# INSTRUCTIONS FOR ADDENDUM RESEARCH INVOLVING DECEPTION

1. **Background for Investigator:**

You should read Section 7.10 of the [UM Investigator Manual](https://hsro.uresearch.miami.edu/_assets/pdf/hrp-103-investigator-manual.pdf) before submitting this research.

 The Department of Health and Human Services has revised the regulations for human subjects research effective January 21, 2019. The rule allows for most social behavioral research to qualify as exempt or exempt with limited IRB review. Most studies involving deception or incomplete disclosure do not qualify for an exemption. Exemption Category 3 may apply if the research provides subjects with advance notice of the deception. For more information about exemptions and deception research, you may refer to the [Investigator Manual](https://hsro.uresearch.miami.edu/_assets/pdf/hrp-103-investigator-manual.pdf), HRP-103, Sections 5.1.

1. **How to Use This Addendum:**
* This addendum is to be used as a supplement to the main protocol. It can be embedded within the protocol or added to the end of the protocol.
* Please take the time to read all italicized instructions and questions.
* Delete the red italicized instructions before submitting to the IRB.
* Depending on the nature of what you are doing, some sections may not apply to your research. If so, delete the section.

**(Please remove the instructions and use only the content going forward)**

**Addendum to Protocol**

1. Objectives/ Aims of the Deception

Justify the use of deception and explain why deception is necessary to achieve the goals of the study. Explain if you considered alternative methods not involving use of deception and why you are not using these alternatives.

 *Click here to enter text.*

1. Deception or Incomplete Disclosure Procedures *(Note: If you are audio and/ or videotaping the participant, Florida law requires you to inform the participants and obtain their permission. The law applies even when your research involves deception.*

Describe the deception or the incomplete disclosure procedure:

 *Click here to enter text.*

1. Consent Process

*When participants are not given complete information about the study or when they are given false information during the consent document, the IRB must waive certain required elements of the consent process (i.e. an explanation of the purpose of the research, a description of the procedures involved, etc.). In most instances the University of Miami requires you to inform the participant (i) that s/he is not receiving complete information about the study; and (2) about the deception as soon as possible, usually immediately after the participant completes the study. This last procedure is called “debriefing.” A copy of the debriefing script, handout or webpage must be included in the IRB protocol documents.*

3.1 The study will obtain consent before initiating study procedures.

[ ]  The consent process will not inform subjects of the following:

*Click here to enter text.*

[ ]  The consent process will provide the following false information to the participants:

*Click here to enter text*

The consent process will inform the participant that the information they received:

[ ]  Is incomplete.

[ ]  Is false

*If no, justify the decision to provide incomplete information or false information to the participant.*

*Click here to enter text.*

The consent process will inform the participant that they will receive complete and truthful information about the study after they finish their participation.

[ ]  Yes [ ]  No

*If no, provide justification for not informing participants that they will receive the complete and truthful information after they finish the study.*

*Click here to enter text.*

3.2 The debrief will be conducted in the following manner:

The study team will debrief participants:

[ ]  In person

[ ]  Online

[ ]  Via handout

[ ]  Other *(Describe debriefing process.)* *Click here to enter text.*

**[ ]**  N/A. *(Provide justification)* Participants will not be debriefedbecause*Click here to enter text***.**

*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.*  *If you are delaying the debrief for a specified amount of time, justify the delay and explain when and how debrief will be conducted.*

3.3 The study team will debrief participants:

[ ]  Immediately after participation

**[ ]** Other**.**  *Describe when you will debrief participants and provide justification for the delay*. *You must provide a compelling rationale in your protocol for not debriefing.*

*Click here to enter text.*

1. Risks to Subjects *(Note: Federal regulations prohibit the use of deceptive techniques that place participants at greater than minimal risk)*

*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)*

[ ]  This research involves only minimal risk, if any. The risks involved with deception will be minimized by:

*Explain: Click here to enter text.*

1. Potential Benefits to Subjects

☐ The research cannot be performed in the absence of deception and the benefits of the research will sufficiently outweigh any risks that deception may create.

☐ Other – Describe *Click here to enter text*. *(Compensation for participation is not considered a benefit of the research)*