

PROJECT AMENDMENTS FOR EXEMPT STUDIES

If the <u>Exempt</u> Project Amendment Involves...	Do Submit	Don't Submit	No Longer Exempt
Adding vulnerable populations, such as prisoners; children; pregnant women; non-English speakers; NKU students or employees; individuals with diminished capacity to consent; prisoners; people living in poverty; people who are illiterate; and/or international populations, as participants.	X		It depends
Adding a survey or interview that involves children (i.e. individuals under the age of 18)	X		It depends
Revising survey/interview questions to make substantive changes, adding items, or revising content	X		It depends
Revising surveys/interviews 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)		X	
Revising interview/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).	X		It depends
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).		X	
Adding observational research with children that involves participation by the researchers. For example: changing procedures from observing children playing with toys to add researchers entering the room and leading the activity.	X		It depends
Revising study procedures such that data samples will be individually identifiable when previously, they were not	X		It depends
Adding a new or similar cohort of participants	X		
Increasing the enrollment number		X	
Replacing the Principal Investigator	X		
Adding External Collaborators	X		
Adding a student researcher, if this research will be used for their thesis or dissertation	X		

Adding or removing study personnel, not otherwise listed in above. Note: Only listed personnel can/will be copied on correspondence with the IRB. The PI is responsible for ensuring that all study staff have completed the appropriate online ethics training.		X	
Adding research activities that change the risk to participants	X		It depends
Adding or removing funding	X		It depends
Adding additional types or varieties of food for tasting or consumer preference tests	X		It depends
Revising recruitment materials so long as the NKU recruitment required elements are included		X	
Adding compensation for participants.	X		
Adding extra credit as compensation.	X		
Revisions to the consent/assent/parental consent form or process. These documents are stamped so even minor revisions must be submitted so a new stamped version can be provided.	X		It depends