

Saint Leo University IRB—Defining “Minimal Risk”

What is the Definition of Minimal Risk?

IRBs exist to ensure that studies on human subjects effectively protect all involved from unnecessary risk and harm. Federal guidelines provide the definition for assessing “minimal risk.” The definition for minimal risk is as follows: “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.”

Understanding Minimal Risk

The above definition includes some obvious breadth of interpretation. IRBs understand the subjects of the above definition as generally referring to healthy persons living in a safe environment. Any element of a study which disrupts emotional or physical safety beyond the scope of normal life raises the level of risk beyond the federal definition. A study which includes a level of risk beyond minimal automatically demands greater scrutiny from the IRB.

Application Clarity

Above all else, an application must clearly present the parameters of its study and provide all of the necessary details for understanding the study and the effects on its subjects. Providing the IRB with clear explanations of the populations sought and the procedures of the study ensure that the IRB can make the best and fastest assessment of risk.

Examples

Much of the research done at Saint Leo University is of a social and behavioral nature. When conducting research, here are some items to consider when evaluating risk:

1. Loss of time is a discomfort for many individuals. The time needed to participate should always be identified in the form of a range, (e.g. 20 to 30 min to complete). Be sure to avoid overly conservative estimates of the time needed to complete the study.
2. Recalling traumatic or distressing events is normally a distressing activity, and the justification for this must be clearly stated in the application.

Examples of such events could include, but are not limited to, both physical and psychological trauma such as bullying, torture, rape, victim of a crime, victim of sexual or other types of harassment.

In the above examples, information concerning clinical/counseling resources should be provided.

3. Studies that include questions concerning prior activities considered to be highly personal (especially if illegal or causing social harm), such as drug use or the use of pornography, may be considered above minimal risk.

4. Researchers should minimize the chance of damaging the subjects' relationships with others (e.g., asking a dating couple to discuss their relationship problems; or asking employees about their dissatisfactions with their supervisors and making such information available to their employer).
5. If there is any risk of harm to the participants in the study, the rationale must be clearly stated in the application.
6. All necessary measures should be taken to protect the participants' confidentiality and anonymity.