

VS

UNDERSTANDING THE DIFFERENCE BETWEEN RESEARCH AND PROGRAM EVALUATION

This handout is intended as a practical guide to help distinguish between research activities, which fall under federal human subjects regulations (45 CFR 46), and program evaluations, which are generally conducted for accountability and quality improvement. While many Council-funded activities involve data collection, most are evaluation projects and do not meet the definition of human subjects research. If there is uncertainty about how to classify an activity, consult with an IRB or a qualified colleague before proceeding.



PFH PARTNERSHIPS FOR HEALTH

DOMAIN	RESEARCH	PROGRAM EVALUATION
Definition	A systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l)).	Systematic collection and analysis of information about a program’s activities, outcomes, or processes to improve effectiveness and inform decisions.
Primary Purpose	To test a hypothesis, develop theory, or generate knowledge that applies beyond the specific study setting.	To assess or improve a specific program or service, usually for accountability or quality improvement.
Intended Use of Findings	Dissemination to the broader scientific community (e.g., publications, presentations, generalization to other settings).	Internal use by the sponsoring agency or stakeholders to improve program design, delivery, and outcomes.
Audience	Academic / scientific community, policymakers.	Program managers, funders, community partners, participants.
Oversight	Must comply with the Common Rule (45 CFR 46) if involving human subjects. IRB review (expedited or full) is required.	Generally not considered human subjects research; IRB review not required unless data collection poses risk (e.g., sensitive identifiable data).
Risk Level	May involve interventions, experimental designs, or sensitive data.	Usually minimal risk; often uses program records, surveys, or interviews about services.
Examples	Studying whether a new training model for service coordinators improves outcomes across multiple states.	Assessing if a Council-funded training increased knowledge among providers in your state.