SUNY OLD WESTBURY
Institutional Review Board

Waiver of Documentation of Informed Consent

For Requesting a Waiver of the Documentation of Informed Consent
All forms must be submitted via email to irb@oldwestbury.edu.

Section 1. PROTOCOL INFORMATION

1A. Primary Investigator:
1B. Protocol Number:
1C. Project Title:
1D. Is this research regulated by the US Food and Drug Administration? ◯ Yes ◉ No

Section 2. REQUEST FOR WAIVER OF DOCUMENTATION

A consent procedure which does not document obtained consent through a physical signature may be approved by the IRB under certain conditions. To request IRB approval of a consent procedure which does not document consent through a physical signature, provide a response to **only one** of the following. All participants must be offered a copy of their consent, even if the documentation requirement is waived. It is also possible that the IRB may require you to provide a copy of the consent form regardless of waiver. **Note**: You cannot waive consent for the collection of biospecimens.

A. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (Note: A waiver of documentation of informed consent is not permissible under this category if the research is subject to FDA regulations) ◯

B. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the consent (for example, no risk surveys or interviews; benign observation of public behavior). (Note: a "consent script" may still be required) ◉

C. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm and the research presents no more than minimal risk of harm to subjects. ◯