UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-411 CHECKLIST: Waiver of Written Documentation of Consent

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The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when research involves the waiver of written documentation of consent. This checklist, or equivalent, may be used for all reviews (initial, continuing, amendment, review by the convened IRB, and review using the expedited procedure). It does not need to be completed or retained.

IRB Number:	
Investigator:	

Section 1: California Requirements (all must be checked)

Waiver of Written Documentation of Consent

☐ The research does **NOT** meet the State of California's definition of a medical experiment[1]: **(Must be Checked)**

(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; or

(b) The investigational use of a drug or device; or

(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

Section 2: Requirements for Waiver (must meet one of the following)

☐ **1. 45 CFR 117(c)(1)(i) All must be checked**

- ☐ 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.
- ☐ The research is not subject to Food and Drug Administration (FDA) jurisdiction.
- ☐ Each subject or legally authorized representative (LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

☐ **2. 45 CFR 117(c)(1)(ii) All must be checked**

- ☐ The research presents no more than minimal risk of harm to subjects.
- ☐ The research involves no procedures for which written consent is normally required outside of the research context.

☐ **3. 45 CFR 117(c)(1)(iii) All must be checked**

- ☐ The research is not subject to FDA jurisdiction.
- ☐ The subjects or their LARs 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.
- ☐ There is an appropriate alternative mechanism for documenting that informed consent was obtained. Explain:

Section 3: Additional Requirements (all must be checked)

☐ The potential subject will be presented with all of the elements of consent as outlined in the section, **GENERAL REQUIREMENTS** in *OIA-314 B WORKSHEET: Requirements for Informed Consent*, or equivalent. **(One of the following must be checked)**

- ☐ The elements of consent will be provided to the subject or the subject's LAR in written format (information sheet must be approved).
- ☐ The elements of consent will be provided to the subject or the subject's LAR in oral format (consent script must be approved).

☐ The written information sheet or script includes all required elements and appropriate additional elements of consent found in **Section 2: GENERAL REQUIREMENTS** and **Section 3: ADDITIONAL ELEMENTS OF CONSENT** in the *OIA-314 B WORKSHEET: Requirements for Informed Consent*, or equivalent.

[1] California Health and Safety Code Section 24174