

# Clinical Trial Results Information Submission: Good Cause Extension Request Process and Criteria

## I. Overview

This document is intended to explain to responsible parties the process for submitting a good cause extension (GCE) request to extend the deadline for submitting clinical trial results information to ClinicalTrials.gov and describe the information necessary for the National Institutes of Health (NIH) to evaluate a GCE request and make a determination.

Section [402\(j\)](#) of the Public Health Service Act (PHS Act) and the Final Rule for Clinical Trials Registration and Results Information Submission (“the Final Rule” or “[42 CFR Part 11](#)”) establish requirements and deadlines for the submission of clinical trial results information for applicable clinical trials (ACTs). In general, the standard submission deadline for clinical trial results information for ACTs is no later than one year after the study’s Primary Completion Date. Section [402\(j\)\(3\)\(E\)\(vi\)](#) of the PHS Act authorizes NIH to “provide an extension of the deadline for submission of clinical trial [results] information . . . if the responsible party for the trial submits to the [NIH] a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted.” In [42 CFR 11.44\(e\)](#), the Final Rule implements this provision and clarifies the deadlines and requirements for requesting an extension for good cause. If a responsible party submits a GCE request by the applicable deadline, and if the extension request is granted, the responsible party has until the extended date to submit clinical trial results information.

In addition to Section [402\(j\)](#) of the PHS Act and the [Final Rule](#), the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information ([NOT-OD-16-149](#)) establishes the expectation that all investigators conducting clinical trials funded in whole or in part by NIH will ensure that those trials are registered with ClinicalTrials.gov and that clinical trial results information for the trials is submitted to ClinicalTrials.gov consistent with the timeframes described in Section 402(j) of the PHS Act and the Final Rule. NIH-funded recipients or their designated principal investigators may also submit GCE requests for NIH-funded clinical trials. (For additional information specific to NIH-funded clinical trials, see section V.)

Section II of this document describes the process for submitting a GCE request, and section III describes general criteria for evaluating the GCE request. Section IV describes a list of reasons generally considered “good cause” and “not good cause” for granting extension requests. Section V describes special considerations related to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information ([NOT-OD-16-149](#)).

## II. Good Cause Extension Request Process

### (A) Submission and Deadlines

GCE requests must be submitted<sup>1</sup> through the ClinicalTrials.gov Protocol Registration and Results System (PRS) at any time *prior* to the date of (i.e., the day before) the submission deadline on which clinical trial results information would otherwise be due (i.e., the standard results submission deadline or an extended deadline if an extension request was granted or a certification for delay was submitted).<sup>2</sup> NIH *will not* accept GCE requests submitted on or after the submission deadline on which clinical trial results information would otherwise be due. Each GCE request must include the following: (1) a complete description of the reason(s) why clinical trial results information cannot be provided by the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request, and (2) an estimated date on which the clinical trial results information will be submitted. Sufficient detail should be provided, including the steps that will be taken to meet the estimated submission date, a description of mitigating steps to avoid further delay, and any other information needed to address the criteria in section III of this document.

Consistent with Section 402(j)(3)(E)(vi) of the PHS Act, more than one GCE request may be submitted for the same ACT after a previous GCE request was granted.<sup>3</sup> The deadline for submitting subsequent GCE requests is the same as for the initial GCE request. In particular, the request must be made any time *prior* to the date of (i.e., the day before) the submission deadline on which clinical trial results information would otherwise be due. NIH *will not* accept requests submitted on or after the submission deadline on which clinical trial results information would otherwise be due.

### (B) GCE Request Review and Decision Notification

The GCE request will be reviewed in accordance with the criteria in section III of this document. NIH will provide an electronic response via the PRS (“PRS notification”) to the responsible party indicating whether the requested extension demonstrates good cause and has been granted. If the extension request is granted, the responsible party has until the extended date to submit clinical trial results information. If NIH determines that the requested submission date is not commensurate with the explanation provided in the request, NIH may grant the request but identify a submission deadline that is earlier than the requested submission date. In this case, the responsible party must either (1) submit clinical trial results information by the submission deadline identified in the PRS notification, or (2) appeal the NIH-identified earlier deadline as described in section II.(C).

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<sup>1</sup> For information on how to submit a GCE request, see the To Request Certification or an Extension subsection of table 4 in [section 8.1.2](#) of the PRS User’s Guide.

<sup>2</sup> 42 CFR 11.44(e)(1)(i) states that “[t]he responsible party must submit a request for an extension to ClinicalTrials.gov prior to the date on which clinical trial results information would otherwise be due in accordance with paragraph (a), (b), (c), (d), (e), or (f) of this section,” and the Preamble reiterates this requirement. 81 Fed. Reg. 65076, 65078.

<sup>3</sup> For more information, see [What is the process to submit a subsequent good cause extension request for delayed submission of results information for an applicable clinical trial \(ACT\) that was previously granted an extension of the deadline?](#)

If NIH determines that the GCE request does not constitute “good cause,” the request will be denied. If the request is denied, the responsible party must either (1) submit clinical trial results information by the later of the date on which clinical trial results information would otherwise be due or 30 calendar days after the date that the PRS notification was issued by NIH, or (2) submit an appeal as described in section II.(C).

### (C) Appeals

Responsible parties may appeal a denied GCE request or NIH-identified earlier deadline specified in a granted extension request. The appeal must explain why the initial decision to deny the GCE request or to grant the GCE request with an earlier deadline than requested should be overturned or revised, with sufficient detail to allow for the evaluation of the appeal. Responsible parties should provide further elaboration of the grounds for the request or highlight factors that justify an extension. The appeal should only address why NIH’s initial decision was incorrect; new bases for an extension request should not be presented for the first time in an appeal and will not be considered. Only one appeal may be submitted for a denied GCE request.

The appeal must be submitted no later than 30 calendar days after the date that the PRS notification was issued by NIH. Appeals should be submitted via PRS. NIH will provide an electronic notification to the responsible party communicating whether the appeal is granted or denied.

If NIH grants the appeal, the responsible party has until the extended date specified in the electronic notification to submit clinical trial results information. If NIH denies the appeal of a denied GCE request, the responsible party must submit clinical trial results information by the later of the date on which clinical trial results information would otherwise be due, or 30 calendar days after the electronic notification denying the appeal was sent by NIH.

As described in section II(B), NIH may grant a GCE request but identify a submission deadline that is earlier than the requested submission date. In other words, the GCE request was granted but the deadline was denied. In such cases, the responsible party may appeal the denied deadline specified in the granted GCE request. If NIH denies the appeal of a denied deadline specified in a granted GCE request, the responsible party must submit clinical trial results information by the later of the date specified in the PRS notification granting the GCE request, or 30 calendar days after the electronic notification denying the appeal was sent by NIH.

### III. Good Cause Extension Request Criteria

A GCE request must include the following: (1) a complete description of the reason(s) why clinical trial results information cannot be provided by the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request in accordance with the general criteria list below, and (2) an estimated date on which the clinical trial results information will be submitted. Extension requests will be evaluated on a case-by-case basis using the following general criteria to support a determination of "good cause." These include, but are not limited to:

(A) General Criteria

- (1) The circumstances and their impact leading to the GCE request, including steps the responsible party is taking to mitigate the impact of those circumstances
- (2) The extent to which the factors underlying the GCE request are outside the responsible party's control
- (3) The steps that will be taken during the requested extension, why they are necessary to mitigate the circumstances leading to the GCE request, and whether the requested submission date is commensurate with the explanation provided in the request
- (4) Whether information is internally consistent with relevant data element definitions and is consistent with information provided in other sections of the study record
- (5) The number of, and explanations for, any previous GCE requests and the proposed submission deadline in previous requests

**Requests must provide sufficient information for evaluation using the criteria listed above. Requests that do not provide sufficient information may be denied.**

(B) General Formatting Criteria and Other Considerations

- (1) The GCE request must be in English.
- (2) Acronyms and abbreviations should be spelled out, with the acronym or abbreviation provided in parentheses immediately after, at least the first time they are used in the GCE request.
- (3) The responsible party should not include specific personal health information in the GCE request.

#### IV. Generalized List of Situations That May Be Considered "Good Cause" and "Not Good Cause" for Granting an Extension Request

The situations presented in this section are reasons that would generally be considered to constitute "good cause" and "not good cause" provided that the responsible party shows there was a direct impact on the ability to submit timely clinical trial results information and that other general criteria are met. There are likely to be only a few situations that would constitute "good cause." Even where circumstances exist that are similar to the situations described below, all GCE requests will be evaluated on a case-by-case basis.

(A) Situations That May Be Considered "Good Cause" for Granting an Extension Request

- Need to preserve the integrity of the science of a study for which data collection is ongoing, including situations in which the submission of results information for the primary outcome(s) of an ACT would impair or otherwise bias the ongoing collection, analysis, and/or interpretation of data for secondary outcome(s). For example, the protocol or statistical analysis plan prespecified that study data will be blinded for more than one year after the study's Primary Completion Date, and reporting would introduce bias to the ongoing collection, analysis, and/or interpretation of data for

the secondary outcome(s) or adverse events. Such prespecified blinding must have a scientifically valid basis.

- Emergencies that prevent the timely submission of clinical trial results information, including situations in which one or more data collection sites are affected by natural disasters or catastrophic events outside the responsible party's or sponsor's control. The responsible party's ability to submit clinical trial results information in a timely manner must be directly affected by the emergency, such as through personnel changes or by changes or damage to a facility, study property, or data due to the emergency.
- Termination of the study close to the standard results submission deadline. This could occur if the date that the decision was made to terminate the study is much later than the date that the final subject in the terminated study was examined or received an intervention for a primary outcome measure (i.e., the actual Primary Completion Date). If the termination date is close to, but not beyond, the standard submission deadline for clinical trial results information under [42 CFR 11.44\(a\)](#), there may not be sufficient time to complete data analysis for enrolled subjects and submit clinical trial results information via the PRS.
- Reporting delays due to unexpected personal emergency circumstances, including emergency situations faced by the responsible party or key personnel, such as death or extended personal illness.

(B) Situations That Would Be Considered “Not Good Cause” for Granting an Extension Request

- Certification of delay should have been submitted rather than a GCE request. A GCE request should not be submitted under circumstances where a certification of delay under [42 CFR 11.44\(b\)](#) or [\(c\)](#) would be available.
- Awaiting journal publication. A study must report clinical trial results information even if the data have not yet been published.<sup>4</sup>
- Pending U.S. Food and Drug Administration (FDA) or other regulatory or health agency review. A study must report clinical trial results information even if the data are under FDA or other regulatory or health agency review, consistent with any certification of delay submission, as applicable.
- Ongoing data analysis without sufficient explanation. All studies are expected to be able to complete data analysis within one year of the Primary Completion Date unless there are unexpected circumstances that prevent the timely completion of the analysis. Analysis that is not yet complete, without further explanation, is not adequate justification for “good cause.”

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<sup>4</sup> NOTE: The International Committee of Medical Journal Editors (ICMJE) has [stated](#) that results information submission to ClinicalTrials.gov in compliance with Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) will not be considered “prior publication” and will not preclude future publication.

- Events that might reasonably have been avoided or anticipated through standard contingency planning (e.g., transition planning for key staff who leave an organization or a change of vendor) will generally not be considered to constitute “good cause.”
- Extending the study recruitment period. Needing more time than anticipated to recruit trial participants does not constitute “good cause.” If recruitment takes longer than planned and impacts the Primary Completion Date, the responsible party should update the Primary Completion Date accordingly in the study record in the PRS. The standard submission deadline for clinical trial results information for ACTs will adjust to no later than one year after the study’s updated Primary Completion Date.

### (C) Hypothetical Examples of Extension Requests

The following hypothetical examples, with fictional data, are provided to illustrate the type of information and level of detail needed in good cause extension requests to allow NIH to evaluate whether the requests demonstrate good cause. Please note that these examples may or may not constitute good cause and are only provided for illustrative purposes.

#### *Emergencies or Other National Public Health Emergency*

The responsible party for an ACT with a standard results submission deadline of December 1, 2020, had work redirected during a national public health emergency, so the data analysis for the ACT was delayed. Beginning in March 2020, the principal investigator for the ACT, an infectious disease physician, had work priorities shifted heavily from research to clinical care during the COVID-19 pandemic. In addition, access to the study site was strictly limited after March 2020, delaying completion of the data analysis. Therefore, the responsible party submitted a GCE request on November 1, 2020, describing the situation necessitating an extension and the steps to be performed during the extension and requesting a 6-month extension until June 1, 2021, to submit summary results information for the ACT.

#### *Natural Disaster or Other Catastrophe*

The responsible party for an ACT with a standard results submission deadline of September 1, 2022, lost all results data and ongoing analyses for the ACT when a major hurricane hit its facilities on August 26, 2022. Furthermore, access to the necessary technology to recreate the analyses was significantly affected. However, the data were backed up on servers in another location, and the responsible party anticipated being able to replace the needed technology by late September 2022 and recreate the analyses from the backed-up data by late November 2022. Therefore, the responsible party submitted a GCE request on August 31, 2022, describing the situation necessitating an extension and the steps to be performed during the extension and requesting a 3-month extension until December 1, 2022, to submit summary results information for the ACT.

#### *Need to Preserve Integrity of the Science of a Study with Blinding or Masking*

All study personnel will remain blinded to individual treatment assignment from the time of randomization until the final database lock on August 1, 2023. Therefore, it will not be possible

to submit unblinded summary results information until October 1, 2023, and the responsible party submitted a GCE request.

#### *Study Termination Near the Standard Results Submission Deadline*

The study was terminated on December 31, 2023, by the data monitoring committee due to low enrollment over the past year. The Primary Completion Date was backdated to February 25, 2023 (Actual). Due to this unanticipated change to the Primary Completion Date, summary results information was now due 2 months after the study termination date. The responsible party needed 6 months to prepare summary results information. Accordingly, they submitted a GCE request for a 6-month extension, until August 25, 2024, to allow time to clean and analyze the data and submit information to ClinicalTrials.gov.

#### *Personal Illness*

The unexpected illness of the study statistician between April and July 2023 delayed progress on data analysis for 3 months, and it was not possible to replace the statistician in that time. Results were due on September 15, 2023. The responsible party submitted a GCE request explaining why the statistician is uniquely qualified and requesting a 3-month extension, until December 15, 2023, to allow time to finish the data analyses.

NOTE: The responsible party should not include personal medical information in the extension request justification. An explanation of the impact of the staff member's illness on the study, steps to be taken during the requested extension, and the estimated date on which clinical trial results information will be submitted are what is needed.

#### V. Special Considerations for NIH Funding Recipients

For NIH-funded and NIH-supported clinical trials, recipients should be aware that any GCE request could impact other aspects of the contract or grant award. Therefore, the submission of a GCE request does not constitute a prior approval request (e.g., no-cost extension, carryover) or a request for contract modification (e.g., contract extension, change to deliverable due date).