

Guidance on Revising Informed Consent Documents

After completing the [human research COVID-19 risk evaluation checklist](#), researchers may need to make changes to approved informed consent documents. For any study under which researchers plan to begin or continue enrolling subjects, one of the following must be completed:

Presumed standard risk

If completion of the human research COVID-19 risk evaluation checklist results in a determination that a study is presumed to present standard risk to subjects, add the following paragraph to the section titled, “What are the risks of taking part in the study?” in the approved informed consent document:

“This study requires that you meet personally with a researcher. Because any contact with other people brings the risk of infection with coronavirus (or COVID-19), we want to ensure that you carefully consider your participation. You should have been provided a document explaining how COVID-19 is affecting research generally. If you have specific questions about this study and COVID-19, please ask the researchers. If you have any concerns about your health, please contact your health care provider.”

Potential elevated risk

If completion of the human research COVID-19 risk evaluation checklist results in a determination that a study has the potential to elevate risk to subjects, researchers will need to revise the approved informed consent document through an amendment. The language to be inserted in the section titled “What are the risks of taking part in the study?” depends on the procedures and conditions that elevate risk to subjects in the study. After revising this section, review the rest of the informed consent form and make any other necessary changes.

Study withdrawal

If the study requires the use of safety procedures that require subject compliance (e.g., providing their own face mask, remaining six feet away from researchers), consider adding the following paragraph as a new section within the informed Consent form: “Is there anything I have to do to be in the research study?”

“We may ask you to do something in order to keep yourself or others safe, like wear a facemask or remain a certain distance away from others. If you are not able to do these things, we may ask that you withdraw from the research study.”