

## Research Involving Deception or Concealment

“Concealment” is involved when the investigators do not reveal all the relevant details of the protocol (not the whole truth/incomplete disclosure) to the participants.

“Deception” is involved when participants are intentionally told something untrue (not the truth) about the study or study procedures.

In order for the IRB to adequately review the research, investigators have to describe the reasons for deception or concealment, including:

1. The necessity for deceiving or concealing information from the study participants, 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; and
3. Whether the investigator(s) will debrief the participants about the concealment or deception after the data collection session(s):
  - a. If participants **will not** be given additional information, the investigator(s) have to provide a valid explanation (e.g., an explanation of why providing additional information would do more harm than good).
  - b. If participants **will be** given additional information, the investigator(s) have to describe how the information will be shared with the participants and include the documents for IRB review. Debriefing templates are available on the IRB forms page, <http://www.clemson.edu/research/compliance/irb/forms.html>.

Deception or concealment may only be permitted when a waiver of some or all of the required elements of informed consent is justified, per 45 CFR 46.116(d). The following criteria must be satisfied and described on the IRB application:

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