Ensuring the Rights of Study Participants

Resources for Philanthropic Organizations

This presentation and its accompanying materials were made possible by a generous grant from the David & Lucile Packard Foundation

Agenda

- Introduction to Human Subjects Protection

- Identifying Potential Risks & Issues

- Tools & Resources for Philanthropic Organizations

- Scenarios

- Q & A

Disclaimer: This document does not constitute legal advice. It is meant to educate users about the protection of study participants and introduce them to the Institutional Review Board process.

Human Subjects Protection

- Ensures that research and evaluation study participants are treated **fairly, equitably, and respectfully**

- Suggests the need for funders to spot **potential issues** to consider when reviewing grants, contracts, and program-related investments (PRIs)

- Allows philanthropic organizations to fund **ethically sound** research and evaluation

What is an Institutional Review Board (IRB)?

- Independent committee of "human subjects protection"

- Reviews protocols and study materials to:

  - Assess project **ethics**

  - Promote fully informed and voluntary **participation**

  - Maximize participant **safety**

- Studies should highly consider IRB review when they have:

  - Potential participant **risks**

  - **Vulnerable** populations

  - **Sensitive** and/or **identifiable** data

  - Intentions to **publish** data in a peer-reviewed journal

Potential Risks & Issues in a Focus Group

Discussion Questions:

- Are there any **potential risks** to a person participating in this focus group?

- Are any of the questions **sensitive**?

- What other **confidentiality** issues came up for you?

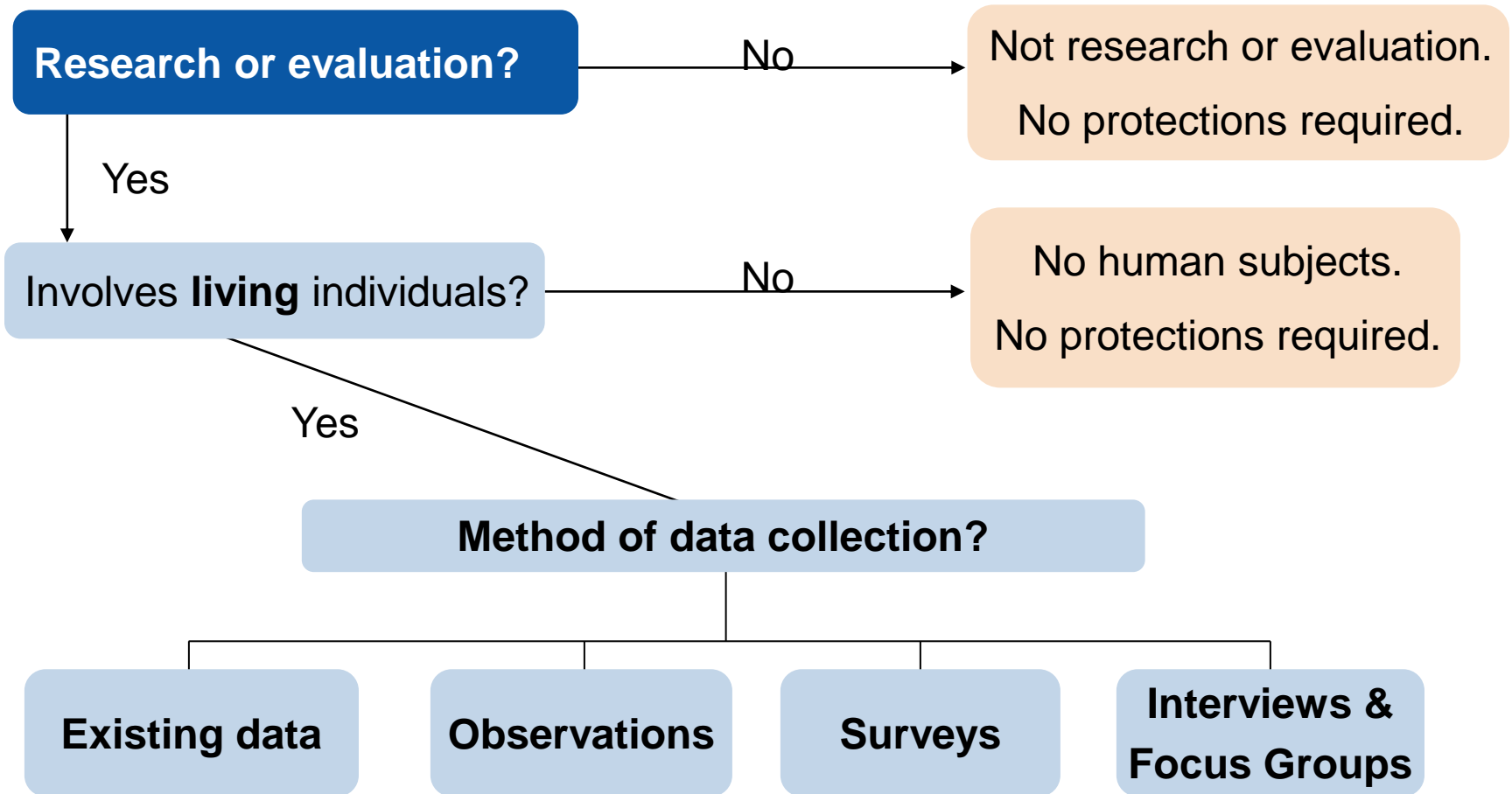- Can you think of other **concerns** for the participants?

Tools & Resources

- Data collection methods often correlate with risk level

Higher

Risk

Lower

- Individual interviews and focus groups

- Surveys

- Observations

- Existing data

- Funders and study investigators should identify what risks might be present in a study and determine what next steps are necessary

- If there are potential risks, consider IRB approval

Decision Tree – Starting Point

Research or evaluation? —— No ——→ Not research or evaluation.

No protections required.

Yes

Involves **living** individuals? —— No ——→ No human subjects.

No protections required.

Yes

Method of data collection?

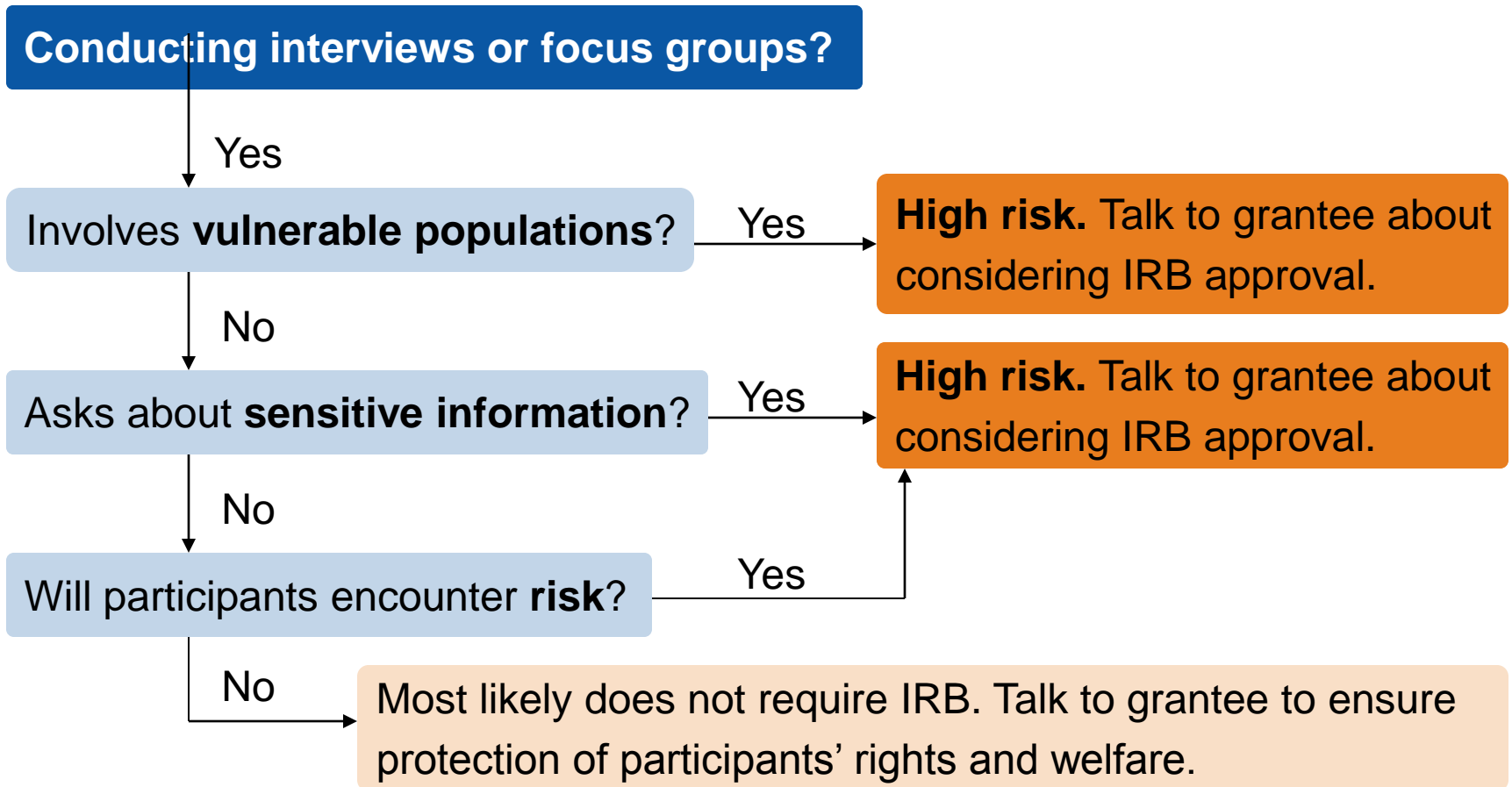**Existing data** **Observations** **Surveys** **Interviews & Focus Groups**

Issue Spotting Guidelines

Guidelines outline risk factors aside from data collection methods

A. Potential Risks

B. Equitable Selection

C. Informed Consent

D. Privacy & Confidentiality

E. Identifiable & Sensitive Information

F. Vulnerable Populations

G. Research in Public Schools

H. International Research/Evaluation

I. Publishing Findings

Decision Tree – Focus Group

Conducting interviews or focus groups?

Yes

Involves **vulnerable populations**? — Yes → **High risk.** Talk to grantee about considering IRB approval.

No

Asks about **sensitive information**? — Yes → **High risk.** Talk to grantee about considering IRB approval.

No

Will participants encounter **risk**? — Yes ↑

No → Most likely does not require IRB. Talk to grantee to ensure protection of participants' rights and welfare.
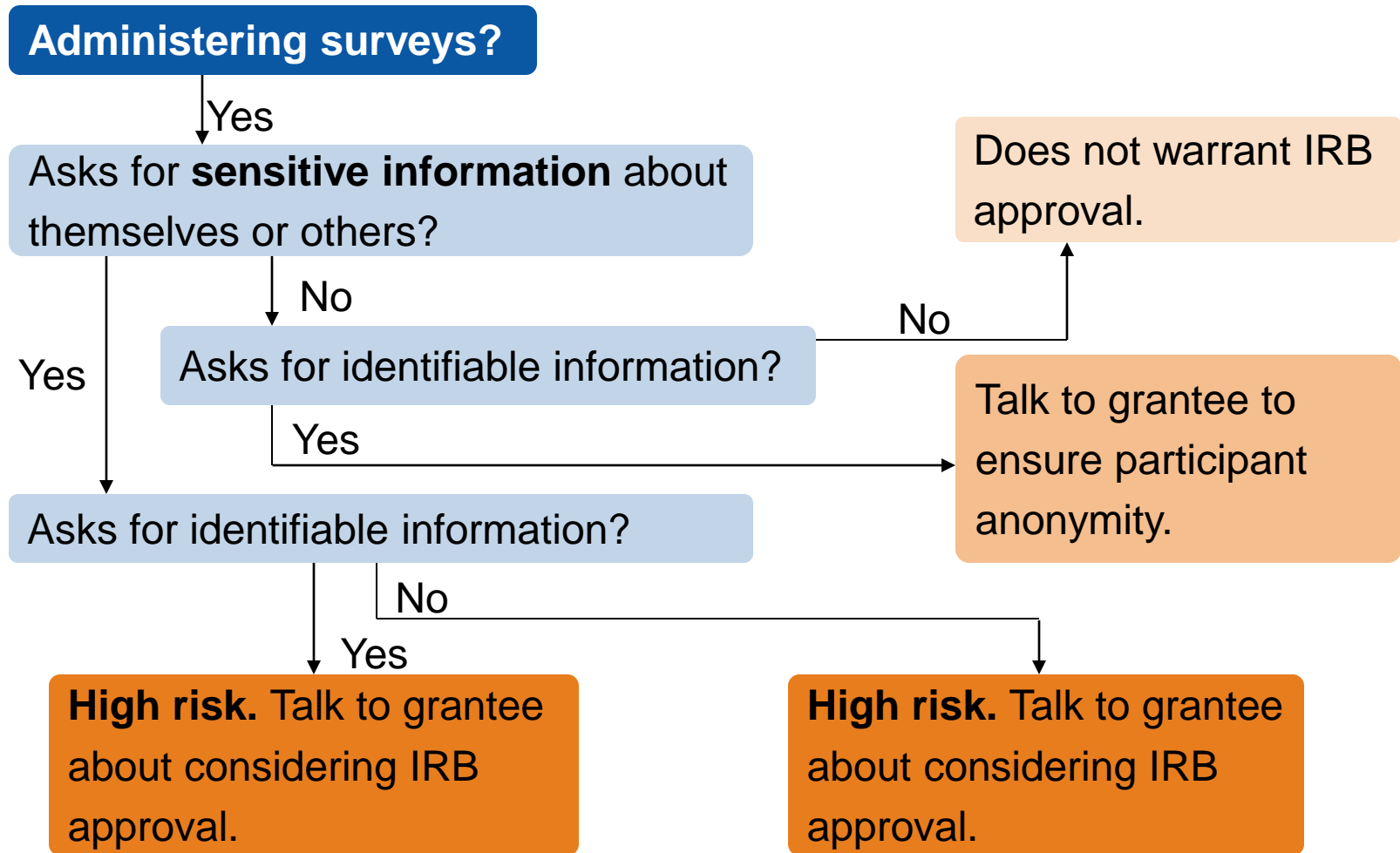
Potential Risks & Issues in a Survey

Discussion Questions:

- Are there any **potential risks** to a person filling out this survey?

- Do the answers to any of the questions include **identifiable information**?

- Are any of the questions **sensitive**?

Decision Tree – Survey

Administering surveys?

↓ Yes

Asks for **sensitive information** about themselves or others?

No →

Asks for identifiable information?

No → Does not warrant IRB approval.

Yes → Talk to grantee to ensure participant anonymity.

Yes ↓

Asks for identifiable information?

Yes ↓ **High risk.** Talk to grantee about considering IRB approval.

No → **High risk.** Talk to grantee about considering IRB approval.

Survey Debrief

Is the provided information:

- Identifiable?

  - Clearly identifiable

  - Not identifiable

  - Identifiable depending on context

- Sensitive?

  - Clearly sensitive

  - Not sensitive

  - Sensitive depending on context

- Targeting a vulnerable population?

SURVEY

What is your name?

What is your street name? _____

Do you have access to clean water?   Y / N

What is your favorite color? _____

How would you describe where you live? *(Circle one)*

House/Apartment   Institution

Hotel   Shelter

                        Street/Homeless   Other

Have you ever used any illegal substances?   Y / N

What kind of diapers do you buy? _____

Do you have credit card debt?   Y / N

Are you receiving public assistance?   Y / N

Do you know anyone in your office who can
do a headstand?   Y / N   If yes, who? _____

Do you know anyone who's cheated on their income tax? Y / N
↳ If yes, was it you? Y / N   If no, what is their name? ↴
_____

When is your birthday? _____

Do you know someone who is currently in jail?   Y / N
↳ If yes, what is your relationship with that person? ↴

Summary of Resource Documents

Human Subjects Protection Overview	Tools & Guidelines

- Issues Spotting Guidelines
- Data Collection Decision Trees

Example Materials	Additional Resources

- Grant Scenario
- IRB Approval Process
- Information & Consent Form
- Language for Interview Protocols

- Definition Guide
- History of Human Subject Protection
- Additional External Resources

Summary of Training Toolkit

- Activity Guide

- PowerPoint Presentation

- Mock Focus Group

- Sample Survey
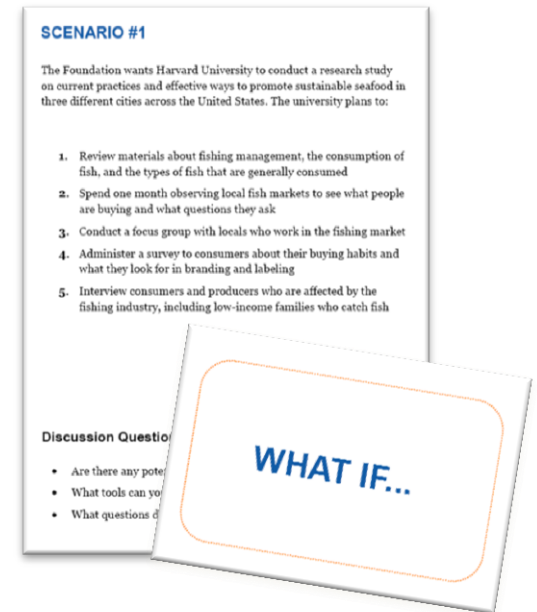
- Scenarios and *What If?* Cards

Scenarios

Read and discuss the scenario at your table.

1. Sustainable seafood

2. After-school programs

3. Family planning for teenagers

Discussion Questions:

- Are there any **potential issues** inherent in these plans?

- What **tools** can you use to figure out potential issues?

- What **questions** do you have for the grantee?

SCENARIO #1

The Foundation wants Harvard University to conduct a research study on current practices and effective ways to promote sustainable seafood in three different cities across the United States. The university plans to:

1. Review materials about fishing management, the consumption of fish, and the types of fish that are generally consumed
2. Spend one month observing local fish markets to see what people are buying and what questions they ask
3. Conduct a focus group with locals who work in the fishing market
4. Administer a survey to consumers about their buying habits and what they look for in branding and labeling
5. Interview consumers and producers who are affected by the fishing industry, including low-income families who catch fish

Discussion Questio

- Are there any pote
- What tools can yo
- What questions d

WHAT IF...

Questions

Permissions