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 his/her 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 venerable 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 survey, 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 statements 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’s 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 survey, 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 statements 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’s 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, electronic-based survey, 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 statements 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’s 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.

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 _____________________________
Signature ___________________________
Date ______________

Informed consent with Minors or Member 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.

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**
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’s 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 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 email address of the parents/legal guardian as follows:

By entering your email 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 Signature ____________________________
Date ________________

END