



Risk Assessment and Informed Consent Guide

The Southern Baptist Theological Seminary

Definitions

The following definitions and categories are used in regard to human subjects in research.

1. **Risk** – the measure of discomfort and/or harm to which a human subject is exposed and/or may experience as a result of participation in research.
2. **Risk Areas with Human Subjects** – *psychological* (mental stress and/or emotional distress), *sociological* (relational stress and/or positional distress), *physiological* (bodily harm to self and/or bodily harm to others), and/or *spiritual* (individual stress and/or religious community distress).
3. **Minors** – any person under the age of 18 regardless of academic standing. Research involving minors automatically requires parent/guardian approval to participate in the research *in addition to* the informed consent for the level of risk to the minor.
4. **Members of a Vulnerable Population** – any person unable to make their own decisions, regardless of age. Research involving members of a vulnerable population automatically requires parent/guardian approval to participate in the research *in addition to* the informed consent for the level of risk to the vulnerable population member.

Instructions

Complete the *Assessment of Risk to Human Subjects in Research* form and calculate the level of risk to human subjects in your study. Include the appropriate *Informed Consent Statement* for the calculated level of risk on instrumentation, permission forms, verbal instructions, etc. as appropriate to the means of gathering data with human subjects.

Low Risk Informed Consent

For cover letters, permission forms, paper-based surveys, electronic-based surveys, Internet-based surveys, etc., add the following to the beginning of the instrument or instructions to participants. Include the “Agreement to Participate” title and the informed consent statement without modification, except as necessary for grammatical purposes. Replace the [bracketed] material with the content indicated. *Italicize content as indicated.*

Agreement to Participate

The research in which you are about to participate is designed to [describe the research purpose in the language of the participant]. This research is being conducted by [insert researcher name] for purposes of [describe the reason for the research, such as project research or dissertation research]. In this research, you will [describe in simple terms what participants will be asked to do]. Any information you provide will be held *strictly confidential*, and at no time will your name be reported, or your name identified with your responses. *Participation in this study is totally voluntary and you are free to withdraw from the study at any time.*

By your completion of this [describe the type of instrument or activity being completed, such as survey or interview], you are giving informed consent for the use of your responses in this research.

Medium Risk Informed Consent

For cover letters, permission forms, paper-based surveys, electronic-based surveys, Internet-based surveys, etc., add the following to the beginning of the instrument or instructions to participants. Include the “Agreement to Participate” title and the informed consent statement without modification, except as necessary for grammatical purposes. Replace the [bracketed] material with the content indicated. *Italicize content as indicated.*

Agreement to Participate

The research in which you are about to participate is designed to [describe the research purpose in the language of the participant]. This research is being conducted by [insert researcher name] for purposes of [describe the reason for the research, such as project research or dissertation research]. In this research, you will [describe in simple terms what participants will be asked to do]. Any information you provide will be held *strictly confidential*, and at no time will your name be reported, or your name identified with your responses. *Participation in this study is totally voluntary and you are free to withdraw from the study at any time.*

By your completion of this [describe the type of instrument or activity being completed, such as survey or interview], and checking the appropriate box below, you are giving informed consent for the use of your responses in this research.

I agree to participate

I do not agree to participate

High Risk Informed Consent

For cover letters, permission forms, paper-based surveys, etc., add the following to the beginning of the instrument or instructions to participants. Include the “Agreement to Participate” title and the informed consent statement without modification, except as necessary for grammatical purposes. Replace the [bracketed] material with the content indicated. *Italicize content as indicated.*

Agreement to Participate

The research in which you are about to participate is designed to [describe the research purpose in the language of the participant]. This research is being conducted by [insert researcher name] for purposes of [describe the reason for the research, such as project research or dissertation research]. In this research, you will [describe in simple terms what participants will be asked to do]. Any information you provide will be held *strictly confidential*, and at no time will your name be reported, or your name identified with your responses. *Participation in this study is totally voluntary and you are free to withdraw from the study at any time.*

By your completion of this [describe the type of instrument or activity being completed, such as survey or interview], and signing your name below, you are giving informed consent for the use of your responses in this research.

Name _____

Signature _____

Date _____

For electronic-based surveys, Internet-based surveys, etc., replace the last paragraph of the agreement to participate statement and the signature line with a request for the E-mail address of the participant as follows:

By your completion of this [describe the type of instrument or activity being completed, such as survey or interview], and entering your E-mail address below, you are giving informed consent for the use of your responses in this research.

Name _____

E-mail _____

Date _____

Informed Consent with Minors or Members of a Vulnerable Population

Research involving minors or members of a vulnerable population automatically requires parent/guardian approval to participate in the research *in addition to* the informed consent for the level of risk to the minor or vulnerable population member.

For hardcopy permission forms, use the following statement. *Require a separate form for each participant, even if there are multiple minors or members of a vulnerable population in the study under the supervision of the same parent or guardian.* Include the “Agreement to Participate” title and the informed consent statement without modification, except as necessary for grammatical purposes. Replace the [bracketed] material with the content indicated. *Italicize content as indicated.*

Agreement to Participate

You are being requested to give permission for a minor or member of a vulnerable population under your legal supervision to participate in a study designed to [describe the research purpose in the language of the participant]. This research is being conducted by [insert researcher name] for purposes of [describe the reason for the research, such as project research or dissertation research]. In this research, a person will [describe in simple terms what participants will be asked to do]. Any information provided will be held *strictly confidential*, and at no time will a person’s name be reported, or a person’s name identified with his or her responses. *Participation in this study is totally voluntary, and the person you are giving approval to participate in this study is free to withdraw from the study at any time.*

By signing your name below, you are giving informed consent for the designated minor or member of a vulnerable population to participate in this research if he or she desires.

Participant Name _____

Parent/Guardian Name _____

Parent/Guardian Signature _____

Date _____

For electronic-based or Internet-based permission forms, replace the last paragraph of the agreement to participate statement and the signature line with a request for the E-mail address of the parent/legal guardian as follows:

By entering your E-mail address below, you are giving informed consent for the designated minor or member of a vulnerable population to participate in this research if he or she desires.

Participant Name _____

Parent/Guardian Name _____

Parent/Guardian E-mail _____

Date _____

END

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