**Waiver to Obtain/Document/Alter Informed Consent**

**Instructions:** Complete the sections as described in the “Section Notes”. Enter your information in the **colored boxes** or place an **“X”** in front of the appropriate response(s).

|  |
| --- |
| **SECTION A: Request to Waive Informed Consent/ Request to Alter Informed Consent** |
| **Section Notes…**   * Complete this section **ONLY** if you are requesting a Waiver to Obtain Consent or Alter Informed Consent. * Answer A1 – A2 **OR** A3 – A7 * Answer A8 (REQUIRED) |

**Answer A1 – A2 OR A3 – A7**

**[\_\_] A1.** The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

**Explain:**

|  |
| --- |
|  |

**[\_\_] A2.** The research could not practicably be carried out without the waiver or alteration.

**Explain:**

|  |
| --- |
|  |

**[\_\_] A3.** The research involves no more than minimal risk to the subjects;

**Explain:**

|  |
| --- |
|  |

**[\_\_] A4.** The waiver or alteration will not adversely affect the rights and welfare of the subjects;

**Explain:**

|  |
| --- |
|  |

**[\_\_] A5.** The research could not practicably be carried out without the waiver or alteration;

**Explain:**

|  |
| --- |
|  |

**[\_\_] A6.** 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; and

**Explain:**

|  |
| --- |
|  |

**[\_\_] A7.** Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Explain:**

|  |
| --- |
|  |

**Answer A8 (REQUIRED)**

**[\_\_] A8.** No subject has already refused consent for their data or biospecimens to be used in this way.

**Explain:**

|  |
| --- |
|  |
| **SECTION B: Request to Waive Documentation of Informed Consent** | | |
| **Section Notes…**   * Complete this section **ONLY** if you are requesting a Waiver to Document Informed Consent.   + I.E., the research participant is not signing the consent form. * Answer B1 – B3 **OR** B4 – B5 **OR** B6 – B8   + A request to waive documentation of informed consent CANNOT be granted if:   + B1, B2, or B3 is marked “No”   + B4 or B5 is marked “Yes”   + B6, B7, or B8 is marked “No” | | |

**Answer B1 – B3 OR B4 – B5 OR B6 – B8**

**B1.** If consent was documented, would the only record linking the subject and the research be the informed consent form?

**[\_\_] Yes**

**[\_\_] No**

**B2.** If consent was documented, would the principal risk to the subject be the potential harm from a breach of confidentiality?

**[\_\_] Yes**

**[\_\_] No**

**B3.** Will each subject be asked whether he/she wants documentation linking the subject with the research, and the subjects wishes will govern?

**[\_\_] Yes**

**[\_\_] No**

**B4.** Does the research present more than minimal risk of harm to subjects?

**[\_\_] Yes**

**[\_\_] No**

**B5.** Are any procedures involved for which written consent is normally required outside of the research context?

**[\_\_] Yes**

**[\_\_] No**

**B6.** Are the subjects or legally authorized representatives members of a distinct cultural group or community in which signing forms is not the norm?

**[\_\_] Yes**

**[\_\_] No**

**B7.** Does the research present no more than minimal risk of harm to subjects?

**[\_\_] Yes**

**[\_\_] No**

**B8.** Is there an appropriate alternative mechanism for documenting that informed consent was obtained?

**[\_\_] Yes**

**[\_\_] No**

**IMPORTANT: Complete all applicable sections and attach to your IRBManager submission in the Attachment Page (Y1).**