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Enhanced Checks for Compliance with Clinical Trial Registration and Reporting in RPPR

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Posted November 9, 2021

Enhanced checks on non-compliance with clinical trial registration and reporting came into effect in eRA’s Human Subjects System on October 1 that could delay your RPPR submission if you are late on either front (see details in **[eRA news item](https://era.nih.gov/news/era-enhancements-new-errors-non-compliance-clinical-trial-registration-and-reporting-time)**).

Remember that all NIH-funded clinical trials are expected to register and submit results information to [**Clinicaltrials.gov**](https://clinicaltrials.gov/ct2/home), as per the “[**NIH Policy on Dissemination of NIH-Funded Clinical Trial Information**](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm).”

These new checks will now result in an error for grant recipients upon submission of a Research Performance Progress Report (RPPR) when clinical trial registration (required 21 days after enrollment of first participant) and/or results reporting (required 12 months after trial actual primary completion date) is overdue.

* Currently, grant recipients receive a warning if they are not in compliance with clinical trial registration at 21 days after the enrollment of the first participant. They will also now see a new error if they are more than 30 days past this date.
* Similarly, the current warning for results reporting will change to an error; grant recipients will now receive an error when results are overdue by more than 12 months after the trial’s actual primary completion date.

The clinical trial registration error for RPPR submission or red bar to award will be resolved when:

* the recipient completes the required registration and provides the NCT# (Clinicaltrials.gov identifier) on the Human Subjects Clinical Trial Information (HSCT) form, or by
* providing the [**ClinicalTrials.gov**](http://www.clinicaltrials.gov/) registration receipt that is received upon submission of the trial registration information to [**ClinicalTrials.gov**](http://www.clinicaltrials.gov/). The receipt must be uploaded in other attachments section of the HSCT form (Section 5.1) as a PDF document. The file name must be CTgov\_Registration\_Receipt.pdf.

The results reporting error or award bar will be resolved when:

* results are submitted in Clinicaltrials.gov, or by
* the ClinicalTrials.gov submission receipt for a (1) Good Cause Extension request or (2) Certification of Delayed Submission of Results Information from ClinicalTrials.gov has been provided. The receipt must be uploaded in the other attachments section of the HSCT form (Section 5.1) as a PDF document. The file name must be CTgov\_Registration\_Receipt.pdf.

**Note:**  Please see the NIH guide notice [**NOT-OD-22-008**](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-008.html) for additional details.