**Application Form for Reportable Event**

**IMPORTANT DEADLINE: Submit within the required deadline(s) outlined in** [**Policy IRB-01**](http://research.downstate.edu/irb/irb-policies.html)**.**

**CAUTION: DO NOT ATTACH OR PROVIDE ANY PROTECTED HEALTH INFORMATION (PHI) IN IRBNET.**

**INSTRUCTIONS:**

1. **Complete this form and submit in IRBNet.**

***Note: For external reportable events, please use the “Application for Acknowledgement” form, rather than using this form.***

1. **Please upload any relevant documents with the package.**
2. **The IRBNet package must be electronically signed by the PI before submitting the package to the IRB.**
3. **GENERAL INFORMATION**
   1. **Protocol Title**
   2. **Principal Investigator (PI) Name:**
   3. **PI Phone #**
   4. **PI Email :**
   5. **If someone, other than the PI, is the main contact for this submission, please provide his/her contact information below:**
      1. **Name (if not PI):**
      2. **Role on Study:**
      3. **Phone:**
      4. **Email:**
4. **Proposed Types of Event(s) being Reported:**

*Note: The IRB may make a different determination.*

1. **Government inspection**
2. **Potential Violation (or Breach) of Confidentiality, Privacy, or Information (Data) Security**

*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.*

1. **Incarceration of a Research Participant in a study not approved by the IRB to include Prisoners**.

**If checked, answer the following:**

* 1. **Indicate whether the research participant is still incarcerated  Yes  No**
  2. **Provide the date the incarceration began, if known:**
  3. **Provide the date the incarceration ended, if known:**

1. **FDA action or FDA change to a HUD**
2. **Internal Serious (or Alarming) Adverse Event(s) (SAE). If checked, answer the following:**
   1. **Was the AE definitely, probably, or possibly related to the investigational agent (drug, biologic, or device)?**
      1. Yes, definitely related to the investigational agent
      2. Yes, probably related to the investigational agent
      3. Yes, possibly related to the investigational agent
      4. No- Not related to the investigational agent (No need to report to IRB, unless required by sponsor)
      5. 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
   2. **Indicate why the event is serious or alarming:**
      1. The adverse event resulted in death. The death is suspected to be attributable to an outcome of a Research AE.
      2. 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.
      3. 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).
      4. The adverse event resulted in a prolongation of hospitalization. The hospitalization of the Research Participant was prolonged as a result of the AE.
      5. 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.
      6. 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.
      7. 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.
      8. The AE was alarming. State reasons:
   3. **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:**
3. **Research related injury involving provision of healthcare**
4. **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**
5. **New Information that Indicates a Change to the Risks or Potential Benefits of the Project**
6. **Significant New Finding**
7. **Changes Initiated to Eliminate an Apparent Immediate Hazard**
8. **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. If checked please provide the following date(s):**
   1. **Date(s) of the use of the investigation agent:**
   2. **Date approved by the Department Chair:**
   3. **Date approved by the Medical Director:**
   4. **Date IRB Chair notified:**
   5. **Date prospective informed consent was obtained (when feasible):** 
      1. **If informed consent was not feasible, provide the date the treating physician and another physician certified the event in medical record that informed consent was not feasible (enter N/A if date was provided for consent above):**
9. **Protocol Deviation, Protocol Violation, or Research Error**
10. **Complaint of a Research Participant that cannot be resolved by the research team**
11. **Premature Termination or**  **Suspension of the Research by someone other than the Downstate IRB (e.g., external IRB, sponsor, investigator, or institution)**
12. **Enrollment Hold**
13. **Administrative Hold**
14. **FDA Clinical Hold**
15. **LOCAL (Internal) Unanticipated Problems Involving Risks to Participants or Others (UPIRPO)**

**If checked, confirm all the criteria below 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.**

1. **Unanticipated Adverse Event (UAE) for Clinical Trials with an IND**
2. **Unanticipated Incidental Finding (UIF)**
3. **Unanticipated Adverse Device Effect (UADE)**
4. **Report(s), check type below:**

***Note: These reports may be submitted via an amendment, rather than using this 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):**

1. **Other (specify):**
2. **Answer the following questions:**
   1. **Is this a follow-up report?  Yes  No**
      1. **If yes,** 
         1. **IRBNet package #(s) of previous report(s)?**
         2. **Follow summary of the event(s) (include the participant study ID#(s) or control #(s), if applicable):**
         3. **Resolution date:**
      2. **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:** 
            1. **Internal site - SUNY Downstate (list specific location):**
            2. **External site -Collaborating study site (list specific location):**
            3. **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:**
   2. **Is a change needed to the research related to this report (e.g., protocol change, informed consent change, notification to research participants)?**
      1. **Yes, the amendment is included with this report.**
      2. **Yes, the amendment is pending. IRBNet package #:**
      3. **No**
   3. **Check if the event adversely impacted any of the following:**
      1. **rights, welfare, or safety of the research participant(s). If checked, explain your response:**
      2. **willingness of any research participant to continue participation. If checked, explain your response:**
      3. **integrity of the research data. If checked, explain your response:**
      4. **new risk or safety issue**
      5. **increase in frequency or magnitude of previously know risk**
      6. **any harm experienced by a research participant or other individual**
      7. **any other aspect of the research. If checked, explain your response:**
   4. **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 **Please explain your response:**

* 1. **Is there a reasonable possibility that the event may have been caused by the procedures in the research?**

Yes  No **Please explain your response:**

* 1. **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 **Please explain your response:**

* 1. **If there were any negative impacts, provide a corrective action plan, including plans to prevent recurrence:**
  2. **Was the sponsor notified**?  Yes  No  N/A, this is not a sponsored study
  3. **Is there a DSMB (Data Safety Monitoring Board) or similar central safety review board in place for this study?**  Yes  No
  4. **If there were any negative impacts, provide a corrective action plan, including plans to prevent recurrence:**
  5. **Is the event being reported within the required timeframe?**
  6. **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:**
  7. **Provide any additional information for the IRB to consider:**