



## Research Involving Deception or Incomplete Disclosure

### Purpose

- 1) This policy describes the circumstances by which the Institutional Review Board (IRB) allows the use of deception and incomplete disclosure in research involving human participants.

### Policy

- 1) The IRB will employ special consideration when it reviews research that utilizes deception or incomplete disclosure.
- 2) Deception occurs when researchers give false information to subjects or intentionally mislead them about some key aspect of the research.
  - a) Examples of deception:
    - i) The subject is given a "cover story" which falsely describes the purpose of the study, but provides a feasible account of the researcher's objective.
    - ii) The study includes a researcher's "confederate," an individual who poses as a participant, but whose behavior in the study is actually part of the researcher's experimental design
- 3) Incomplete disclosure occurs when researchers withhold information about the specific purpose, nature, or other aspects of the research. Withholding information may or may not be considered deception.
  - a) An example of incomplete disclosure:
    - i) The subject is informed about the purpose of the study or a certain procedure in general terms that are true but not detailed enough to reveal the researcher's main or specific objective.
  - b) An example of incomplete disclosure that is also deception:
    - i) The study involves audiotaping or videotaping of subjects without their knowledge or prior consent.

Requirements of the study, to be addressed in the IRB submission.

IRB Study Actions	Incomplete Disclosure	Deception
Justify the need in IRB study	Required	Required
Include in consent process / received participant authorization	Not required	Required for exempt protocols; not required for expedited and full review
Debriefing of participants	Recommended	Required*

\* Except in cases where the debriefing could cause harm.

### Use of Incomplete Disclosure and Deception in IRB studies.

	<b>Exempt</b>	<b>Expedited</b>	<b>Full</b>
Incomplete Disclosure	X	X	X
Deception	Maybe*	X	X

\* When authorized by the participant. See Exempt categories for more information

- 4) The use of deception must be justified and there should be no reasonable alternative method that would be equally effective to answer the research question. The researcher must demonstrate that the deception is necessary to conduct the study.
- 5) Research involving deception or incomplete disclosure may involve a waiver or alteration of some or all the required elements of informed consent or a waiver of the documentation of informed consent as outlined in the federal regulations. Therefore, consideration of the population, the research question, the risks of participating, and the benefits should be weighed carefully.
- 6) To approve research involving deception or incomplete disclosure, the study procedures cannot involve greater than minimal risk to participants.
- 7) The Chapman IRB reviews all research involving deception either by expedited review procedures or by the convened IRB, except that authorized deception may be authorized under Exempt Category 3.
- 8) With research involving deception or incomplete disclosure, participants should be debriefed after their participation and provided the option to have their data withdrawn prior to analysis, when appropriate. Debriefing may be inappropriate when it presents an unreasonable risk of harm without a countervailing benefit.
- 9) The IRB may approve research involving deception that enrolls vulnerable populations such as children; however, additional scrutiny is applied to the scientific rationale of utilizing vulnerable populations in research involving deception. Note that Exempt Category 3 cannot be used for research in children.
- 10) Prospective subjects must not be deceived about research that is reasonably expected to cause physical pain or severe emotional distress.

### Investigator Responsibilities

- 1) The principal investigator (PI) should clearly describe that the proposed research involves deception or incomplete disclosure in their initial submission to the IRB, and the use of deception must be justified.
- 2) Researchers should mitigate the risks of harm or negative consequences of participation in research involving deception and incomplete. Generally speaking, research should not involve participants feeling a loss of dignity, self-esteem, or trust for individuals held in high esteem (e.g., clergy, teachers, clinicians).
- 3) Generally, PIs must debrief participants when deception is used. It may be inappropriate to debrief participants when the debriefing may cause more harm than the deception itself. For example, if a student is eligible for participation based on a certain physical characteristic (e.g., weight), it may not be appropriate to debrief the student following their participation.
  - a) The PI must provide the IRB a plan for debriefing participants that includes:

- i) The timing for the debriefing. Generally, the IRB expects investigators to debrief participants immediately following the study procedures. However, it may be necessary to wait to debrief participants if the debriefing could jeopardize the integrity of the study. For example, PIs may wish to debrief participants after all study data are collected to ensure students do not inform other students about the true intent of the study, which would compromise the study results. In this situation, the IRB anticipates that participants will be debriefed within a year following their participation in the research.
  - ii) Who debriefs participants. The IRB expects research personnel knowledgeable about the research and the deception to debrief participants.
- b) The PI must provide the IRB with a script or form to be used during the debriefing session with the participant unless the IRB determines that such debriefing would cause harm to the participants. Participants should be provided detailed information about the deception and an explanation as to why it was necessary. Chapman researchers are encouraged to utilize the [template debriefing form](#) located on the IRB website.
  - c) After debriefing, the PI must ask participants if they would like their study information withdrawn and withdraw the study information should this be requested by the participant.

## **IRB Responsibilities**

- 1) Studies involving incomplete disclosure may be reviewed by exempt, expedited procedures or at convened full board meetings depending on the risks to participants and type of deception used in the research.
- 2) Studies involving deception may qualify for exemption when it is pre-authorized by the participant during the consenting process. Otherwise, all studies involving deception must be reviewed under expedited or full review procedures.
- 3) The IRB, IRB Chair, or designee takes the following into account when reviewing research involving deception:
  - a) The scientific value and validity of the research
  - b) Alternative procedures that could be used
  - c) Examination of the submission to ensure the deception in and of itself does not unduly influence study participation (e.g., a study in which college students are told they will receive compensation of \$100 where the compensation is the deceptive aspect of the study—meaning, the participants will not actually receive \$100 for their participation)
  - d) Inducement of harm and the reduction of harm through debriefing
  - e) The privacy implication(s) to participants and the confidentiality of study data
  - f) The timing of the debriefing (e.g., immediately following the procedure or after all participants have completed the study)
- 4) The IRB, IRB Chair, or designee shall apply common sense and sensitivity to the review of proposed research involving deception. The IRB will:
  - a) Determine whether the PI has justified the need for deception.
  - b) Review the debriefing script or form.

- c) Determine whether participants have been provided the option to have their data removed from analysis.
  - d) Determine whether the proposed participant population is suitable for the research.
  - e) Determine whether the informed consent is adequate and reveals as much as possible regarding the study procedures.
- 5) If the IRB waives the documentation of informed consent or waives or alters some or all elements of informed consent per the federal regulations, this is documented by the IRB and outlined in the approval letter to the PI.
  - 6) The IRB administrator(s) will ensure that submissions involving deception have complete information for the IRB, the IRB Chair, or designee to make the determinations for approval.
  - 7) IRB reviewers will document the rationale for approving research involving deception in the reviewer checklist and in the findings text box when making a decision in Cayuse IRB.