IRB GUIDANCE ON THE USE OF DECEPTION OR INCOMPLETE DISCLOSURE IN RESEARCH

1. OVERVIEW

The IRB recognizes that deception or 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. However, the regulations for obtaining informed consent from research (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 IRB. To determine when certain restrictions apply, the IRB 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.

2. DEFINITIONS AND EXAMPLES

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

- 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.
- Participants complete a quiz and are falsely told that they did poorly, regardless of their performance.
- Participants who don’t know they are in a research study are observed to see how they behave when they find valuables (e.g., wallet, laptop) unattended in a public location.
- 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.

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 include:

- Participants are asked to take a quiz for research, but they are not told the research question involves how background noise affects their ability to concentrate.
- Participants are told they are completing a survey to evaluate customer service when the true purpose of the study is to correlate psychological responses with patient care satisfaction.

Incomplete disclosure that is also deception. An example:

- The study involves audiotaping or videotaping of subjects without their knowledge or prior consent.
3. IRB GUIDELINES

3.1 Level of IRB Review

Research involving incomplete disclosure but no deception may be reviewed as Exempt. Research employing deception may not be reviewed as Exempt. Research that involves mild deception where the topic is not sensitive and the participants are not vulnerable may be reviewed as Expedited but is more likely to be reviewed by the Full Board. The IRB Reviewer, in consultation with the IRB Chair and/or the IRB Coordinator, will make the determination whether Full Board review is required. Principal investigators should expect that any proposal sent for Full Board review will require a longer review time which could delay the start of the research by up to two months.

3.2 Criteria for IRB Approval

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

1. 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 any physical or psychological risks, discomforts, or unpleasant emotional experiences of the study.

4. If the study design allows, subjects should be told during the original consent process that some information is being withheld or is incomplete, and that they will receive more information after the research is over. This is sometimes known as “authorized deception” because it provides participants with an opportunity to decide whether or not to participate, knowing that they aren’t receiving complete information. However, researchers often believe that even vague references to hidden purposes will affect subjects' behavior and make the study impracticable. Investigators should either add such language to their consent forms when it is possible or note in their protocols why it is not feasible to do so.

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 3.3, Informed Consent.

6. Whenever appropriate, researchers should debrief participants. The debriefing should occur as early in the study as the design permits, preferably at the conclusion of a subject’s participation, but no later than the conclusion of the research. See information about the debriefing process below in section 3.4, Debriefing.
3.3 Informed Consent

The basic principles that guide the ethical conduct of human research support complete informed consent that provides participants with sufficient information in an understandable format to allow them to choose what will happen to them. However, research designs that use deception or incomplete disclosure do not allow participants to prospectively provide complete informed consent for research participation.

In studies involving deception and/or incomplete disclosure, fully informed consent is not obtained from subjects prior to participation. When the consent process will not disclose pertinent information about the research, the IRB 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(d).

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 waiver or alteration will not adversely affect the rights and welfare of subjects;
iii. The research could not practically be carried out without the waiver or alteration; and
iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

3.4 Debriefing

Debriefing the participant 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 IRB may require a re-consent for use of data as part of the debriefing process after study participation.

3.4.1 Exceptions to Debriefing Requirement: There may be rare instances when debriefing would be inappropriate, such as when the debriefing itself 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 IRB would not recommend or require detailed debriefing.

3.4.2 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 IRB 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 not to reveal such information to others).
3.4.3 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 simple, 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. (These reasons should also be clearly explained, in language that is sensitive to subjects' possible discomfort or embarrassment at having been deceived).

3. An opportunity for the subject to ask questions.

4. *If indicated*, an opportunity for the subject to withdraw the provided data. (The IRB 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 debriefing form 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.)

4. **APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.102 (i): Definition of minimal risk
45 CFR 46.116: General requirements for informed consent
45 CFR 46.116 (d): Criteria for waiver of one or more elements of informed consent
Belmont Report
UND IRB Standard Operation Procedure 701: Informed Consent
UND IRB Standard Operating Procedure 702: Informed Consent Waivers
UND IRB Standard Operating Procedure 703: Informed Consent Documentation

5. **REFERENCES**


University of California, Berkeley, Committee for the Protection of Human Subjects Guidelines on Deception and Incomplete Disclosure in Research, April 2010.


6. **DOCUMENT VERSION**

v.1.0: May 8, 2015
7. APPENDICES

7.1 Flowchart for Protocols Containing Deception or Incomplete Disclosure

7.2 Debriefing Examples
7.1: Flowchart for Protocols Containing Incomplete Disclosure or Deception

Does the protocol conform to all other regulations and standards for exempt or expedited research protocols?  

Yes  

Is the deception or incomplete disclosure unrelated to an increase in risk of physical injury or severe emotional distress or other negative consequences that could foreseeably arise?  

Yes  

Does this protocol only use incomplete disclosure rather than deception? (See policy guidance above for definitions.)  

Yes  

Does the consent form fully disclose to participants the procedures and/or any tasks they will be asked to complete?  

Yes  

Is the deception limited to either a) concealing the true purpose of the study from participants (i.e., using a 'cover story'), or b) using a research confederate (real or pretend)?  

Yes  

This protocol may qualify for expedited review. Contact the IRB office for assistance (701-777-4279).

No  

This protocol requires Full Board review.

No  

No
For the study entitled: ________________________________

Dear Participant;

During this study, you were asked to ________________________________1. You were told that the purpose of the study was to ____________________2. The actual purpose of the study was ____________________3.

We did not tell you everything about the purpose of the study because ________________4.

You are reminded that your original consent document included the following information about voluntary participation: You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you have any concerns about your participation or the data you provided in light of this disclosure, please discuss this with us. We will be happy to provide any information we can to help answer questions you have about this study.

Now that you know the true nature of the study, you have the option of having your data removed from the study. If you do so, there will be no penalty. You will still receive full credit or payment for your participation in the research (if applicable). Please contact the PI if you do not want your data to be used in this research and it will be withdrawn.

Study contact for questions about the study or to report a problem: If you have questions, concerns, or complaints or think the research has hurt you, please contact me at (contact info), or my faculty advisor, (name, contact info).

IRB contact about your rights in the study or to report a complaint: Research at the University of North Dakota involving human participants is carried out under the oversight of the Institutional Review Board in the office of Research Development and Compliance. This research has been reviewed and approved by the IRB. For information about the rights of people who take part in research, please contact the Institutional Review Board at 701-777-4279.

If you have experienced distress as a result of your participation in this study, a referral list of mental health providers is included for your use.5 (Please remember that any cost in seeking medical assistance is at your own expense.)

Please again accept our appreciation for your participation in this study.

Instructions:
1. Using information from the original consent document, describe the task.
2. State the purpose, as written in the consent.
3. State the actual purpose.
4. Reasons for not being forthright; and how/why the study was successful.
5. Include, if applicable, and provide a list of medical/mental health providers for the participants’ associated with UND or in the geographic area, if applicable.
Thank you for your participation in our research study, [insert name of study].

I would like to discuss/share with you in more detail the study you just participated in and to explain exactly what we were trying to study.

Before I tell you about all the goals of this study, however, I want to explain why it is necessary in some kinds of studies to not tell people all about the purpose of the study before they begin. [alternate language for deception studies: “… to not tell people all about the procedures in which they will be asked to participate.”]

As you may know, scientific methods sometimes require that participants in research studies not be given complete information about the research until after the study is completed. Although we cannot always tell you everything before you begin your participation, we do want to tell you everything when the study is completed.

We don't always tell people everything at the beginning of a study because we do not want to influence your responses. If we tell people what the purpose of the study is and what we predict about how they will react, then their reactions would not be a good indication of how they would react in everyday situations.

[insert explanation of study purpose, describe the information about the study purpose or the study procedures that was withheld and explain the reason why the information was withheld, as applicable.]

If other people knew the true purpose of the study, it might affect how they behave/answer questions, so we are asking you not to share the information we just discussed.

Now that the study has been explained, do you agree to allow the investigator to use the data that we collected from your participation in this study? [If you decide not to allow the use of your data in the research, you will still receive full credit or payment for your participation in the research.]

I hope you enjoyed your experience and I hope you learned some things today. If you have any questions later please feel free to contact me. [provide sheet with contact names, addresses, telephone numbers, emails, for Principal Investigator, Faculty Sponsor, other co-investigators]

Do you have any other questions or comments about anything you did today or anything we've talked about? If you have questions, concerns, or complaints or think the research has hurt you, please contact me at (contact info), or my faculty advisor, (name, contact info).

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Thank you again for your participation.