118 Determination Memo

1. Purpose

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.

2. General Information

A. The policy governing the use of Institutional Data is found in the IRB Policy, “Request for JIT Memo to Sponsor for Human Subjects Work to Occur Later.”

B. 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 §46.101 (b) or (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.

C. 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

There are no specific training requirements associated with obtaining a 118 Determination Memo.

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 system. In the Query section, answer Yes to the question “Has a funding agency requested 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.

### Funding Information

- **Funding Category**: 
  - Caltech PTA Award
  - Non PTA Award
  - Pending Funding
- **Non-PTA Award Number**: Enter if pending
- **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. Upon receipt of your request, the Caltech 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 Caltech IRB Administrator can generate and sign 118 Memos on behalf of the Caltech 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.
REQUEST FOR JIT MEMO TO SPONSOR FOR HUMAN SUBJECTS WORK TO OCCUR LATER

45 CFR § 46.118 allows for certain participant studies that are not yet defined or that will be delayed to later years of an award to delay IRB review. Proposals/awards describing such participants’ activity 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 §46.101 (b) or (i), no participants may be involved 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.

Upon request of the PI, through a Caltech IRB Query, the Caltech IRB may issue a memo, pursuant to 45 CFR 46.118, (118 Determination Memo) that can be provided to a sponsor certifying that (1) the proposed participant 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 participant study may begin or be charged to sponsor’s award. The Caltech IRB Administrator can generate and sign 118 Memos on behalf of the Caltech IRB. Please see Caltech IRB SOP 9: 118 Determination Memo for the detailed process.