Committee for the Protection of Human Subjects at Dartmouth College

REPORTING OF UNANTICIPATED PROBLEMS INVOLVING RISK TO SUBJECTS OR OTHERS (UPRs) INCLUDING SERIOUS ADVERSE EVENTS (AEs) TO THE CPHS

**Is the event unexpected** (in terms of nature, specificity, severity, or frequency) given a) the research procedures described in the protocol AND b) the characteristics of the subject population being studied?

- **YES**
- **NO**

**Is the event 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)*?

- **YES**
- **NO**

**Is the event serious?** Serious means any adverse event that results in any of the following: death, a life-threatening experience, inpatient hospitalization or prolongation of hospitalization, a persistent or significant disability/incapacity, a congenital anomaly/birth defect, or any other adverse event that, 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 listed in this definition.

- **YES**
- **NO**

**Does the event suggest that the research participation may place subjects or others at greater risk of harm** *(including physical, psychological, economic or social harm)*?

- **YES**
- **NO**

**Will the event result in a temporary or permanent interruption of study activities by the PI or sponsor to avoid potential harm?**

- **YES**
- **NO**

**Is the event INTERNAL?** Did the event occur at a site under the jurisdiction of the Dartmouth CPHS? Or involve a Dartmouth participant or other person

- **YES**
- **NO**

**Is the event EXTERNAL?** Event occurred at a site NOT reviewed by the Dartmouth CPHS (at another institution or it is a multicenter site for a clinical trial). Or it is new information not linked to one discrete event that increases risk or decreases benefit?

- **YES**
- **NO**

**Are either of the following are true?** *(a) Dartmouth PI has concluded that an immediate change to the protocol is necessary to address the risks raised by the event, OR (b) The sponsor, external IRB at the site where the problem or event occurred, or DSMB has required amendments to research protocol or consent documents as a result of the event*

- **YES**
- **NO**

**Report to the IRB as soon as possible in order to ensure safety of all participants.**

**Report to the IRB in summary form at the time of continuing review, or as part of a DSM review and report.**

**Report to the IRB promptly using the CPHS Reporting Form.**

**v. 12/06/2017**