Touro University Nevada **I**nstitutional **R**eview **B**oard (**IRB**)
874 American Pacific Drive
Henderson, NV. 89014
Telephone: (702) 777-8687 Email: tun.irb@tun.touro.edu

Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

General Definition of Unanticipated Problem:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

General Definition of Adverse Event:

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subjects participation in the research, whether or not considered related to the subjects participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

SECTION 1: General Information

1. Principal Investigator (PI) Contact Information:

Last Name: _____ First Name: _____

Department: _____ Position: _____

Phone: _____ E-mail: _____

2. Study Title:

_____

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3. Human Subject Application Number: _____

4. Is this research supported in whole or in part by a grant or contract?

☐ Yes ☐ No

Funding Agency(s), Foundation, or Business: _____

PI on Grant/Contract: _____ OGRD #: _____

Grant Title/Contract: _____

5. Details of the person reporting the event:

Last Name: _____ First Name: _____

Department: _____ Position: _____

Phone: _____ E-mail: _____

6. Role of the person reporting the event:

_____

7. Location of the event:

_____

8. Name of the entities that need the report of the event (examples: funding agency, company, FDA, DHHS etc.,):

_____

SECTION 2: Unanticipated problem/Adverse Event Information

1. Is the event an unanticipated problem or adverse event (refer to definition on page 1)?

_____

2. Explain the nature of the unanticipated problem or adverse event (how many people involved, seriousness of the event):

_____

3. Describe the corrective actions or substantive changes (changes to the protocol, modifications of inclusion exclusion criteria, implementation of additional procedures, suspension of enrollment of new subjects, suspension of research procedures , modification of informed consent documents, provision of additional information):

_____