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

Deviation Definition: Any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB and or the Sponsor.

Major Deviation: DOES have a major impact on the subject's right, safety or wellbeing, or the completeness, accuracy and reliability of the study data.
Some examples (not an inclusive list):

- Failure to obtain informed consent, i.e., there is no documentation of informed consent, or informed consent is obtained after initiation of study procedures;
- Enrollment of a subject who did not meet all inclusion/exclusion criteria;
- Subject met the withdrawal criteria during the study but was not withdrawn;
- Performing study procedure not approved by the IRB;
- Failure to report serious unanticipated problems/adverse events involving risks to subjects to the IRB and (if applicable), the sponsor;
- Failure to perform a required lab test that affects subject safety or data integrity;
- Drug/study medication dispensing or dosing error;
- Subject receiving wrong treatment (receiving an excluded concomitant medication);
- Study data collection conducted outside of required time frame that, in the opinion of the PI or IRB, may affect subject safety;
- Failure to follow safety monitoring plan;
- Breach of confidentiality; for example: a follow-up letter to a subject participating in a study on illegal drug use is sent to the wrong address. The person who receives the letter by mistake opens. The letter clearly identifies the subject by name and the content of the letter provides information that the subject is an illegal drug user. The subject's loss of confidentiality significantly impacts the subject in a negative way because the subject could then be reported to the police for illegal drug use;
- Falsifying research protocols, data, IRB documents, and medical record information;
- Performing tests or procedures beyond the individual's professional legal scope of practice or privilege status (credentialing);
- Working under an expired or false professional license or certification;
- Failure to follow federal and/or local regulations, and intramural research policies;
- Repeated minor deviations.
- Instituting a procedure on one or more enrolled subjects that is not specified in the protocol.

Minor Deviation: DOES NOT have a major impact on the subject's right, safety or well-being, or the completeness, accuracy and reliability of the study data.
Some examples (not an inclusive list):

- Implementation of unapproved recruitment procedures; move to major
- Missing original signed and dated consent form (only a photocopy available);
- Missing pages of executed consent form;
- Inappropriate documentation of informed consent, including:
  - missing subject signature;
  - missing investigator or designee's signature;
  - copy not given to the person signing the form;
  - someone other than the subject dated the consent form;
  - individual obtaining informed consent not listed on IRB approved study personnel list;
- Use of invalid consent form, i.e. consent form without IRB approval stamp or outdated/expired consent form;
- Failure to follow the approved study procedure that may affect subject safety or data integrity;
  - Study procedure conducted out of sequence;
  - Omitting an approved portion of the protocol;
  - Failure to perform a required lab test;
  - Missing lab results, inadvertent loss of samples and data
  - Enrollment of ineligible subject (e.g. subject's age was 6 months above age limit);
- Study data collection conducted outside of required timeframe; for example: Follow up study visit occurred 1 day out of the " window of time" described in the protocol, but was due to the subject's inability to travel long distance during inclement weather, but had minor or no impact on the safety of the study;
  - drawing a 13th tube of blood from a subject where the protocol specifies that 12 samples will be collected for the study
- Over-enrollment beyond IRB approved enrollment;
- Enrollment of subjects after IRB-approval of study expired or lapsed; Move to major
- Failure to submit continuing review application to the IRB before study expiration.

This report should be submitted to the IRB within
5 days of discovering the deviation.

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SECTION 1: Research Study Information

1. Principal Investigator (PI) Contact Information:
   Last Name: _____First Name:_____
2. Human Subject Application Number: _____
3. Study Title: _____
4. Details of the person reporting:
   Last Name: _____First Name:_____ _____

   Phone: _____ Email: _____
5. Role of the person reporting: _____

SECTION 2: Information about the Deviation

1. List the deviation (s) and describe: _____
2. This deviation (s):

   ☐ **does** increase the risk to participants in the approved protocol

   ☐ **does not** increase the risk to participants in the approved protocol
3. Was the deviation due to: Investigator error ☐ Subject error ☐ Circumstance ☐
4. Was there a corrective action taken? ☐ Yes ☐ No

   If yes, describe the corrective action: _____
   If no, describe how and what the corrective action will be taken and anticipated date of resolution: _____
5. Explain how you will prevent the future occurrences of this problem: _____
   _____
6. Was the participant adversely affected by the deviation (s)? ☐ Yes ☐ No

   If yes, submit an Adverse Event Form
7. Will the participant remain in the study? ☐ Yes ☐ No

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8. Has this deviation been reported to the sponsor? ☐ Yes ☐ No

If no, explain: _____
_____

9. Has this deviation (or similar) previously occurred in this study? ☐ Yes ☐ No

10. Does this deviation affect the integrity of the study data? ☐ Yes ☐ No

11. Do the research procedures need to be modified? ☐ Yes ☐ No

a. If yes, complete the request for modification form and submit to IRB

b. If no, explain why: _____
_____

12. Do the consent forms or the consenting process need to be modified? ☐ Yes ☐ No

c. If yes, complete the request for modification form and submit to IRB

d. If no, explain why: _____
_____