Amending an Existing Protocol vs. Submitting a New Protocol: Guidance for Researchers

When proposing changes to an existing study, it is important to consider whether the changes may warrant the 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 application. The IRB must examine any amendment using the same review criteria and ethical standards as a new submission.

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

- ***Do the proposed changes alter the research hypotheses? Is there a change in the study purpose and/or aims?***
  - If the basic research question remains intact, then a new application 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 application may be warranted.
    - The IRB must assess the risks and benefits of the research and balance the risks of the research against the benefits. A new application 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 application may not be warranted.
    - For example, if the only changes involve substituting one questionnaire for another similar one or adding different stimuli of the same type, then submitting an amendment is likely the best course of action.
  - If the new procedures/methods deviate substantially from those proposed in the original research plan, then a new application may be warranted.
    - **From the researcher perspective:** 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, which in turn may cause non-compliance with the approved protocol and/or affect the level of risk to participants. Submitting a new study may be more appropriate.
    - **From the IRB perspective:** 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. Thus, what could be an expedited review of a new protocol may instead necessitate a full board review due to the need consider all possible combinations of materials and experimental procedures for all possible participants. In this case, a new application would be the best course as submitting an amendment could lead to a more complicated review process than warranted (i.e., multiple rounds of revisions, inappropriate assignment to full board, among others).

- ***Are new populations being added, especially where new necessary protections are needed?***
  - If new populations are being added, but they would NOT be considered vulnerable AND it does NOT change the risk assessment or risk minimization plans, then an amendment is likely appropriate.
  - If new populations are being added and they would be vulnerable and/or the risk assessment and risk minimization plans need to be revised, then a new applications may be appropriate.
- ***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 for 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 application may be appropriate.
    - Protocols that have been open for an extended period may include irrelevant information as portions of the research may be complete, creating confusion about what activities are ongoing.
    - As new information on risks becomes available, ongoing studies may not reflect the most current information and potentially exposes participants to unnecessary risk. Additionally, revisions to regulations may have occurred in between the time of initial approval and when new information has become available; the most current regulatory expectations will need to be applied. A new application would allow the protocol to be refined to meet the aims of the current research objectives and regulatory requirements, 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 application 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 application can cleanly delineate this new focus and ensure an approved protocol is accurate and relevant to the planned research.
- ***Are you proposing new analyses (secondary analysis of existing data)?***
  - If you are receiving new funding to conduct new analyses, a new submission is required.
  - If you are engaging in a new collaboration that is under a legal agreement to conduct new analyses, a new submission is required.
  - If you are adding a site for sharing, this should be done as part of a repository protocol. Please contact the IRB for guidance on how to set this up.

If you have any questions about this topic, or need further information, please submit a consultation request.