



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

October 19, 2022

[Name], Authorized Official

Johns Hopkins University

Reference [Grant Number]

Dear [Authorized Official],

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: Number

PI Name: Name

Period of Performance: X-Y

NIH Institute/Center: NIDA

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), [NIH Grants Policy Statement, Section 4.1.3.1](#).

NCTXXXXXXXX

[Study Title]

Primary Completion Date: XX/XX/XXXX

Compliance with the NIH policy is a term and condition of this grant award; however, NIDA has been unable to verify that results information has been submitted to [ClinicalTrials.gov](#) for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. **Please respond to this letter no later than November 19, 2022** with the following information pertaining to the above- referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the contact information below.

Thank you for your attention to this important matter. Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Pam

---

Pamela Fleming

Email: [pfleming@nih.gov](mailto:pfleming@nih.gov) | phone (301)480-1159

3WFN, MSC 6021 | 16071 Industrial Drive | Gaithersburg, MD 20877