The Ordinary Life Experiences Rating Scale: Development of a New Instrument to Measure Minimal Risk in the Context of the Office for Human Research Protections (OHRP)

Terminology

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Problem Statement Background: Federal regulations, at 45 CFR 46.102(i), define “minimal risk” as research where “the probability and magnitude of harm or discomfort...are not greater in and of themselves than those ordinarily encountered in daily life...or routine physical...tests.” The OHRP IRB Guidebook (last updated in 1993), provides a descriptive benchmark by suggesting that the point of comparison should be that of a routine physical examination involving a blood draw. Psychological risks are inherently subjective, and IRB committees are tasked with judging how participants will react to research. To date there is no instrument or scale available to compare participants’ reactions to minimal risk benchmarks. The present study seeks to ameliorate this problem.

Research Question: How do participants’ reactions to research compare with minimal risk benchmarks, and can they be directly measured?

Description of the Research Methods: A pool of items was developed in an effort to tap a variety of ordinary life experiences that may cause psychological distress. Fifty-one items involving distress-causing situations were generated, covering such themes as social embarrassment (e.g., accidentally hurting another’s feelings), environmental nuisances (e.g., waiting on a long line in a loud office), and loss (e.g., having a beloved pet pass away). Participants were asked to rate each item on an 11-point scale, anchored by “Not at all Distressing” to “intensely Distressing.” The scale was administered to a volunteer sample through a web-based application. Links for the web survey were posted on www.socialpsychology.org and similar sites for the promotion of online research. A total of 225 usable surveys were returned, though many surveys had multiple missing data points, making the effective sample size for most analyses 211.

Results: Distress ratings ranged from a mean of 9.10 (unexpected breakup of romantic partner) to 1.96 (how distressing was THIS survey?). Each item was reviewed for skew, and those with very high skew were removed. Ultimately, a list of 15 items were reserved to reflect a broad cross-section of stressors, including items related to OHRP benchmarking for minimal risk, and to consist of items with relatively low skew. Psychometric properties are reported.

Conclusion: The resulting scale can be used by researchers in any area of socio-behavioral research to compare how participants felt about their own participation as compared to OHRP benchmark stressors such as blood draws.

Limitations: Volunteer sample, more testing is needed for validity.

Next Steps: Results will be published to make the scale widely available.