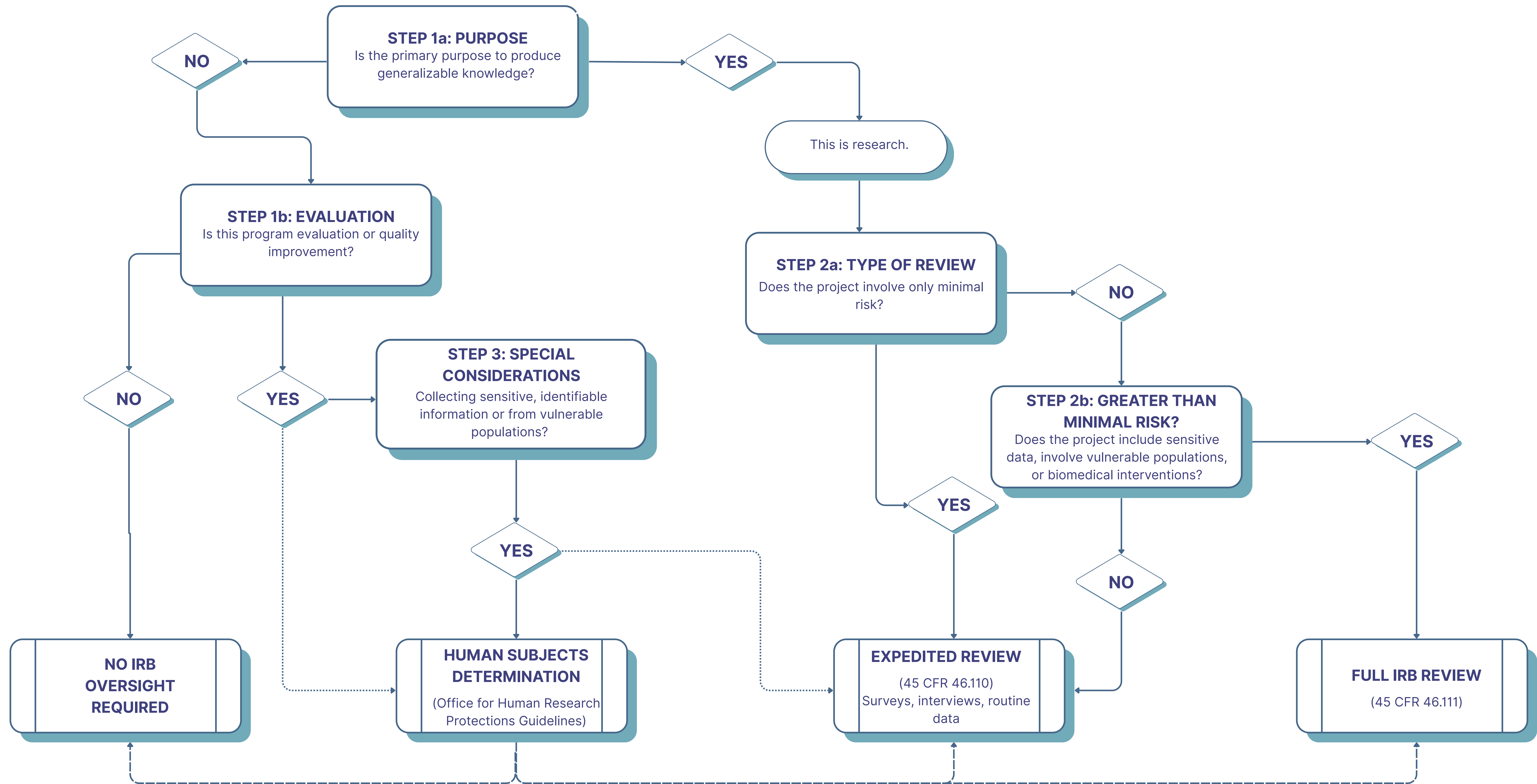


IRB REVIEW PATHWAY: QUICK GUIDE FOR EVALUATION AND RESEARCH ACTIVITIES

This decision tree is intended as a practical tool to guide initial decision-making about whether IRB review may be required. It is not a substitute for applicable regulations or institutional policies. Final determinations should be made in consultation with an IRB or a qualified colleague if uncertainty remains.



TERMINOLOGY

Generalizable knowledge: Knowledge that is intended to extend beyond a specific program or setting and can be applied to populations, settings, or situations outside of the immediate project. Often associated with publication or dissemination to broader audience (45 CFR 46.102(l)).

Identifiable data: Information where the identity of the participant is or may be readily ascertained by the investigator or is linked to the participant (directly or indirectly). This includes names, contact information, or coded data with a key (45 CFR 46.102(e)(1)).

Minimal risk: Probability and magnitude of harm / discomfort anticipated are not greater than those ordinarily encountered in daily life or during routine physical or psychological tests (45 CFR 46.102(j)).

Program evaluation: Systematic collection and analysis of information about a program's activities, characteristics, and outcomes to make judgements, improve effectiveness, and/or inform decisions about future programming. Generally considered not human subjects research under 45 CFR 46.102.

Sensitive data: Information that, if disclosed, could place participants at risk of harm (legal, social, financial, employability, insurability, or reputation). Examples include health records, substance use, sexual behavior, mental health status, and illegal behaviors (Office for Human Research Protections guidance).

Quality Improvement (QI) projects: Activities designed to improve internal practices, processes, or services within an organization. Generally considered no human subjects research under 45 CFR 46.102.

Vulnerable populations: Groups who may be more susceptible to coercion or undue influence, requiring additional protections. Examples include: pregnant women, human fetuses, and neonates (Subpart B); prisoners (Subpart C); Children (Subpart D); and individuals with impaired decision-making capacity (Office for Human Research Protections guidance).

