

Appendix 1

Examples of Critical Events

Approval Date: 22 MAY 2012

No.: DWD-POL-RA-017.01A1

Effective Date: 22 JUN 2012

Examples of Critical Events

Examples of *unanticipated problems* involving risks to participants or others may include but are not limited to:

- a. Loss of a computer that contains participants' private identifiable information
- b. Loss of study agent, resulting in a delay of administering study agent for an agent that holds out the prospect of providing a direct benefit to participant
- c. Participant experiences physical violence (e.g., domestic) as a result of participating in a clinical research study
- d. Inadvertent disclosure of family member's or partner's health status (e.g., Human Immunodeficiency Virus (HIV), tuberculosis (TB), or Hepatitis B positive), due to participation in the research
- e. Participant receives wrong study agent and does not experience any adverse effects. Note that receiving the wrong study agent is always an unanticipated problem, regardless of whether the participant experiences any adverse event.
- f. Participant is hospitalized for grade 4 pancreatitis that is unexpected and there is a reasonable possibility that the AE is related to participation in the research. Note that this incident meets the criteria of a Serious Adverse Event (SAE) and is reportable to DAIDS in an expedited timeframe.

Examples of *serious noncompliance* may include but are not limited to:

- a. Failure to obtain prospective, legally authorized informed consent
- b. Failure to conduct the research in accordance with the Institutional Review Board (IRB)/Ethics Committee (EC)-approved study
- c. Failure to obtain continuing review
- d. Failure to maintain accurate study records, submit required adverse event reports, report changes to the research, or report unanticipated problems posing risk to participants or others to the IRB/EC
- e. Screening procedures to assess participants eligibility performed before obtaining informed consent
- f. Participant enrolled in research during period of time when there was no current IRB/EC approval
- g. Participant enrolled in research for which the participant did not meet eligibility criteria, with possible serious health-related consequences to participation

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Examples of *continuing noncompliance* include, but are not limited to:

- a. Consistently late submission of continuing review materials
- b. Consistently late submission of IRB/EC required adverse event and protocol deviation reports
- c. Consistently late submission of IRB/EC required progress reports
- d. Consistently uses expired version of informed consent document