DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Memo to Primary Investigators:

April 17, 2007

The Division of Microbiology and Infectious Diseases (DMID) is the sponsor of many clinical studies and as such has an obligation to review the Investigator's compliance with the signed FDA agreement (Form FDA-1572) (21 CFR 312.56), DMID's Terms of Award, or DMID's Investigator of Record Form. One of these responsibilities includes the investigator reporting to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others.

The term "unanticipated problems" has recently undergone some regulatory clarification.

On January 18, 2007 OHRP posted on its website OHRP's formal "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events" (dated January 15, 2007). The guidance can be found by going to the Policy Guidance [by topics] page on the OHRP website at http://www.hhs.gov/ohrp/policy/index.html, and clicking on either "Adverse Events" or "Unanticipated Problems" from the list of guidance topics.

The FDA has recently issued draft guidance entitled "Guidance for Clinical Investigators, Sponsors, and IRBS" Adverse Event Reporting -Improving Human Subject Protection." This draft guidance is in concert with the OHRP guidance and can be accessed at www.fda.gov/OHRMS/DOCKETS/98fr/07d-0106-gdl0001.pdf - 04-06-2007 - Text Version.

DMID brings these guidances to your attention and reminds all investigators of their responsibilities.

If you have any questions please contact Wendy Fanaroff, Safety Coordinator, the Division of Microbiology and Infectious Diseases, Office of Clinical Research Affairs at 301-451-3027.