SAMPLE FORMAT FOR SERIOUS ADVERSE EVENT REPORT

DATE

MEMORANDUM FOR (Office Symbol - Institutional Review Board)

FROM: (Your Office Symbol / Investigator(s) Name, Address)

SUBJECT: Serious Adverse Event

1. **Protocol Number:** (XXX-YYYY-NNNN)

2. **Protocol Title**:

3. **Type of Adverse Event**: **Serious Adverse Event**

Serious Adverse Event: ***(****Serious Adverse Event,choose one of the types listed below, delete others)*

a) Death – report all deaths (except National Cooperative Oncology studies, report fatal toxicity's.)

b) ***Life-threatening adverse experience*** *– report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that continued involvement in the research protocol (e.g., that the use or continued use of product under investigation would result in the patient's death.) Examples: pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure (except National Cancer Institute studies: report life threatening tonicities)*

c*)* Inpatient hospitalization or prolongation of existing hospitalization – report if admission to the hospital or prolongation of a hospital stay results because of an adverse event. Examples: anaphylaxis; bleeding causing or prolonging hospitalization.)

d) **Persistent or significant disability/incapacity** – report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. Examples: CVA due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.

e) **Congenital anomaly/birth defect** – report if there are suspicions that exposure during the course of a research study (e.g., investigational drug/device) prior to conception or during pregnancy resulted in an adverse outcome in the child. Examples: malformation in the offspring cause by thalidomide.

f) Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon

appropriate medical judgment, they may **jeopardize the patient or subject** and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

4. **Signature of Principal Investigator**: *(Please note that only the PI, may sign the adverse event report)*

5. **Signature of the IRB Chairman**:

SAMPLE FORMAT FOR UNEXPECTED ADVERSE EVENT REPORT

DATE

MEMORANDUM FOR (Office Symbol - Institutional Review Board)

FROM: (Your Office Symbol / Investigator(s) Name, Address)

SUBJECT: Unexpected Adverse Event

1. **Protocol Number:** (XXX-YYYY-NNNN)

2. **Protocol Title**:

3. **Type of Adverse Event**: **Unexpected Adverse Event**

Unexpected Adverse Events - In general, an unexpected adverse event is any untoward experience not identified in the protocol and or the consent form. For investigational drugs, unexpected is defined as any adverse drug experience that is not listed in the current labeling for the drug product. These include events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. The key to classifying adverse events is they are not listed in the current product label, in the Investigator's Brochure and not included in the risk **46 AFI40-402 1 SEPTEMBER 2000** description section of the current protocol and informed consent document. (National Cancer Institute studies: report previously unknown toxicity's) *Any adverse experience associated with the study that is both serious and unexpected must be reported to the IRB immediately (within 24 hours – even if all the information is not known). Summarize the serious, unexpected adverse event below. You must answer ALL the questions below for each AE)*

a) Date of AE Type of Adverse Event *date (e.g. death, allergic reaction)*

b) Relationship of adverse event to the study: *(Choose only one.)*
Definitely Probably Possibly Unlikely Definitely Not

c) If this is a multi-center study, does the AE involve a patient enrolled at this institution? *Y / N*

d) Classify the severity of the AE: *(choose one: fatal, life-threatening, severe, moderate, mild)*

e) Describe the adverse event. *(Include information on any medications or medical devices under investigation, route of administration, dosage, and reason for use, action taken regarding product use, clinical outcome. You may attach the safety report if this is an adverse event being reported by multi-center clinical trials)*

4. **Signature of Principal Investigator**: *(Please note that only the PI, may sign the adverse event report)*

5. **Signature of the IRB Chairman**: