

Guidance: Just-In-Time (JIT) or Similar Request

Overview

Some sponsors, including <u>NIH</u> & <u>NSF</u> will accept new grant proposals with the understanding that the researcher will proceed with the IRB review process upon receiving notification of a score in the fundable range. This is sometimes referred to as the "Just-in-Time" [JIT] procedure. If your grant application receives a just-in-time notice, you still need to submit a completed IRB protocol and related documents for review to the IRB. As soon as you receive the first autogenerated JIT email request and determine that your score is likely to be competitive for an award, you should begin the initial new protocol submission or modification process with the IRB if you have not already done so. If your IRB submission's approval is pending as the JIT submission date approaches, the pending status does not jeopardize your funding opportunity and there is no cause for alarm.

Definitions

118 Determination: The federal regulations at <u>45 CFR 46.118</u> allows for determinations to satisfy federal sponsor requirements (e.g., Just-In-Time) to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Human subject research activities cannot begin until a full application and all applicable material (e.g., consents, surveys, tools) have been developed, submitted, and IRB approval (§46.111) has been obtained.

Review Process

Please see the following flowchart for an overview of your best pathway forward. To modify an existing study, please see Modification to Protocols. To request a 118 letter, email a completed copy of the 118 Determination Request (on our Forms Page) to IRBReview@northeastern.edu with a note on your sponsor's preferred timeline.

References

Code of Federal Regulations, Title 45, Part 46.118

NIH Just-in-Time Procedures

NSF Proposal & Award Process

