

Attachment Requirements for Surveys, Questionnaires, and Interview Guides

CPHS has re-evaluated its requirements concerning the level of detail needed for instruments used to collect data from research subjects. To reduce investigator burden and speed up review turn-around times, flexibility regarding these requirements will be applied to qualifying projects. A research study must meet **both** of the following conditions to qualify for this flexibility:

1. **The study must be classified as minimal risk.** As defined in the federal regulations, *minimal risk* means that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”
AND
2. **The research study must NOT involve any of the following:**
 - Federal funding or funding from non-Public Health Service (PHS) agencies that adhere to federal regulations in their award contracts ([see current list](#)).
 - Prisoners as subjects.
 - Federal personnel or the Department of Veterans Affairs.
 - Procedures, devices, or drugs subject to FDA oversight.
 - Biomedical procedures.
 - Clinical interventions.
 - Sponsor or other contractual restrictions.
 - An NIH-issued Certificate of Confidentiality to protect identifiable research data.
 - Deception of subjects.

If the research study meets all of the above criteria (1 & 2), then the content of the data collection instruments (e.g., surveys, questionnaires, interview questions) to be used need not be the final versions in order for the research protocol to be approved. However, *a draft version of each instrument must be provided with the submission.*

Additional exclusions:

- **Focus groups:** Group situations involve different privacy/confidentiality concerns; therefore, this flexibility does not apply to research surveys or questionnaires to be used for focus groups. Such instruments must be submitted in *final* rather than draft form for approval.
- **Sensitive topics:** Any questions related to sensitive topics (e.g., suicidality) must be specified in *final* rather than draft form.

Changing or modifying study instruments

After the study is approved, minor changes may be made by the investigator without filing an amendment or requiring further review by CPHS/OPHS. Examples of minor changes include edited or revised versions of currently approved questions or items, removal of questions, or

addition of similar questions. On the other hand, if the investigator wishes to make substantive changes to the instrument which may affect subject risks, such as adding new categories of questions or more sensitive questions/topics (including but not limited to suicidality, illegal or highly stigmatizing behavior, immigration status, personal health information), an amendment must be submitted to CPHS/OPHS and the changes approved before the new or revised questions may be included in the study.