**For Exempt determinations (no Limited Review):**

This study is Exempt from further review and you may change study documents and procedures without submitting an amendment, except in the cases described below.

If you are planning to resume your in-person human subjects research (HSR) activities you must submit a plan by selecting the “Submit Plan to Resume In-Person HSR activities” option from the summary page. Do not resume in-person HSR activities until you receive notification from the HRPP that you may implement your plan.

Amendments are needed for exemptions when:

1. Your changes increase the level of risk (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.).
2. Your changes move the research into a new category of review or would require limited review. Click here for common examples.

* Substantial changes to study objectives and/or methods.
* Sensitive questions whose exposure would put participants at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation.
* Minor participants where none were included before.
* Vulnerable populations where none were included before (e.g., non-incidental inclusion of students, employees, prisoners).
* Deception.
* Methods to collect data from wearable devices.
* Collection of biological specimens.
* Existing data where the participants are identifiable.

1. You are adding a new phase or sub-study.
2. You are adding a collaborator or a new data collection site.
3. You are switching to a new principal investigator.
4. You are adding or removing a co-investigator or other study team member.
5. You are making changes to [recruitment materials or advertising](https://www.research.vt.edu/sirc/hrpp/resources/worksheets.html) that may contradict Virginia Tech’s guidance on ethical recruitment. (Link to resources)

If in doubt, contact your Protocol Coordinator to ask whether an amendment is needed for your changes.