|  |  |
| --- | --- |
| **PI NAME** |  |
| **STUDY TITLE** |  |

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| --- |
| An IRB may waive the requirement for a signed consent form for some or all subjects in certain situations.[[1]](#footnote-1) A waiver of documentation of consent does not waive the requirement to obtain informed consent. In cases in which the documentation requirement is waived, the IRB may require subjects be provided with a written statement (e.g., Information Sheet) regarding the research.[[2]](#footnote-2) |

**Choose ONE reason to support a waiver of documentation of informed consent:**

|  |  |  |
| --- | --- | --- |
| **1.** |  | That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or Legally Authorized Representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. (*Not allowed for FDA-Regulated research.)* |
|  | 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. |
|  | If the subjects or legally authorized representatives are members of a distinct cultural  group or community in which signing forms is not the norm, that the research presents no  more than minimal risk of harm to subjects and provided there is an appropriate  alternative mechanism for documenting that informed consent was obtained. |

**Is this request for (choose ONE):**

|  |  |  |
| --- | --- | --- |
| **2.** |  | All subjects |
|  | Some subjects. Identify group of subjects and provide rationale: |

**Indicate how consent will be obtained (choose ALL that apply):**

|  |  |  |
| --- | --- | --- |
| **3.** |  | Subject will be given an Information Sheet to read and will provide consent verbally. (Submit Information Sheet for IRB review.) |
|  | An Information Sheet will be mailed with a questionnaire/survey to the subject and return of the questionnaire/survey will indicate consent. (Submit Information Sheet for IRB review.) |
|  | Subject will be told verbally about the study and will provide consent verbally. (Submit a Consenting Script for IRB review.) |
|  | Subject will read the consent via the Internet and indicate consent by selecting an “I agree” button or similar. (Submit Internet Consent Text for IRB review). |
|  | Other. Describe: |

1. 45 CFR 46.117(c)(1), 21 CFR 56.109(c)(1) [↑](#footnote-ref-1)
2. 45 CFR 46.117(c)(2), 21 CFR 56.109(d) [↑](#footnote-ref-2)