



Scope: This document is intended to guide researchers in determining the circumstances for which an Approval-In-Principle Application is appropriate.

General Considerations

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 where selection of activities is the institution's responsibility, training grants in which activities involving human subjects remain to be selected, and projects where human subject involvement will depend on the design and development of study materials and instruments.

An Approval in Principle (AIP) is designed to help facilitate review of research lacking definite plans for the involvement of human subject research in accordance with the regulations set forth in 45 CFR 46.118. The AIP process and approval allows UO Sponsored Project Services (SPS) to release funds associated with preliminary phases of research that are preparatory to planned human subject research activities. However, the AIP application materials must clearly demonstrate development activities are supported by the award.

The AIP application is not for IRB review and approval. No human subject research activities may occur under the AIP approval. A protocol application must be submitted for review and approval by the University of Oregon Institutional Review Board (IRB) prior to initiating human subject research activities.

If approved, the AIP approval period will be issued with an expiration date based on the stated anticipated start date for human subject research activities in the application. In advance of the expiration date and prior to implementing human subject research activities, investigators will need to submit an application and obtain either an exempt determination or IRB approval.

Contact RCS with any questions about whether an application or proposal would qualify for an AIP.