

When do I need to submit a Modification to HRPO?

Federal regulations require an investigator to obtain *prior* approval from the IRB for any changes previously approved research. Exceptions are allowed when the change is necessary to eliminate apparent immediate hazards to participants. The exception typically would not apply to non-treatment studies, which generally do not provide direct benefit to research participants.

The Behavioral team reviews Modifications each Monday. Modifications requests that are received by noon on Friday will be reviewed that Monday. You will receive feedback (questions or approval) within 1-2 days of review.

Examples of Modifications that **Need** to be Reviewed

1. Participants are having a difficult time maintaining focus throughout the 4 hour testing session. Therefore, the Project Director decides to replace the single 4 hour testing session with two 2-hour sessions to be held on consecutive days.
 - ✓ This is a change in protocol. Any time you increase or decrease the number of testing sessions, an amendment needs to be reviewed and approved.
2. A PD is having a difficult time recruiting participants for her study. To increase recruitment she decides to lower the age cut-off for older adults from 65 to 60.
 - ✓ This change, or any other change in the inclusion/exclusion criteria, must be submitted and approved as an amendment.
3. After talking with his faculty advisor, a PD realizes that he needs to collect a measure that was not included in the eIRB submission approved by HRPO.
 - ✓ Before this measure can be administered, an amendment must be approved by the HRPO.
4. A PD originally anticipated that his testing session would take no more than 1 hour. After running the first four participants, it is clear that the session really runs closer to 90 minutes and in one case approached two hours. The approved protocol includes compensating participants 1 credit or \$10 per hour of participation.
 - ✓ The PD needs to submit an amendment to increase session length and alter compensation.
5. After running several participants, a PD realizes that one of her measures isn't really necessary and decides to drop it. This won't change the session length or compensation.
 - ✓ This is a change in research. Even though there won't be a change in session length or compensation, an amendment needs to be submitted to remove the measure from your protocol.
6. When approval was originally given the by HRPO, the study was funded by Departmental funds. The PD has just learned that a grant, which was pending at the time of initial submission, will be awarded.
 - ✓ An amendment needs to be submitted and approved.
7. The PD of an existing study has graduated and accepted a job offer at another University.
 - ✓ Before leaving, the Pd needs to either submit: (i) a final report to close the study, or (ii) an amendment identifying a new PI/PD who is still affiliated with Washington University and will continue the research project.

Examples of Modifications that **Do NOT** need to be Reviewed

1. The PD has asked a colleague to help with data analysis. The PD will provide the colleague with an SPSS file with coded data. The colleague will not be given access to the key linking the code number to the participants' personal information.
 - As the colleague does not meet the definition of “engaged” in research, a modification does not need to be submitted to add him to the study team.
2. Before sending recruitment letters out to potential participants a research assistant notices that there are several typos in the letter.
 - An amendment does not need to be submitted to the HRPO in order to correct typos in recruitment materials/study measures. Additionally, revising survey items to make the question more clear to participants does not need to be submitted. Only submit an amendment if your intent is to revise the content of the recruitment material/study measure.
3. Data collection was completed faster than usual and now the study is in the data analysis phase. This information will be related to the HRPO with the next continuation.
 - An amendment does not need to be submitted to inform the HRPO that data collection is finished or to update a timeline contained in the protocol.
4. The PD had a flyer approved with her initial submission. The PD wants to reorganize the information on the flyer and update their research assistant's contact information.
 - As long as the content of the flyer is unchanged and the use of the flyer is unchanged (where it will be used), a modification does not need to be submitted to the HRPO.
5. An undergraduate research assistant was listed as an engaged study team member on the initial application. Halfway through the semester the RA finds that he is unable to continue working in this lab.
 - A modification does not need to be submitted to remove this individual from the study team. Remove or do not list this RA on the next continuation application.