Touro University Nevada

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.**