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**
[X] **No**

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

[ ] **Yes**
[X] **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).