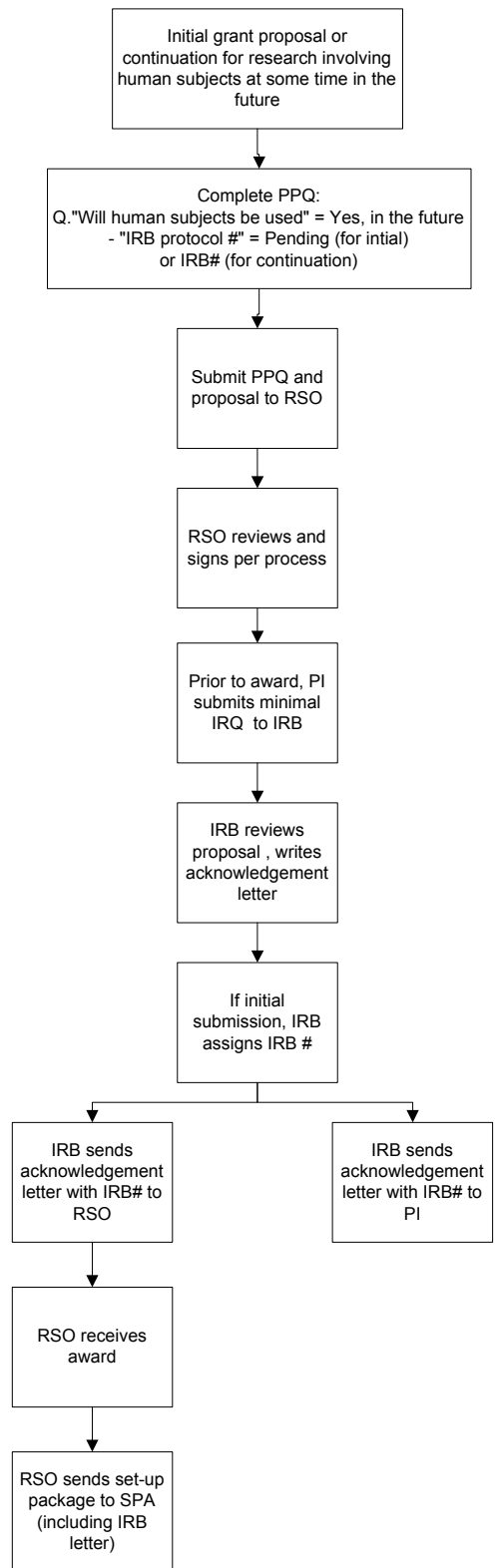




Preaward Process for Proposals Involving Human Subjects at a Future Time¹

Some proposals are submitted for funding that include research with human subjects (including data or tissue), but the research involving human subjects will not be performed until non-human research is conducted first. Examples of these types of proposals could include some training grants (such as T32s, F32s), long-term awards (such as K grants), multicenter cooperative grants (U01s, U10s), program projects, and grants supporting doctoral student dissertations. In this situation, it is difficult to create a relevant IRB submission due to the lack of detail known by the time of grant award. Therefore, for these types of projects note that human subjects will be involved in the application on the PPQ and indicate “they will be used in the future”. Prior to award receipt and account set-up, the investigator must complete the mandatory information required in the initial review questionnaire (IRQ) and submit it with a copy of the associated grant submission to the IRB. Note in the IRQ that human subjects will be used in the future. The IRB will review the submission, issue an IRB number to the project, and write an acknowledgement letter to the investigator stating a full IRB submission is required prior to involving human subjects in the project. See the flowchart below for an overview of this process.



- ¹Examples:
- Training grants (T32s, F32s)
 - Long-term awards (K grants)
 - Multicenter Cooperative grants (U01s, U10s)
 - Grants supporting doctoral student dissertations