Form: Reportable Event Prompt Reporting Form Version 6/30/2020	DePaul University Office of Research Services Institutional Review Board 14 East Jackson Blvd, Suite 1030 Chicago, Illinois 60604-2201 Email: orp@depaul.edu Phone: (312) 362-7593 Web: http://research.depaul.edu

Form completion or revision date:

Principal Investigator:

Name (Last):			(First):	
Degree:	Status:	Title:	Dept.:	College/School:
Phone:		DePaul Email:		Alternate Email:

Faculty Sponsor: (If you are a student, in a staff position functioning as a training position, or a fellow, you must have a faculty sponsor when you are the Principal Investigator.)

Name (Last):			(First):	
Degree:	Status:	Title:	Dept.:	College/School:
Phone:		DePaul Email:		Alternative Email:

I. Project Information:

1. Protocol Number:
2. Project Title:
3. Current level of review: ☐ Exempt ☐ Expedited ☐ Full

Use the form to report all types of events that must be reported promptly (within 5 working days of the event or learning of the event) to the IRB per DePaul policy (See the Instructions for Completing the Reportable Events Form on the forms and templates page of the IRB website.)

The type of events that do not require prompt reporting to the IRB include:

- Local adverse events or problems that are expected based upon the protocol or consent risk sections or that are not associated with a greater risk of harm to the subject or others than was previously known based upon the information provided in the protocol application or consent.
- External adverse event or problem lacking documentation that an analysis has occurred which determined the event/problem is unanticipated, related or possibly related and associated with a greater risk of harm than was previously known.

The types of events that should be promptly reported with this form include:

- Unanticipated adverse events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs)
- New information that unexpectedly alters the risk or benefits to the research subjects
- Subject death

- Significant protocol deviations
- Significant protocol violations
- Serious adverse events
- Noncompliance
- Subject complaints that cannot be handled by the PI
- Any other events that require prompt reporting according to DePaul policy, i.e., breaches in confidentiality

I. Type of Report
   a. ☐ Initial Report ☐ Follow up Report- Date of Initial Report: ____
   b. ☐ Internal Event (happened in subjects enrolled by DePaul researchers at a protocol- approved performance site.
   c. ☐ External Event (happened at a collaborating site under the jurisdiction of a collaborating investigator and potentially another IRB)

II. Study Related Information:
   a. Indicate the number of subjects currently enrolled in the research. ____
   b. Indicate the status of the research (check all boxes that apply):

      ☐ Subject recruitment and enrollment is ongoing

      ☐ Research interventions/interactions are ongoing for enrolled subjects

      ☐ Research is in long-term follow-up only

      ☐ Research is in data analysis only

      ☐ Research is completed

      ☐ Research activities have been voluntarily halted

      ☐ The IRB has suspended research activities

III. Type of Reportable Event (Check all that apply. Some events may represent more than one category of event.)

☐ Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO)

☐ Serious Adverse Event (SAE) (Check the type of SAE below.)

☐ Subject Death -Report if you suspect that the death was an outcome of the adverse event

☐ Life Threatening (placed the subject at immediate risk of death from the event as it occurred)

☐ Inpatient hospitalization or prolongation of existing hospitalization- Report if hospitalization of prolonging hospitalization occurred while enrolled in the research.

☐ Persistent or significant disability/incapacity - Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions

☐ Congenital anomaly/Birth defect- Report if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

☐ Other Serious /Important Medical Events- Report when the event, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes noted above.

☐ The problem or adverse event does not fall under the IRB's prompt reporting requirements, but in the PI's judgement, prompt reporting of the event(s) is in the best interest of the subject(s) because it may affect the safety and/or welfare of subjects and/or change the risk level of the study.

☐ New Information that unexpectedly alters the risk or benefits to the research subjects

☐ Noncompliance

☐ Protocol Deviation/Violation

☐ Subject Complaint

☐ Financial Harm

☐ Emotional/Psychological Harm

☐ Other Explain:

IV. Provide a detailed description of the event, incident, problem, or new information. Include the following information:

- Date(s) of event or problem
- Date the event or problem became known to the researchers
- Subject ID number(s) or identifier(s) (do not provide full name of the subject), if the event involves an individual subject or subjects
- Location of event
- An explanation of what occurred and the relationship in time to the research activity
- An assessment of the seriousness of the event or problem (as defined above for a SAE)
- An assessment of whether the event or problem was related or not related to the research- usually reported as related, possibly related, or unrelated
- An assessment of whether the event or problem was unanticipated or previously unknown or potentially anticipated (listed as a risk in the consent document or protocol)
- An assessment as to whether the event or problem poses risks or problems for the research subjects or others that is greater than previously known or recognized

V. Actions Taken:

a. Provide a detailed description of the actions taken in response to the incident or problem, including dates of actions/responses and any treatment provided. Keep in mind the plan to address the event or problem should be one to minimize or eliminate risk to the current subject(s) and put steps in place to prevent an issue from recurring in the future.

b. Will any changes to the protocol be made as a result of the event/problem?

☐ No ☐ Yes

i. If yes, explain the changes that will be made. Keep in mind the changes will need to be submitted as an amendment:

VI. Outcome

a. If the event involves an individual subject or subjects, indicate the outcome for the subject(s). Check all that apply.

☐ Continues research intervention/interaction
☐ Continues research follow-up only
☐ Research participation completed
☐ Temporarily stopped research interventions or interactions
☐ Subject withdrew from participation or died
☐ Investigator withdrew the subject from the research
☐ Other Explain:
☐ NA

VII. Has this problem occurred previously in this study? No ☐ Yes ☐

Explain:

VIII. Have the risks of the research or the risk/benefit ratio of the research been altered by this event/issue? No ☐ Yes ☐

Explain:

IX. Informed Consent Process

a. The problem or issue is currently listed in risk section of the currently approved consent document, parent/legal guardian permission, and/or assent.

Yes ☐ No ☐ NA ☐

i. If no, indicate how you will revise the documents to reflect the new risk(s).

b. The subjects previously enrolled, currently enrolled and/or future subjects will be informed of the problem or issue.

Yes ☐ No ☐

i. Indicate which groups of subjects will be informed about the issue.

☐ Past subjects
☐ Current subjects
☐ Future subjects

c. If yes, describe your plan for informing past subjects, currently enrolled subjects and/or future subjects.