When to Submit Project Revisions

Studies reviewed by the full board or by an expedited procedure: Researchers may not initiate changes to research without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects

Studies determined to be FLEX or exempt: The following changes do not require IRB review:

1. Revising surveys or interview questions to make minor edits that do not alter the nature of the questions being asked (e.g., fixing typos/grammatical errors, restating the same questions for clarity, reordering the questions, splitting one question into multiple questions)
2. Revising interview or focus group questions to include follow-up clarifying questions (i.e., questions that cannot be known to the researcher in advance because they are based on the individual responses of the participants).
3. Adding study personnel who meet all of the following criteria: (a) Are affiliated with OSU, (b) are not going to serve as the principal investigator, (c) are not a student conducting the study for a thesis or dissertation. **Note**: The PI is responsible for ensuring that all study staff have completed the appropriate online ethics training ***before*** they are added to the study team.
4. Revising recruitment materials, so long as the four required elements are still present and they conform to the OSU policy

If a change is planned that is not listed below, please contact the HRPP office for additional information about requirements for review.

Examples of changes and the related requirement for review	Do submit if the study is:	
	FLEX or Exempt	Expedited or Full Board
Adding federal funding or a plan for future federal sponsorship (e.g., proof of concept studies for federal RFPs, pilot studies intended to support a federal grant application, training and program project grants, no-cost extensions). This includes research funded or otherwise regulated by a federal agency that has signed on to the Common Rule, including all agencies within the Department of Health and Human Services	✓	✓
Adding FDA-regulated components	✓	✓
Adding an NIH-issued or pending Certificate of Confidentiality	✓	✓
Adding prisoners or parolees as subjects[i]	✓	✓
Adding funding with contractual obligations or restrictions that require the application of the Common Rule or which require annual review by an IRB	✓	✓
Adding a federally classified research component (research procedures and/or results are legally knowable only by individuals with United States government security clearance)	✓	✓
Adding or revising a clinical intervention regardless of funding source[ii]	✓	✓
Registering the study with ClinicalTrials.gov[iii]	✓	✓
Adding populations who may require additional safeguards, such as children, pregnant women, non-English speakers, OSU students or employees, individuals with diminished capacity to consent, people living in poverty, people who are not literate, and/or international populations	✓	✓
Adding a survey, questionnaire, interview, or focus group that involves children (i.e. individuals under the age of 18)	✓	✓
Revising survey or interview questions to make substantive changes, adding items, or revising content	✓	✓
Revising surveys or interview questions to make minor edits that do not alter the nature of the questions being asked (fixing typos/grammatical errors, restating the same questions for clarity, reordering the questions, splitting one question into multiple questions)		✓
Revising interview or focus group questions to include additional planned initial or follow-up questions (i.e. any question that is known in advance to the researcher is a planned question).	✓	✓
Revising interview/focus group questions to include follow-up clarifying questions (i.e. questions that cannot be known to the researcher in advance because they are based on the individual responses of the participants).		✓
Adding observational research with children that involves participation by the researchers. Example: Changing procedures from observing children playing with toys to add researchers entering the room and leading the activity.	✓	✓
Adding research procedures that are subject to the FDA Regulations	✓	✓
Revising study procedures such that data or samples will be individually identifiable when previously they were not	✓	✓
Adding a new or similar cohort of participants	✓	✓
Increasing the enrollment number		*full board only*
Replacing the Principal Investigator	✓	✓
Adding External Collaborators	✓	✓
Adding a student researcher, if this research will be used for their thesis or dissertation	✓	✓
Adding study personnel who will serve in roles not listed above.		✓
Adding research activities that change the risk to participants	✓	✓
Adding or removing funding	✓	✓
Adding additional types or varieties of food for tasting or consumer preference tests	✓	✓
Revising recruitment materials so long as the 4 required elements are still present and they conform to the OSU policy		✓
Adding compensation or extra credit. This requires a project revision because it involves a revision to the consent document.	✓	✓
Revisions to the consent, assent, and parental consent form or process.	✓	✓
Revisions involving changes to, or additions of, conflicts of interest declarations or disclosures for study team members (including those not listed on the application).	✓	✓

[i] Incidental incarceration will not invoke subpart C of the Common Rule. The subjects continued participation is under the investigators overall responsibility to protect the rights and welfare of subjects.

[ii] For the purposes of this policy, clinical intervention is defined as one that is intended to change or assess a health-related processes and/or endpoint. Examples include but are not limited to the use of drugs, dietary supplements, devices, blood draws, imaging (e.g., DXA, x-ray), delivery systems (e.g., telemedicine, face-to-face), diet, cognitive therapy, exercise, and any intervention that includes treatment, prevention, or diagnostic strategies. This definition has been adapted from one offered by NIH as part of their clinical trial FAQs.

[iii] Studies must be registered with ClinicalTrials.gov if: (1) they involve drugs, devices, or biologics that are regulated by the FDA, or (2) they are funded by the NIH and meet the NIH definition of a clinical trial, or (3) there is a plan to publish the results in a medical journal and the study meets the International Committee of Medical Journal Editors (ICMJE) definition of a clinical trial. If "yes" to either (1) or (2) above, regulatory flexibility initiatives will not be applied to these studies.