

When do proposed changes warrant a modification or amendment request versus a new IRB application?

When proposing changes to an existing approved protocol, it is important to consider whether the changes may warrant submission of a new protocol rather than a modification/amendment. It is a misconception that modification or amendment requests are easier and faster than submitting a new application. Xavier's IRB must examine any modification/amendment using the same standards for review and approval as any other submission. A modification or amendment that does not adequately explain changes, includes inconsistencies, or does not provide the appropriately revised materials will slow the review process and result in follow-up communications with the IRB. In some cases, a new application is easier to develop, review and approve.

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

1.	<i>Do the proposed changes alter the research hypotheses? Is there a change in the study purpose and/or aims?</i> • If the basic research question or purpose remains intact, then a new application may not be warranted. • If the research question has changed, even if it builds on the knowledge learned from a prior approved protocol, then a new application may be warranted.
2.	<i>How will the procedures/methods change?</i> • If the procedures/methods to be used remain essentially the same, then a new application may not be warranted. ○ For example, if the <i>only</i> changes involve substituting one questionnaire with another <i>similar</i> questionnaire or adding different stimuli of the <i>same</i> type, then submitting a modification/amendment may be appropriate. • If the new procedures/methods deviate from the original approved protocol, then a new application may be warranted. ○ If the changes to the procedures/methods result in a study that is different (e.g., asks a different research question) from the approved protocol, modifications/amendments can affect the quality of review and may not be appropriate. Submitting a new study may be necessary.
3.	<i>How long ago was approval obtained?</i> • If the approved protocol reflects a longitudinal study and if changes are otherwise closely related to the previously approved protocol (see item #2), then submitting an amendment may be appropriate. • If the approved protocol is not intended as longitudinal research and was approved in previous academic years, a new application may be appropriate.
4.	<i>When might a modification or amendment really be a new IRB application?</i> If the modification or amendment includes changes to two or more of the following criteria, the IRB would likely consider it to be a new study and the investigator(s) would be asked to submit a new protocol. • Study population • Study procedures • Study purpose [This guidance also applies when modifications/amendments are submitted to the same approved protocol successively across time.]