MEMORANDUM

DATE: February 6, 2017

TO: NICHD Clinical Investigators

FROM: Clinical Director, NICHD

SUBJECT: NICHD policy: Required Reporting of Deaths

The NICHD data safety and monitoring plans for all NICHD protocols state that deaths will be reported to the Clinical Director within 7 days after the PI first learns of the event. According to SOP 16, the PI is to report all deaths (that are not serious UPs) to the CD as soon as possible, but not more than 7 days after the PI first learns of the event, unless otherwise specified by the CD and documented in the protocol. Further, for not serious UPs, the PI must report all UPs that are not Serious to the CD not more than 14 days after the PI first learns of the event.

In accordance with the above requirements, the NICHD policy for reporting of deaths to the Clinical Director will be as follows:

1) Any death of a study participant in an open drug study, IND and non-IND, including data analysis studies, will be reported to the NICHD Clinical Director within 7 days after the PI first learns of the event. Reporting requirements to the IRB will follow FDA regulations, GCP guidelines and SOP 16.

2) Any death of a study participant in a natural history study occurring within two years of being seen at NIH will be reported to the NICHD Clinical Director within 7 days after the PI first learns of the event. If the PI is notified of a death outside of the two year time frame and the PI feels the death has a relationship to the study, the death will be reported to the NICHD Clinical Director within 7 days after the PI first learns of the event. Reporting requirements to the IRB will follow FDA regulations, GCP guidelines and SOP 16.

3) When reporting the above deaths to the Clinical Director, please include the IRB protocol coordinator, Donna Peterson, on the email.
4) The protocol team will notify medical records of all deaths and check the scheduling system to remove any future appointments.

Forbes Porter, MD, PhD