New York College of Health Professions
Institutional Review Board for Research with Human Subjects (IRB)
Unanticipated Problem/Adverse Event Report/
Unanticipated Adverse Device Effect for NYCHP Subjects

Please review the IRB's policy on Unanticipated Problems and Adverse Events found at (**https://nycollege.edu/**).

Date of this Report:	
IRB Protocol #:	**NYCHP School/Center:**

Project Title:

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Principal Investigator Information

Name		Relationship to NSU: Faculty □ Staff □ Student □
Home Mailing Address (for students) City/State/Zip:		
Office Phone:	Home Phone (for students):	Email:

Study Sponsor:
Has the sponsor been notified? Yes □ No □
Date of Notification:

Unanticipated Problem/Adverse Event/Unanticipated Adverse Device Effect Information
Submit 1 Adverse Event Report for each subject. You may use additional sheets to describe the nature of the adverse event. If a separate notification is required for sponsored studies and/or regulatory agencies, please include a copy of that notification.

Participant #	Date of Adverse Event	Description of Unanticipated Problem/Adverse Event	Was the Adverse Event Unexpected? Yes □ No □

Was the Adverse Event Serious? Yes □ No □	Study Related Adverse Event? Yes □ No □	Does the adverse event suggests that the research places subjects or others at a greater risk of harm? Yes □ No □
Should the protocol and/or consent forms be revised Yes □ No □ Does the event have implications for the conduct of the study? Yes □ No □		Will additional information be given to enrolled subjects? Yes □ No □
If Yes, please submit a copy of the corrected amendment forms with **bold** changes and a clean copy incorporating the changes.		

Principal Investigator's Signature: _____ Date: _____

New York College of Health Professions
Institutional Review Board
IND Safety Report

Date:	**IRB Protocol #:**
Principal Investigator:	**NYCHP School/Center:**

Project Title:

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Study Sponsor:

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IND Safety Report dated:

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Serious Adverse Event / Sentinel Event Information:

Description of Serious or Sentinel Event	Date of event

I have personally reviewed the IND safety report of a serious adverse event

_____

Principal Investigator Date

DEFINITONS:

1. Unanticipated Problems (non FDA research) are considered to include any incident, experience, or outcome that meets all of the following criteria:
    Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related outcomes, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
    Related or possibly related to participation in the research (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
    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.
2. For FDA governed research, please note that the criteria of an unanticipated problem is slightly different.
    Unexpected
    Serious
    Would have implications for the conduct of the study (e.g., requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator's brochure).
3. Serious Adverse Events are defined as follows:
    Death
    Congenital Anomaly/Birth Defect
    Hospitalization Required or Prolongation of a Hospitalization
    Life Threatening Event
    Significant or Persistent Disability/Incapacity

IND Safety reports are generated when a serious adverse event which may be related to the study drug and not expected occurs in any protocol using the study drug. IND safety reports must be reported to the IRB in keeping with the Unanticipated Problems and Adverse Event Reporting policy.