**Research that Includes Deception or Incomplete Disclosure**

There may be an occasion when a researcher needs to use an element of deception or to withhold specific study details from study participants in order to answer a research question.  These can be a valuable research techniques; however, the use of deception of any kind in research raises ethical and regulatory concerns regarding subject autonomy and respect for persons.

The CSU IRB has historically reviewed any protocol that had an element of deception via the full-board review process; however, studies that include Incomplete Disclosure may now be reviewed via the exempt-review process. The 2018 Common Rule revised regulations incorporates a new exemption that includes incomplete disclosure, a form of deception, in the review criteria (104(d)(3)(iii). This guidance is to provide researchers information to help you decide when the new Exempt #3 criteria may be appropriate for your research, what information to provide to the IRB in your protocol submission so that the reviewers can assess the risks to benefits of the use of this study design in your research, and sample text to be used in the consent process.

What is the distinction between Deception in Research and Incomplete Disclosure?

* **Deception** involves **intentionally providing inaccurate or false information** to subjects.

Note: Protocols that include this form of Deception will be reviewed by the full IRB at their convened meeting.

* **Incomplete Disclosure** involves **withholding information about the study purpose** and/**or reason for procedures** **in order to prevent biasing the results**.

Note on incomplete disclosure limitation: Incomplete disclosure does not extend to withholding information from subjects about what specifically they will be asked to do.

**Not eligible to be reviewed as incomplete disclosure**:

* + A protocol that informs subject that they will be asked to complete one 60-minute session but provides no information about what they will be asked to do in the session;
  + Any protocol that involves manipulating an individual’s environment, without that person’s prospective agreement to participate in research

**Risk Level**: Only study procedures that involve minimal risks (as determined by the IRB) can include deception or incomplete disclosure.

Examples Deception vs. Incomplete Disclosure:

* **Deception**: In order to induce stress, study personnel tell subjects that they will give a speech that evaluators will observe on video, but the subjects’ speeches will not actually be recorded or observed.
* **Incomplete Disclosure**: To further understanding of how representations of same sex couples depicted in commercials influence consumer behavior, subjects are exposed to advertisements featuring gay couples and straight couples while their heart rate, facial muscle movement, and sweat responses are recorded. Subjects are informed that their reactions to the commercials are being studied, but not that the researchers are examining if the sexual orientation of characters in commercials influences them.

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What is new in the 2018 Common Rule? Deception/Incomplete Disclosure in Exempt Research

Protocols that include incomplete disclosure are eligible for exemption IF the risk level is no greater than everyday living, the subject population are adults, the study procedures meet the review criteria as outlined in Exempt category #3 Benign Behavioral research, and the participants prospectively agree to take part in the research knowing that he/she will be unaware of or misled regarding the true nature or purpose of the research.

See exempt criteria #3: 104(d)(3)(iii)



IRB REVIEW CONSIDERATIONS AND ADDRESSING DECEPTION IN EPROTOCOL

**IRB Review Considerations:**

When reviewing protocols that involve deception, the IRB members will consider:

1. The scientific value and validity of the research.
2. The benefits gained by knowledge relative to the potential harm caused by deception.
3. The efficacy of alternative procedures.
4. The certainty that deception does not extend to influence participants’ willingness to participate.
5. The possibility of experimentally induced harm and the ability of the proposed procedures to remove such harm through debriefing.
6. The potential of deception to facilitate unwanted and inappropriate invasions of privacy.

**What information to include in your protocol Submission:**

“Protocol” portion of protocol, “Summary, Purpose, and Procedures” section (3d): “State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in attachments section.”In this section of protocol:

* 1. Justify the use of deception and explain in lay language why deception is necessary to achieve the goals of the study.
  2. State whether or not you believe the withheld information will affect the participant’s decision to participate in the research and why.
  3. Explain if alternative methods not involving the use of deception were considered and why these methods are not being used.
  4. For any protocol that involves deception, the IRB requires that all participants be debriefed. Accordingly, a debriefing file should be uploaded with your protocol. Describe your debriefing procedures and explain when participants will be debriefed and who will debrief them. The IRB generally expects the debriefing to be immediate. Any delay in debriefing must be explained and adequately justified. Subjects must have the opportunity to ask questions about the new information and be given the opportunity to withdraw from the study and have their data removed. The IRB’s preference would be that the participant is given an opportunity on the debriefing form to document their request to withdraw their data

Risk Section of protocol (8a-8c): Explain if the use of deception is likely to cause the participant psychological discomfort (i.e., stress, loss of self‐esteem in response to experimental manipulations, embarrassment at being deceived, or guilty at having been induced to commit regretted acts), and explain how these risks will be minimized during the research and after the research is complete.

**DEBRIEFING -** Unless a researcher can provide an acceptable justification for not debriefing the participants at the conclusion of the study, the IRB requires that all participants be debriefed. A debriefing file should be uploaded with your protocol. Your debrief must include the rationale for the study design, the true study purpose, and a description of the information that was false or incomplete. Provide references/websites for further reading on the research topic to make the debriefing an educational tool. When possible, include a documented option for the participant to withdraw his/her data after finding out about the deception. Offer to provide the participants a copy of the study results. Please find a Debrief Template in our Consent Template Section [Templates - Research Integrity and Compliance Review Office (colostate.edu)](https://www.research.colostate.edu/ricro/irb/templates/)

**CONSENT** - As a reminder, Incomplete Disclosure can only be considered to meet the Exempt #3 Benign Behavioral review criteria **IF** each participant is prospectively informed that s/he will be unaware of or misled regarding the true nature or purpose of the research. This language should be included in your consent process. Please find a Consent template for use of Incomplete Disclosure in our Consent Template Section (hyperlink) and see below for some examples of language that you may use to prospectively inform your participants.

**Examples of language that you may use to prospectively inform your participants includes:**

* Due to the nature of this study, we are not able to disclose the purpose of this research at this time. However, we will hold a debriefing session to answer your questions and tell you about the study after your participation.
* The full purpose of this research cannot be disclosed before you participate, but will be told to you at the end of the study.
* The purpose of this research project is to examine how decisions are made in negotiation. We are not able to provide you all details about the study at the beginning of the study, but we will provide more information during/after your participation.

**June 15, 2018 Ethics Committee of the American Psychological Association Rule and Procedures**

<https://www.apa.org/ethics/code/#807>

**8.07 Deception in Research**   
(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

(b) Psychologists do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.

(c) Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data. (See also Standard [8.08, Debriefing](https://www.apa.org/ethics/code/#808).)

**8.08 Debriefing**   
(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.

(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.

(c) When psychologists become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.