Date 21 Jan 09

From Chairperson, Institutional Review Board, NCI

Subject Reporting of Death due to Progressive Disease as a Serious Adverse Event

To Principal Investigators, NCI

As presently written, all deaths are required to be reported to the NCI IRB as serious adverse events (SAE). As many protocols at the NCI follow subjects until death, as many as 20-25% of all SAE(s) submitted to the NCI IRB are death due to progressive disease. The NCI IRB reviewed this policy at its most recent full board meeting, 12 Jan 09, and determined that rapid notification of these events does not result in added protection of the human subjects, and therefore is not necessary.

The NCI IRB will require:
- principal investigators (PIs) initiating new protocols that intend to follow subjects until death exclude death due to progressive disease in the SAE section of their protocols.

The NCI IRB recommends:
- PIs of active protocols submit an amendment that excludes death due to progressive disease as an SAE. This amendment would need to be approved before ceasing rapid submission of these events to the Board.

All deaths should continue to be reported at time of continuing review regardless of attribution.

We would recommend adding to the second and third bullets of the SAE section of the protocols, “except deaths due to progressive disease”.

For example:
- All other deaths not included in the SAE category above, except deaths due to progressive disease.
- All deaths that occur within 30 days of the last dose of study drug or treatment, except deaths due to progressive disease.
As always, please let me know if you have any questions or concerns. You can contact me directly by e-mail or phone at salzerw@mail.nih.gov or (301) 402-6268.

Sincerely,

//signed electronically//

Wanda Salzer, MD
Chair, NCI IRB