

## Activity: Is It Human Research?

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### **Introduction**

There are many activities that involve people that are similar to human research. Sometimes it can be very hard to tell the difference. However, as we are learning, there are special rules for research that involves human participants. It is important to know the difference between things that are human research and those that are not.

This exercise will help us determine what kinds of activities are subject to federal guidelines for human research.

There are several definitions in the **Glossary of Key Terms** that should be reviewed with learners prior to starting this activity. These are:

### **Data Collection**

The process of getting information in research. Data collection may include direct contact with research participants. For example, doing surveys and interviews involves interacting with participants and asking them questions to get information. Data collection can also include observation. For example, research may involve watching people do something, such as grocery shopping, and writing down information about them and what they do. Data collection can also involve getting information about people from records that already exist, such as medical, laboratory, or school records.

### **Human Research**

A study that collects information from or about living people.

### **Research Participant (Human Subject, Research Subject, Subject, Participant)**

A living person about whom information is collected in research. We prefer the term “participant” rather than “subject.” Participant implies active engagement in the research (research *with* participants) rather than passive involvement (research *with* subjects). However the term “human subjects” is still used in many formal research-related documents and guidelines.

### **INSTRUCTIONS**

This activity can be structured in several different ways. You can have all students complete the worksheet on their own and then discuss answers as a group. You can also go through the questions as a group, and either discuss answers as you go or after all questions have been answered.

## Part 1 Handout

*Think about each activity. Decide whether it fits the definition of “human research” that you have just learned. It’s okay if you’re not sure. Not all questions have an easy yes or no answer.*

1. To find out how well a new medicine works, people in Group A get a new medicine, and people in Group B get the old medicine and their health is compared.
2. A telephone survey asks Chicago residents their views on metered street parking.
3. A reporter stops you on the street and asks your opinion about the new parking meters for a TV news segment.
4. Your son’s school sends home a survey about family meals for parents to complete and return in a sealed envelope.
5. Your doctor recommends that you attend a free program at a nearby community center. He says the program is effective in helping people manage their hypertension.
6. A student collects the addresses of all the schools, parks, and liquor stores in the neighborhood and puts them on a map.
7. While browsing the Internet you see a link that says: “Are you a smoker? Click here if you would like to participate in a research study about your smoking habits.”
8. You ask a neighbor to tell you about her involvement in the civil rights movement.
9. A neurologist looks at the medical records of patients diagnosed with multiple sclerosis to see what tests were done to rule out other diagnoses.

## Discussion Case: “Just Sign Me Up!”

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*Bill works at a local community-based organization and runs several after-school programs for youth. He is well-liked by all the parents and their children. He has been asked by the head of the organization to help recruit parents to participate in a research study on parenting. Parents will be required to attend 8 one-hour sessions over the course of a few months and fill out questionnaires four times over a period of one year. They will be paid \$10 cash each time they complete questionnaires. One day Bill approaches Elizabeth, a mother of one of the 12 year-olds in his computer club, and asks her if she'd be interested in participating in the study. When he hands her the 3-page consent form, Elizabeth quickly says, “I don't need to read this whole thing. If you think this study's okay, just sign me up. I'll do it!”*

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**Can Bill sign up Elizabeth to be in the study?**



### TAKE AWAY MESSAGE

In research, it is not enough for participants to agree to participate – they must know exactly what they are agreeing to. The federal regulations for research that we discussed in Part 1 outline what details are required for “informed” consent.

**What is the difference between saying “yes” and understanding what you say yes to?**

**TAKE AWAY MESSAGE**

It is a pretty universal rule that lying is wrong. In research, this is especially true. Because of all the research abuses that we learned about in Part 1, telling participants the truth about research participation – and not just the truth, but all the important details that might affect participation – is very important

**What reasons might Elizabeth have for saying yes before she has read the consent form?**

**TAKE AWAY MESSAGE**

There are a variety of reasons that people may say yes (or no) to research participation.

**What should Bill do next?**

**TAKE AWAY MESSAGES**

We are bombarded daily with lots of information, and it can be overwhelming. Life is fast paced, and everyone has busy schedules. Asking people to participate in research is adding to their burden, and asking people to take extra time to read long consent forms can be uncomfortable. Not reading “the fine print” is very common. We can all think of a time when we have signed something without really reading – a cell phone contract, a child’s report cards, petitions, and forms at the doctor’s office or the hospital.

## Part 2 Handout

Think about how you might feel or act differently if you were asked to participate in a research study by: a stranger; a neighbor; your doctor; the principal of your child's school; or a friend's daughter working towards a masters degree.

### TAKE AWAY MESSAGES

- It is much harder to say no to someone you know. If you trust the person asking, then it is quite easy to say yes. But research is a unique situation and participating is a personal decision. Everyone has different ideas about what risks they are willing to take and what personal information they are willing to share.
- People may overestimate the benefits of research participation if they know the person asking them.

**How can getting informed consent make the research experience better - for the participant and for the research team?**

### TAKE AWAY MESSAGE

If the public believes that researchers do not follow rules, lie to participants, and treat them like "human guinea pigs," then people may not want to participate in research. This will limit the ability of researchers to recruit enough people into studies and gather good data. This will have a negative effect on the usefulness of research.

## Role Plays: Informed Consent In Action

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Role plays should be done in small groups of 2 or 3 depending on the size of the class. Students should spend about 20 minutes doing role plays. Then the entire group should come together to discuss.

This activity can be done using one of the model consent forms or ideally, the consent form for the study on which participants will actually be working. Role players will need to study the consent form and the notes below prior to the role plays

Individuals in each small group should take turns being the person obtaining informed consent and the participant. The observer role is optional and can be replaced by discussion. (Observer/discussion notes can also be the basis of the larger group discussion).

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### **Role Play 1: *Understanding***

*George:* Responsible for obtaining informed consent.

*Rita:* 60-year old woman. Has diabetes and meets other inclusion criteria. Has limited reading skills and poor eyesight. Makes excuses about why she does not want to read the form. Makes incorrect statements about the research. Asks questions that show that she does not understand what is involved in research participation.

*Observer/Discussion:* Note different strategies that George can use to help Rita understand the study without making her feel uncomfortable.

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### **Role Play 2: *Inclusion/Exclusion Criteria***

*Martha:* Responsible for obtaining informed consent

*Joseph:* Does not have diabetes and therefore does not meet inclusion/exclusion criteria. Still wants to participate because the research study provides \$10. Lies about having diabetes in order to try to qualify. Tries to persuade Martha that she should let you sign up because you really need the money.

*Observer:* Note questions that Martha can ask to ensure that Joseph meets the study's inclusion/exclusion criteria. Note ways that Martha can explain to Joseph why he cannot participate. Note strategies that Martha can use to tell Joseph no without being rude.

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**Role Play 3: Coercion**

*Fred:* Responsible for enrolling participants and obtaining informed consent. Has not successfully recruited anyone today. Begs, pleads, bribes, and uses guilt – i.e., tries everything! to get Rick to sign the consent form. Tells Rick that the research is really going to help him and going to do a lot of good for the community. Tells Rick that he will lose his job if he doesn't sign up enough people. Tells Rick that if he is concerned about privacy, he doesn't have to use his real name or answer questions honestly.

*Rick:* Does not want to participate because he does not have time and is also concerned about his privacy and the confidentiality of the information he will share.

*Observer:* Note what is wrong with the ways that Fred tries to persuade Rick to sign the consent form. Note the various things that Rick does and says to demonstrate that he is not interested. Note what might be some more appropriate ways of dealing with Rick's concerns about privacy.

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**Role Play 4: Participant Questions**

*Kim:* Responsible for obtaining informed consent.

*Janet:* Is interested in the study, but also has a lot of concerns, questions, and ideas about research.

*She wants to know:*

- Why is this research being conducted in my neighborhood?
- Who is this research going to help? What changes can she expect in her community?
- Is she going to be used as a guinea pig? Are scientists going to experiment on her?
- How is her information going to be kept private? Her cousin signed up for a research study, and his identity was stolen 2 weeks later.
- Where is the money for this research coming from? Why isn't that money being used to provide community services?

*Observer:* Note the answers Kim provides in response Janet's questions. Are they accurate and persuasive? What are some other potential responses?

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## Discussion Case: “To Tell the Truth”

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*You work for a youth advocacy agency. The agency is partnering with a local university on a research project. You and a coworker, Mike, are going door-to-door in the neighborhood to find out how many people in each house have asthma. If there is a child in the house with asthma, you then ask a parent to complete a brief survey. You go block by block, with you and Mike each working on opposite sides of the street. That way, you can move through each block quickly but still feel safe. You learned at training that it’s okay to read the survey out loud and fill in answers for people, but that you should write down the answers while the person is telling them to you.*

*When you get back to your car, you notice that Mike is writing an awful lot on one of the surveys. You ask what he is doing, and he responds, “Oh, the person in the blue house asked me to read the questions to them, so I’m just filling in the answers.” You also notice that he’s marked only one of the houses on his block as still needing to be surveyed, when you were pretty sure there were at least 2 others with no answer at the door.*

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**Would you say something to Mike?**

**What would you say?**

**Who should you tell about Mike’s behavior?**

## Discussion Case: “Secrets”

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*(This case has been adapted from “Ethical Protections in Community-Engaged Research,” Michigan Institute for Clinical & Health Research, Stephanie Solomon and Patricia Piechowski-Whitney)*

Mary is employed as a data collector for a survey to find out more information about the needs of people in her community who are HIV positive. For the next two weeks, she is supposed to sit at a table in the lobby of a community clinic that serves people who are HIV positive and also provides HIV and other STD testing and counseling services. She is supposed to ask everyone who walks by if they would be willing to take 10-15 minutes to fill out a health survey. This way, she does not ever ask people directly if they are HIV positive. Instead, HIV status is a question within the survey, and those who answer yes are directed to complete an extra set of questions. People are told not to write their names on the survey in order to keep the answers private.

While she is working, she sees her neighbor, Joe, who has also been romantically involved with her cousin Sandy for a few months. Mary asks Joe to complete a survey. He agrees, but Mary is not sure that Joe recognizes her. Mary is supposed to place each survey in a sealed envelope and not look at the answers.

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**If you were Mary, would you be tempted to look at Joe’s survey to find out if he is HIV positive?**

**What if you don’t look at Joe’s survey, but you tell your cousin that you saw Joe at the clinic. Is this okay?**

## Part 3 Handout

Researchers partner with local communities so that participants can interact with someone who is familiar. However, this case demonstrates how problems can occur when research places people in situations where they might learn private information about people they know. What are some of the “pluses” and “minuses” of being involved in research in one’s own community?

How might this study have been planned better in order to avoid this problem?