Amending a Protocol vs. Submitting a New Protocol

When proposing changes to an existing study, it is important to consider whether the changes may warrant submission of a new protocol rather than an amendment. It is a misconception that adding an amendment to an existing study will be easier and faster than submitting a new protocol. The IRB must examine any amendment using the same review criteria and standards as a new submission. An amendment that results in an overly long protocol with many inconsistencies and/or the inclusion of information and documents that are no longer relevant can be confusing to reviewers. In some cases, a new protocol which is current and consistent will be easier to review and faster to approve.

When deciding whether to submit an amendment or submit a new protocol, consider the following:

* *Do the proposed changes alter the research hypothesis? Is there a change in the study purpose and/or aims?*
  + If the basic research question remains intact, then a new protocol may not be warranted.
  + If the focus or research question has changed, even if it builds on the knowledge learned in an existing study, then a new protocol may be warranted.
    - The IRB must assess the risks and benefits of the research and balance the risks of the research against the benefits. If the research question has changed then the benefits are likely to have changed. A new protocol may be warranted to evaluate the balance of risks against the benefits.
* *How will the procedures/methods change?*
  + If the procedures/methods to be used remain essentially the same, then a new protocol may not be warranted.
    - For example, if the only changes involve substituting one questionnaire another similar questionnaire or adding different stimuli of the same type, then submitting an amendment is likely to be the best course of action.
  + If the new procedures/methods deviate substantially from those proposed in the original research plan, then a new protocol may be warranted.
    - If the changes to the procedures/methods result in a study that is substantially different from the one(s) originally proposed, studies can become unwieldy with multiple study add-ons, can blur the focus of the research, and can affect data quality. This can cause confusion and errors among research team members and lead to non-compliance with the approved protocol and/or impact risks to participants. Submitting a new study may be more appropriate.
    - If the changes result in a “menu” of procedures that may be used, it may become difficult for the IRB to assess the risks of the research to individual participants. Reviewers will need to consider all possible combinations of materials and experimental procedures for all possible participants. In this case, a new protocol would be the best course as submitting an amendment could lead to multiple rounds of revisions.
* *How long has the study been open?*
  + If the protocol is intended as a longitudinal study or is operating within the planned study timeline and if changes are otherwise closely related to the previously approved study, then submitting an amendment is likely appropriate.
  + If the protocol is not intended as longitudinal research and has been active for several years, the information within the protocol can become inaccurate as institutional policies, lab settings, and research personnel change. A new protocol may be appropriate.
    - Protocols that have been open for an extended period may include irrelevant information as portions of the research may be complete and this can create confusion about what activities are ongoing.
    - As new information on risks becomes available, studies that have been ongoing may not reflect the most current information and potentially exposes participants to unnecessary risk. A new protocol would allow the protocol to be refined to meet the aims of the current research objectives, ensuring that the study is being conducted consistent with the approved protocol, and that it will reach completion.
* *Will the study utilize new funding?*
  + If new funding is awarded to support the research as currently approved, then an amendment protocol to associate the funding is appropriate.
  + If new funding points to new directions for the research and the aims and research design need to change, a new protocol can cleanly delineate this new focus and ensure an approved protocol is accurate and relevant to the planned research.

 If in doubt, please contact the IRB-HSR. The staff would be happy to discuss proposed changes with you.

*From: University of Oregon*