DEPARTMENT OF CONTRACTS & GRANTS
YOUR PARTNER IN RESEARCH ADMINISTRATION

NewsFlash!

Announcement: The National Institutes of Health (NIH) electronic Research Administration (eRA) has announced system updates that will affect the submission process for NIH Research Performance Progress Reports (RPPRs).

New RPPR & HSS Submission Requirements:
With the launch of the new Human Subject System (HSS), investigators completing their RPPR inclusion enrollment updates will now automatically open a separate screen for enrollment data entry. This requires two separate submission steps for the enrollment data file and the full RPPR file. The NIH RPPR Instruction Guide is in the process of being updated.

In summary:

- Investigators will need to enter inclusion enrollment updates via ASSIST in the Human Subjects and Clinical Trials (HSCT) form.
- When completed, Investigators will need to update the ASSIST file status to "Ready for Submission" and notify their DCG Officer prior to the submission of their RPPR file.
- The DCG Officer will then submit the updated HSCT form.
- The DCG Officer will then submit the RPPR consistent with current procedures.

Please note: If the DCG Officer does not receive or submit the ASSIST HSCT updates prior to the RPPR submission, the RPPR file will not reflect the updates made to the inclusion enrollment data. Both the DCG Officer and the Investigator will receive a warning if the HSCT is not updated, but it will not prevent the submission. Should the RPPR be submitted before the HSCT form, please consult with the HSS online help on How to Change the Application Status and Resubmit.

New Validations:
HSS has released new validations, which include warning and error messages for the RPPR. DCG Officers will notify Investigators of additional actions that may be needed to ensure submission.

The validations for Section 6 and other fields on the Human Subjects Clinical Trials Form have been added:

Scenario	RPPR Validation
Study's inclusion Monitoring code is marked as Yes, but there is no planned	***Warning message:*** "Planned counts are required to be greater than zero for Inclusion

enrollment data and the study is not an existing dataset or delayed onset.	Enrollment Reports <IER#, IER#> under Study<Study#>, Inclusion Enrollment Reports<IER#,IER#> under Study <Study #>. Please click on the Human Subjects link in G.4 to update the Inclusion Enrollment Report(s) in Section 2 of the Human Subjects and Clinical Trials Information form.
Enrollment of first participant was more than 21 days ago, but a Clinicaltrials.gov identifier (NCT) has not been provided.	***Warning message:*** "Enrollment for <study title> has begun but no Clinicaltrials.gov Identification Number (NCT) has been provided. Please complete Clinicaltrials.gov registration and use the Human Subjects link in G.4 to add the NCT number in the Human Subjects and Clinical Trial Information Form item 1.5."
The actual Primary Completion Date is more than 12 months ago and results have not been reported to ClinicalTrials.gov.	***Warning message:*** "The study <study title> Primary Completion date is more than 12 months in the past and results have not been submitted to ClinicalTrials.gov. The responsible party should submit results to Clinicaltrials.gov."
Project level and study level clinical trial codes are discrepant	***Warning messages:*** ***When project-level CT code is No:*** "One or more study records is listed as a clinical trial; however, this grant has a clinical trial indicator of No. Please contact your NIH Program Officer." ***When project-level CT code is Yes:*** "None of the study records are listed as clinical trials; however, the grant

	has a clinical trial indicator of Yes. Please contact your NIH Program Officer."
Sec 6. Study Primary Completion Date is missing on the form	***Error Message:*** Study Primary Completion Date is missing for Study<Study Title>. Please click on the Human Subjects link in G.4 to update the Study Primary Completion Date in section 6 of the Human Subjects and Clinical Trials Information form.
Sec 6. Study Final Completion Date is missing on the form	***Error Message:*** Study Final Completion Date is missing for Study<Study Title>. Please click on the Human Subjects link in G.4 to update the Study Final Completion Date in section 6 of the Human Subjects and Clinical Trials Information form.
Sec 6. Completion of primary endpoint date analyses is missing	***Error Message:*** Completion of primary endpoint data analyses date is missing for Study<Study Title>. Please click on the Human Subjects link in G.4 to update the Completion of primary endpoint data analyses date in section 6 of the Human Subjects and Clinical Trials Information form.
Sec 6. Reporting of results in ClinicalTrials.gov is missing.	***Error Message:*** Reporting of results in ClinicalTrials.gov date is missing for Study<Study Title>. Please click on the Human Subjects link in G.4 to update the Reporting of results in ClinicalTrials.gov date in section 6 of the Human Subjects and Clinical Trials Information Form.

Sec 6. Is this an applicable clinical trial under FDAAA answer is missing.	***Error Message:*** Is this an applicable clinical trial under FDAAA answer is missing for Study<Study Title>. Please click on the Human Subjects link in G.4 to update Is this an applicable clinical trial under FDAAA in section 6 of the Human Subjects and Clinical Trials Information Form.
Completion of primary endpoint data analyses date is more than 12 months after the Primary Completion Date	***Warning Message:*** Completion of Primary endpoint data analyses date cannot be later than 12 months from Primary Completion Date for Study <Study Title>. Please click on the Human Subjects link in G.4 to update the Primary endpoint data analyses date in section 6 of the Human Subjects and Clinical Trials Information Form.
Reporting results in Clinicaltrials.gov date is more than 12 months after the Primary Completion Date	***Warning Message:*** Reporting of results in Clinicaltrials.gov date cannot be later than 12 months from primary completion date for Study<Study Title>. Please click on the Human Subjects link in G.4 to update the Reporting of results in ClinicalTrials.gov in section 6 of the Human Subjects and Clinical Trials Information Form.

New HSS features and updates can be accessed here, along with links to training, information, and online help.

Questions?

If you have any questions, please contact the DCG Officer assigned to your unit.