Attachment 6 - Certification to Delay Submission of Results Information (DRAFT)

A. From ClinicalTrials.gov Results Data Element Definitions for Interventional and Observational Studies (DRAFT), January 18, 2017:

▼8. 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. Alternatively, the responsible party may request an extension of the results submission deadline for good cause. The extension must be granted by the NIH Director.

Delay Results Type [*] : Select one

- Certify Initial Approval: Trial studies an FDA-regulated drug product (including a biological product) or device product that was not approved, licensed or cleared by FDA for any use before the Primary Completion Date of the trial, and the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval, licensure, or clearance of the drug product (including a biological product) or device product under study.
- Certify New Use: Trial studies an FDA-regulated drug product (including a biological product) or device product that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the trial and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug, product (including a biologic product) or device product) has been filed or will be filed within one year with FDA.
- Extension: Request, for good cause, an extension of the deadline for submitting results information

Note: If a responsible party who is both the manufacturer of the drug product (including a biological product) or device product studied in an applicable clinical trial and the sponsor of the applicable clinical trial submits a certification under "Certify New Use," that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria: (1) the applicable clinical trial is required to be submitted in an application or premarket notification seeking approval, licensure, or clearance of a new use; (2) the applicable clinical trial studies the same drug product (including a biological product) or device product for the same use as studied in the applicable clinical trial for which the initial certification was submitted. [42 U.S.C. 282 (j)(3)(E)(v)(II) and 42 CFR 11.44(b)(3)]

Intervention Name(s)
Definition: Provide the name of one or more drugs, biological products or devices to which the certification applies. For drugs use generic name; for other types of interventions provide a brief

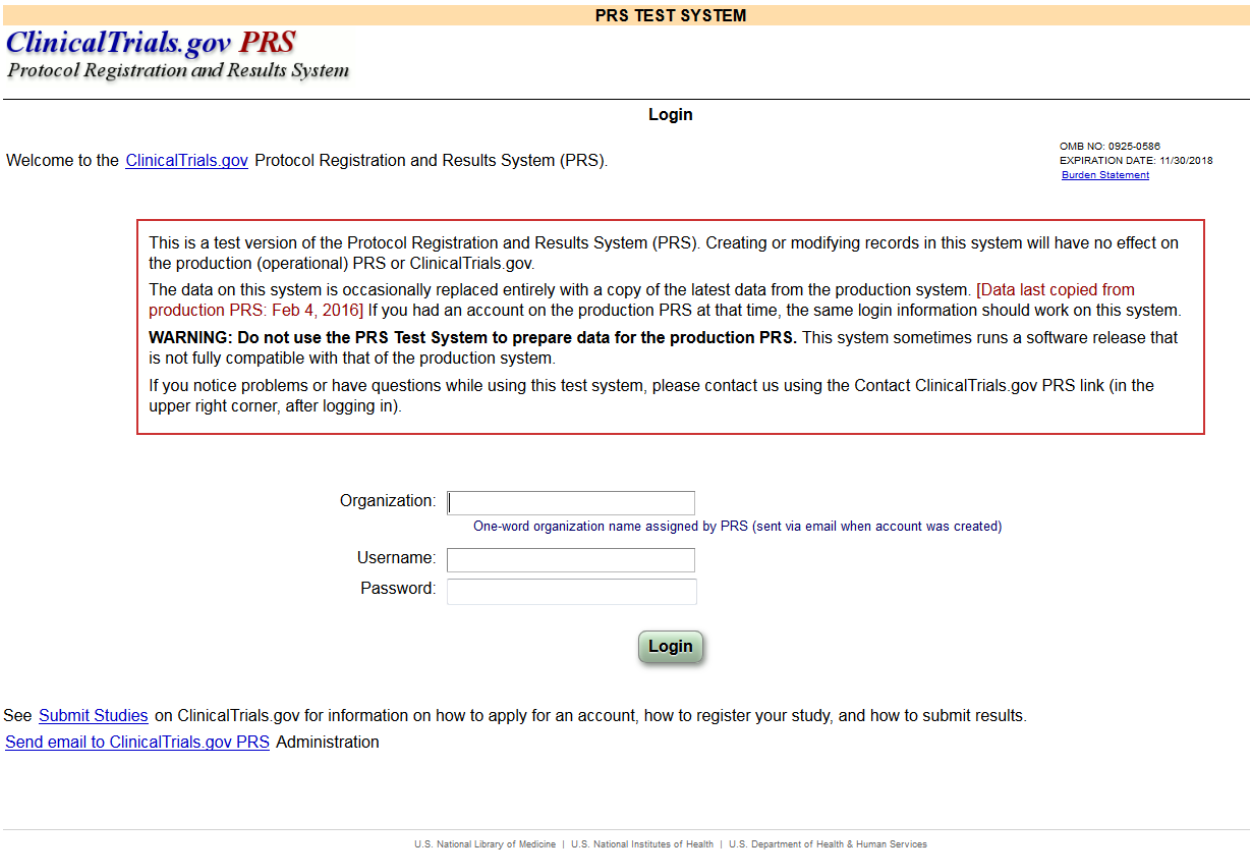
descriptive name. The name(s) entered should match Intervention Name(s) provided in the protocol section.

FDA Application Number(s)
Definition: Provide at least one FDA application number (for example, NDA, BLA, or PMA number), if available, when Delay Results Type is "Certify Initial Approval" or "Certify New Use."

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. Note that "pending publication" and delays in data analysis for unspecified causes are not considered good cause for an extension.
Limit: 999 characters.

B. From the PRS Test System:



PRS TEST SYSTEM

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 11/30/2018
Burden Statement

This is a test version of the Protocol Registration and Results System (PRS). Creating or modifying records in this system will have no effect on the production (operational) PRS or ClinicalTrials.gov.

The data on this system is occasionally replaced entirely with a copy of the latest data from the production system. [Data last copied from production PRS: Feb 4, 2016] If you had an account on the production PRS at that time, the same login information should work on this system.

WARNING: Do not use the PRS Test System to prepare data for the production PRS. This system sometimes runs a software release that is not fully compatible with that of the production system.

If you notice problems or have questions while using this test system, please contact us using the Contact ClinicalTrials.gov PRS link (in the upper right corner, after logging in).

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

See Submit Studies on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
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

OMB NO: 0925-0586
EXPIRATION DATE: 11/30/2018
Burden Statement

Public reporting burden for this collection of information is estimated to average 7.0 hours per response for initial registration, 2.0 hours for each of 8 updates to the registration information during the course of the trial, 25.0 hours per response for initial results submission, 8.0 hours for two substantive updates to the results information. These estimates include the time for reviewing instructions, searching existing data sources, gathering 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 currently 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

Content entered in this form may be displayed on ClinicalTrials.gov.

* Delay Results Type:	Certify Initial Approval
Intervention Name(s):	* A descriptive intervention name is required when delay is due to certification for initial approval or new use. The name(s) entered should match Intervention Name(s) in the protocol section.
FDA Application Number(s):	Add Application Number Provide an FDA application number (e.g., NDA, BLA, or PMA number), if available, when delay is due to certification for initial approval or new use.
Requested Submission Date:	Not Applicable
Explanation:	Not Applicable

OK Cancel Delete

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