

Tip Sheet: Delayed Onset Determinations

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Overview

Some NIH funding proposals fund development work that is necessary in order to finalize the phase(s) of the research that involve human participants. The NIH Grants and Funding Glossary defines “delayed onset” as follows:

“Research is anticipated within the period of award but definite plans are not yet known and cannot be described in the application.”

(<https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy>)

Examples of research with a delayed onset design include:

(1) A researcher may need to travel to an international locale and meet with local experts in order to refine the most appropriate way to interact with participants or collect the research data.

(2) A researcher may need to hire research staff to modify an existing behavioral intervention to be used with a new participant population, that is the target of the new funding proposal.

NOTE: Delayed onset is different than “delayed start”, which is defined as “Research plans can be described at time of application, but research will not immediately begin (will occur later in the funding period).” <https://grants.nih.gov/grants/glossary.htm#DelayedStart>

For Delayed Onset Study proposals, when the funding agency requires IRB “approval” before methods/instruments are developed, researchers should **contact the UCLA OHRPP** to obtain an administrative review of the funding proposal, to determine whether a Delayed Onset Determination may be issued prior to submission for UCLA IRB review or Certification of Exemption from UCLA IRB review.

This Tip Sheet explains how to obtain that determination.

How to Request OHRPP Delayed Onset Determination

STEP 1 The Principal Investigator (“PI”) of a funding application for a Delayed Onset Study that does not include defined plans to involve human subjects should request a Delayed Onset Determination via email to the OHRPP (girb@research.ucla.edu). The email inquiry should include:

- a. Copy of the entire funding proposal, including the research aims, methodology, and a description of any proposed collaboration with other institutions or individuals; and
- b. Explanation of what procedures or details are yet to be developed, and the timeline for that development work.

STEP 2 OHRPP staff will perform an administrative review of your funding proposal to confirm that there are no human subjects research activities that the UCLA IRB can review or Certify Exempt from IRB review. OHRPP staff may contact the researcher to obtain clarification and/or additional details necessary to issue a Delayed Onset Determination.

STEP 3 OHRPP staff will issue one of the following:

1. If eligible, a Delayed Onset Determination that provides: (a) written confirmation of administrative review of the funding proposal and (b) written assurance that the research with human participants will not commence until that IRB review and approval has occurred.
2. If the funding proposal does not qualify for a Delayed Onset Determination, OHRPP staff will notify the PI in writing and request that the PI submit a webIRB application for UCLA IRB review or Certification of Exemption from UCLA IRB review.

Additionally, OHRPP will assess eligibility for Single IRB (sIRB) review when applicable.

Investigator Responsibilities

The PI of a funding proposal for a Delayed Onset Study is responsible for the following:

- Providing the UCLA OHRPP a copy of the final version of the funding proposal.
- Providing to their UCLA OCGA officer a copy of the OHRPP Delayed Onset Determination letter, if issued. <https://ocga.research.ucla.edu/contact-us/>
- Submitting a webIRB application for review and approval as soon as plans to involve human subjects are finalized. **If using an external IRB** to review for UCLA, the PI is responsible for (a) submitting an application for review to the external IRB and (b) also registering the external IRB review as a “reliance registration” in webIRB.

For research that includes multiple phases/components -- e.g., focus groups for intervention development, procedures to pilot test the intervention, and finally trial of the intervention – the PI should **contact OHRPP staff** for guidance on whether phases/components should be submitted as amendments or new applications.

OHRPP Responsibilities

Authorized OHRPP staff will:

- Review the funding proposal to confirm that the proposal does not include definite plans that may be submitted for UCLA IRB review or Certification of Exemption from UCLA IRB review.
- Confirm that the investigator has provided adequate information regarding what procedures or details are yet to be developed, and the timeline for that development work.
- Review the funding proposal to identify additional collaborating institutions or investigators who may be “engaged” in the research, assessment of applicability of sIRB requirements, and preliminary determination of sIRB review responsibility when applicable.

Authorized OHRPP staff will provide written notification to the proposal PI:

1. A Delayed Onset Determination if applicable;
2. A request for a webIRB application if a Delayed Onset Determination is not applicable; and
3. An assessment of the applicability of sIRB requirements and responsibility when applicable.

Resources and References

National Institutes of Health (NIH)

General Application Guide for NIH and other PHS Agencies

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#Delayed>

Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research – Expectations for Applications/Proposals

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-004.html>

Single IRB Policy for Multi-Site Research

<https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm>

Department of Health and Human Services (HHS)

Engagement of Institutions in Human Subjects Research

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

UCLA OHRPP

[Guidance and Procedure: Funding Applications and UCLA IRB Review](#)

Webpage: IRB Reliance <https://ohrpp.research.ucla.edu/irb-reliance/>