

Delayed Results

(Optional)

A responsible party may delay the deadline for submitting results information if one of the two certification conditions below applies to the clinical study and the certification is submitted prior to the date of (i.e., the day before) the standard submission deadline for results information. The standard submission deadline for results information is no later than 1 year after the ACT's primary completion date. Alternatively, the responsible party may request an extension of the results submission deadline for good cause if the request is submitted prior to the date (i.e., the day before) that results information would otherwise be due. The good cause extension request must be granted or denied by the NIH Director. Responsible parties may appeal denied requests or the NIH-identified earlier deadline specified in a granted extension request. [The Good Cause Extension Request Process and Criteria](#) (PDF; January 2024) explains to responsible parties the process of submitting a good cause extension request or appeal, the information to include in such requests, and the criteria NIH uses to evaluate such requests.

Delay Results Type [*]:

Select one

- **Extension:** Request, for good cause, an extension of the deadline for submitting results information

Requested Submission Date [*]

(Required when Delay Results Type is "Extension.")

Definition: Estimate of the date on which the clinical study results information will be submitted, if the Delay Results Type is "Extension".

Explanation [*]

(Required when Delay Results Type is "Extension.")

Definition: Description of the reason(s) why clinical study results information cannot be provided according to the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request. Such detail includes reason(s) for the extension and proposed requested submission date, steps that will be taken to meet the requested submission date, a description of mitigating steps to avoid future delay, and any other information needed to address the criteria in Section III of the NIH [The Good Cause Extension Request Process and Criteria](#) (PDF; January 2024) document. Note that "pending publication" and delays in data analysis without sufficient explanation are not considered good cause for an extension.

Limit: 999 characters.

Appeal Justification [*]

(Required for a responsible party to file an appeal regarding an NIH decision to deny a request to extend the deadline for submitting results information [for good cause] or grant an earlier deadline than specified in the extension request)

Definition: An explanation of the reason(s) why the initial decision to deny the GCE request or grant the GCE request with a shorter deadline than requested should be overturned or revised, with sufficient detail to allow for the evaluation of the appeal. Only provide further elaboration of the grounds for the request or highlight factors that justify an extension and why the initial decision was incorrect. Note that new bases for an extension request should not be presented for the first time in an appeal and will not be considered.

Limit: 999 characters.

Classic PRS

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 03/31/2026
[Burden Statement](#)

NOTICE

The Modernized PRS is now the primary website for Protocol Registration. After logging in, you will be directed to the new website. The Classic PRS remains available for users who need to access features that have not yet been migrated to the Modernized PRS.

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

Login

See [How to Apply](#) on ClinicalTrials.gov for information on how to apply for a PRS account.

See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.

[Send email to ClinicalTrials.gov PRS Administration.](#)

[U.S. National Library of Medicine](#) | [U.S. National Institutes of Health](#) | [U.S. Department of Health & Human Services](#) | [HHS Vulnerability Disclosure](#)

OMB No: 0925-0586
EXPIRATION DATE: 03/31/2026

Public reporting burden for this collection of information is estimated to average from 15 minutes to 45 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0586). Do not return the completed form to this address.

Edit Delayed Results Information

[Definitions](#)

* Delayed Results Type:	Extension Certifications and extension requests must be submitted prior to (i.e., the day before) the results information submission would otherwise be due according to 42 CFR 11.44.
Intervention Name(s):	Not Applicable
FDA Application Number(s):	Not Applicable
Requested Submission Date:	Month: <input type="text" value="-- Please Select --"/> Year: <input type="text"/> <small>* The estimated date on which the clinical trial results information will be submitted is required for good cause extension requests as specified in 42 CFR 11.44(e)</small>
Explanation:	<div style="border: 1px solid gray; height: 40px; width: 100%;"></div> Characters remaining: 999 <small>* Explanation is required when delay is due to extension.</small>

Appeal Delayed Results Decision

Enter Justification:

****Implementation of this feature is currently in progress for the Modernized PRS**