DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: December 11, 2015

TO: Harvey Fort
Office of Management and Budget (OMB)
Reports Clearance Officer, DHHS

FROM: Seleda M. Perryman
Chief, Project Clearance Branch

SUBJECT: Change Request for the Process Assessment Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events Policy Implementation (CEPI) Program, 0925-0712, Exp. Date: 03/31/2018

NIH is requesting a non-substantive change to simplify the analysis approach under 0925-0712 which was originally approved by OMB in March 2015. This is a request for OMB to approve a modification to the Process Assessment Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events Policy Implementation (CEPI) Program Assessment. Based on the very low response rate to the Critical Events Policy Implementation (CEPI) Program survey for both DAIDS staff and extramural researchers/external stakeholders, the original proposed analysis (i.e. cross sectional time series analysis) is not practical for comparing Time 1 responses to Time 2 responses. The original technique not only requires a larger number of survey respondents, but also requires the same respondents at Time 1 as at Time 2. As only 13 DAIDS staff and 48 researchers/stakeholders completed a survey at Time 1, it is not practical to model the data in a manner that examines intra-individual change over time (i.e. Time 1 to Time 2) since there will likely be subject attrition at Time 2 (the estimated attrition from Time 1 to Time 2 is at least 10 percent).

All National Institute of Allergy and Infectious Diseases (NIAID)/ Division of AIDS (DAIDS) –supported and/or –sponsored clinical research falls under the reporting requirements of applicable U.S. regulatory agencies, including HHS's Office for Human Research Protections (OHRP) and the Office of Research Integrity (ORI). DAIDS has named events that are reportable to these HHS agencies "Critical Events". Institutions are responsible to report critical events that occur under covered research to, amongst others, DAIDS. DAIDS developed a policy and a manual to provide guidance to DAIDS staff, extramural researchers, and external stakeholders on DAIDS and relevant regulatory agency requirements for reporting critical events. The policy was finalized in May 2012.

The information collected through the focus groups and survey will be analyzed to determine what improvements should be made to the CEPI Program.

The non-substantive change discussed above does not impact the original burden hours.

Copy of the current and revised Statement B document are attached.

Attachments: Contain the revised instructions and examples of the affected modified forms based on the revised instructions.

Your full consideration is appreciated.