**Request for Waiver or Alteration of Informed Consent**

**Instructions:**

This form should accompany the Application for Review of Human Subject Research (OSP – HS – 01)
if you are requesting a waiver of documentation of informed consent, or a waiver of complete disclosure (a waiver of informed consent, or alteration of the required elements of consent.) **Please consult with the IRB Administrator before submitting any informed consent waiver request.**

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| --- | --- |
| Protocol # (if already assigned, otherwise, leave blank): |  |
| Project Investigator Name |  |
| Project Title |  |
| Version Date, if applicable |  |

***For an explanation of elements of informed consent and requirements for waivers of informed consent, see 45.CFR 46.116 and \_\_.117 at*** [***http://www.hhs.gov/ohrp***](http://www.hhs.gov/ohrp)***.***

Indicate which of the following type of waiver you are requesting, and for which study population of participants, and then complete the relevant sections. Provide explanation for each item checked. Select all that apply:

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| 1. [ ] **Waiver of Documentation of Consent (Written Agreement to Participate)**:
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| To request a waiver of documentation of informed consent (you will provide consent information and obtain agreement to participate, but will not have the participant sign a document), please select **one** of the following three statements. Note: To provide consent information, the IRB requires the investigator to provide subjects with an information sheet regarding the research. Submit the information sheet with your application. Please **be specific** in explaining why one of these statements is true for your research. |
| Study population for which you are requesting: |
| 1. [ ]  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. *If you select this answer and the IRB grants the waiver of written consent request, each participant must be asked whether s/he wants documentation linking her/him with the research and the subject’s wishes will govern.*
 |
| *Please explain:* |
| 1. [ ]  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 *(e.g., asking individuals on the street about eating habits).*
 |
| *Please explain:* |
| 1. [ ]  The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.
 |
| *Please explain:* |
|  |

**Waivers of Complete Disclosure**

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| 1. **Waiver of Complete Disclosure**
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| 2A. [ ] **Complete this Item if you are requesting EITHER a Waiver of Consent OR an Alteration of Required Elements of Consent**:  |
| In accordance with 45 CFR 46.116(d), to request to completely waive the informed consent process, OR to request an alteration of the required elements of informed consent, you must provide a response to all of the following five statements, (points 2A.i through 2A.v), with respect to your research. Item 2 disclosure waiver requests would be used if you intend to not disclose to subjects that they are participating in research, or you will disclose the research to subjects but intend to only provide partial information. To qualify for IRB approval, ALL must be answered and you must justify your response. Please be specific in explaining why each statement is applicable to your research. . |
| Study population for which you are requesting: |
| * 1. [ ]  The research in its entirety involves no more than “minimal risk” to participants.
 |
| *Please explain*: |
| * 1. [ ]  The research could not be practicably carried out without the waiver or alteration.
 |
| *Please explain:* |
| * 1. [ ]  If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
 |
| *Please explain:* |
| * 1. [ ]  The waiver will not adversely affect the rights and welfare of the participants.
 |
| *Please explain*:  |
| * 1. [ ]  Whenever appropriate, participants will be provided with additional pertinent information after participation.
 |
| *Please explain*: |
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| 2B. [ ]  **Complete this item if you are requesting an Alteration of the Required Elements of Consent (Incomplete Disclosure)** |
| If you **will** provide information (disclose) and obtain agreement (consent), but you are requesting to waive or alter any of the required elements of informed consent in your disclosure, you must complete both part 2A (above) and part 2B (below, statements 2B.i through 2B.ix).  |
| Study population for which you are requesting: |
| According to the basic elements of informed consent, the following information should be provided to each subject. Please check the box next to the element(s) you are **requesting to alter or waive** and proceed to the questions below: |
| 1. [ ]  A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 |
| *Please explain why this will not be included*: |
| 1. [ ]  A description of any reasonably foreseeable risks or discomforts to the subject.
 |
| *Please explain why this will not be included*: |
| 1. [ ]  A description of any benefits to the subject or to others which may reasonably be expected from the research.
 |
| *Please explain why this will not be included*: |
| 1. [ ]  A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 |
| *Please explain why this will not be included*: |
| 1. [ ]  A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
 |
| *Please explain why this will not be included*: |
| 1. [ ]  For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
 |
| *Please explain why this will not be included*: |
| 1. [ ]  An explanation of whom to contact for answers to pertinent questions about the research a research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.
 |
| *Please explain why this will not be included*:  |
| 1. [ ]  A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
 |
| *Please explain why this will not be included*: |
| 1. [ ]  If identifiable information or identifiable biospecimens will be collected, a statement that either:
2. Identifiers might be removed from information or biospecimens, and after such removal, information or specimens could be used for future research studies or given to another investigator for future research studies without additional informed consent from the subject; OR
3. The subject’s information or biospecimens collected as part of the research will not be used or distributed for future research studies, with or without removal of identifiers.
 |
| *Please explain why this will not be included*: |
|  |

*For further information, please contact the Office of Sponsored Projects at 202-633-7118 or OSPCompliance@si.edu.*