Risk Evaluation Form

**Risk Assessment Table for Research Studies**

This Risk Evaluation Form is developed in line with international research ethics standards, drawing from established guidelines by organizations such as the World Health Organization (WHO), the U.S. Department of Health & Human Services (HHS), and the Declaration of Helsinki. It incorporates best practices from leading institutions, including Harvard University’s Committee on the Use of Human Subjects, Stanford University’s Institutional Review Board (IRB), and the University of California System. Their standards ensure a thorough assessment of potential risks, prioritizing participant safety and ethical research conduct.

**Section 1: Study Overview**

**Research Title:** [Insert Research Title Here]

**Principal Investigator:** [Insert Name Here]

**Contact Information:** [Insert Email and Phone Number Here]

**Date of Submission:** [Insert Date Here]

**Brief Description of the Study:**

[Provide a concise summary of the research purpose, methodology, and participant involvement.]

**Participant Population:**

[Describe the demographics of the participants (age, gender, etc.).]

**Section 2: Risk Assessment**

**Who is Exposed to the Hazard?** (e.g., participants of the research, including university staff, students, children, and other research subjects).

**Assessing Risk:** Use the table below to determine your risk level based on potential harm and likelihood:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Potential Harm | Unlikely | Possible | Likely | Almost Certain |
| None | No harm. | No harm. | No harm. | No harm. |
| Low | Minor issues | Minor issues | Minor issues | Minor issues |
| Moderate | Moderate risk | Moderate risk | Moderate risk | Moderate risk |
| High | High risk | High risk | High risk | High risk |
| Very High | Very high risk | Very high risk | Very high risk | Very high risk |

**Definitions of Potential Harm:**

**None**: No expected harm to participants. This applies to studies involving anonymous surveys or data collection on non-sensitive topics where participation does not elicit any physical or emotional risk.

**Low**: Minor issues may arise, such as brief discomfort or slight emotional distress (e.g., temporary frustration during surveys). This includes risks associated with the collection of data from vulnerable populations, such as children, where additional support may be required.

**Moderate**: Situations that could result in time away from regular activities, increased anxiety, or temporary emotional upset due to the nature of questions asked (e.g., discussing sensitive topics). This is particularly relevant in qualitative studies where deeper personal insights are explored.

**High**: Risks involving serious emotional or psychological impact, which could necessitate intervention (e.g., discussions around trauma). This includes the potential for severe legal implications if sensitive data is mishandled. Extra care is required when collecting data from vulnerable groups, such as individuals with mental health challenges or children.

**Very High**: Circumstances that pose immediate risks to participants' safety or well-being, including psychological harm or threats to life. This includes studies that may unintentionally provoke severe reactions in participants, especially vulnerable individuals, necessitating rigorous ethical oversight and safety protocols.

**Mitigation Strategies:**

**For Moderate to Very High Risks:** Describe specific precautions you will implement:
[Detail measures here.]

**Effectiveness of Precautions**: (Will these precautions reduce the inherent risk?)

[Provide comments here.]

**Residual Risk Assessment:** Select the remaining risk level:

[ ] None [ ] Low [ ] Moderate [ ] High [ ] Very High

**Note:** If the residual risk is not in the "None" or "Low" range, additional measures may be necessary, or you may need to redesign your research proposal. Consult with relevant oversight bodies for higher-risk studies.

**Post-Study Feedback Mechanism:**

Include a section for feedback from participants to evaluate risk management effectiveness.

* 1. **Experience Overview**: Ask participants to describe their overall experience during the study. This may include aspects such as comfort, clarity of instructions, and any concerns they had.
	2. **Risk Management Evaluation**: Include specific questions related to risk management, such as:
1. Did you feel safe during the study? (Yes/No)
2. Were the risks explained to you clearly before participation? (Yes/No)
3. Did you encounter any unexpected emotional or physical discomfort? (Yes/No; if yes, please describe)
	1. **Suggestions for Improvement:** Provide an open-ended section where participants can offer suggestions for enhancing safety and comfort in future studies.
	2. **Final Comments**: Allow space for any additional comments or feedback participants may want to provide.

**Section 3: Risk Mitigation Strategies**

1. **Measures to Minimize Risks:**

[Outline steps taken to reduce identified risks, including informed consent processes, researcher training, and support resources for participants.]

1. **Data Protection and Confidentiality:**

[Describe how participant data will be protected, including anonymization, secure storage, and access restrictions.]

1. **Emergency Procedures:**

[Detail procedures for addressing adverse events or participant distress during the study.]

**Section 4: Participant Information**

1. **Informed Consent Process:**

[Explain how informed consent will be obtained and the information provided to participants.]

1. **Withdrawal from Study:**

[Outline participants' rights to withdraw from the study at any time without penalty.]

**I confirm that an appropriate risk assessment has been conducted.**

**Signature of Principal Investigator:**

**Signature of Principal Researcher:**

**Date:**