YALE UNIVERSITY INSTITUTIONAL REVIEW BOARDS
REPORTING OF UNANTICIPATED PROBLEMS INVOLVING RISK TO SUBJECTS OR OTHERS (UPIRSOs) INCLUDING ADVERSE EVENTS (AEs) TO THE IRB

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

Report to the IRB in summary form at the time of continuing review

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)?

NO

YES

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

Report to the IRB immediately (if possible), but no more than 5 calendar days after the Principal Investigator becomes aware of the event using Form 710 FR 4

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

YES

NO

Report to the IRB within 5 calendar days of the Principal Investigator becoming aware of the event using Form 710 FR 4

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)?

OR

NO

Are either of the following are true? (a) Yale 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 within 15 calendar days of the Principal Investigator becoming aware of the event using Form 710 FR 4

Is the event INTERNAL? Event occurred at a site under the jurisdiction of the Yale IRB (IRB-of-Record)

Yes

Is the event EXTERNAL? Event occurred at a site NOT under the jurisdiction of the Yale IRB (at another institution or it is a multicenter site for a clinical trial)

OR

Yes

Last Revised 4/3/2014