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| ***A close up of a sign  Description automatically generated*** | NIH Protocol Summary For Delayed Onset Studies |

# **NIH Protocol Summary Template**

The UCLA Clinical and Translational Science Institute (CTSI) Grants Submission Unit has created this protocol summary template as a tool to facilitate the development of required components for NIH applications involving Delayed Onset Studies. Each section contains requirements from the NIH and these guidelines should be removed before finalizing. Please be aware of components for which [Text Field rules apply](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/rules-for-text-fields.htm) and their character limitations. It is not meant to replace your review of all applicable notices, guidelines, and updates from the NIH related to the specific funding opportunity being responded to. Investigators and research administration staff should continue to refer to NIH’s official policies and guidelines available here: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general-forms-h.pdf>.

This template refers only to those sections of FORMS-H related to human subjects and clinical trials for applications on or after January 25th, 2023; it does not cover the entirety of the SF424 or other portions of the grant application process. Investigators should always remember to refer to the specific Funding Opportunity Announcement (FOA) for any submission-specific information, including whether clinical trials are allowed and other FOA-specific requirements that may not be reflected on this form.

Questions? Contact the UCLA CTSI Grants Submission Unit at [gsu@mednet.ucla.edu](mailto:gsu@mednet.ucla.edu) or (310) 267-4258.

# **Delayed Onset Study Record.**

Add a Delayed Onset Study Record. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. Provide the study name and a justification for omission of human subjects study information.

**Delayed Onset Study(ies)**

Multiple delayed onset studies can be grouped in a single record.

**Study Title** **(600 character limit):**

If your application includes multiple delayed onset studies, study title should be, “Multiple Delayed Onset Studies”.

**Anticipated Clinical Trial?**

Check the box if you anticipate that this study will be a clinical trial. If you are including multiple delayed onset studies in one delayed onset study entry, and you anticipate that any of these studies will be a clinical trial, check the “Anticipated Clinical Trial?” checkbox.

**Justification** (Additional guidelines available [here](https://ctsi-sandbox.healthsciences.ucla.edu/sites/g/files/oketem271/files/media/documents/Delayed_Onset_Justification_Guidelines.docx).)

1. Explain why human subjects study information is not available at the time of application.
2. Acknowledge that all PHS requirements will be met before the start of any study.
3. Acknowledge GCP requirements and verify all personnel participating in the research will meet requirements before start of any study.
4. If sIRB policy will apply to your study (i.e. domestic multi-site studies), include information regarding how the study will comply with the single IRB requirement prior to initiating any multi-site studies. NOTE: sIRB info is no longer required, except for AHRQ applications. Guidelines [here](https://ctsi-sandbox.healthsciences.ucla.edu/sites/g/files/oketem271/files/media/documents/3.2_Single_IRB_Plan_sIRB_Guidelines.docx).
5. If study will meet the definition of a clinical trial, include the dissemination plan [here](https://ctsi-sandbox.healthsciences.ucla.edu/sites/g/files/oketem271/files/media/documents/4.7_Dissemination_Plan_Guidelines.docx).

**For delayed onset studies, do not complete the PHS Human Subjects and Clinical Trials Information Form.**