SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

Institutional Review Board Policy

IRB Policy #:	**225**
Policy Title:	***Just-in-Time/118 process***
Date Approved:	**December 9, 2022**
Date Reviewed:	

Purpose:
The purpose of this document is to describe available options and process steps when a project lacks immediate plans for involvement of human subjects and is grant funded by agencies that allow for .118 determinations.

46.118 Determinations can be granted 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.

Policy:

Certain types of applications for grants, cooperative agreements, or contracts are 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 set forth in the application or proposal. These include activities such as:

1. institutional type grants when selection of specific projects is the institution's responsibility
2. research training grants in which the activities involving subjects remain to be selected
3. projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

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.

Investigators whose projects meet the activities outlined in 1-3 (above) and such activities are supported by a granting agency that allows for .118 letters, may petition the IRB for a .118 determination. Such determinations are not approvals for human subjects work. No human subjects may be involved until a protocol is approved by the IRB.

Six months from the date identified on the IRB .118 memo, the PI must certify to OSPA and the ORC that either: a) the project continues to lack immediate plans for the involvement of human subjects, their data, or their specimens; or b) provide documentation to demonstrate that IRB approval has been obtained.

References

1. U.S. Department of Health and Human Services, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html

2. Ibid.