

FAQ: Research involving Deception or Concealment

Q: What are the definitions of deception and concealment in research protocols?

A: “Deception” is involved when participants intentionally are told something untrue (not the truth). “Concealment” is involved when the researcher intentionally does not reveal initially to the participant all the relevant details of the protocol (not the whole truth / incomplete disclosure).

Q: When am I allowed to use deception or concealment?

A: Deception or concealment can only be permitted when a waiver of the usual informed consent requirement is justified under the criteria present in 45 CFR 46.116(d). Specifically, all four of the following criteria must be satisfied:

1. The research involves no more than minimal risk to subjects.
2. The waiver will not adversely affect the rights and welfare of the subjects.
3. The research could not be carried out practicably without the waiver.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.

Q: What does the IRB need to consider a researcher’s request for deception or concealment?

A: In order for the IRB to adequately review the research, investigators should justify, in detail, on the application form, the reasons for deception or concealment, including:

1. The necessity for deception or concealment, including why there are no effective alternative procedures that do not involve deception or concealment.
2. How the potential benefits of the research justify the use of deception or concealment
3. Whether the investigator will provide additional pertinent information to the subjects.
 - a. If subjects will *not* be given additional pertinent information, why not (e.g., an explanation of why providing additional pertinent information would do more harm than good).
 - b. When/how the subjects will be given the Debrief Consent Form/Permission to Use Data collected in a Research Study to have an opportunity to give/not give their consent.

Q: How do I tell participants about the deception/concealment after I have collected their data?

A: The Debrief Consent Form/Permission to Use Data collected in a Research Study Form is used to inform participants about the deception or concealment, the exact nature of the deception or concealment, and the reasons for the deception or concealment. As part of this process and after being fully informed about the deception or concealment, participants must be provided with the opportunity to not have their data used in the study. Specifically, after full disclosure, participants must be provided with the following or other comparable wording that has the same intent, unless waived by the IRB.*

Please initial your choice:

_____ *You may not use the data collected from me. Please destroy all data collected from me immediately.*

_____ *I give permission to have my data used in this research project.*

* Participants in exempt studies are not required to initial their choice, but they must be given the choice of removing their data from use in the research study, unless waived by the IRB.