Section 118 Designation

SOP 123
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Purpose

This document describes the standard operating procedures for determining certain types of applications for grants, cooperative agreements, or contracts qualify for a 45 C.F.R. § 46.118 designation.

Background

Certain types of applications for grants, cooperative agreements, or contracts may be submitted to federal departments or agencies with the knowledge that human subjects may be involved within the period of support, but definite plans would not normally be described in the applications. Under the federal regulations, e.g., 45 C.F.R. § 46.118, those applications need not to be reviewed by an institutional review board (IRB).[1] In these cases, the principal investigator (PI) should submit a request to the Human Studies Program (HSP) to designate the applications as under 45 C.F.R. § 46.118. Such designation is called Section 118 designation, for short. The designation applies to applications to federal departments or agencies that have adopted the Common Rule, such as the Department of Health and Human Services and Department of Defense.

Polices

Applications for Grants, Cooperative Agreements, or Contracts That May Be Designated Under 45 C.F.R. § 46.118

The HSP may approve a request for Section 118 designation if the following criteria are met:

- Human subjects may be involved within the period of support;
- Definite plans for human subjects research are not described in the grant proposal;
- An application is being submitted to a federal department or agency;
- The request is for one of the following:
  - Institutional type grants where selection of specific subgrants is the institution's responsibility;
  - Training grants where research activities involving human subjects remain to be selected; or
  - Indefinite projects where human subjects' involvement will depend on
    - completion of instruments;
    - prior animal studies; or
    - purification of compounds;

  and
- Assurance from the PI that no human subjects will be involved in any study supported by these awards until the study is reviewed and approved by the IRB.

IRB Review

[1] 45 C.F.R. § 46.118 (2013).

A PI must seek IRB review and approval when the plan on human subjects becomes definite. The PI may not initiate any research activities involving human subjects before the IRB approval.

Procedures

Requesting Section 118 Designation

1. **Submitting a Request for Designation.** The PI submits a request for Section 118 designation to the HSP using **APP 14 New Application for 118 Designation**.
   - 1.1 If the request is for an application on an institutional type grant or a training grant, the PI should include the following information in the request:
     - 1.1.1 Grant title;
     - 1.1.2 Name and contact information of the PI;
     - 1.1.3 Name of the funding agency;
     - 1.1.4 Specific aims of the application;
     - 1.1.5 Who will be authorized to select grantees;
     - 1.1.6 The name, duties, and authority of the finance officer for the grant; and
     - 1.1.7 How long the grant is expected to last.

   - 1.2 If the request is for an application on an indefinite project, the PI should include the following information in the request:
     - 1.2.1 project title;
     - 1.2.2 Name and contact information of the PI;
     - 1.2.3 Additional investigators, if applicable;
     - 1.2.4 A description of the project and the reason justifying the designation;
     - 1.2.5 The name of the funding agency;
     - 1.2.6 Date when the PI anticipates research activities to begin; and
     - 1.2.7 Date when the PI anticipates the plan on human subjects to be definite enough to submit for IRB review.

   - 1.3 A certification by the PI that no human subjects will be enrolled or no data will be collected from human subjects for a subgrant study under the grant or for the indefinite project before the subgrant study or the project is reviewed and approved by the IRB.

2. **Reviewing by the HSP.** After the HSP receives a request for Section 118 designation, it will assign the request an HSP number and start the review process on the request.

3. **Issuing Approval of the request.** The HSP will issue a letter if it approves the request for Section 118 designation.
   - 3.1 If the request is for an application on an institutional type grant or a training grant,
     - 3.1.1 the approval expires one year from the approval date of the request; and
     - 3.1.2 the HSP will inform the PI in the letter that the PI must file an annual report before the expiration date.

   - 3.2 If the request is for an application on an indefinite project, the HSP will inform the PI in the letter that, before initiating any research activities involving human subjects, the PI must apply for IRB review when the plan on human subjects becomes definite.

   - 3.3 This designation does not allow the PI to initiate any research activities involving human subjects.

3.4 The PI may initiate research activities involving human subjects only if the IRB has reviewed and approved the human subjects research.

After the Request Is Approved

Annual Reports

1. Before the expiration date, the PI for the institutional type grant or training grant must submit an annual report (**APP 15 Annual Report – 118 Designation – Institutional/ Training)** including
   1.1 A list of subgrants funded by the grant during the past year and their HSP identifying numbers, the names of the PI for the subgrants, and approval dates of the subgrant studies by the IRB.

2. The HSP will review the report for accuracy and completeness.

3. If the HSP approves the annual report, it will approve the Section 118 designation for another year.

Indefinite Projects

When the plan on human subjects becomes definite, the PI must apply for IRB review before initiating any research activities involving human subjects.

Materials

- APP 14 New Application for 118 Designation
- APP 15 Annual Report – 118 Designation – Institutional/ Training
- TMP 431 Letter of Approval – 118 Designation – Institutional/ Training
- TMP 432 Letter of Approval – 118 Designation Renewal – Institutional/ Training
- TMP 433 Letter of Approval – 118 Designation – Undefined Research

References

- 45 CFR 46.118