**Red text is instructional. Delete all red text prior to submitting this form.**

**118 Determinations are granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Funds may not be used to conduct research with human subjects until an IRB application has been reviewed and approved.**

|  |  |  |
| --- | --- | --- |
| **Basic Information** | | |
| **Title of Study:** |  |
| **Short Title:** |  |
| **Principal Investigator Name:** |  |
| **Principal Investigator’s Department/Unit:** |  |

# Funding Information

**Indicate the funding source for the project. Please list the name of the funder, and the institutional proposal number or award number, if available, that you received from Sponsored Projects. eIRB tip: For externally funded projects, the institutional proposal or award number provided must be linked in the “Study Funding Sources” section in eIRB.**

|  |  |
| --- | --- |
| **Federal Funding**, including flow-through federal funding (i.e., NIH, NSF, DoD, etc.) | Name of funding source: |
| Institutional Proposal or Award Number: |
| Funding Agency Number: |

# 118 Request Information

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| --- |
| **§46.118 Applications and proposals lacking definite plans for involvement of human subjects:** Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution’s responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under §46.101(i) or exempted under §46.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research. |

**Explain why human subjects study information is not available at the time of this application.**

**Items needed for approval, as applicable:**

* Copy of the award/grant application
* Award/grant application number