

<b>118 DETERMINATION MEMO</b>	<b>SOP 6.10.01</b>
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## 1. Purpose & Policy

The purpose of this SOP is to provide guidance to researchers wishing to obtain a memo to provide to federal sponsors at Just in Time (JIT) notifying the sponsor that human subjects research on a sponsored project is not yet ready for IRB review, and that no work with study participants, including recruitment, will be conducted until full IRB approval is obtained. [IRB Policy Section 6.10](#).

## 2. General Information

- A. [45 CFR § 46.118](#) allows for certain human subjects studies that are not yet defined or that will be delayed to later years of an award to postpone IRB review. Proposals/awards describing such human subjects' work need not be reviewed by the Caltech IRB before the award may be made by the sponsor. However, except for research exempted or waived under [§46.104 \(b\)](#) or [§46.101 \(i\)](#), no study participants may be involved (including, but not limited to, recruitment, preliminary activity, or surveys) in any project supported by these awards until the project has been reviewed and approved by the Caltech IRB, and certification has been submitted, by Caltech, to the sponsor.
- B. NSF can accept a determination notice that establishes that the PI may conduct preliminary or conceptual work that does not involve study participants.

## 3. PI Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with 118 memos; however, investigators should carefully read and follow this guidance.

## 4. Procedure

- A. If you have a JIT request or other request from a research sponsor for human subjects research and you do not yet have an IRB protocol prepared and the human subjects work need not start at the inception of the award, you may request a memo, pursuant to 45 CFR 46.118, which you can send to your sponsor.

- B. Initiate an Initial Query in the IRB Protocol Application System (PAS). In the *Query* section, answer Yes to the question “Has a funding agency requested a memo or notification of “Delayed Onset of Research” or a “118 Determination Memo”?”

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Information for Initial Query

\* All query questions are required to answer.

1) Sponsor Request for Early Determination:

Yes   
  No   
 Has a funding agency requested a memo or notification of “Delayed Onset of Research” or a “118 Determination Memo”?

- C. In the *Funding* section, select the *Funding Category* (Caltech PTA Award, Non PTA Award, or Pending Funding). If there is an award, enter the Award portion of the PTA into the dropdown list. Once an award is selected, the details of the award will automatically populate. If funding is still pending, provide the agency name and proposal reference number. Attach a copy of the proposal to this section of the application.

Funding Information

\* Caltech Role in this Funding:  Primary Awardee   
 Sub-Awardee (receive funds from prime awardee partner org - enter info below)

\* Funding Category:  Caltech PTA Award   
 Non PTA Award   
 Pending Funding

\* Non-PTA Award Number:   
(must be unique within this protocol. If funding is pending, please enter placeholder number):

\* Funding Agency:

Start Date:

End Date:

\* Funding Agency Type:  DOD   
 PHS/NIH   
 NSF   
 NASA   
 Non-Federal

\* Are any Partner Orgs being paid from this Caltech Award?  Yes (Fill in Procurement Contact and Partner Org)   
 No

- D. Complete all other sections of the Initial Query and submit for review.
- E. The IRB may issue a memo that you can provide to a sponsor certifying that (1) the proposed human subjects research is currently not yet ready for review by the IRB, (2) that it will be reviewed and approved at a later date, and (3) such review and approval will be completed before any work with study participants may begin or be charged to sponsor’s award.
- F. The IRB Administrator can generate and sign 118 Memos on behalf of the IRB.
- G. The 118 Memo will be valid for 1 year at which time you will need to apply to extend the 118 Memo or submit your application to the IRB for review and approval of your human subjects research.