DECEPTION AND INCOMPLETE DISCLOSURE IN RESEARCH

This guidance document is intended for investigators planning to conduct research that involves use of deception or incomplete disclosure. Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

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A. Overview

The CPHS recognizes that deception and incomplete disclosure may be valuable research methodologies, yet their use presents special challenges to ensure that the research is conducted ethically. At times, especially in social and behavioral research, deception or incomplete disclosure is necessary to avoid study bias or test a hypothesis that requires the participant's misdirection. On the other hand, the regulations for obtaining informed consent from research participants (§45 CFR 46.116) in general require full disclosure of all elements relevant to the subject's participation in the research. *Deception and incomplete disclosure raise concern as they may interfere with the ability of the subject to make a fully informed decision about whether or not to participate in the research.*

Thus, proposed research involving deception or incomplete disclosure necessitates special considerations by the CPHS. To determine when certain restrictions apply, the CPHS will consider the extent to which the deception in a given study interferes with the subject's ability to give informed consent. This includes distinguishing whether "deception" or only "incomplete disclosure" (without deception) is involved, whether there is sufficient justification for use of such measures, and whether there is an appropriate consent and debriefing process in place.

B. Definitions and Examples

1. ***Deception*** occurs when an investigator gives false information to subjects or intentionally misleads them about some key aspect of the research. (This is sometimes referred to as "active deception.")

2. ***Incomplete disclosure*** occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research. *Withholding information may or may not be considered deception*.

Examples of *deception*:

- The subject is given a "cover story" which falsely describes the purpose of the study, but provides a plausible account of the researcher's objective.

- 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.

Example of *incomplete disclosure*:

- 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.

For additional examples and guidance, please see the FAQ on Incomplete Disclosure and Deception in Research.

C. Points to Consider

In keeping with federal regulations and ethical codes established by the Belmont Report and the American Psychological Association, CPHS will consider the following points when reviewing research involving the use of deception or incomplete disclosure:

1. As explained in Section D of this document, the study must not involve any more than minimal risk to the subjects.

2. The use of deceptive techniques must be justified by the study's prospective value AND there should be no reasonable alternative method that would be equally effective (i.e., the researcher must demonstrate that the deception is necessary to conduct the study).

3. Prospective subjects must not be deceived about research that is reasonably expected to cause physical pain or severe emotional distress.

4. If the study design allows, subjects should be told in the consent form or during the consent process that some information is being withheld or is incomplete, and that they will receive more information after their participation in the research, or the entire research project, is complete. (See Section E of this document for more in debriefing.) However, a researcher may have good reasons not to debrief, if, for example, they believe that even vague references to hidden purposes will affect subjects' behavior and make the study impracticable, or if debriefing might harm the subject. In this case, investigators should note in their protocols why it is not feasible to debrief – at all, or fully debrief – at the end of an individual's participation.

5. In addition, the research must meet the criteria for a waiver of one or more elements of informed consent, as described below in section D, *Informed Consent.*

6. NOTE: Use of incomplete disclosure or deception is rarely permitted in exempt studies; such studies typically are reviewed as expedited rather than exempt. Please refer to Exempt Research for specific guidance before submitting an exempt application.

D. Informed Consent:

When a study involves deception and/or incomplete disclosure, the consent process does not meet the standard of "fully informed consent." When the consent process will not disclose pertinent information about the research, the CPHS must consider whether the research meets all of the

criteria for a waiver of one or more elements of informed consent as set forth in federal regulations at 45 CFR 46.116(f)(3).

The criteria for a waiver of one or more elements of informed consent are:

i. The research involves no more than minimal risk to subjects;

ii. The research could not practicably be carried out without the waiver or alteration;

iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

iv. The waiver or alteration will not adversely affect the rights and welfare of subjects; and

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

E. Debriefing:

Debriefing the participant, when feasible and appropriate, is an important aspect of the informed consent process in deceptive studies. It gives the investigator an opportunity to explain any deception or incomplete disclosure involved, as well as to help the subjects deal with any distress or discomfort occasioned by the research. If the study involves deception at the time of subject enrollment or consent that may have influenced the subject's decision about participation, and/or the deception would likely be perceived by subjects as an invasion of privacy (e.g., videotaping without prior consent), *the CPHS may require re-consent for use of data as part of the debriefing process after study participation*.

***Exceptions to Debriefing Requirement*:** There may be instances when debriefing would be inappropriate, such as when the debriefing itself may undermine the coherence of the research design, or may present an unreasonable risk of harm without a countervailing benefit. For example, if an individual were selected for participation in a study about group behavior based on a previously measured "negative" behavior or characteristic, it might not be appropriate for the debriefing to describe the selection process. In such cases, the CPHS would not recommend or require detailed debriefing.

***Delayed Debriefing*:** In certain cases, debriefing immediately after a subject's participation would compromise study results (e.g., the study is ongoing and early subjects might tell others about it, making it impossible for the researchers to obtain valid/unbiased results from later subjects). Under such circumstances the CPHS may approve a delayed debriefing process, such as sending debriefing information to participants via email or regular mail (if subjects' contact information is kept), or giving subjects a website URL where they can get debriefing information when the study has been completed. (In some cases, it may be sufficient to ask the subject being debriefed to not reveal such information to others.)

***In general, the debriefing process should consist of the following**:*

1. Disclosure of the deceptive aspect(s) of the study, and what the actual study objective was. This should be presented in clear lay terms, similar to the consent document. Extremely technical/ detailed explanations of study hypothesis, intentions of each task, etc., are not typically required.

2. An explanation of the reasons for the deception. The reasons should be clearly explained, in language sensitive to subjects' possible discomfort or embarrassment at having been deceived.

3. An opportunity for the subject to ask questions.

4. *If required by CPHS*, an opportunity for the subject to withdraw the provided data. The CPHS will decide on a case-by-case basis whether it is necessary to *re-consent* subjects to use study data obtained under deceptive premises. For example, in cases that involve only incomplete disclosure, a post-study information sheet that gives additional information about the study but does not ask for re-consent to use data will usually be acceptable. In contrast, when deception at the time of subject enrollment or consent is likely to have influenced the subject's decision about whether or not to participate in the research, or when the deception would likely be perceived by the subject as an invasion of privacy, the subject's signature to permit use of such data will usually be required.

The debriefing document should be submitted on UCB letterhead as part of the consent documentation for CPHS review. Signed documents should be retained and included in the maintenance plan for consent documents described in the Confidentiality section of the protocol. Please refer to the attached sample for assistance in creating an appropriate debriefing form.

[SAMPLE]

Debriefing Form
Study Title
CPHS# [*Protocol ID*]

Our research actually focuses on the development of "status hierarchies" in small groups. In many small groups such as project teams, ad hoc committees, or juries, some people tend to "take charge" more than others. However, the process by which these small group hierarchies develop is not well understood. In this study, we are attempting to understand what happens when two members of a group disagree as to who should take charge.

To try and obtain unbiased or natural reactions, we had to give you some false information at the beginning of the study. We informed you that, based on your scores on the tests from the prescreening packet, we had determined that you were the most suited to lead the group in the group task, and we told you that you were the only member in the group who received this information. But in fact, we gave this same information to one other group member, i.e., we also told this group member that he or she was the person best suited to lead the group. Thus, each of you was under the impression that you were uniquely suited to lead the group.

This was necessary for us to better understand how status disagreements proceed and how they are resolved. By telling two of you that you were each best suited to lead the group, it was much more likely that a status disagreement would emerge. Without telling two of you, it was more likely that only one person would attempt to "take charge," and thus no status disagreement would occur. We apologize for misleading you, but we believe this was the only way to examine the processes that are the object of our research. In designing this study, we took care to minimize any possible risks or discomforts that might be related to the deception.

[*If obtaining re-consent*: Now that you understand the true nature of our study, you have the chance to refuse the use of the data we collected from you for research purposes. You are free to ask us not to use your data in our study analysis. If you decline to let us use your data, you will still receive the $15 payment just as you would if we use your data in our analysis. This is entirely voluntary, but we hope to analyze as much data as possible to better understand the processes by which status hierarchies develop in groups.]

[*If appropriate*: Because this experiment is ongoing, we request that you not share the true nature and purpose of this experiment with others who might potentially participate in our study.]

If you have any questions about this research you may ask them now, or contact me, NAME OF LEAD INVESTIGATOR, later at (xxx) xxx-xxxx or LI@berkeley.edu. If you have any questions regarding your treatment or your rights as a participant in this research project, please contact the University of California, Berkeley Committee for Protection of Human Subjects at (510) 642-7461 or subjects@berkeley.edu.

[*If <u>not</u> obtaining re-consent, end the form here, e.g.*: You may keep this debriefing form for your future reference. Thank you again for your participation in our research!]

[*If obtaining re-consent*: If you agree to allow us to use the data, please sign this form below. You may keep the other copy of this form for your future reference.]

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I have read this debriefing form and I agree to allow the use of my data for research purposes.

_____
Name (printed)

_____ _____
Signature Date