THE WILLIAM PATERSON UNIVERSITY OF NEW JERSEY

**INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECT RESEARCH**

 c/o Office of Sponsored Programs Chair: Professor Michelle Gonzalez (GonzalezM77@wpunj.edu)

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William Paterson University of New Jersey Institutional Review Board

Adverse Effect/Event Report Form

**Instructions:** Complete this form and email it to inform the IRB via e-mail (irbadministrator@wpunj.edu) of the Adverse Effect/Event within 24 hours of the adverse effect/event. Answer all questions below.

**Principal Investigator First and Last Name:**

**E-mail:**

**Phone:**

**Faculty Advisor First and Last Name (if Student Researcher):**

**E-mail:**

**Sponsor (if funded):**

**Sponsor email address:**

**Title of Protocol:**

**Protocol Number:**

**Event Date:**

**Date event reported to PI:**

**Event report:** ☐ Initial ☐ Follow-Up

If a Follow-Up, give the date when the Initial Adverse Effect Form was submitted:

**Site:** ☐ WPUNJ campus ☐ External site If External site, please give the name of the site:

**Brief description of the event:**

**Action taken:**

**Causality: In the opinion of the PI is this event related to the subject’s participation in the research or a research activity?:**

☐ Definite ☐ Probable ☐ Possible ☐ Unrelated

**Event Severity Classification:**

☐ Serious Unexpected ☐ Moderate Unexpected ☐ Non-Serious, Unexpected

☐ Serious Expected ☐ Moderate Expected ☐ Non-Serious, Expected

**Protocol Modification:** Is it your intention to modify the protocol/consent form to address increased monitoring for this adverse event or to provide new information to the research subject?

* Yes and I will submit a modification request form with revised protocol and/or consent documents.
* No. Explain rationale:

# DECLARATION: I certify that I have reviewed the attached report and conclude that the risk- benefit ratio of the research continues to be acceptable, and that the risks are minimized to the greatest extent possible. By signing below, I certify that the information contained in this report is correct.

**Principal Investigator:**

Signature Print Name Date

**Faculty Sponsor: (if P.I. is a student)**

Signature Print Name Date

# The WPUNJ-Institutional Review Board:

IRB Chair Signature Print Name Date