DEPARTMENT OF CONTRACTS & GRANTS

YOUR PARTNER IN RESEARCH ADMINISTRATION

NewsFlash!

Announcement: As part of The National Institutes of Health's efforts to comply with 21st Century Cures requirements to enhance accountability and transparency in NIH clinical research, NIH has developed a new Human Subjects System (HSS), which consolidates human subjects and clinical trial information in once place. Information captured in HSS is generally submitted on the PHS Human Subjects and Clinical Trials Information form in application packages submitted for due dates January 25, 2018 or later and Research Progress Performance Reports (RPPR). Post-submission updates to human subjects and clinical trial-related information (including human subjects protections, participant and enrollment information, and Clinicaltrials.gov registration and reporting information) must be made in HSS via the eRA Commons Status page after **June 9, 2018.**

HSS will replace the Inclusion Management System (IMS), used for reporting participant sex/gender, race, and ethnicity information. The Inclusion link will no longer appear on the Commons Status page as of June 9, 2018.

Key Changes

1) NIH will migrate enrollment records currently in IMS to HSS. Updates to enrollment records must be submitted to NIH no later than June 8, 2018 or entered in HSS. Updates not submitted by June 8, 2018 will not be available in HSS and must be re-entered.

2) NIH recipients completing an RPPR (Research Progress Performance Report) will be prompted to access HSS to update inclusion enrollment reports. Recipients may access the system through the Human Subjects link in the RPPR or the eRA Commons Status page.

3) Section 6: Clinical Trial Milestone Plan is intended for use in progress reports for competing applications submitted on or after January 25, 2018 and is not currently required unless otherwise noted in the Funding Opportunity Announcement or terms and conditions of award. Recipients should refer to the RPPR Instruction Guide for guidance.

4) The HSS system includes a new interface and workflow. When submitting studies to NIH, Signing Officials will submit all study records associated with an application at one time rather than separately.

5) Participant-level sex/gender, race, ethnicity and age data may be submitted in a CSV file to populate the Inclusion Enrollment Report. Participant level data will be required for applications submitted January 25, 2019 or later. See NOT-OD-116 for additional information.

6) Investigators and signing officials may make study updates or corrections (including just-in-time or off-cycle updates) by accessing HSS through the Human Subjects link in the eRA Commons Status page. Some changes, including those involving increased risk to human participants, may require prior approval by NIH.

7) Users are currently unable to delegate authority for HSS updates and/or submissions to another user. Delegation authority is expected to be available in a future enhancement of HSS.

Additional information about the Human Subjects System (HSS) is available at: https://era.nih.gov/hss_overview.cfm.

Additional information about the PHS Human Subjects and Clinical Trials Information form is available at: https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm.

Questions? If you have any questions, please contact your DCG Officer in the Department of Contracts and Grants.