

## GUIDANCE: When to submit amendments for Exempt Research

Unlike research that has been reviewed by the IRB through the Expedited pathway or the Full Board, studies that have previously been determined to be Exempt can be changed without further IRB review so long as the changes will not alter the IRB's Exempt determination. To reduce administrative burden, the IRB has compiled the below list of modifications to Exempt studies that do not need to be submitted prior to being implemented.

The below list is not exhaustive so please reach out to us at [irb@ucsd.edu](mailto:irb@ucsd.edu) if you have a situation which you do not think needs to be submitted prior to implementation. One of our team members will be happy to evaluate the specific circumstances and let you know whether a submission is required.

This list may be updated as new circumstances are brought to the attention of the IRB.

- Editorial or administrative changes to consent documents or other study documents.
  - E.g., correction of typographical errors, updating phone numbers, etc.
- Adding non-sensitive questions to a survey or interview or revising current questions.
  - E.g., correction of typographical errors, revising questions to be gender neutral, etc.
  - “Non-sensitive questions” are questions that **would not** reasonably place the subject at risk of criminal or civil liability or otherwise be damaging to the subject's financial standing, employability, educational advancement, or reputation if the confidentiality of the research data were compromised.
- Removing questions from a survey or interview.
- Adding a new recruitment modality (e.g. flyer, social media posting, etc.) so long as the content of the material was previously reviewed and approved by the IRB.
- Increasing or decreasing the number of subjects, unless you are adding a new subject population.
- Changes in the inclusion/exclusion criteria for a study which does not add a new vulnerable population.
- Revising the dates of data collection or the period of time over which the study will be conducted.
- Study team/personnel changes (except a change in PI).