



# Ensuring the Rights of Study Participants

*Training Toolkit for Philanthropic Organizations*

These documents were made  
possible by a generous grant from:

the David  
Lucile &  
**Packard**  
FOUNDATION

Prepared by:

BTW *informing change*

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# Table of Contents

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<b>Preface</b> .....	<b>i</b>
<b>Activity Guide</b> .....	<b>1</b>
<b>PowerPoint Presentation</b> .....	<b>5</b>
<b>Mock Focus Group</b> .....	<b>23</b>
<b>Sample Survey</b> .....	<b>27</b>
<b>Scenarios</b> .....	<b>30</b>
<b><i>What If? Cards</i></b> .....	<b>33</b>

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# Preface

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## ABOUT BTW *informing change*

At BTW we are driven by our purpose of *informing change* in the nonprofit and philanthropic sectors. We partner with our clients to improve their effectiveness and build a culture of learning and continuous improvement through applied research, evaluation, and strategy projects. We develop products that present useful information in an easy-to-understand format, designed to be readily applied to practice. Our information-based services focus on the fields of health, education, youth engagement, and philanthropy.

To find out more about BTW and our services, visit [www.btw.informingchange.com](http://www.btw.informingchange.com).



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# Activity Guide

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## PURPOSE

This activity guide identifies ways that the *Ensuring the Rights of Study Participants: Resource Documents for Philanthropic Organizations (Resource Documents)* and supporting *Training Toolkit (Toolkit)* can be used by philanthropic organizations to understand and articulate the importance of ensuring the protection of research and evaluation study participants, otherwise known as human subjects. The *Resource Documents* provide basic knowledge and useful tools for foundation staff to spot potential areas for their grantees to consider in order to ensure ethically sound studies that involve individuals.

Please see this activity guide as a jumping off point for your own creativity in ways to share and use the resources and tools. We encourage you to adapt these activities (e.g., change examples to align with the work of your foundation or program area) or develop new activities to meet the unique circumstances of your work.

## SAMPLE ACTIVITIES

The following list describes several suggestions of how the documents can be used with foundation staff.

- Distribute all or specific sections of the *Resource Documents* (e.g., Issue Spotting Guidelines, Data Collection Decision Trees) to new staff with other orientation materials.
- Conduct trainings with staff at the start of each grantmaking season, during the commencement of evaluation efforts or at other appropriate times. These trainings can be conducted as part of an all-staff meeting, with groups of staff in each grantmaking area or in other relevant groupings.
- Post the *Resource Documents* electronically with other Foundation reference documents for staff to access on an as-needed basis.
- Pose a question periodically to staff through internal communication channels about a potential study being considered by the foundation, making note of the *Resource Documents* as a useful tool to consult in these types of situations.
- Convene a “brown bag lunch” for foundation staff to discuss a current article or blog posting that relates to protecting the rights of study participants.
- Host a mock focus group, discuss a study scenario or administer and discuss the sample survey during a staff meeting or other internal meeting to refresh staff on the importance of spotting these issues in their work.

## OVERVIEW OF TRAINING TOOLKIT

To facilitate the training process, BTW has developed the *Training Toolkit* to help foundation staff share and engage with the *Resource Documents*.

### PowerPoint Presentation

The PowerPoint presentation gives foundation staff an overview of what it means to spot issues related to protecting participants in research and evaluation studies. The presentation includes an introduction to the concept of human subjects protection and the IRB process, and it takes the audience through several activities to

familiarize themselves with identifying potential risks and issues with research and evaluation studies. The activities build on the *Resource Documents* to involve participants in an engaging way.

## Mock Focus Group

The *Toolkit* includes a mock focus group script to identify potential human subjects risks and issues when conducting a focus group. The script can be discussed separately or as part of the PowerPoint presentation. Four participants are needed to act out this live mock focus group. The script provides descriptions of each person's role, focus group questions, and guidelines for the mock discussion.

Follow these steps to use the Mock Focus Group.

1. Print enough scripts for all four players in the mock focus group.
2. Ask for four volunteers, and assign each a role (Facilitator, Participant 1, Participant 2 or Participant 3).
3. Have each participant read his or her character's description to the full group.
4. Have the participants read the script to the full group.
5. With the entire group, discuss the following:
  - Are there any **potential risks** to the people participating in this focus group (e.g., physical, psychological, legal, economic, and/or social risks)?
  - Are any of the questions **sensitive** (e.g., pertaining to health status, religious beliefs, drug use, social service use)?
  - Did any **confidentiality** issues come up for you (i.e., how is identifiable information being safeguarded)?

## Fictional Scenarios & *What If?* Cards

The *Toolkit* includes fictional research and evaluation scenarios that can be discussed separately or as part of the PowerPoint presentation. In this activity, small groups of three or four staff members should read and discuss each scenario about a hypothetical study that is supported by a foundation. Building on principles established in early slides of the PowerPoint Presentation and identified in the Issue Spotting Guidelines section of the *Resource Documents*, participants engage in discussion about the protection of study participants in the fictional scenarios.

During the discussion, the *What If?* cards can be circulated to the groups to introduce new complexities and implications to the scenarios for further discussion. The *What If?* cards can also be tailored and updated to better fit a foundation's target audience or reach.

Follow the steps below to use the Fictional Scenarios and *What If?* cards.

1. Print one copy of each scenario for each group.
2. Print a copy of the double-sided *What If?* cards. Cut out the individual cards so that each card contains one question.
3. Divide participants into groups of three or four people.
4. Distribute scenarios and a few *What If?* cards to each group for discussion.
5. Give participants approximately 10 minutes to discuss the scenarios using the discussion questions below. You can assign a different scenario to each group or ask each group to discuss all scenarios. The groups should discuss the following questions:
  - Are there any **potential issues** inherent in these plans (e.g., risks, confidentiality, sensitive information)?

- What **tools** can you use to figure out potential issues (e.g., Issue Spotting Guidelines, Data Collection Decision Tree)?
  - What **questions** do you have for the grantee?
6. After participants have discussed the three discussion questions, ask them to turn over the *What If?* cards, one by one, and discuss if the cards raise any additional considerations.
  7. After the discussion, ask each group to report out for two minutes to summarize the key points discussed or highlight one particularly interesting component of their discussion. The focus of the report-out can be tailored to specific group needs or interests.

## Sample Survey

The *Toolkit* also includes a survey activity to generate discussion about the rights of study participants when administering surveys. The activity builds on information presented in both the *Resource Documents* and PowerPoint presentation and can be used during the presentation or as a stand-alone activity. In this activity, participants fill out a 13-question mini-survey. After completing the survey, participants engage in discussion based on three discussion questions.

Follow the steps below to use the Sample Survey.

1. Print enough copies of the survey for each participant in the group.
2. Distribute surveys to participants.
3. Before taking the survey, explain that participants can feel free to make up responses.
4. Participants should take three minutes to complete the survey individually or in pairs.
5. Referencing the Survey Decision Tree (provided in the PowerPoint Presentation and *Resource Documents*), discuss the following questions with the group:
  - Do the responses to the survey make the participant clearly **identifiable**, unidentifiable, or identifiable depending on context (i.e., responses reveal personal information that can be linked to an individual's identity)?
  - Are the questions clearly **sensitive**, not sensitive, or sensitive depending on context (e.g., pertaining to health status, religious beliefs, drug use, social service use)?
  - Are there any questions that may identify a respondent as someone who is part of a **vulnerable population** (e.g., prisoners, children, pregnant women)?



# PowerPoint Presentation

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# 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

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# 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.

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# 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



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# 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

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# Potential Risks & Issues in a Focus Group

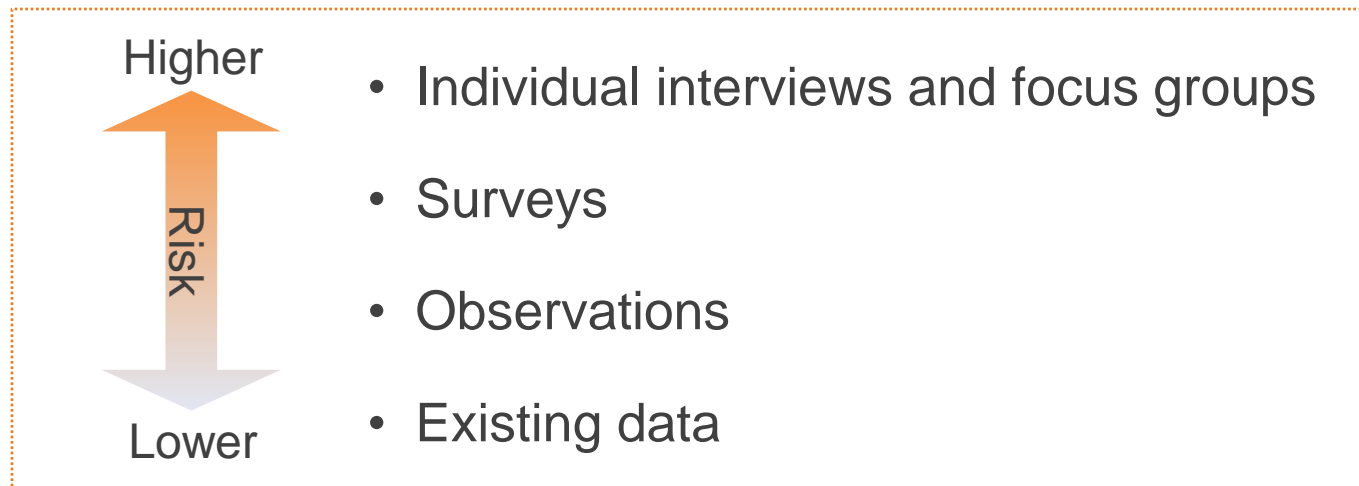
## Discussion Questions:

- 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?

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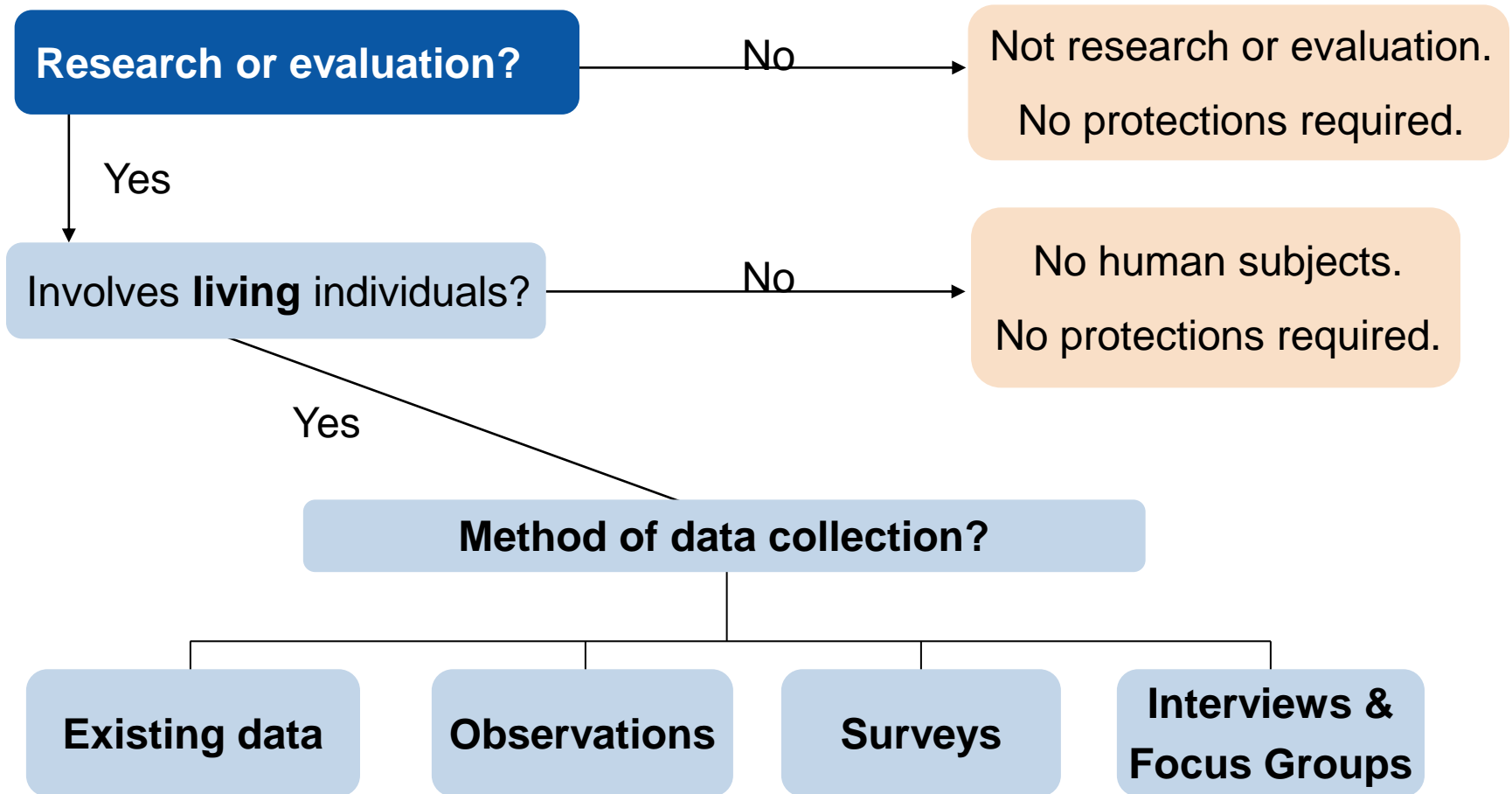
# Tools & Resources

- Data collection methods often correlate with risk level



- 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





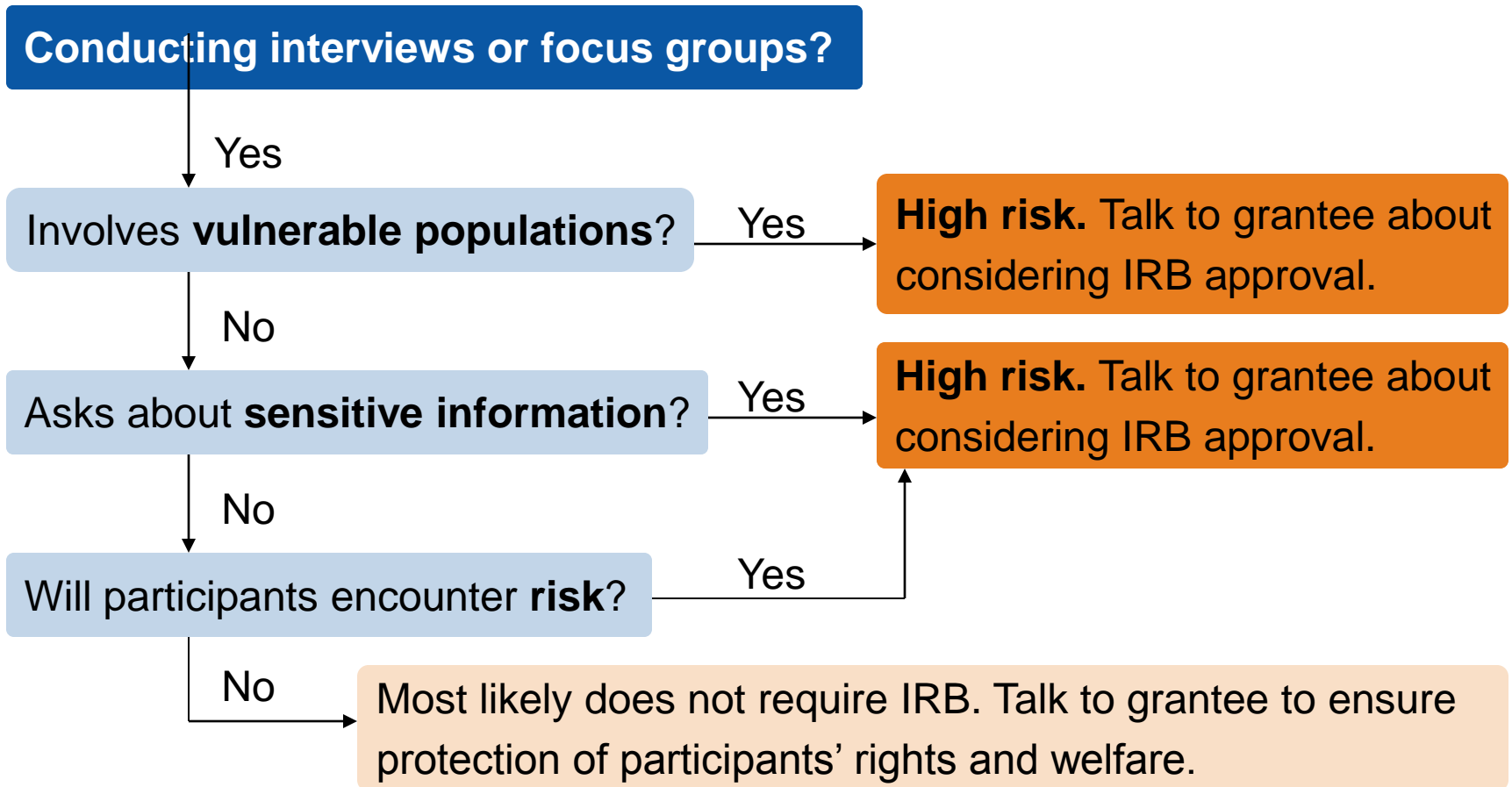
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# Issue Spotting Guidelines

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



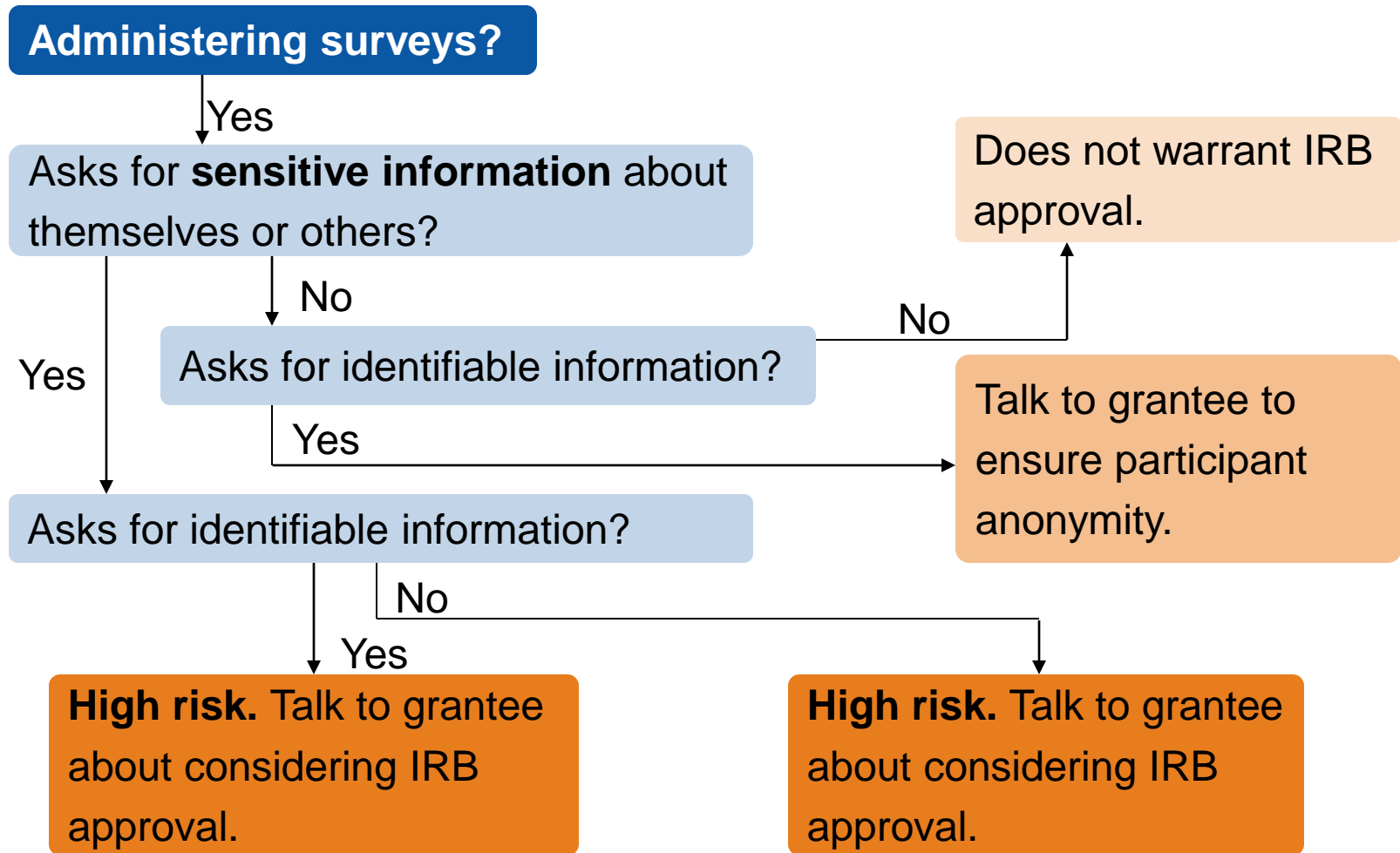
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# Potential Risks & Issues in a Survey

## 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



# 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	Shelter
Hotel	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? \_\_\_\_\_ ↴

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# 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

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# Summary of Training Toolkit

- Activity Guide
- PowerPoint Presentation
- Mock Focus Group
- Sample Survey
- Scenarios and *What If?* Cards

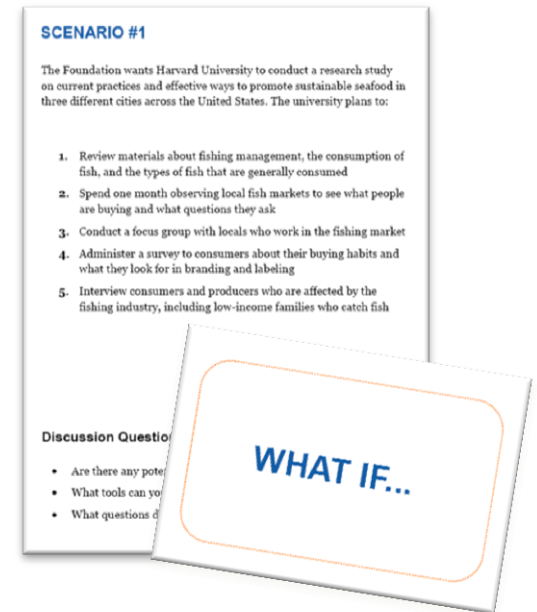
# Scenarios

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?





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# Questions



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# Permissions



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# Mock Focus Group

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## FOCUS GROUP TOPIC

The Peoples' Community Center (the Center) in your town is planning to offer new programming. A community center staff member is seeking feedback about whether they should begin a community garden project, offer nutrition classes or provide a parenting class.

## ROLES

- **Facilitator:** You are the focus group facilitator. You are a staff member at the People's Community Center and are seeking community feedback in order to best tailor the Center's new programming.
- **Participant 1:** You are a 30-year-old, white, pregnant, high school teacher who is currently out of work. You are concerned about sustaining day care for your 5-year-old son and the child you are expecting.
- **Participant 2:** You are a 17-year-old Latino youth who will be graduating from high school next year. You are interested in learning more about healthy food for you and your family.
- **Participant 3:** You are a 40-year-old African American program staff member at a local nonprofit organization. You are interested in working with the Center to create an outside space to teach about healthy food and promote community cohesiveness.

## FOCUS GROUP QUESTIONS

1. Do you currently participate in events and activities at the Center?
2. Currently, what is your biggest concern about your community?
3. How would your involvement at the Center change if we were to offer one of the following:
  - A community garden project
  - Evening nutrition classes
  - Evening or weekend parenting classes
4. How have state budget cuts impacted your family? How have they impacted your involvement at the Center?

## SCRIPT

**Before the focus group begins, the facilitator and participants should read their character roles out loud to the audience.**

**Facilitator:** Thank you for taking the time to participate in this focus group. The People's Community Center is always working to best meet our community's needs and provide programming to ensure community cohesiveness. We are at an exciting juncture in the Center's development and are planning to begin a new program. During this discussion, we want to talk with you about what type of programming will best meet your needs and match your interests. None of your identifying information will be shared with the Center so I encourage you to speak candidly. Let's start with my first question: Do you currently participate in events and activities at the Center?

- Participant 1:** Yes. I come for story time with my five-year-old.
- Participant 2:** Yes! I use the gym and I'm a tutor for the after-school homework help program.
- Participant 3:** Not personally. We use the community room as a meeting space for a book club I run through my organization.
- Facilitator:** Great. What is your current biggest concern about your community?
- Participant 2:** Yeah, eating nutritious food with my family is something I am really interested in. I know my friends are talking about this, too.
- Participant 3:** Hmm, well, one concern at the top of my list is energy use and how it affects individual families and the environment. My organization has been involved with working to get more affordable solar energy available in the city.
- Participant 1:** I am concerned about maintaining health insurance and eating enough nutritious food at home over the next few months.
- Facilitator:** Based on those concerns and your current involvement here at the Center, how would your involvement change if we were to offer a community garden project, evening nutrition classes or evening or weekend parenting classes?
- Participant 3:** I guess I might attend, if the program related to my organization's work.
- Participant 2:** Well, it's hard to say. I'd like to say I'm interested in coming to whatever programming the Center offers, but I'm not sure I have the time since I also have a job after school. I think my friends should really come to the parenting classes, though.
- Participant 1:** Hm. I'm sure some of my former students would be interested in these new programs. But, for me it's hard to imagine having the time or money to do any of those things. Would I have to pay? I might not be able to come to any of the programs if I have to pay.
- Facilitator:** That's a really important point. Most of our programming here is offered on a sliding scale. No one is turned away for a lack of funds, especially given the current economy. On that same note, would you be willing to share a little about how the economy and budget cuts have impacted your family and your involvement at the Center?
- Participant 1:** The cuts have been major for us. I recently lost my job, which is really difficult with another baby on the way. We've come to rely more on the Center for community meals and clothing donations. I'm collecting unemployment but am nervous about the upcoming months and what will happen after the baby is born.
- Participant 2:** The Center has been pretty important to my family in the past few years—when I am not taking care of my younger brother, he comes here for tutoring and programming after school so that my mom can work. We only live a few blocks away, so it's easy for us to get here by ourselves.
- Participant 3:** Recently I've heard more of the people who participate in my organization reference the Center and talk about attending programs here.
- Facilitator:** Great. Thank you all for your participation.

## DISCUSSION QUESTIONS

With the entire group (mock focus group participants and observers), discuss the following questions.

1. Are there any **potential risks** to the people participating in this focus group (e.g., physical, psychological, legal, economic, and/or social risks)?
2. Are any of the questions **sensitive** (e.g., pertaining to health status, religious beliefs, drug use, social service use)?
3. Did any **confidentiality** issues come up for you (i.e., how is identifiable information being safeguarded)?

# Sample Survey

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## 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)*

<b>House/Apartment</b>	<b>Institution</b>	<b>Shelter</b>
<b>Hotel</b>	<b>Street/Homeless</b>	<b>Other</b>

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? ↴  
\_\_\_\_\_



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When is your birthday? \_\_\_\_\_

Do you know someone who is currently in jail? **Y / N**

↳ If yes, what is your relationship with that person? ↴  
\_\_\_\_\_



## DISCUSSION QUESTIONS

1. Do the responses to the survey make the participant clearly **identifiable**, unidentifiable, or identifiable depending on context (i.e., responses reveal personal information that can be linked to an individual's identity)?
2. Are the questions clearly **sensitive**, not sensitive, or sensitive depending on context (e.g., pertaining to health status, religious beliefs, drug use, social service use)?
3. Are there any questions that may identify a respondent as someone who is part of a **vulnerable population** (e.g., prisoners, children, pregnant women)?

# Scenarios

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## SCENARIO #1

A 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 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 #2

A foundation awarded a grant to an evaluation consulting firm to develop a written and video case study about technical assistance for after-school programs. The evaluator plans to:

1. Review program documentation, reports, and resources that are publicly available or provided by the foundation
2. Observe and videotape students and staff at an after-school program on a public school site
3. Conduct group and individual interviews by phone and in person with thought leaders, after-school program providers, and California Department of Education staff

### 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 #3

A foundation awarded a grant to a community health clinic to evaluate its family planning program for teenagers. The clinic plans to:

1. Review internal and publicly available program documentation, reports, and resources
2. Administer surveys to teenagers who come to the clinic about their reasons for using the program and their behavioral changes. The survey is anonymous but asks for their age and zip code, as well as about their sexual behavior
3. Conduct interviews with the family planning program administrators about their interactions with 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?

## What If? Cards

---

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

### **All Scenarios**

... this study was to be carried out in Argentina?

### **All Scenarios**

... the grantee wanted to publish the findings?

### **All Scenarios**

... the study was conducted by a collaboration of independent consultants?

### **All Scenarios**

... the study was conducted by a university?

### **All Scenarios**

... the study was conducted by a national evaluation firm?

### **Scenario #1**

... the interviews were videotaped?

### **Scenario #1**

... the producers were interviewed while on the job at fish markets?

### **Scenario #1**

... the focus groups were divided by socioeconomic status or income?

### **Scenario #2**

... the observation was videotaped?

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**

**WHAT IF...**



### **Scenario #2**

... the evaluators want to interview children in the after-school programs?

### **Scenario #2**

... the evaluators want to review performance assessments of after-school workers?

### **Scenario #3**

... the clinic wants to review patient medical records for teens completing the survey?

### **Scenario #3**

... the clinic wants to observe teens in the clinic waiting room?

### **Scenario #3**

... the clinic wants to interview parents with their teens?

### **Scenario #3**

... the clinic wants to conduct focus groups with teens on the same issues covered in the survey?



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