|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Under this waiver, the investigator is still **required to provide informed consent** to the potential subject, but the subject’s signature is not required on the form.  Along with this waiver request, you must submit a consent statement or written script that will be provided or presented to the potential subject. The consent statement or script must contain all the elements of informed consent. | | | | | | | | |
| **Project Title:** | | | |  | | | | |
| **Principal Investigator(s):** | | | | | | |  | |
| **Date of Submission:** | | | | | |  | | |
|  | | | | | | | | |
| **Submission Instructions:**   * Read the criteria for waiver or alteration of written documentation of consent * Select the appropriate reason for request   + Check the box for 1, 2, or 3 * Submit one copy with IRB Application | | | | | | | | |
| **Criteria for Waiver or Alteration of Written Documentation of Informed Consent:**   1. *The research involves no more than minimal risk to the subjects.* 2. *The research could not practically be carried out without the waiver or alteration.* 3. *If the research contains identifiable private information or identifiable biospecimens, the research could not be carried out without using such information or biospecimens in an identifiable format* 4. *The waiver will not adversely affect the rights and welfare of the subjects.* 5. *The subjects will be provided be provided with additional pertinent information after participation.* | | | | | | | | |
| **Request for waiver of written documentation of informed consent is based on:** | | | | | | | | |
| 1. | | |  | | | | | |
| A signed consent form is the only record linking the subject to the research | | | | | | | | |
|  | | Explain: | | |  | | | |
|  | AND | | | | | | | | |
| The principal risk would be potential harm from a breach of confidentiality | | | | | | | | | |
|  | | Explain: | | |  | | | |
|  | AND | | | | | | | | |
| Each subject (or legal representative) will be asked if they want to sign a Consent Form | | | | | | | | | |
|  | | Explain how this will be done: | | | | | |  |
|  | AND | | | | | | | | |
| The research is **NOT** subject to FDA regulation | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| 2. | |  | |
| The research presents no more than minimal risk of harm to subjects | | | |
|  | | Explain: |  |
|  | AND | | | |
| The research involves no procedures for which written informed consent is normally required outside of the research contexts | | | | |
|  | | Explain: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 3. |  | | |
| The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm | | | |
|  | Explain: |  | |
|  | AND | | | |
| The research presents no more than minimal risk of harm to subjects | | | | |
|  | Explain: |  | |
|  | AND | | | |
| There is an appropriate alternative mechanism for documenting that informed consent was obtained | | | | |
|  | Explain how this will be done: | |  |

IRB Office use only:

|  |  |  |  |
| --- | --- | --- | --- |
| Waiver approval date: |  | IRB Identification Number: |  |

|  |  |  |
| --- | --- | --- |
| Approved by: |  |  |