

Touro University Nevada Institutional Review Board (IRB)

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**Addendum 5: Waiver of Documentation (Signature of Participant) of Informed Consent, Permission or Assent Process**

|  |  |
| --- | --- |
| **Principal Investigator:** |  |
| **Study Title:** |  |

Note: *The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Condition #2 below. The FDA does not accept Condition #1.*

**If you have multiple consent, permission or assent forms that need alteration or omission of the elements, submit the addendum 5 for each request separately and include it with your IRB application.**

This addendum request is for

[ ]  Consent form

[ ]  Permission form

[ ]  Assent Form

**CHOOSE ONE OF THE FOLLOWING JUSTIFICATIONS FOR REQUESTING WAIVER OF DOCUMENTATION**

1. [ ]  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 (i.e., a study that involves subjects who use illegal drugs).

*Under this condition, each subject must be asked whether (s) he wants to sign a consent form; if the subject agrees to sign a consent form, AND only an IRB approved version should be used.*

1. Justify why your research meets this condition:
2. Does this research involve procedures that are minimal risk except for the linking of the consent document to private information?

[ ]  Yes [ ]  No

If “**yes**”, describe what potential harm a subject may experience as a result of a breach in confidentiality

**OR**

1. [ ]  The research presents no more than minimal risk to the subject and involves no procedures for which written consent is normally required (i.e. a cover letter on a survey, or a phone script). Justify why your study meets this condition:
2. Does this study involve procedures that, outside of the research context, would require written consent? [ ]  Yes [ ]  No

If “**yes**”, waiver of documentation is not appropriate.

**OR**

1. [ ]  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, AND there is an appropriate alternative mechanism for documenting that informed consent was obtained. Justify why your study meets **all three** of these conditions: