DECISION TREE: REPORTING TO NJH HRPP OFFICE FOR ALL IRBs OF RECORD

**ADVERSE EVENT**

Is the event unexpected?

- **NO**
  - At a minimum, is it possibly related to study participation?
    - **NO**
    - Does the event pose a greater risk of harm?
      - **NO**
      - Please record on the Deviation Log and submit at continuing review.
      - **YES**
      - Please complete NJH Interim Event Report form and submit to NJH HRPP Office within 7 days.
        - **YES**
        - Does the Investigator determine that new information may impact the health, right, welfare, or willingness of subjects to continue in the research?
          - **NO**
          - If Local Event: Report to Sponsor and external IRB of Record if applicable. Please record on the Adverse Event log or Sponsor log and submit at continuing review.
          - **YES**

- **YES**
  - In the preliminary opinion of the investigator does the event:
    - Create an increase in risks to subjects?
    - Adversely affects the rights, welfare, or safety of subjects?
    - Adversely affects the scientific integrity of the study?
    - Willful violation of policies and/or federal regulations?
    - Continuing non-compliance?
      - **NO**
      - Please complete NJH Interim Event Report form and submit to NJH HRPP Office within 7 days.
      - **YES**
      - Does the Investigator determine that new information may impact the health, right, welfare, or willingness of subjects to continue in the research?
        - **NO**
        - If Local Event: Report to Sponsor and external IRB of Record if applicable. Please record on the Adverse Event log or Sponsor log and submit at continuing review.
        - **YES**

**PROTOCOL DEVIATION or NON-COMPLIANCE**

In the preliminary opinion of the investigator does the event:

- Create an increase in risks to subjects?
- Adversely affects the rights, welfare, or safety of subjects?
- Adversely affects the scientific integrity of the study?
- Willful violation of policies and/or federal regulations?
- Continuing non-compliance?
  - **NO**
  - Please record on the Deviation Log and submit at continuing review.
  - **YES**
  - Please complete NJH Interim Event Report form and submit to NJH HRPP Office within 7 days.