



118 Determination / Just in Time (JIT) Guidance

VU Human Research Protections Program (HRPP) Guidance

What is a 118 determination and Just in Time (JIT) Request?

In the federal regulations, there is a provision (45 CFR 46.118) which allows for an Institutional Review Board (IRB) to certify that projects with certain type of grants, cooperative agreements, or contracts from federal agencies or departments may involve a human subjects research component within the period of support, but definite plans and specific details for that human research are not yet determined. This notification from the VU IRB is called a *118 Determination*.

Often times, the 118 determination is requested due to a federal funder's request (e.g., NIH, NSF), typically tied to a *Just in Time (JIT)*. A *Just in Time (JIT)* request is a process for researchers to submit time sensitive aspects of a research study for review without a full submission due to a quick federal funding timeline (e.g., in order to release funds or to begin certain aspects of the study that do not involve human research participants). As part of a JIT, many researchers request to receive a .118 determination from an IRB if there is a tentative plan to involve humans in the research, but they are not yet fully developed.

A .118 determination is not an IRB approval for human research because the IRB has not fully reviewed and approved the study. Researchers must submit to the VU HRPP their study with all relevant research-related documents for IRB review when plans for human research are solidified. **Human research may not begin until the IRB review is conducted and IRB approval is received.**

45 CFR 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.

How do I submit a .118 determination?

VU researchers requesting a .118 determination from the VU IRB must submit the 118 determination request as a new study in VU HRPP's electronic IRB system called VERA.

Note: The documents the VU HRPP will review for 118 determinations are:

- VERA Form
- Grant Proposal + Any Supporting Documentation from Funder for the 118 Determination Request

In VERA, please follow the instructions below:

- ✓ Select "Create New Study" to begin completing the VERA Form
- ✓ Ensure the "Title of Study" and "Short Title" matches the grant proposal study title.
- ✓ Under "Brief Description": type "*118 Determination Request*".
- ✓ Under "Study Funding Sources", attach the grant proposal and any supporting documentation from funder for the 118 request. Note, 118 determinations only apply to federal funding.

- ✓ **Complete the 118 Determination Request Form (HRP-902)** and attach it in VERA where it requests a protocol to be attached. **Do not attach a protocol or other study documents.**
- ✓ **Department chair approval is not required** for 118 determination requests.

Upon the IRB review and determination, researchers will receive a *118 Determination Letter* from the VU IRB. The 118 Determination approval will be issued for one year. Investigator(s) must submit a continuing review for a 118 determination before the expiration date of the one-year approval.

Resources

- 45 CFR 46.118

ⁱHuman research and human subjects research are used interchangeably in this guidance document.