**UNEXPECTED EVENT FORM**

**CURRENT DATE:**

**PROJECT TITLE**:

**PROJECT NUMBER:**

**PRINCIPLE INVESTIGATOR**:

Name:

Department:

Degrees:

Campus Mailing Address:

Campus Phone:

E-mail Address:

**CO-INVESTIGATORS NAMES:**

**DATE OF IRB APPROVAL**:

**NUMBER OF SUBJECTS ENROLLED IN RESEARCH:**

**HOW MANY UNEXPECTED EVENTS ARE BEING REPORTED**:

**DESCRIPTION OF EACH UNEXPECTED EVENT** (include date):

**NECESSARY CHANGES:**

A change in research protocol is necessary: \_\_\_\_\_\_ Yes \_\_\_\_\_\_\_ No;

If yes, attach description of necessary changes.

A change in the consent form is necessary: \_\_\_\_\_\_ Yes \_\_\_\_\_\_\_ No;

If yes, attach revised consent form with changes highlighted.

Participants will be notified of new safety information: \_\_\_\_\_ Yes \_\_\_\_\_\_ No;

If no, indicate why the participants need not be informed of the new information.

If yes, attach letter, or script of notification and indicate when they will be informed.