DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: December 11, 2015

TO: Stephanie Mok
Office of Management and Budget (OMB)
Reports Clearance Officer, DHHS

FROM: Mikia Currie
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).

Under the original data collection protocols, sampling the same individuals from Time 1 and Time 2 was proposed in order to assess intra-individual change over time via longitudinal modeling. This is a method of observing change over time that accounts for unobserved variation in subjects from Time 1 to Time 2. Due to the low response rate at Time 1, we anticipate not reaching a sufficient threshold of subjects at Time 2 to be able to carry out these advanced data modeling techniques. As opposed to running longitudinal modeling, we are shifting our strategy to assessing the differences between Time 1 and Time 2 in a cross-sectional fashion. In other words, we will sample from the entire database again at Time 2 (as opposed to limiting recruitment to solely those that completed the Time 1 survey) with the goal of comparing group mean differences. This is

a slightly less robust method of assessing change in programmatic outputs over time, but still adheres to the original evaluation objectives.

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. We anticipate the burden hours for external stakeholders and extramural researchers being substantially decreased in the event that the same response rate is collected at Time 2 under the revised data collection protocols. At Time 1, the actual response rate was approximately $1/8^{th}$ the anticipated response rate. Therefore, if we obtain a similar response rate at Time 2, this decreases the burden hours on extramural researchers/external stakeholders by a factor of eight. In the event that our targeted sample size is met for this sub-population (n=400), burden hours will remain unaffected.

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.