

## Research Risk Assessment Rubric

The Research Risk Assessment Rubric is to determine the type and extent of risk that a proposed research project entails for human subjects. Researchers should complete this rubric before developing the HSR Application and Consent Form so they can address the types of risk illuminated by the rubric in these documents.

Unless otherwise required, a research project that scores entirely as “minimal risk,” does not necessitate HSR approval.

	<b>Minimal Risk Score: 1</b>	<b>Risk with Benefit Score: 2</b>	<b>Risk with No Benefit Score: 3</b>
<b>Psychological Risk</b>	Mental or emotional stress that is no more than ordinarily encountered in daily life or during the performance of routine psychological examinations or tests.	Mental or emotional stress that is more than ordinarily encountered in daily life or during the performance of routine psychological examinations or tests but has clear benefits for participants in research.	Mental or emotional stress that is more than ordinarily encountered in daily life or during the performance of routine psychological examinations or tests and has no clear benefits for participants in research.
<b>Sociological Risk</b>	Relational stress that is no more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	Relational stress that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests but has clear benefits for participants in research.	Relational stress that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests and has no clear benefits for participants in research.
<b>Physiological Risk</b>	Physical stress that is no more than ordinarily encountered in daily life or during the performance of routine physical examinations or tests.	Physical stress that is more than ordinarily encountered in daily life or during the performance of routine physical examinations or tests but has clear benefits for participants in research.	Physical stress that is more than ordinarily encountered in daily life or during the performance of routine physical examinations or tests and has no clear benefits for participants in research.

<p><b>Spiritual Risk</b></p>	<p>Stress related to religious beliefs or religious community participation that is no more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.</p>	<p>Stress related to religious beliefs or religious community participation that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests but has clear benefits for participants in research.</p>	<p>Stress related to religious beliefs or religious community participation that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests and has no clear benefits for participants in research.</p>
<p><b>Vulnerability Risk</b></p>	<p>Stress related to power imbalances between the researcher and research participant that is no more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.</p>	<p>Stress related to power imbalances between the researcher and research participant that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests but has clear benefits for participants in research.</p>	<p>Stress related to power imbalances between the researcher and research participant that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests and has no clear benefits for participants in research.</p>
<p><b>Intrusiveness Risk</b></p>	<p>Stress caused by research practices that is no more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.</p>	<p>Stress caused by research practices that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests but has clear benefits for participants in research.</p>	<p>Stress caused by research practices that is more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests and has no clear benefits for participants in research.</p>

## How to Score the Rubric

Garrett-Evangelical follows the guidelines of the United States Department of Health and Human Services Office of Human Research Protections for determining the risk to human subjects during research. This Office identifies three levels of risk: minimal risk, risk with benefits to the participant, and risk without benefits to the participant.

If the participant is seventeen (17) years of age or younger, the research automatically requires HSR approval. However, if it is minimal risk in relation to all other categories, it still can be approved with the inclusion of parental consent. See appendix on research with minors.

**Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [Health and Human Services, Office of Human Research Protections, 45 CFR 46.102(i)]

Determining that a research activity presents no more than minimal risk involves comparing the possible harms or discomforts experienced in normal daily life or during routine physical or psychological examinations or tests with the possible harms or discomforts that will be faced by subjects as a consequence of research participation. The nature of the harms or discomforts (e.g., physical, psychological) should be considered, as well as the chances that they will occur and the seriousness of their impact if they were to happen. Depending on what kind of experience(s) are involved in participation in a specific research activity, it may be easier to compare the anticipated experience of participation in research to the possible harms or discomforts of daily life, or to the possible harms or discomforts of a routine physical or psychological examination or test. Including measures to prevent or decrease the likelihood of harm or discomfort from the research may affect whether the proposed research activity involves no more than minimal risk <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>.

If it is determined that the research will involve risk that is more extensive than a person would usually experience in the course of their daily lives or through routine forms of testing, then the Researcher must determine whether the risk offers benefits for the participant or not.

**Risks with benefits to the participant** means that the research will involve risk that is more extensive than a person would usually experience in the course of their daily lives or through routine forms of testing, but the “risks to [participants] are reasonable in relation to anticipated benefits...[for the participants]. In evaluating risks and benefits, the [Researcher] should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies [Participants] would receive even if not participating in the research). The [Researcher] should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those [benefits].” [Health and Human Services, Office of Human Research Protections, 45 CFR 46.111(a.2)]

The benefits must be clearly identifiable, measurable, accessible, and direct to the Participants as a result of participating in the research. The benefits should be in the same category as the risks.

For example, someone may face sociological risk by sharing personal information in a group, but the research structure would be such that this risk is balanced by the possibility of greater intimacy and fellowship within that group as a result of that sharing.

Benefits that are not directly accrued to the Participant should not be included in this category. So, a project that seeks to develop heuristic models for discussing uncomfortable topics in church groups in order to benefit denominational policy would not be a “risk with benefits to the Participant.” While there might be a larger benefit available to the church, the research would not be structured to provide identifiable, measurable, accessible, and direct benefits to the Participants.

**Risks without benefits to the participant** means the research will involve risk that is more extensive than a person would usually experience in the course of their daily lives or through routine forms of testing, and that will not directly benefit those who participate in it.

In this situation, the Researcher must explain: 1) Why the research being proposed must be conducted in this format rather than in one that offers direct benefits to the Participant. 2) What generalizable and/or long-term knowledge or other benefits will arise from the research that legitimizes putting Participants at risk. [Adapted from Health and Human Services, Office of Human Research Protections, 45 CFR 46.406]

Psychological Risk

This is a risk of causing mental and/or emotional distress for the participant.

Risk factors include asking participants to reflect on personal, private, or sensitive material. Below are examples of risk levels in this category:

Minimal Risk	Sharing commonly known information about self
Risk with benefit to Participant	Participating in classes on a subject the participant knows little about (risk of feeling ignorant, benefit of learning)
Risk without benefit to Participant	Sharing about a traumatic experience

Sociological Risk

This is a risk of causing stress based on how the person relates to those around them. Below are examples of risk levels in this category:

Minimal Risk	Participating in a survey in which only the Researcher sees the answer, or being observed in a public activity where the Participant commonly relates to other people, such as at worship
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Risk with benefit to Participant	Sharing about a controversial topic in a group of peers with the possibility of working toward greater understanding within that group (risk of alienation or embarrassment, benefit of greater group coherence)
Risk without benefit to Participant	Sharing about a controversial topic in a group with only the goal of creating a structure for long-term improvement for the church.

### Physiological Risk

This is a risk of causing bodily harm, including physical stress caused by exertion or anxiety. Below are examples of risk levels in this category:

Minimal Risk	Meeting together in a place the participant feels their physical wellbeing is safe and that requires no additional physical exertion.
Risk with benefit to Participant	Being part of lengthy meetings or meetings that occur later at night or early in the morning for the sake of spiritual formation (risk of being tired or impatient, benefit of being involved in greater spiritual practices)
Risk without benefit to Participant	Going to a place where a Participant feels unsafe or would have a reason to fear for their physical wellbeing to participate in the research.

### Spiritual Risk

This is a risk of causing participants to have negative associations with their faith or with a religious community. Below are examples of risk levels in this category:

Minimal Risk	Observing Participants during routine, public practices of faith, such as during worship or fellowship activities
Risk with benefit to Participant	Being asked to reflect on times of serious doubt related to a Participant's religious beliefs as part of a spiritual formation process (risk of having beliefs shaken, benefit of having doubts addressed so that the Participant's beliefs are stronger)
Risk without benefit to Participant	Being exposed to material that directly attacks the Participant's beliefs or the Participant's chosen religious community to determine effectiveness of said material.

### Vulnerability Risk

This is a risk caused by a power imbalance between the Researcher and the participant. Below are examples of risk levels in this category:

Minimal Risk	Researcher is a peer to the Participants or the Researcher only gathers data in existing public spaces where the Participants gather anyway.
Risk with benefit to Participant	Researcher is the pastor of the church where the Participant is a member. The Researcher is gathering information that will be used to improve the Participants experience of congregational involvement (risk of awkward conversations with the pastor, benefit of an improved experience at church).
Risk without benefit to Participant	Researcher is in a professional supervisory position over the Participant. Researcher is gathering information about the overall effectiveness of a program or the organization where they work.

Also, social context and privilege must be considered in ranking this. If the Researcher is part of a socially dominant group while the participant is part of a socially marginal group, that would increase the risk level for the Participant even if the risk was minimal otherwise.

### Intrusiveness Risk

This is a risk of the participant having intrusive research practices used on them. Risk factors include whether the project will be conducted in a way that fits within the participant's usual patterns of life. Below are examples of risk levels in this category:

Minimal Risk	Voice recording, taking notes at a public event where the Participant usually attends.
Risk with benefit to Participant	Video recording for the sake of reviewing the Participant's presentation of something (risk of being recorded, benefit of learning how to improve in presenting as a result of analyzing the video)
Risk without benefit to Participant	Conducting a very long survey or interview that will be used to gather data that is amalgamated with many others to address systemic or institutional concerns.