SUNY Downstate IRB & Privacy Board

FORM 20-B3: Application for Reportable Event

(Version 11.16.2021)

Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.

Note: Free Adobe Reader available at: www.adobe.com

Section 1: General Information:

A. IRBNet Number:

B. Protocol Title:

C. PI* Name and Degree

**Note: Provide "Principal Clinician" for HUD for clinical use and expanded access projects.*

E. PI Department/College

F. PI Status Downstate Faculty

When applicable, include information about a **Co-PI (optional) below:

***Note: If more than one Co-PI, attach separate sheet with the additional information*

G. If applicable, Co-PI Name and Degree:

H. If applicable, Co-PI Department/College:

I. If applicable,Co-PI Status NA -No Co-PI

J. Additional contact person (Name, E-mail, phone #, and role, e.g.., Research Coordinator):

Section 2: Summary of Event(s) and Corrective Actions:

A. Provide a Summary of the Event(s):

B. Provide corrective actions including plans to prevent recurrence or indicate if not applicable:

C. ☐ Check if this study relies on the oversight of an external IRB (sIRB, Central IRB, Commercial IRB, WCGIRB, ADVARRA, BRANY, NCI-CIRB, etc) & include their determination letter.

Section 3: Proposed Type(s) of Event(s) Being Reported:

NOTES:

1)Submit within the required deadline(s) as noted below.

2) For definitions consult Policy IRB-01 or applicable Federal regulations.

3)The IRB may make a different determination.

4)Upload relevant documents with the submission.

5)Include any applicable Amendment with this submission.

6)Do not attach or provide any protected health information (PHI) in IRBNet.

a) ☐ **Government inspection** (Report to IRB within 24 hrs if serious; otherwise 5 days)

b) ☐ **Potential Violation (or Breach) of Confidentiality, Privacy, or Information (Data) Security** (Report to IRB Immediately)

Note: The final determination of a 'Privacy Breach' and/or 'Information (Data) Security Breach' is made by the Downstate Privacy Officer and/or Information Security Officer.

c) ☐ **Incarceration of a Research Participant in a study not approved by the IRB to include Prisoners**. (Report to IRB Immediately if research participant is actively incarcerated; otherwise within 5 days)

If checked, answer the following:

i. **Indicate whether the research participant is still incarcerated**

☐ **Yes** ☐ **No**

ii. **Provide the date the incarceration began, if known:**

iii. **Provide the date the incarceration ended, if known:**

d) ☐ **FDA action or FDA change to an HUD.** (Report to IRB Immediately)

e) ☐ **Internal Serious (or Alarming) Adverse Event(s) (SAE).** (Report to IRB within 24 hrs.)

If checked, answer the following:

a. **Was the AE definitely, probably, or possibly related to the investigational agent (drug, biologic, or device)?**

i. ☐ Yes, definitely related to the investigational agent

ii. ☐ Yes, probably related to the investigational agent

iii. ☐ Yes, possibly related to the investigational agent

iv. ☐ No- Not related to the investigational agent (No need to report to IRB, unless required by sponsor)

v. ☐ Pending (e.g., IN CASES OF DEATH), when relationship of study product is under investigation, check the "Pending" box indicated until relationship has been determined. Update the IRB accordingly with a follow-up report

b. **Indicate why the event is serious or alarming:**

i. ☐ The adverse event resulted in death. The death is suspected to be attributable to an outcome of a Research AE.

ii. ☐ The adverse event resulted in a life-threatening experience. The Research Participant was at substantial risk of dying at the time of the AE, or use or continued use of the device or other medical product might have resulted in the death of the participant.

iii. ☐ The adverse event resulted in an initial hospitalization. The admission of the Research Participant was the result of the AE. Emergency Department visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening, required intervention to prevent permanent impairment or damage; other serious medically important event).

iv. ☐ The adverse event resulted in a prolongation of hospitalization. The hospitalization of the Research Participant was prolonged as a result of the AE.

v. ☐ The adverse event resulted in a persistent or significant disability or incapacity. The AE resulted in a substantial disruption of the Research Participant's ability to conduct normal

life functions, i.e., the AE resulted in a significant, persistent or permanent change, impairment, damage or disruption in the Participant's body function/structure, physical activities or quality of life.

vi. ☐ The adverse event resulted in a congenital anomaly or birth defect. It is suspected that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

vii. ☐ The adverse event resulted in the need for medical, surgical, behavioral, social, or other intervention to prevent outcomes such as the above. It is believed that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, due to the use of a medical product.

viii. ☐ The AE was alarming. State reasons:

c. If reporting a death, please provide the date of death, if known (if not known, type "unknown"). If not reporting a death, type N/A:

f) ☐ **Research related injury involving provision of healthcare.** (Report to IRB within 24 hrs.)

g) ☐ **Non-Compliance with federal or state regulations governing human research or with the requirements or determination of the IRB, allegation of Non-Compliance, or apparent (possible) Non-Compliance.**
(Report to IRB within 24 hrs if serious; otherwise, within 5 days.)

h) ☐ **New Information that Indicates a Change to the Risks or Potential Benefits of the Project** (Report to IRB within 24 hrs if serious; otherwise, within 5 days.)

i) ☐ **Significant New Finding** (Report to IRB within 24 hrs if serious; otherwise, within 30 days.)

j) ☐ **Changes Initiated to Eliminate an Apparent Immediate Hazard.** (Report to IRB within 5 days.)

k) ☐ **Expanded Access, Emergency Use, or Compassionate Use of an Unapproved Drug Unapproved Biologic, or Unapproved Device, when there is no time for IRB approval of the investigational agent.** (Notify IRB Chair ASAP & report to IRB within 5 days.)

If checked please provide the following date(s):

a. **Date(s) of the use of the investigation agent:**
b. **Date approved by the Department Chair:**
c. **Date approved by the Medical Director:**
d. **Date IRB Chair notified:**
e. **Date prospective informed consent was obtained (when feasible):**

f. ☐ **Check, if informed consent was not feasible AND provide the date the treating physician and another physician certified the event in medical record that informed consent was not feasible:**

l) ☐ **Protocol Deviation, Protocol Violation, or Research Error**

(Report to the IRB within 5 days, if it adversely affects the rights, safety, or welfare of the research participant; or the research participant's willingness to continue participation; or the integrity of the research data, including information security requirements; otherwise report to IRB before continuing review or project closure.)

m) ☐ **Complaint of a Research Participant that cannot be resolved by the research team** (Report to IRB within 24 hrs if serious; otherwise, within 5 days.)

n) ☐ **Premature Termination or Suspension of the Research by someone other than the Downstate IRB (e.g., external IRB, sponsor, investigator, or institution)**. (Report to the IRB within 5 days.)

o) ☐ **Enrollment Hold.** (Report to the IRB within 5 days.)

p) ☐ **Administrative Hold.** (Report to the IRB within 5 days.)

q) ☐ **FDA Clinical Hold.** (Report to the IRB within 5 days.)

r) ☐ **LOCAL (Internal) Unanticipated Problems Involving Risks to Participants or Others (UPIRPO)** (Report to IRB within 5 days if serious; otherwise, within 30 days.)

If checked, confirm <u>all the criteria below</u> apply to the incident, experience, or outcome:

☐ **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 research participants 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 the research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.**

Note: When item r is checked above, provide additional details in Section 4, items d, e, and f.

s) ☐ **Unanticipated Adverse Event (UAE) for Clinical Trials with an IND**
(Report to IRB within 5 days if serious; otherwise, within 30 days.)

t) ☐ **Unanticipated Incidental Finding (UIF)**
(Report to IRB within 24 hrs if serious; otherwise, within 30 days.)
Note: Answer additional questions pertaining to UIF reporting at the end of Section 4.

u) ☐ **Unanticipated Adverse Device Effect (UADE)**
(Report to IRB ASAP but no later than 10 days)

v) ☐ **Report(s), check type below:** (Report to IRB within 30 days.)
Note: If preferred, these reports may be submitted within 30 days of receipt via an amendment application form or an acknowledgment application form (for research with external IRB oversight) rather than using this reportable event application form.

- ☐ **Interim Analysis report**
- ☐ **Data Monitoring Committee (DMC) report**
- ☐ **Data and Safety Monitoring Board (DSMB) report**
- ☐ **Written Report of Study Monitor or Auditor**
- ☐ **Other Report (describe):**

w) ☐ **Adverse Event (AE)** *(NOTE: Only report individual AEs to the IRB when required by the sponsor; otherwise, please provide summary at the time of continuing review or within 1 year when annual continuing review is not required).*

x) ☐ **Other (specify):**

Section 4: Answer the following questions:

a) Is this a follow-up report? ◯ Yes ◯ No

i) If yes,

(1) IRBNet package #(s) of previous report(s)?

(2) Follow-up summary of the event(s) (include the participant study ID#(s) or control #(s), if applicable):

(3) Resolution date:

ii) If no, answer the following:

(1) Event date:

(2) Date study team first become aware of the event?

(3) Indicate location where the event occurred:

(a) Internal site - SUNY Downstate (list specific location):

(b) External site -Collaborating study site (list specific location):

(c) Other (list specific location):

(4) Please provide a summary of the event(s) (include the participant study ID#(s) or control #(s), if applicable):

(5) Resolution date:

b) Is a change needed to the research related to this report (e.g., protocol change, informed consent change, notification to research participants)?

i) ◯ Yes, the amendment is included with this report.

ii) ◯ Yes; however, the amendment is pending submission.

iii) ◉ No

c) Check if the event adversely impacted any of the following:

- **i) ☐ rights, welfare, or safety of the research participant(s).**
- **ii) ☐ willingness of any research participant to continue participation.**
- **iii) ☐ integrity of the research data. If checked, explain your response:**
- **iv) ☐ new risk or safety issue**
- **v) ☐ increase in frequency or magnitude of previously know risk**
- **vi) ☐ any harm experienced by a research participant or other individual**
- **vii) ☐ any other aspect of the research.**

If any items are checked above (item "c"), provide more details on the impact:

d) Given the protocol-related documents approved by the IRB or the characteristics of the research participant population being studied, was this event expected?

◯ Yes ◉ No

Rationale for determining whether the event was expected:

e) Is there a reasonable possibility that the event may have been caused by the procedures in the research?

◯ Yes ◉ No

Rationale for determining whether the event was related to the research:

f) Does this event suggest that the research places the research participants or others at a greater risk of harm than was previously known or recognized?

◯ Yes ◉ No

Rationale for determining if risk increased:

NOTE: If "Yes" is selected for d, e, and, f above, also check item r in Section 3.

g) Does the PI consider this event to be serious?

◯ Yes ◉ No

h) **Was the sponsor notified?** ◯ Yes ◯ No ◉ N/A, this is not a sponsored study

i) **Is there a DSMB (Data Safety Monitoring Board) or similar central safety review board in place for this study?** ◯ Yes ◉ No

j) **Is the event being reported within the required timeframe?** ◉ Yes ◯ No

k) **If the event is not being reported within the correct time frame, please provide a plan of corrective action, so this does not happen again:**

l) ☐ Check here, if reporting an Unanticipated Finding (UIF) and answer the questions below:

i) **Type of UIF:**

- a. ☐ **Radiology exam result**
- b. ☐ **CLIA certified lab test result**
- c. ☐ **Non-CLIA certified lab test result/research lab finding**
  - i. ☐ **Follow-up testing in CLIA certified lab confirmed research results**
  - ii. ☐ **Follow-up testing in CLIA certified lab is pending**
  - iii. ☐ **Clinical validation is not appropriate nor possible, as explained below:**
- d. ☐ **Other (describe):**

ii) **Explain why the UIF is clinically significant and/or medically actionable and/or has a safety, health, reproductive, welfare, or psychiatric importance for the research participant:**

iii) **Describe disclosure and action plan (to be approved by the IRB). Include: 1) name of licensed professional(s) or trained non-professional(s) who will disclose the UIF the research participant, 2) time frame for communication, 3) plans to disclose to a parent, legal guardian, or legally authorized representative, if applicable, 4) plans for allowing participant to withdraw themselves, specimens, and/or data from future analysis/ reporting 5) plan for future care for the research participant**

Section 5: Additional information (optional):