**118 Determination Form**

This application is used to request IRB certification that materials for a grant application have been determined to meet criteria under [45 CFR 46.118](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.118) and not to request an IRB approval or determination of a research study. This application is used when subjects may be involved within the period of support, but definite plans would notnormally be set forth in the application or proposal. This application should not be used in conjunction with an IRB application where definite plans are planned for the research. Contact the [IRB office](mailto:irb@bu.edu) with questions.

**SECTION A: Contact Information** **Date:**

**Principal Investigator:** Click or tap here to enter text.

**Principal Investigator Dept:** Click or tap here to enter text.

**Contact Information :** Click or tap here to enter text.

**Additional Contact Person:** Click or tap here to enter text.

**Contact Information:** Click or tap here to enter text.

**SECTION B: Project Information**

1. **Project Title:** Click or tap here to enter text.
2. **Project Sponsorship:** Click or tap here to enter text.
3. **Project Summary:**

Click or tap here to enter text.

1. **Project Status:**

Click or tap here to enter text.

1. **Explain how/why this project meets criteria under \***[**45 CFR 46.118**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1118)

Click or tap here to enter text.

1. **Provide a timeline for the protocol development and when it is expected that an application for research involving human subjects will be submitted to the IRB**

Click or tap here to enter text.

**SECTION C: Certifications and Signature**

**I confirm that research with human subjects will not occur on this project until IRB approval has been obtained and the research.**

**My grant has been submitted with this form.**

**Principal Investigator Signature**: 

**\*§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.