**Guidelines for Deception, Incomplete Disclosure, and Debriefing in Human Subjects Research**

The TCU IRB follows certain criteria when utilizing deception in research, including active

deception and deceptive incomplete disclosure. While the use of deception may be a valuable

methodology to avoid bias or test a hypothesis, these techniques raise important ethical issues.

 **Deception** is when an investigator gives false information to research participants and intentionally misleads them about some key aspects of the research. Relating to the purpose of the study, the role of the researcher or other participants, the true nature of the procedures, or other parts of the study. Deception is common in studies that evaluate human behavior and may occur either as a part of the Consent Process or within the study procedure themselves. The rationale for deception in this setting usually is to stimulate behaviors in participants that would not occur without an active manipulation, in contexts where it is not possible to obtain accurate information about how people behave when they know they are being observed or evaluated.

**Incomplete Disclosure** is when the investigator withholds some information about the real purpose of the study or the nature of the research procedures during the Consent Process to avoid biasing results.

The use of deception/incomplete disclosure in human subjects’ research raises special concerns for the IRB to consider with regard to informed consent and analysis of risk and benefits.

Unethical uses of deception in research can cause distress to those being deceived and undermine public trust in the research enterprise. When studies use deception or incomplete disclosure in their procedures, the IRB will determine whether the deception/incomplete disclosure is necessary to make the research scientifically valid and feasible. The IRB will consider whether the study population is appropriate for the study procedures that involve deception /incomplete disclosure of information and will consider potential harms of these methods. The IRB never allows for deception/incomplete disclosure that affects the participant’s willingness to take part in the study.

**Deception may only be used:**

* When the risk is no greater than minimal; and
* When the research is not feasible without the deception; and
* When debriefing is provided

Examples of Deception:

* In order to induce stress, research personnel tells participants that they will give a speech that will be evaluated and observed on video, when the participants’ speeches will not actually be recorded or observed.
* Participants complete a quiz and are falsely told that they did very poorly, regardless of their performance.
* In a study of anxiety, participants are told to expect mild pain during the course of the study, but no painful procedures are administered.
* Research Personnel tells participants that they will be engaged in a cooperative task with other participants, but instead, participants will actually be interacting with study personnel.

Examples of Incomplete Disclosure:

* Participants are to take a quiz for research, but they are not told the research questions involve how background noise affects their ability to concentrate.
* Participants are told they are completing a survey to evaluate customer service when the study’s true purpose is to correlate psychological responses with patient care satisfaction.

**Deception for Exempt review**

The 2018 Revised Common Rule allows for deception to be approved as Exempt, if participants authorize the deception through a prospective agreement to participate in research whereby the participant is informed that he or she will be unaware of or misled regarding the nature or purpose of the research, and the research falls into one or more Exempt research categories.

**Information to Include in Your Protocol Document**

* In the Consent Procedures, explain the process of debriefing statement that will be given to participants and the script that will be used by the investigators to orally explain the study (see below for guidance regarding the debriefing).
* In the Study Procedures, justify the use of deception and explain why deception is necessary to achieve the goals of the study. Explain if alternative methods not involving use of deception were considered and why these methods are not being used.
* In the Potential Risks, explain if use of deception is likely to cause the participant psychological discomfort (i.e., stress, loss of self-esteem, embarrassment) while the deception is taking place. Explain how this risk will be minimized during the experiment and after the experiment is complete (i.e. full debriefing).
* In the Potential Benefits section, describe how the potential benefits of the research justify the deception.
* Request a Waiver or Alteration of Informed Consent. When participants are not given complete information about the study in the consent document, the IRB must determine that research qualifies for a waiver or alteration of the required elements of the consent process (i.e., an explanation of the purpose of the research, a description of the procedures involves, etc.) This request can be made under the Consent Procedures.

**Informed Consent**

The basic principles that guide the ethical conduct of human research include a complete informed consent, that provides participants with sufficient information in an understandable format to allow them to choose what will happen to them.

Deception and incomplete disclosure may interfere with the ability of the research participants to make a fully informed decision about whether or not to participate in the research. In general, deception is not acceptable if, in the judgment of the IRB, the participant may have declined to participate had they been informed of the true purpose of the research. Research using deceptive methods involves omitting one or more of the required elements of consent, usually all or part of the true study purpose and the risk of the deception itself. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, provided the IRB finds that:

* The research involves no more than minimal risk to the participants;
* The waiver or alteration will not adversely affect the rights and welfare of the subjects;
* The research could not practicably be carried out without the waiver or alteration; and
* Whenever possible, the subjects will be provided with additional pertinent information after participation (a complete debriefing).

When appropriate, researchers are encouraged to consider using a prospective consent process that informs participants that a study will not be described accurately or that some procedures will be deceptive and provides them an opportunity to decide whether or not to participate on these terms. Below is sample language for consent forms:

*For scientific reasons, this consent form does not include all of the information about the research question being tested. The researchers will give you more information when your participation in the study is over.*

**Debriefing Procedures**

The debriefing process, including any written materials, will be explained to the IRB as a part of the submitted protocol. The debriefing should include a detailed description of the ways in which deception was used and explain why the principal investigator was unable to disclose this information before the study. The researcher is responsible for ensuring that the participants leave the research setting with an accurate understanding of the deception unless the IRB approves a waiver.

As indicated above, the debriefing must occur “when appropriate.” It may be inappropriate when: debriefing regarding the deception may cause more harm than the deception itself. For example, suppose a student is selected for participation in a study based upon certain physical characteristics (i.e., weight). In that case, it might not be appropriate for the debriefing to describe that aspect of the selection process. The timing of the debriefing is also an important consideration. Generally, the IRB expects that participants will be debriefed immediately following their participation in the study. However, it is possible that an immediate debriefing may compromise study results. Participants who have completed the study might tell others about it. If they have been debriefed and may share that information with prospective participants, thus compromising the scientific validity of the study. The IRB recommends the use of the following strategies to handle this situation. If participant names and contact information are collected as part of study procedures, debriefing information can be sent when the study is completed via mail, email, or phone.

If participant names and contact information are not collected, researchers can:

* Give participants a URL where they can get debriefing information and a date upon which it will be available.
* Have each participant address an envelope to themselves before they leave the study session and send them debriefing information when the research is completed.

In most cases, the IRB expects that participants will be given a debriefing statement to take with them after the study is complete and after participants have been given an oral debriefing (script) immediately following completion of the study. Both the debriefing statement and the debriefing script must be reviewed and approved by the IRB.

The process to debrief participants must be explained in the IRB protocol. Address the following elements:

* Indicate who will debrief participants. The IRB expects that this person is a research team member, someone knowledgeable about the research and the deception. If the research is student-directed (i.e., related to graduate studies, master’s thesis, or doctoral dissertation), the IRB expects that the student researcher will debrief participants.
* Indicate when participants will be debriefed. Again, the IRB generally expects that participants will be immediately debriefed after they complete the study. Any delay in debriefing must be explained and justified.
* Provide a rationale for any elements of the deception that will not be revealed to participants.

At a minimum, the debriefing statement must include the following (Please complete and include the **Debrief Form/Script with your submission** :

* Label the form as “Debriefing Statement.”
* Study title
* PI name and contact information for follow-up questions
* Student researcher’s name and contact information, if applicable, for follow-up questions.
* Thank participants for taking the time to participate in the study
* Explain what was being studied (i.e., purpose, hypothesis, aim). Use lay terms and avoid the use of jargon.
* Explain how participants were deceived
* Explain why deception was necessary in order to carry out the research
* Explain how the results of the deception will be evaluated
* If the study involves the use of audio or video-recording an individual participant, give the

participant an opportunity to withdraw his/her consent for the use of the recordings and,

potentially, withdraw from the study altogether, after the true purpose of the study is

revealed. The IRB suggests that participants be given at least 48 hours to make this decision and

provide contact information for whom participants should contact regarding their withdrawal

from the study. This option must be given to participants even if they were video or audio recorded during a focus group or during an experiment involving other participants. If a

the participant decides to withdraw; the PI must use video editing tools to make an individual who withdraws unidentifiable. If tools are not available, the PI cannot use the video or audio

recording.

* If the study did not involve audio or video recording but involves sensitive topics, it may be appropriate to give participants an opportunity to withdraw their consent and potentially, withdraw from the study all together, after the the true purpose of the study is revealed. This option must be given to participants, and the IRB suggests that participants be given at least 48 hours to make this decision and provide contact information for whom participants should contact regarding their withdrawal from the study.
* Provide participants an opportunity to withdraw their consent to participate or to withdraw their data from the study.
* Please inlcude:
	+ Explain anticipated or observed results so far
	+ Offer to provide them with study results
	+ Provide references/website for further reading on the topic
	+ Provide a list of resources participants can seek if they become distressed after the study.

The TCU IRB has provided a deception research debriefing form template for researchers to use.

 Source material provided in this guidance is provided by *University of Connecticut IRB.*