



Touro University Nevada Institutional Review Board (IRB)
874 American Pacific Drive
Henderson, NV. 89014
Telephone: (702) 777-8687 Email: tun.irb@tun.touro.edu

REQUEST FOR AMENDMENT

Principal Investigator: _____ IRB #: _____

Project Title: _____

1. Amendment Description (**Check all as appropriate**):

Amendment to currently approved procedures on the application (for example: changes to General information section, data collection methods section, confidentiality section, subject recruitment section, risk and benefits section etc.)

Amendment to Recruitment materials

Amendment to Addenda (1-10)

Amendment to currently approved Consent/Assent/Permission forms

Amendment to Debriefing forms

Amendment to Data collection tools

Amendment to Investigator brochure

Other: _____

2. List and describe the proposed changes to each document or sections on the application: _____

3. State the reason for the proposed changes: _____

4. Potential risks to the participants **as a result of this amendment: (Check all that apply)**

No Changes

Not Applicable

Invasion of privacy to the subject or family

Breach of confidentiality

Physical harm or discomfort

Psychological/emotional discomfort or distress

Psychological effect that is more than discomfort or distress

Social stigmatization

Economic (e.g. employment, insurability)

Legal

Any study related activity which subjects might consider sensitive, offensive, threatening, or degrading?

Withholding standard care and procedures

Significant time or inconvenience

Other: _____

5. Indicate which of the categories listed below accurately describes the overall potential risk level on items in question 4 of this amendment form:

No Changes

Not Applicable

Not greater than minimal risk¹

Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition

Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects

6. How will you minimize or handle these potential risks in order to protect subjects' rights and welfare (e.g. compensation, counseling, etc.)?

Not Applicable

Explain in detail if Applicable: _____

7. Is it possible that you will discover a subject's previously unknown physical or psychological condition (e.g. disease, depression, suicidal ideation, genetic predisposition, etc.) **as a result of your revised procedures?**

Yes

No

Not Applicable

If yes, what would they be and how will you handle these situations?

Explain in detail: _____

8. Is there a change in benefits **as a result of this amendment?**

Yes

No

¹ "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102 (i)

Not Applicable

If yes, describe the expected benefits of this amendment (Note: compensation is not considered a benefit) (Check and explain all that apply):

A. To the individual subjects:

Explain in detail: _____

B. To society:

Explain in detail: _____

9. Do the benefits of this amendment outweigh the increased risks to the participants? (e.g. risk/benefit ratio)

Yes

No

Not Applicable

If yes, describe how:

Explain in detail: _____

10. Did you attach amended material, as applicable (Note: **Highlight/Bold/Underline all changes**)?

Yes

How to Submit:

1. All submissions (Amendment and the supporting materials) should be emailed to tun.irb@tun.touro.edu Subject line: Either "Amendment to expedited review" or Amendment to full board review" and IRB #. If someone else (e.g. Co-PI or staff) is submitting the Amendment request on behalf of Principal Investigator (PI), the submission should be copied to PI.