

DECEPTION & INCOMPLETE DISCLOSURE IN RESEARCH	SOP 6.3.01
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1. Purpose & Policy

This SOP provides guidance on the ethical use of deception or incomplete disclosure in research and describes related responsibilities of investigators. Additionally, this SOP outlines considerations of the Institutional Review Board (IRB) when reviewing and approving research involving deceptive methodologies and associated implications for the informed consent process. [IRB Policy Section 6.3](#).

2. General Information

- A. Informed consent, a vital component of The Belmont Report’s principle of respect for persons, becomes of special concern when deception or incomplete disclosure is used in research. Informed consent requires that participants enter research voluntarily and with adequate information about what it means to participate.

In certain situations, investigators may find it valuable to use deceptive methodologies in their research. For example, such use may be especially helpful in social and behavioral studies, where revealing the true purpose or nature of the research to prospective participants might compromise the validity of the study or introduce bias into the research results.

The IRB would generally require exceptional justification for studies that involve deception with Caltech students or personnel. The reason for this is that, given the small size of the Caltech community, public knowledge that studies use deception could reduce the validity of future participation.

The following criteria must be met for the IRB to consider approving a protocol using deception:

- The study involves no greater than minimal risk to the participants,
- The risks are disclosed to participants,
- There are no suitable alternatives to the deceptive methodologies available,
- The intention is never to persuade participants to join a study they may not have otherwise,
- The study never places participants in a position of engaging in illegal or stigmatized behavior,
- The study never places participants at financial, physical, legal, psychological, or social risk,
- The study could not practicably be carried out without the requested waiver or alteration of informed consent,
- The waiver or alteration of informed consent will not adversely affect the rights and welfare of the participants,

- Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

B. Definitions

Deception: When an investigator gives false information to participants or intentionally misleads them about some key aspect of the research. Examples include:

- An investigator describes an activity to participants as being more difficult than it truly is.
- An investigator tells participants they performed poorly on a task, regardless of their actual performance.

Incomplete Disclosure: A type of deception that involves withholding information about the study's real purpose or the nature of the research procedures. Examples include:

- An investigator asks participants to complete an exercise without disclosing that the study aims to assess how intermittent distractions affect their performance.
- An investigator informs participants that the study measures the time it takes them to complete a task but intentionally omits that their accuracy will also be evaluated.

Prospective Agreement: When an investigator informs prospective participants during the informed consent process that there are certain aspects of the research that will not be revealed or explained to them until after the study.

Debriefing: When an investigator informs participants that they were intentionally given false, misleading, or incomplete information about the study. The goal of debriefing is to reduce any harm which may have been caused by the deception or incomplete disclosure.

3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with deception and incomplete disclosure; however, investigators should carefully read and follow this guidance.

4. Procedure

A. Investigator Responsibilities

Investigators take on special responsibilities when they use deception or incomplete disclosure in their research. Investigators should always provide truthful answers to prospective or enrolled participants when asked a direct question about the research. Research where deception or incomplete disclosure is used may require prospective agreement from participants. Additionally, investigators should have an adequate plan for debriefing and disseminating research results to participants.

B. IRB Review

Research using deception or incomplete disclosure may qualify for exempt, expedited, or full committee IRB review depending on the nature, purpose, and other key aspects of the study. While protocols involving incomplete disclosure are eligible for exemption, protocols involving deception are ineligible unless a prospective agreement statement is included in the informed consent form.

C. Initial Query

1. In the *Query* section under *Human Subjects Research*, answer “Yes” to the question “Does this study involve deception or incomplete disclosure?”

☐ Yes ☐ No

Does this study involve deception or incomplete disclosure?

2. Answer the two follow-up questions regarding the use of a prospective agreement statement and debriefing.

If the answer is Yes, attach the requested documents.

Will you include a prospective agreement statement in the informed consent form or verbally during the consent process?

☒ Yes ☐ No

Please attach informed consent or a copy of the statement if given verbally.

Will you debrief participants following the study?

☒ Yes ☐ No

Please attach a copy of the debriefing script.

If the answer is No, provide justification.

Will you include a prospective agreement statement in the informed consent form or verbally during the consent process?

☐ Yes ☒ No

Please provide justification.

Will you debrief participants following the study?

☐ Yes ☒ No

Please provide justification.

D. Full Application

1. In the Study Participation section, check the appropriate box to indicate that the research will involve deception or incomplete disclosure.

Use of Deception: ☐ This research involves the use of deception. Deception is when a researcher gives false information to participants or intentionally misleads them about some key aspect of the research.

Use of Incomplete Disclosure: ☐ This research involves the use of incomplete disclosure. Incomplete disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures.

2. Provide justification for the use of deception or incomplete disclosure in the supplied text box. Include the following elements in your response:

- The risk to benefit ratio of the research,
- Why use of deception or incomplete disclosure is justified and necessary,
- How potential benefits of the research justify use of deception or incomplete disclosure,
- How special consideration has been given to the consent and debriefing process,
- When, how, and by whom information will be provided during debriefing, and
- Attach a copy of the debriefing script.

Use of Deception: ☒ This research involves the use of deception. Deception is when a researcher gives false information to participants or intentionally misleads them about some key aspect of the research.

* Justification for Deception:

Use of Incomplete Disclosure: ☒ This research involves the use of incomplete disclosure. Incomplete disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures.

* Justification for Incomplete Disclosure:

3. Additionally, address the following questions in your response:

- Will you include a prospective agreement statement in the informed consent form or verbally during the consent process? If not, please provide justification.

Will you include a prospective agreement statement in the informed consent form or verbally during the consent process?

☐ Yes ☐ No

- Will you debrief participants following the study? If not, please provide justification.

Will you debrief participants following the study?

☐ Yes ☐ No

4. In the Informed Consent section, choose “Signed Informed Consent obtained by Caltech investigators using a non-Caltech template (please attach)” if alteration of informed consent is necessary.

Informed Consent form has been created.

- ☐ Signed Informed Consent Required
- ☐ Assent Required (For children age 7-17, please attach) in addition to signed parental consent
- ☒ Signed Informed Consent obtained by Caltech investigators using a non-Caltech template (please attach)
- ☐ Informed Consent obtained by another institution (please attach)

In the Informed Consent section, choose “Waiver of Written Informed Consent requested (please attach)” or “Waiver of Informed Consent requested (both written and verbal)” if you would like to request to waive written Informed Consent or waive Informed Consent entirely.

☒ Waiver of **Written** Informed Consent requested (please attach)

☐ Waiver of Informed Consent requested (both written and verbal)

* Justification:

Review and approval of deception or incomplete disclosure requires that the proposed research study be acceptable, in the necessary absence of fully informed consent, on the condition that waiver or alteration of consent is acceptable.

E. Debriefing

1. During debriefing sessions, investigators should:
 - Describe the nature of the deception or incomplete disclosure,
 - Reveal any study information that was previously withheld,
 - Explain the rationale for why it was necessary to use deception or incomplete disclosure,
 - Present the discussion in lay language that is easy for participants to understand, and
 - Provide participants with the opportunity to ask questions.
2. If decided by the investigator, or if required by the IRB, the debriefing can include an option for participants to withdraw their data from the study after they learn the true nature of the research. If the study involves deception or incomplete disclosure at the time of enrollment or consent that could have materially influenced the participant’s decision about study participation, and/or the deception or incomplete disclosure would likely be perceived by participants as an invasion of privacy (e.g., video recording without prior consent), the IRB may require re-consent for the use of data as part of the debriefing process.

If the investigator chooses, or the IRB requires, to provide participants with the option to withdraw their data upon being debriefed, the investigators will need to keep sufficient identifiers or links to identifiers for participants to exercise this option.

3. Additionally, ensure participants are appropriately compensated for their time and participation in debriefing sessions. Follow [SOP: Compensation for Research Participants](#).

5. Informed Consent (IC)

It is best practice for investigators to include a prospective agreement statement in the informed consent form when using deception or incomplete disclosure in research. This ensures that prospective participants are informed that they are being invited to participate in research of which some features will not be revealed until the study has concluded. PAS includes the below template language in the protocol application and informed consent form. These statements should be modified depending on the deceptive methodologies used and whether participants will be debriefed following the study.

Statement for Deception: *This study requires that the investigator and/or study team provide you with false or misleading information about some key aspect of the research, the real purpose of the study, or the nature of the research procedures. This was determined necessary to maintain scientific validity and/or to ensure that bias is not introduced into the research results. [After the study's completion, the investigator will hold a debriefing session with you. During this session, you will be provided with complete and accurate information about the research and given your research results. You will also have adequate opportunity to ask and have your questions answered.]*

Statement for Incomplete Disclosure: *This study requires that the investigator and/or study team provide you with incomplete information about some key aspect of the research, the real purpose of the study, or the nature of the research procedures. This was determined necessary to maintain scientific validity and/or to ensure that bias is not introduced into the research results. [After the study's completion, the investigator will hold a debriefing session with you. During this session, you will be provided with complete and accurate information about the research and given your research results. You will also have adequate opportunity to ask and have your questions answered.]*

When participants are not given a prospective agreement statement or complete information about the study in the Informed Consent document, the PI must include a request to waive or alter the required elements of informed consent in the protocol application.