

GUIDANCE DOCUMENT
Research Protocols and Deception
Aurora Health Care's Research Subject Protection Program (RSPP)

The purpose of this guidance document is to assist investigators /study coordinators regarding research proposals that include potential deception and to provide guidelines to appropriately prepare study materials to account for deception, alteration of informed consent and debriefing.

In research involving deception or incomplete disclosure, the IRBs evaluate the potential harm of debriefing on a case-by-case basis. In most research involving deception, particularly in research which may induce psychological stress, guilt or embarrassment, IRBs follow OHRP's suggestion that subjects be debriefed at the end of their participation. Debriefing should include an explanation of any deception involved and counseling for subjects in dealing with any distress experienced due to their participation in research. The debriefing process can be perceived as the final step in the informed consent process in which the subject is finally informed completely of their participation in the research and given the opportunity to withdraw their data. Approval of research involving deception requires approval of a waiver or alteration of the informed consent process.

If your study includes elements which the participant will not be completely informed of in the initial consent you should consider whether the research constitutes deception. An example of such research would be the inclusion of a sham device/procedure or placebo drug when the subject is led to believe that they will receive a treatment that the investigator believes may produce a result. For example, the subject is not informed of the placebo/sham and believes they will be randomized to a treatment arm. Studies where subjects are informed of the placebo or sham portion and are aware that they may be randomized to that arm do not involve deception. Another example would be if the subject was not fully informed of the studies objective in order to preserve the integrity of the study data and not sway subject response based on their knowledge of the hypothesis.

In research studies involving deception the IRB must consider whether the study qualifies for an alteration of informed consent. In these cases, rather than altering informed consent by removing one of the standard elements, an alteration of informed consent means that the initial consent process does not include all information about the study treatment or procedures that is known to the investigator. The IRB must decide if it is appropriate to alter the initial consent by not including this information and decide whether subjects need to be provided with relevant additional information after the study is complete.

The following page provides specific guidance in filling out the submission form, developing a consent form, and developing a debriefing process for studies that include deception.

Submission application:

Section VII of the submission application covers the request for a waiver or alteration of informed consent. The IRB must determine whether the element of deception qualifies for an alteration of informed consent per the federal regulations.¹ In order to do so, the IRB must find and document that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

This "additional pertinent information" would be provided in the debriefing process.

When requesting an alteration of informed consent you should fill out this section of the submission application and ensure that you have included adequate information for the Board to find and document the determination to alter consent as described above.

Informed Consent Form:

If your study includes deception, the IRBs recommend inclusion of one of the following phrases in the introductory paragraph of the informed consent form:

For scientific reasons, this consent form does not include complete information about the study hypotheses and the research questions being tested. You will be fully debriefed following your participation in the research.

OR

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation.

OR

Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the hypothesis that was tested and other relevant background information pertaining to the study. You will also be given an opportunity to ask any questions you might have about the hypothesis and the procedures used in the study.

Debriefing Process:

Primary goals of a debriefing process:

- Inform subjects of the true goals of the research study,
- Remove any effects of false information they were given,
- Educate participants about the research process, why deception is sometimes necessary, how false beliefs can sometimes persevere,
- Make participants feel that they are an important part of the research process, and
- Give the participants an option to decide whether or not they agree to have their data used after they are fully informed or whether they wish to withdraw their consent now that the consent process is complete.

¹ 45 CFR 46 116(d)

Sample Debriefing Script/Information Sheet:

Thank you for your participation in our research study, *[insert name of study]*.

I would like to discuss with you in more detail the study you just participated in. Do you have any questions about the study before we begin?

As you may know, scientific methods sometimes require that subjects in research studies not be given complete information about the research until after the research 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.

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 and design of the study before they begin.

We don't always tell people everything at the beginning of a study because we do not want to influence your responses to the study. Sometimes in order to determine the effectiveness of an experimental treatment we have to compare the experimental treatment group to a control group to eliminate the placebo effect of using receiving a treatment and only measure the active part. Often we can tell participants that they may receive the control treatment or the experimental treatment through random assignment where the investigator and the subject do not know which they are receiving. However, in some cases if subjects were told about the control group in the beginning of the study they would then know whether they were receiving the active experimental treatment or the inactive control. If we tell people the purpose of the study and inform them that they are in a control group, then their reactions would not be a good indication of how they would react if they thought they were receiving treatment and we would be unable to measure the placebo effect.

Now, I would like to explain exactly what we were trying to study in this investigation.
[insert explanation of study purpose, describe manipulations, etc., as applicable.]

If other people knew the true nature of the experiment, it would affect how they behave, 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 your data that we collected from your participation in this study?

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, or other co-investigators]*

Do you have any other questions or comments about anything you did today or anything we've talked about?

Thank you again for your participation.