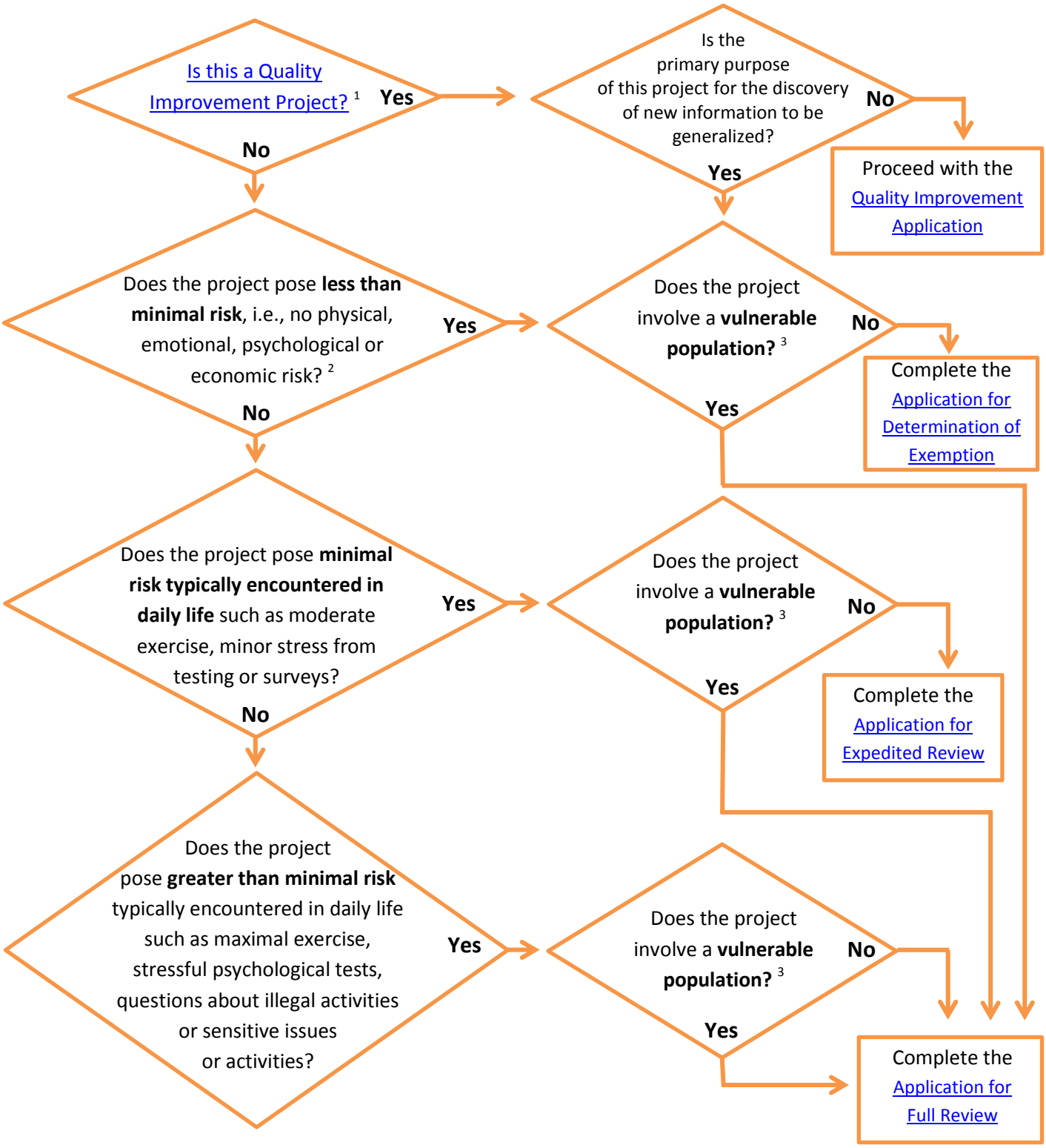
IRB Application Category Decision Tree

Note: The IRB makes the final determination of the review category



[1]Quality Improvement "is specifically initiated with a goal of improving the performance of institutional practice in relationship to an established standard" [Bankert, E.A. & Amdur, R.J. (2006). Institutional review board: Management and function. Sudbury, MA: Jones and Bartlett, p.102]

[2]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" Code 45 CFR 46.102 (i)

[3]Vulnerable subjects include "children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons" CFR21.1, part 56, sec. 111(b)