BUDDIES PROJECT SESSION 14 – Institutional Review Boards (IRB)

Thursday, September 18, 2025

HOUSEKEEPING

- Recording
- Keep cameras on
- Captions available
- Tech issues
- Questions in chat

AGENDA

- BUDDIES Updates
- Presentation on Institutional Review Boards
- Q & A
- Wrap Up

BUDDIES UPDATES

YEAR 4 ANNUAL SURVEY

- Tell us your reflections on Year 4 BUDDIES Sessions
- Complete by Friday, 9/26
- https://www.surveymonkey.com/r/2025BUDDIESSurvey

INSTITUTIONAL REVIEW BOARDS

WHAT IS AN IRB?

- An **independent** committee that reviews research involving human participants
- Ensures that the rights, safety, and welfare of participants are **protected**
- **Oversees** research plans to confirm they are ethical and follow federal regulations

TYPES OF INSTITUTIONAL REVIEW BOARDS

TYPE	TYPICAL LOCATION	STRENGTHS	LIMITATIONS
University-Based IRBs	▪ Colleges and universities with active research programs ▪ Can also operate as commercial IRB	▪ Familiarity with academic research ▪ Often no cost for faculty / staff submissions	▪ High volume = slower ▪ Processes geared towards traditional research rather than program evaluation
Hospital- or Health-System-Based IRBs	Medical centers, hospitals, and health centers	▪ Strong expertise in biomedical and clinical research ▪ Well-versed in protecting vulnerable patient populations	▪ May prioritize clinical studies ▪ Evaluation/QI projects take lower priority ▪ May charge fees for non-staff investigators
Independent / Commercial IRBs	Examples: WCG IRB, Advarra IRB, Sterling IRB	▪ Faster turnaround times ▪ Specialized in serving organizations without their own IRB ▪ Flexible processes for minimal-risk and expedited review	▪ Fee-for-service ▪ Can be cost prohibitive for small community-based organizations
State or Regional IRBs	Some states and large health systems operate shared IRBs to support multiple institutions	▪ Shared resources ▪ Consistent review standards across multiple agencies	▪ Access may be restricted to partner agencies ▪ Not always open to community organizations

Poll

How many of you have had evaluation activities delayed by IRB requirements?

IRB TOOLS AND RESOURCES

- Slide deck and recording
- Evaluation vs. Research Comparison Chart
- IRB Pathway Algorithm
- Office of Human Research Protections Decision Charts
- Sample RFP and sub-recipient language

UNDERSTANDING THE DIFFERENCE BETWEEN RESEARCH AND PROGRAM EVALUATION

VS

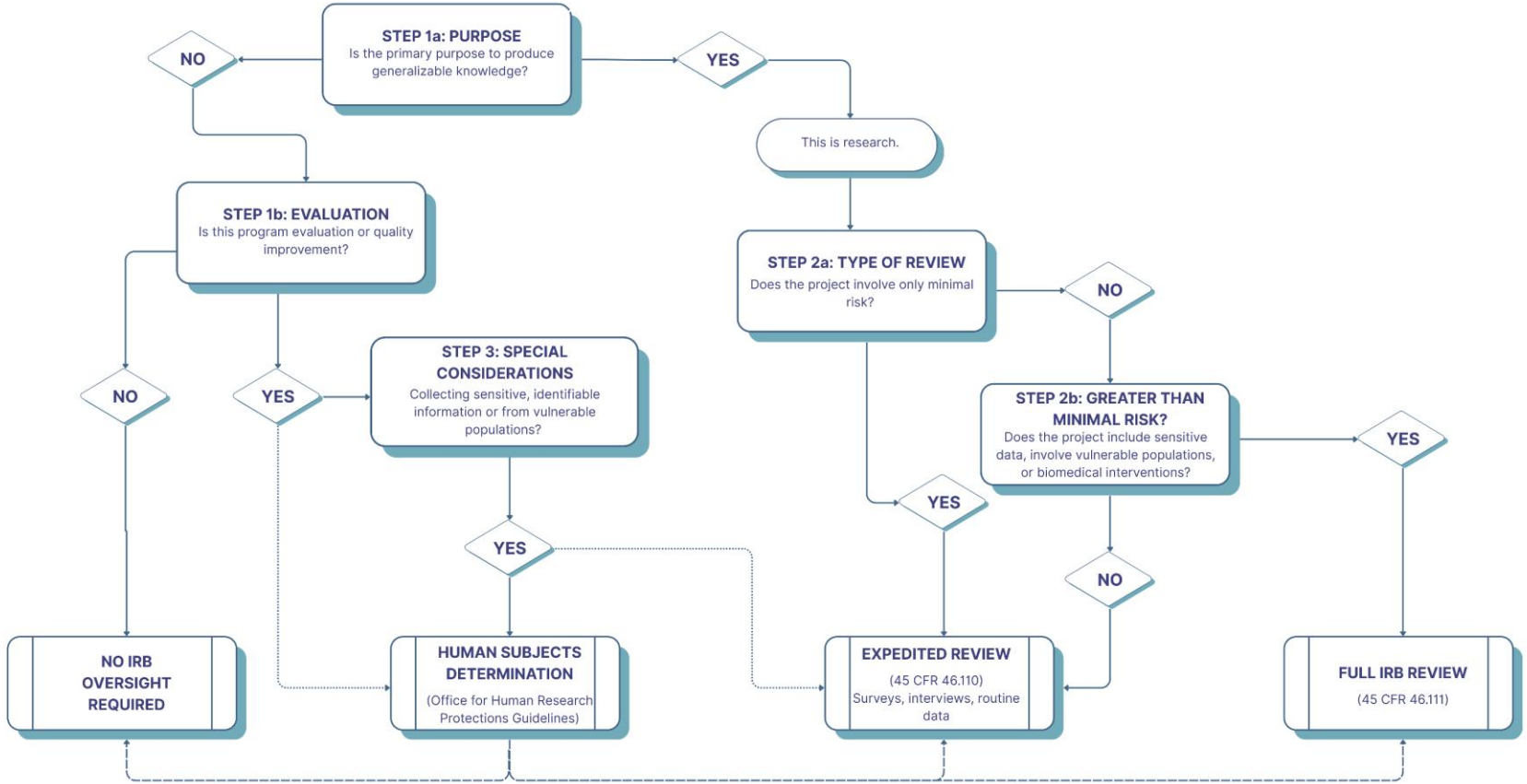
This handout is intended as a practical guide to help distinguish between research activities, which fall under federal human subjects regulations (45 CFR 46), and program evaluations, which are generally conducted for accountability and quality improvement. While many Council-funded activities involve 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.

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).

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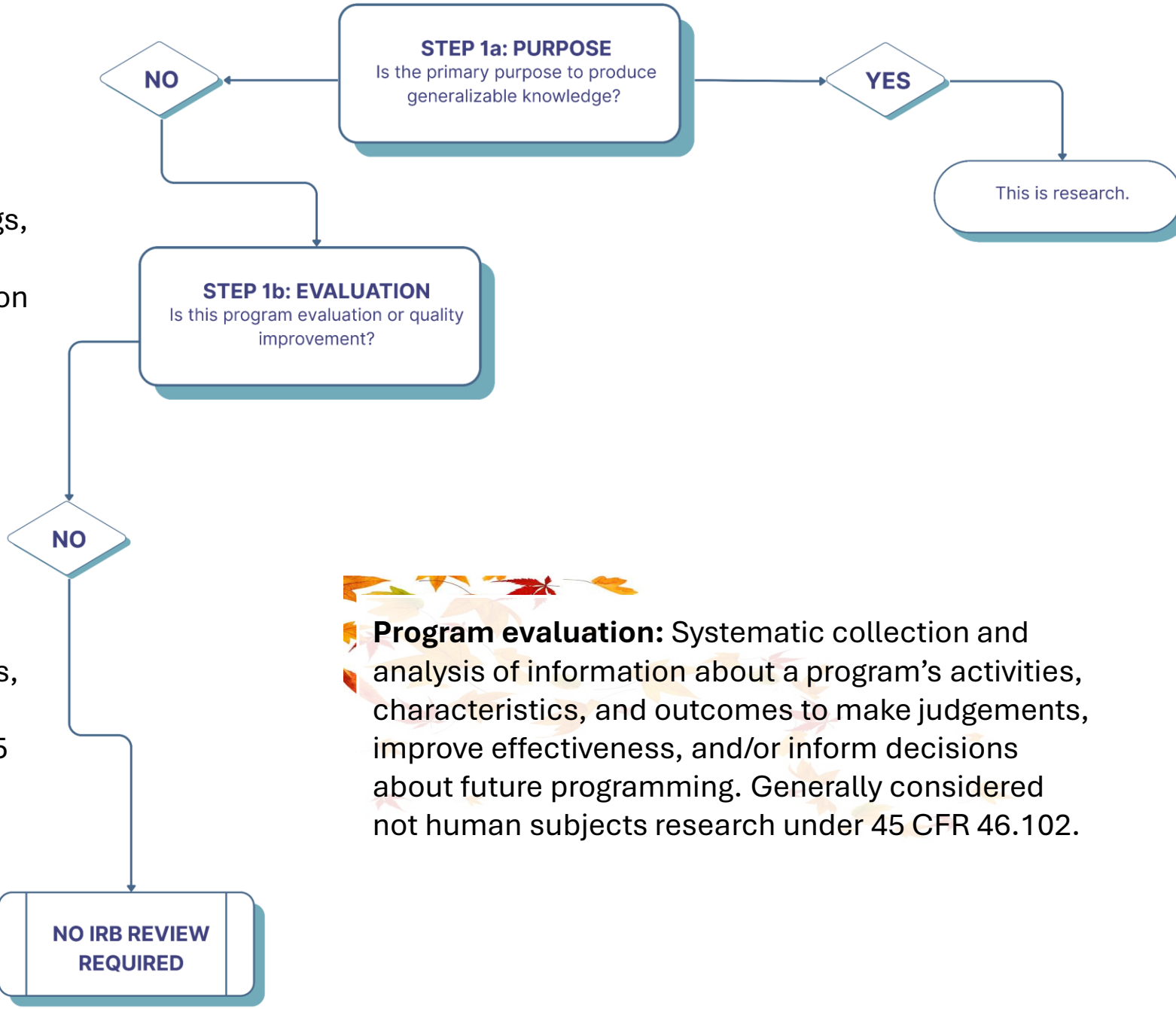

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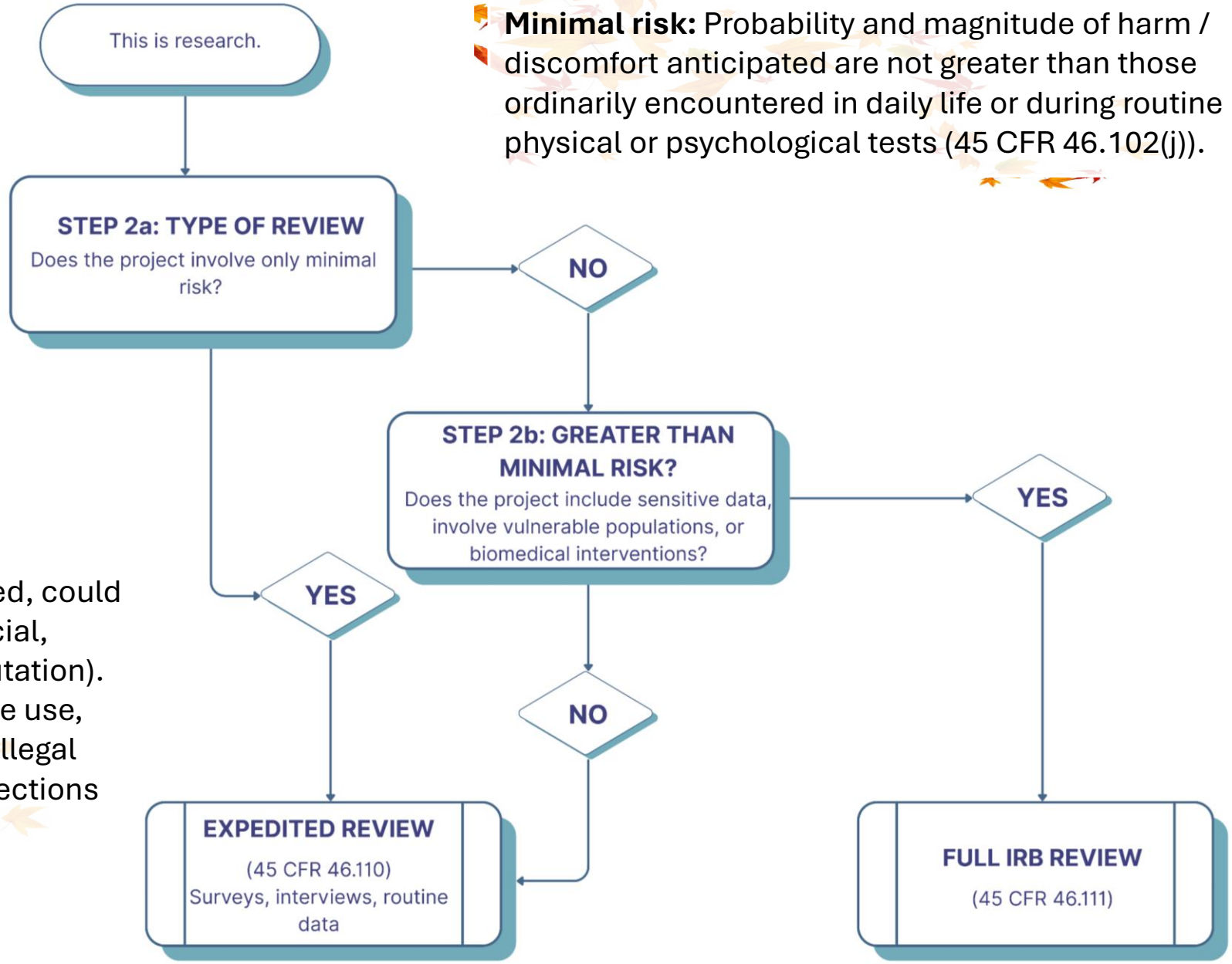

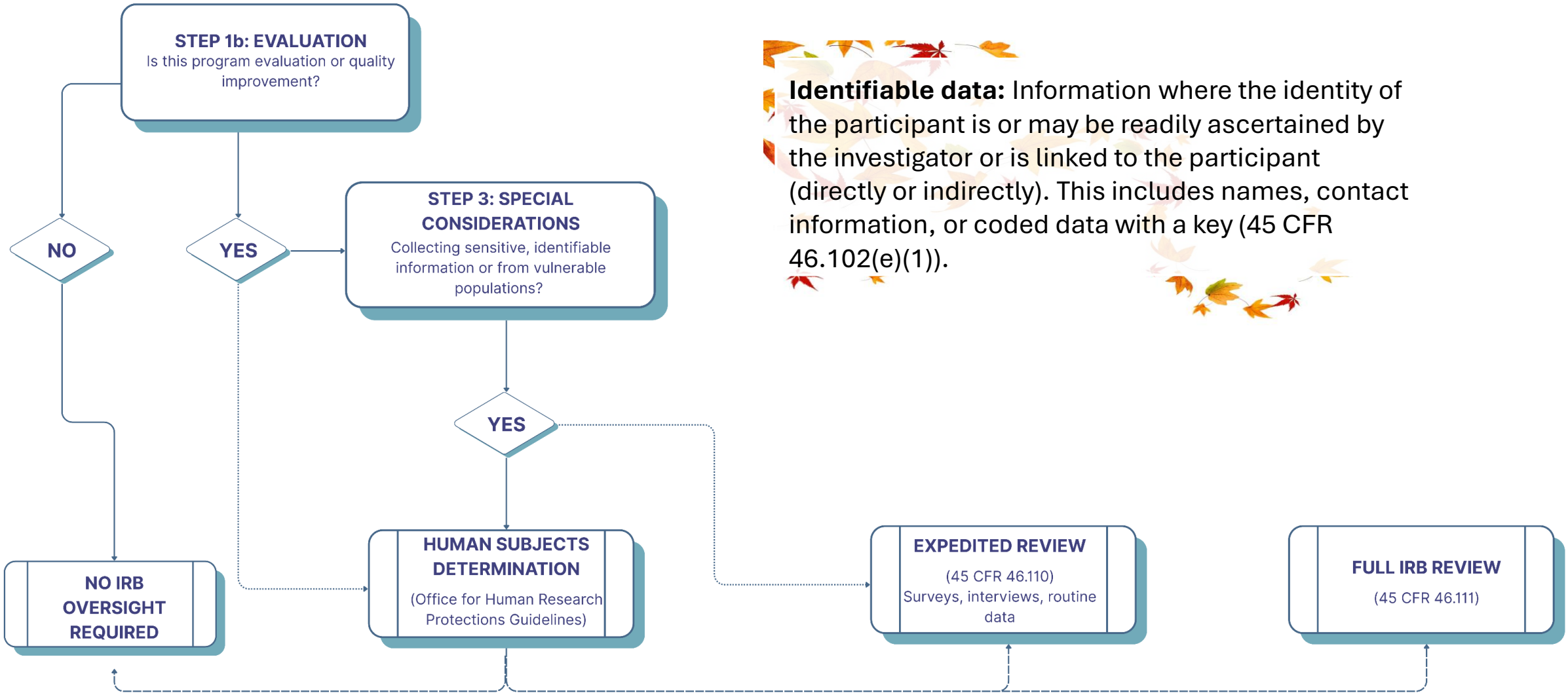

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UNDERSTANDING IRB REVIEW PROCESSES

This handout provides a side-by-side comparison of the different types of IRB review processes under the Common Rule (45 CFR 46). It is intended to help Councils and sub-recipients recognize what each pathway looks like, how long it typically takes, and who is involved in the review. While this tool is designed to support decision-making, it should not replace consultation with an IRB or institutional compliance office when questions arise.

DIMENSION	HUMAN SUBJECTS DETERMINATION	EXPEDITED REVIEW	FULL IRB REVIEW
Definition	Assessment of whether an activity meets the definitions of research and human subject in 45 CFR 46.102.	Review pathway for **minimal risk** projects that fall into categories listed in 45 CFR 46.110.	Required for greater than minimal risk projects or those involving vulnerable populations under 45 CFR 46.111.
What It Looks Like	• Short form (1–2 pages). • Investigator describes purpose, population, and data. • Results in a "Not Human Subjects Research" letter if exempt.	• Standard IRB application with protocol, data tools, and consent forms if applicable.	• Comprehensive application package with protocol narrative, recruitment, detailed consent, risk/benefit analysis.
Who Reviews	Compliance office or IRB staff (administrative review).	IRB chair or designated reviewer.	Full IRB committee at a scheduled meeting.
Typical Timeline	A few days to 1 week.	~2–4 weeks.	1–3 months.

SAMPLE LANGUAGE FOR SUB-RECIPIENTS

- Evaluation activities funded through this RFP are intended for program improvement and accountability. As such, they typically do not meet the definition of human subjects research under 45 CFR 46.102. Applicants should be prepared to work with the Council to determine whether an IRB exemption or expedited review is appropriate.
- Avoid the term ‘study’. Use assessment, evaluation, etc.

Practical Tips

Clarify Intent Early

When drafting scopes of work or RFPs, state clearly that evaluation activities are for *quality improvement and accountability*, not research. This helps prevent unnecessary full IRB submissions.

Document Your Decision

Even if an activity is "Not Human Subjects Research," keep a record (e.g., a copy of the determination letter or a short memo). This shows due diligence if questions arise later.

Use OHRP Decision Charts

The Office for Human Research Protections (OHRP) publishes step-by-step charts to guide determinations. Sharing these with sub-recipients can demystify the process.

Ask About Fees

Some universities and hospitals charge fees for external projects. Independent IRBs may review faster but also charge. Build these costs (if needed) into contracts upfront.

Lean on Expedited Review

If an IRB insists on review, emphasize that most evaluation activities are *minimal risk* and likely qualify for expedited review under **45 CFR 46.110**.

Identify a Point of Contact

Each Council should designate one person familiar with IRB basics who can field questions from sub-recipients and communicate with IRBs as needed.

Consistency Across Partners

Share standard language (like the RFP and sub-recipient language you're drafting) so all partners receive the same message about IRB expectations.

QUESTIONS

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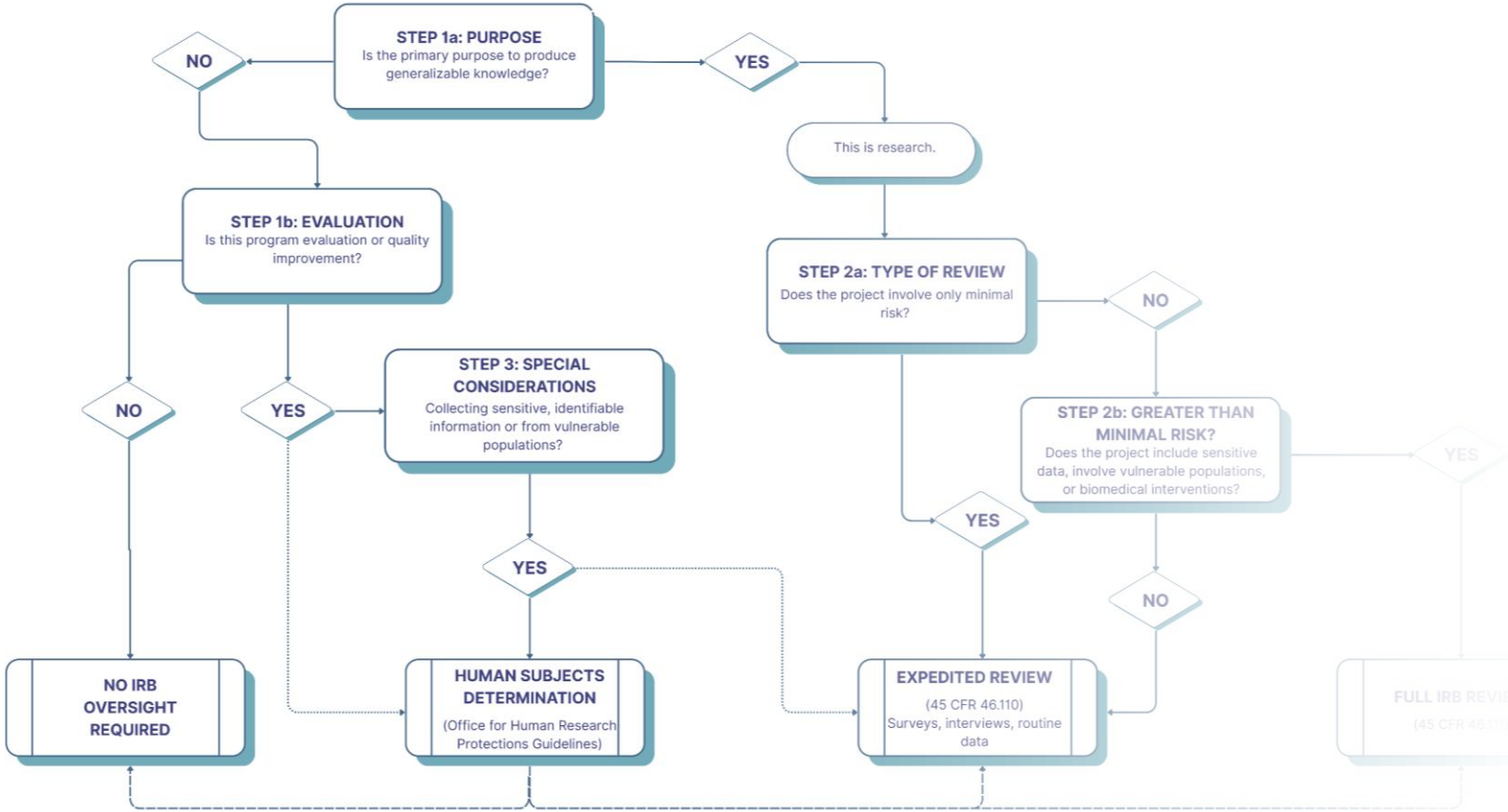

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TEST DRIVE THE ALGORITHM

WRAP UP

- IRBs protect human subjects in research – not all evaluations are research.
- Knowing the Common Rule (45 CRF 46) empowers Councils to push back on unnecessary requirements.
- Use the algorithm and sample language to support your sub-recipients.

SESSION 14 SURVEY

- Please take 5 minutes to share your thoughts on today's session
- Look for the survey in your inbox in the next few days!

ANNUAL SURVEY

- Complete by Friday, 9/26
- https://www.surveymonkey.com/r/2025BUDDIESSurvey
- Link is also in the chat!

THANKS FOR JOINING US!