA regulation.

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**Approval** (IRB Chair: Check all that apply to indicate that the waiver or alteration is approved and to indicate agreement with the investigators protocol specific findings justifying the waiver).

- Waiver or Alteration of the Consent Process
- Request for Incomplete Disclosure, Deception, or Delayed Consent with Post-Study Debriefing

**NOTE:** To approve a waiver of written documentation of informed consent the investigator must provide a written document describing the information to be disclosed. This document must include all required and appropriate additional elements of consent disclosure, unless the consent process has been altered.

**IRB Chair Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_