Touro University Nevada

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

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**Addendum 8: Investigational Drugs, Other Drugs, and Devices**

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

INVESTIGATIONAL NEW DRUG

Investigational new drug" (IND) means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms ''investigational drug'' and ''investigational new drug'' are deemed to be synonymous for purposes of determining whether a Notice of Claimed Investigational Exemption for a New Drug must be submitted to the US Food and Drug Administration (FDA).

If you are using an investigational new drug (IND), complete the following questions.

1. Provide available toxicity data on the drug(s):

1. Describe previous studies on humans:

1. Provide any available literature for review (Attach review materials if needed):

1. If this is a Phase I study, provide available reports of the animal studies:

1. Address whether this study will have a Data Safety Monitoring Board in place:

1. **OTHER DRUGS (Non-IND)**

**If you are using drugs that do not come under IND definition, complete the following questions.**

1. Name of the drug(s):

1. Describe if the drug(s) is FDA approved and over the counter/prescription drug:

1. Dosage of the drug(s):

1. Toxicity data on the drug(s):

1. Describe previous studies on humans:

1. Provide any available literature for review. Attach review materials if needed, and explain as necessary:

1. Address whether this study will have a data safety monitoring Board in place:

1. **INVESTIGATIONAL DEVICE (IDE)**

**A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy.**

If you are using any investigational Device (IDE), complete the following questions.

1. Provide name and source of the device:

1. Provide the current FDA status of the device and IDE number:

1. Address the risk of the device, if not already addressed in the “Risks” section:

1. Provide any relevant material on the device:

1. Clarify the risk level assignment as determined by the sponsor ( e.g., non-significant or significant risk):

Note: There are additional record-keeping requirements and IRB review requirements for studies which fall within FDA purview. Further FDA guidance on Investigational Drugs, Other Drugs, and Devices can be found at the FDA web site.