DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: March 13, 2013

TO: Julie Wise
Office of Management and Budget (OMB)
Reports Clearance Officer, DHHS

FROM: Seleda M. Perryman
Chief, Project Clearance Branch

SUBJECT: Change Request to Adjust Two Currently Approved Forms
(OMB # 0925-0001, Expiration Date 08/31/2015)

In August, 2012 NIH received approval of all pre-award application forms under OMB Collection number 0925-0001, as well as post-award forms in Collection 0925-0002. NIH is requesting small non-substantive changes to the forms which do not change the approved data collection or anticipated burden hours, but will make it easier for the respondents to fill out/understand. Details on these changes are provided below for your information:

Adding a Clinical Trial Indicator to the PHS 398 Cover Page Supplement
NIH has included a clinical trial indicator on application forms for many years. In the most recent PRA approval cycle NIH requested including this field in the Federal-wide SF424 (R&R) Other Project Information field. While this was included in form versions proposed in the Federal Register, the request was dropped from the Federal-wide form in response to comments from the applicant community and other Federal agencies. However, this information still needs to be collected by NIH and the indicator is being added back to the PHS 398 Cover Page Supplement form where it was previously located. This should not increase the response burden or substantively change the data collection; requests for detailed information on proposed clinical trials are already included in the existing forms. The only change is adding a checkbox indicator to aid form functionality and help applicants add clinical trial details in the correct form fields.

A copy of the revised PHS 398 Cover Page Supplement Form with the specific section highlighted is attached.

Changes to Inclusion Forms

Format changes are being requested for the Targeted/Planned Enrollment Table Format Page and Inclusion Enrollment Report Format Page. These forms are used to collect pre-award and post-award data on human subject participants. This allows NIH to report cumulative data on sex/gender, race, and ethnicity of human subjects and ensure compliance with the NIH policy and statutory (P.L. 43-103) requirements on "Inclusion of Women and Minorities as Subjects in Clinical Research".

Since initial submission of the format pages to OMB for approval, NIH has simultaneously been working to improve our systems for monitoring compliance with the inclusion policy and statute and reducing the reporting burden of applicants by simplifying the reporting process. A key part of this is collecting inclusion data using electronic forms submitted through Grants.gov. To implement this change NIH must turn these format pages into electronic PHS 398 forms. NIH must also change the look-and-feel of the approved Targeted/Planned Enrollment Table Format Page and Inclusion Enrollment Report Format Page, though there will be no change to the type or amount of data collected. All changes are to data items included in the currently approved data collections and described in the PHS 398 Application Guide Part II Section 4.3 (http://grants.nih.gov/grants/funding/phs398/phs398.html).

The proposed changes to the Targeted/Planned Enrollment Table and Inclusion Enrollment Report are:

- *Renaming Tables:*
  To improve grantee understanding of what information should be provided on each form, the Targeted/Planned Enrollment Table is being renamed "Planned Enrollment Report" and the Inclusion Enrollment Report is being renamed "Cumulative Inclusion Enrollment Report".

- *Separating and Identifying Reports from Foreign and Domestic Institutions*
  Current instructions (included below) require designation of enrollment data as including either foreign or domestic participants. Addition of a drop-down box eliminates the need for the footnote and asterisk required under the current collection.

  > "When completing the Targeted/Planned Enrollment Tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data include research participants in foreign sites. If the aggregated data only includes participants in foreign research sites, the investigator should provide information in one table with an asterisk and footnote. However, if the study includes both domestic and foreign sites, the investigator should complete two separate tables – one for domestic and another for foreign participants."

- *Requesting Total Enrolled in Study to Date*
  NIH will rely on form calculations to provide as many of the "Total" number calculations and eliminate the need for grantees to provide this separate information. In the past the respondents were responsible for conducting the total calculations, which caused errors. We are removed this field from the proposed form.

- *Modified Field Identifying Study/Protocol Title*
  Current instructions require that "If there is more than one study/protocol, provide a separate table for each." In the proposed form we removed the term "protocol" from both the title and instructions since this term is not strictly defined and causes grantee confusion.

- *Added Field for Comments on Subpopulations and More than One Race designations*
  The instructions for the proposed forms NIH is allowing investigators to "… report on any racial/ethnic subpopulations by listing this information in an attachment to the required table." Additionally, when dealing with participants of more than one race "Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information."

Copies of the current and proposed for the Planned Enrollment Report and the Cumulative Inclusion Enrollment Report are attached.

Your full consideration is appreciated.