

Touro University Nevada **I**nstitutional **R**eview **B**oard (**IRB**)

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**Addendum 6: Waiver of Informed Consent, Permission or Assent Process**

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

I**f you are requesting IRB approval for waiver of informed consent/permission/assent process (i.e. medical record review, deception research, or collection of biological specimens), complete this addendum and include it with your IRB application submission.**

Note: *The IRB does not approve waiver of the consent/permission/assent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations. Contact IRB for regulations that apply to single emergency use waiver or acute care research waiver (TUN.IRB@tun.touro.edu).*

**If you have multiple consent, permission or assent forms that need alteration or omission of the elements, submit the addendum 6 for each request separately and include it with your IRB application.**

This addendum request is for

[ ]  Consent form

[ ]  Permission form

[ ]  Assent Form

**SECTION 1. Does My Study Qualify for a Waiver?**

**There are two separate ways that your study can qualify for waiver of informed consent. Use the following questions to determine if you are eligible.**

1. Is your research part of a public benefit and/or service program conducted by or subject to the approval of state or local officials?

[ ]  Yes [ ]  No

If yes, check the following boxes if applicable. The work is designed to study, evaluate or otherwise examine:

 [ ]  Public benefit or service programs

 [ ]  Procedures for obtaining benefits or services under those programs

 [ ]  Possible changes in or alternatives to those programs or procedures

 [ ]  Possible changes in methods or levels of payment for benefits or services under

those programs

 **If you did not check any boxes**, you are not eligible under 45 CFR 46.116(e). Go to question 2.

 **If you checked one or more boxes**, determine if the following statement is true:

[ ]  The research could not be practicably carried out without a waiver or alteration

**If you checked the box above**, you are eligible under 45 CFR 46.116(e). **Explain why a waiver is necessary, and return this form with your application.**

**If you did not check the box, you are not eligible under 45 CFR 46.116(e). Go to Question 2.**

1. **Check boxes to affirm that each criterion is applicable, and explain your answer for each statment that applies to your study**:

[ ]  The research involves no more than minimal risk to the subject.

*Explain how this condition is met***:**

[ ]  The rights and welfare of subjects will not be adversely affected.

*Explain how this condition is met***:**

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

*Explain how this condition is met***:**

[ ]  **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.

*Explain how this condition is met***:**

[ ]  **Whenever relevant**, the subject will be provided with additional pertinent information after they have participated in the study

*Explain how this condition is met***:**

**If any relevant boxes are not checked, your study does not meet the criteria for a waiver of the informed consent process.**

**If all boxes which are relevant to the study are checked, the study is eligible under 45 CFR 46.116(f). Make sure you fully explained why a waiver is necessary and allowed in Question 2, and return this form with your application.**