Instructor Notes

This workshop series was designed to introduce Community Health Workers (CHWs) to basic research concepts, and provide primary preparation for CHWs to begin work as study recruiters and/or interventionists. It is not intended to replace project-specific training; rather to provide a general introduction to research.

The original curriculum was written for a mixed group of Spanish-speaking Promotoras and clinic staff in Imperial Valley, CA. Certain concepts, discussion points and activities in the curriculum reflect what the authors have learned through work in this community; through focus groups, meetings, and discussions with community leaders. To the extent possible, the curriculum should be modified to honor and address the experiences and circumstances of the community within which it is being presented.

Activities can also be modified to fit time and location constraints. Though they are not included in this training guide, the authors recommend setting aside sufficient time for breaks/light meals, and for a recognition/certification event at the end of the training. The workshop was originally implemented through three weekly 3-hour sessions, which included breaks, dinner and recognition for participants.

Handouts and worksheets were also developed for this training series, and are included at the end of this document. Please note that materials other than the included documents are required for certain activities.
Session 1: Studies and Informed Consent

Needed Materials

Table tents for names (can use folded index cards)
Experiment Score Sheet (Appendix 1)
Flipchart-sized Summary Score Sheet (Appendix 2)
Model Consent Form (Appendix 3)
Consent Form Checklist (Appendix 4)
Flipchart-sized Model Consent Form
Chocolate Sandwich Cookies
Mini-Carrots
Easel with flipchart, and/or dry erase/ chalkboard

Optional Materials

Actual consent forms (provided by actual studies)

Key Vocabulary

Research
Participant
Consent Form / Informed Consent
Experiment
Control Group
Intervention (Group)
Confidentiality
Randomization
Blinding
Institutional Review Board (IRB)
Confidentiality
Risks
Benefits

Description

- Class participates in a hypothetical experiment to determine whether eating a carrot after eating a cookie cleans the cookie from the teeth. Experiment includes having participants play roles of “research participants” and “investigators”. Model consent forms are used and participants are randomized into groups eating the carrot after a cookie, and only eating a cookie. Researchers are blinded, and use guides to determine remaining food on teeth.

- Class uses consent form checklist to review model consent forms from previous activity. Checklist includes descriptions of items legally required on consent forms, as well as recommended items. In pairs and then later as an entire group, class finds...
Objectives
Participants will be able to

- Explain purpose of basic components of clinical/scientific research
- Establish the roles of research participants and investigators in a simple experiment
- Use key vocabulary to describe components of research
- Identify mandated and recommended components of various informed consent documents, and understand basic rationales for these components
- Recognize similarities in basic structure and language among consent documents
- Apply skills when providing and obtaining informed consent

Introduction to Workshop

Ice Breaker / Appreciative Inquiry

- Ask participants to write their names on table tents as shown:

<table>
<thead>
<tr>
<th>Experience in Research (work or as participant)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Names of Family Members</th>
<th>Favorite Food</th>
</tr>
</thead>
</table>

- Allow participants time to introduce themselves and explain their table tents
  - Note overall level of research experience among group, probe for more information if necessary
- Appreciate and congratulate participants for the hard work that they already do for the community’s health
- Explain purpose of workshop series:
  - Train participants to better understand research and be able to explain it to others
  - For some, these concepts may be review. For others, they may be new. Remind not to be embarrassed to ask questions or make comments
- Recognize that their positions in the community (as liaisons) may put them into roles
in research, which differs than other roles they may have
- This course is meant to prepare them for research
- This course does not guarantee that they may be hired for a study, though it is meant to equip them better if that does happen

Activity #1A: Cookie and Carrot Tooth Experiment

We are going to answer a question today through an experiment of our own.

Introduction

Children, especially the youngest ones, do not clean their teeth with their tongues after eating, as do older people.

Dental hygienists and dentists often tell parents of toddlers to give them a crunchy food after they have eaten cookies or chips, to help clean their teeth. This mock experiment is designed to test to see if that works.

Steps

1. Give each student one tooth score sheet and one full-size chocolate sandwich cookie.
2. Explain to the group that before doing the experiment, they are going to practice grading teeth.
3. Divide students into pairs. Have each eat a cookie and then let the pairs score one another. (Students who are unable or unwilling to eat a cookie need not do so, but can score their partner. These individuals should later be assigned as “researchers”, not “research participants”.)
4. Ask all students to clean their teeth with their tongue.
5. Divide class into 1/3 “researchers” and 2/3 “research participants”. (Those that do not eat cookies will be “researchers”).
6. Instructor explains and asks everyone to read the model consent form. The “research participants” will sign the form. One recommendation for this step is to have “researchers” take turns reading segments aloud to entire group.
7. Ask “researchers” to leave the room and to take a tooth score sheet and model consent form with them. One instructor accompanies them outside of the room to emphasize the importance of not knowing which research participants ate the carrots.
8. “Participants” call out a number (1 or 2) and remember that number. Give all odd numbers a cookie. Give all even numbers a cookie and a carrot.
9. All students eat the cookie at same time. Even number students eat the carrot.
immediately AFTER the cookie.

10. Reinforce that research participants should not clean their mouths with their tongues. Explain importance of keeping “researchers” “blinded” to who got carrot, when they re-enter room.

11. Immediately after all is eaten, invite “researchers” back into room. Each “researcher” chooses any two “participants”. Using the tooth score sheet, researchers grade their teeth.

12. Put Summary Score Sheet on flipchart paper. Write in results and calculate average scores for “even” and “odd” students.

Post-Activity Discussion

- Would you say that this activity is research? Why or why not?
  - Research is a systematic way to try to answer a question, so yes, it is
  - It can be used to answer many types of questions – some research involves people. A lot of these studies are trying to answer questions about health
  - Research can be done in labs or in libraries, but a lot of research involves people taking part.

- In this example, what were we trying to find out?
  - Whether eating a carrot after eating a cookie cleans the cookie away from teeth

- In this activity, we explained the experiment to the participants and asked them to sign the consent form before we were able to include them in the experiment. What would have happened if we didn't have them sign the consent form first?
  - Discuss importance of informed consent
  - All studies use consent forms like this one

- In this activity, we used a score sheet to assign numbers for the amount of cookie left on the teeth. What would have happened if we didn't have scores, but just asked you to tell us whether it looked like there was less cookie on the teeth?
  - Importance of objective measures in research

- In this activity, we had two groups, one of which didn't eat the carrot. What would have happened if we only had one group of people who ate the carrot?
  - Introduce idea of control groups – those that did not eat the carrots served as ‘controls’ to compare to those who did eat the carrots

- In this activity, we gave each person a category (“odds” or “evens”), instead of using their names. What would have happened if we used people’s names, instead of categories? What if it was an experiment about something personal, such as weight loss or drugs to treat certain health problems?
  - Introduce idea of confidentiality

- In this activity, people ended up in their groups by chance. What would have
happened if we just let people choose in which group they would be?
- The people that choose one group or the other might be different than randomly chosen people
- For example, people that choose the carrot group may not like the taste of a cookie, and may clean their teeth with their tongue more than those that like the taste of chocolate cookies
- Randomization: Everyone has an equal chance of ending up in either group

- In this activity, the researchers left the room so that they did not know which people were eating the carrots. What would have happened if they stayed in the room and knew who ate the carrots and who did not?
  - Knowing who ate the carrots may have changed the way people look at the teeth. They may "see" what they want to see or expect to see.
  - Blinding: The people who are observing do not know who was given which treatment.

- This activity was looking at a question about health (oral health). In general, what purposes do health and medical studies serve in the real world?
  - To better understand something about people, like what is normal blood pressure
  - To test a new idea to see if it works, for example a new diet or a new medication

- How has medical research benefitted the community in general?
  - Painkillers, antibiotics, chemotherapy, MRI machines, weight-loss programs, smoking cessation programs – all of these were only possible because people volunteered to be in the studies that helped develop these ideas
  - For those reasons, we are very grateful for everyone who has been in a study before. Because of their contribution, we have access to treatments when we need them
  - However, there is always a need for people to volunteer for new studies

**Activity #1B: Informed Consent**

**Introduction**

We have talked about the importance of informed consent in research studies. We will now learn to look at consent forms carefully to find the information that is needed for study volunteers to make informed decisions.

**Steps**

1. Display flipchart-sized printout of Model Consent Form
2. Hand Consent Form Checklists out
3. Explain that items in the checklists come directly from laws requiring that we include
those items
   a. So, this checklist can be used with all consent forms
   b. Page 1 includes the information that is required (if applicable), and page 2 has
      information that is suggested (if applicable)

4. Divide the class into groups. Each group is responsible for finding and numbering
   assigned elements from the checklist on the copies of the model consent forms that
   they have from the previous activity.

5. Once groups have finished, reconvene as a large group and identify elements on large
   model consent form printout together
   a. Use Consent Form Checklist Activity Instructor Guide (Appendix 5)

Optional

6. Repeat activity as a group, using actual consent forms. (This may be helpful if this
   training is utilized as a component of training for a particular study.)
Preparation for Next Session

- Ask participants to share home remedies that are known in the community (e.g., cold remedy, diaper rash, etc.)
  - Prompt if they are stuck: chicken soup for colds

- Ask participants to consult with friends and family to select one home remedy by next week
  - Our “task” for the following week is to design an experiment to “test” these remedies
Session 2: Study Design

Needed Materials

Study Design Worksheet (Appendix 6)
Flipchart-sized Study Design Table (Appendix 8)

Key Vocabulary

Placebo Effect
Blinding/ Blind and Double-Blind Studies
Interventional Study
Observational Study
Randomization
Eligibility
Recruitment
Screening
Informed Consent
Risks
Benefits
Institutional Review Board (IRB)

Description

- Participants are asked to think of home remedies that are used in their communities. With direction of instructor, class designs hypothetical studies to test whether remedies actually work, or whether positive results are due to placebo effect. Using a worksheet, class considers study type, blinding, eligibility, randomization, recruitment, study location, possible risks and benefits to research participants, ethical considerations, and confidentiality.

- Depending on time constraints and home remedies suggested, a study may be designed to compare two or more remedies, or individual studies may be designed. Group discussion to cover key concepts and vocabulary, emphasizing importance of rigorous science and human subjects protection/ ethical considerations in well-designed studies.

- Participants are asked to describe their previous experiences in research. Descriptions prompt discussion about typical research tasks that involve CHWs.

Objectives

Participants will be able to
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- Evaluate factors in effective study design
- Recognize rationale behind certain protocols in research
- Apply basic ethical guidelines to study design
- Explain various key concepts learned in previous activities, though in context of local community
- Recognize local challenges in working in research, and propose potential ways to address these challenges

Activity #2A: Study Design

Pre-Activity Discussion

- Though participants will most likely never be asked to design a study, it is important to understand how studies are designed to be better able to explain them to others and to understand why things are done the way they are

- Talk about US medical system
  - Doctors aren’t able to prescribe medications unless they are first tested through Interventional Studies
  - Home remedies that are passed down through generations often aren’t known to doctors because they haven’t been tested in these types of studies
  - The next activity is going to help us determine if we could set up a hypothetical Interventional Study to see if any of our home remedies can be used medically
  - We are not actually going to test the remedies, but we will look at how experiments are set up

- There are two important factors that keep certain medicines and remedies, no matter how promising they are, from being studied:
  - Can you set up a study that can produce strong enough results to show that the remedy actually works as well or better than other options that are already available?
    - Some factors in answering that question include blinding (to help prevent placebo effect), number of participants, an interventional study (not observational), randomization, and a good way to measure the results. The more of these factors that you have, the more powerful the study results are
  - Will your study be fair, respectful, and beneficial for its participants?
    - Some factors include informed consent, confidentiality, and having potential benefits that outweigh risks
    - The kinds of communities that participate in the study should be the same kinds of communities that could benefit from the results of the study
    - The Institutional Review Board (IRB) reviews the project, and can reject a study if it is not designed well enough

Steps
1. Display large printout of Study Design Grid (Appendix 8)

2. Hand Study Design Worksheets out, either to individuals or to groups
   a. Explain that these worksheets will be used to design studies to test the home remedies
   b. Recommended: Before asking individuals or groups to fill out, go through worksheet as a group, using Instructor Guide (Appendix 7)

3. Once groups or individuals have completed worksheets, go over each project as a group, noting or checking off on the Study Design Grid whether a study can be designed that fits the criteria. See Study Design Table Instructor Guide (Appendix 9).

Activity #2B: Local Context

Steps

1. Instructor leads discussion of research in local context. Participants are asked to describe their previous experiences in research. Descriptions prompt discussion about typical tasks that Community Health Workers are involved with in research, including recruitment, screening, and informed consent.
Session 3: Health and Medical Research in the Community

Needed Materials

Case Study Sheets (Appendix 10 or created by you)
Large flipchart sheets (as many as case studies)
Flipchart markers

Key Vocabulary

Placebo Effect
Blinding/ Blind and Double-Blind Studies
Interventional Study
Observational Study
Representative Sample
Human Subjects Research
Confidentiality
Informed Consent
Bias
Randomization
Recruitment

Description

- Participants work in groups to analyze situations that might occur when community health workers and health providers work as recruiters and/or interventionists in research. Groups present their scenarios and answer discussion questions, while instructor facilitates group discussion.

- Instructor facilitates a participant-generated discussion of local health disparities and research priorities.

Objectives

Participants will be able to

- Describe rationale behind certain protocols in research, and importance of adherence to protocol
- List potential roles in research that community health workers and health administrators may have, and potential situations that may occur as they work in these roles
- Recognize differences and potential conflicts between roles of health educator/ health provider and research recruiter/ interventionist, and evaluate ways to mitigate those conflicts
- Be aware of potential reasons for low retention of study participants, and future ways
Activity #3A: Case Studies

Note: The scenarios used in this activity were created to provide fictional examples of situations that might occur when CHWs and clinic staff work in research. The examples are based on perceptions of research within a specific community, as expressed in focus group and informally. Case studies may be revised to address perceptions and barriers in local contexts.

Steps

1. Divide participants into groups: each group will discuss one case
2. Give each group one Case Sheet, flipchart paper, and a marker. Instruct groups to read cases, discuss questions, and note their answers on flipchart paper. To the extent possible, separate groups into different rooms.
3. If possible: Have co-instructors accompany groups and guide discussions.
4. Once groups have completed questions, reconvene for groups to present their results. Instructor leads large group discussion. Use Case Study Sheets Instructor Guide (Appendix 11).
Activity #3B: Local Context

Steps

1. Instructor leads a second discussion of research in local context. Participants are asked to describe their perceptions of research, participation in research, and barriers to research that people might experience in their community.
   a. The following are potential themes to cover, though these themes may be modified depending on the context of the local community.

   • Key concepts related to possibly inappropriate participation:
     - Agreeing to participate without understanding
     - Agreeing to participate because of feeling coerced to do so
     - Agreeing to participate because you don't want to let a friend down
     - Dropping out for the reasons listed above or other reasons

   • What motivates people to join studies?
     - Personal Benefits
     - Community Benefits

   • Are there connections between a population not being represented in studies and not being served adequately in healthcare?

   • What are priorities for research in this community?

   • What health issues are of the greatest concern to this group?

   • In what types of studies do you envision people being most willing to participate?

   • How do you perceive medical or health research? Who are the kinds of people who participate in medical studies?
Appendices
Appendix 1: Experiment Score Sheet

Tooth Score Sheet

Name of Researcher: ____________________

Date: ____________________

Practice Score: 0 1 2 3 4

Participant Scores:

___________: 0 1 2 3 4

___________: 0 1 2 3 4

Score = 0  
- No food is stuck to the tooth  
- Tooth is clean

Score = 1  
- About 1/4 of grooves are covered by food

Score = 2  
- About 1/2 of the grooves are covered by food

Score = 3  
- About 3/4 of the grooves are covered by food

Score = 4  
- All of the grooves are covered by food.  
- Food may also be stuck to other parts of the tooth
### Appendix 2: Summary Score Sheet

<table>
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<tr>
<th>Evens</th>
<th>Odds</th>
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<tr>
<td>Tooth Score</td>
<td>Tooth Score</td>
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<th>Total:</th>
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<table>
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<tr>
<th>Average:</th>
<th>Average:</th>
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</table>
Appendix 3: Model Consent Form

Model Consent Form to Act as a Research Subject
“What is a Clinical Trial?”

Do Crunchy Foods Clean Teeth of Mushy Foods?

Food stuck to teeth increases the chances of tooth decay and cavities. Foods like bread, cookies, crackers and chips often stick to teeth. Most people cannot brush their teeth in the middle of the day to clean food out. Children do not naturally clean their teeth with their tongue. This makes young children most prone to getting cavities. Many dentists tell parents to give children a crunchy food, like an apple or carrot, to clean out mushy foods. This Research Study will find out whether crunchy foods do or do not really help clean mushy foods from teeth.

If you agree to be in this study, the following will happen to you:
1. You will be asked to eat a cookie
2. You may be asked to eat a carrot
3. You will be asked to open your mouth and have your teeth (molars at the back) examined
4. Your participation will take a maximum of one hour

The benefits of being in this study are:
1. You will be helping dentists know if crunchy foods really help clean teeth
2. This knowledge will help dentists teach patients about reducing tooth decay
3. It is likely that there are no direct benefits to you as a participant

The risks of being in this study are:
• You may not like cookies or carrots
• If you develop an allergy to cookies or carrots, you could get a reaction
• You may be embarrassed having a person look at your teeth
Even though “researchers” must maintain confidentiality, information about your teeth could possibly be leaked. To better assure confidentiality, you can use a fake name to sign this document.

Your name and other identifying information will not be published with the findings. Research records will be kept confidential to the extent allowed by law. Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time. If you have any questions about this study, please call Dr. “Cookie” at 555-5555. If you have questions about your rights as a research participant, please call the Office of Human Subjects Protection at 555-5556. You have a right to keep a copy of this Consent Form.

By signing this form, you agree to participate.

____________________________________  ______________________
Signature                                      Date
Appendix 4: Consent Form Checklist (2 pages)

Consent Form Checklist

Consent Forms need to be understandable so that people can make informed decisions. Certain information has to be included in every consent form. Can you find these required pieces? Mark your consent form with the numbers.

1. A clear statement that this is a research study
2. Why the researchers are doing this study
3. What will happen to people who are in the study
4. How long people are expected to participate in this study
5. An understandable explanation of the risks of participation
6. The possible benefits of participation, or a clear statement that there are no expected benefits
7. A description of how the research team plans to protect participants’ confidentiality
8. If there are treatment options other than being in the study, a clear description of what those alternatives are
9. If being in the study might cause more risk than is ordinary in daily life, a description of how the research team will care for and/or compensate a participant in case he or she has an injury because of being in the study
10. A statement that participation is voluntary – people don’t have to join if they don’t want to and they can drop out of the study any time without being punished
11. Name of the researcher or researchers, and how participants can contact them in case participants have questions about the study
12. Contact information for the Institutional Review Board so participants can talk about any concerns about their rights as research participants

More on back!
**Bonus: Other Things on a Consent Form**

Depending on what kind of study it is, there is other information that may help people to make informed decisions. Some or even all of these things may also be found on a Consent Form.

- Can you see if any of these other pieces are in your consent form?
- Mark on this sheet whether or not you find them.

- Yes
- No

- Why and/or how participants are chosen for this study
- The number of participants that will be in this study
- Any costs that participants will have to pay to be in this study
- Compensation (payment) for participating
- What will happen if a participant decides to leave the study
- Reasons why the research team might remove participants from the study, even if they didn’t ask to be removed
- How researchers will let participants know about any new findings that might affect the participants while they are in the study or after it is over
- A statement that researchers might not know of all the risks (this is called unforeseeable risks)
Appendix 5: Consent Form Checklist Activity Instructor Guide

Model Consent Form to Act as a Research Subject “What is a Clinical Trial”

Do Crunchy Foods Clean Teeth of Mushy Foods?

Food stuck to teeth increases the chance of tooth decay and cavities. Foods like bread, cookies, crackers and chips often stick to teeth. Most people cannot clean their teeth in the middle of the day to clean food out. Children don’t naturally clean their teeth with their tongue. This makes young children most prone to getting cavities.

Many dentists tell parents to give children a crunchy food, like an apple or carrot, to clean out mushy foods. This Research Study will find out whether crunchy foods do or do not really help clean mushy foods from teeth.

If you agree to be in this study, the following will happen to you:

1. You will be asked to eat a cookie
2. You may be asked to eat a carrot
3. You will be asked to open your mouth and have your teeth (molars at the back) examined
4. Your participation will take a maximum of one hour

The benefits of being in this study are:

1. You will be helping dentists know if crunchy foods really help clean teeth
2. This knowledge will help dentists teach patients about reducing tooth decay
3. It is likely that there are no direct benefits to you as a participant

The risks of being in this study are:

1. You may not like cookies or carrots
2. If you develop an allergy to cookies or carrots, you could get a reaction
3. You may be embarrassed having a person look at your teeth
4. Even though “researchers” must maintain confidentiality, information about the condition of your teeth could possibly be leaked. To better assure confidentiality, you can use a fake name to sign this document.

Your name and other identifying information will not be published with the findings. Research records will be kept confidential to the extent allowed by law. Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time. If you have any questions about this study, please call Dr. “Cookie” at 555-5555. If you have questions about your rights as a research participant, please call the Office of Human Subjects Protection at 555-5556. You have a right to keep a copy of this Consent Form.

By signing this form, you agree to participate.

______________________________  ________________________________
Signature                                                            Date

#3: N/A – no other treatment options available
#9: N/A – no more than minimal risk
None of optional items from page 2 of checklist are on this form
Study Design Worksheet

To test an idea, we must design a study that can have strong results, and that is safe, fair and ethical to the people who volunteer for the study.

What is your study question?

What is your study type?

How will you be able to measure your results to answer your question?

Will you be able to have blinding in your study? If so, how?

What kinds of people will be eligible to participate in your study?

Are you able to randomize your participants?
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How will you **recruit** your participants?

**Where** will your study take place?

What are the possible **benefits** to people that participate in the study?

What are the possible **risks** of being in the study?

In your opinion, do the **benefits** outweigh the **risks**?

How will you protect the participants’ **confidentiality**?
Study Design Worksheet – Instructor Guide

To test an idea, we must design a study that can have strong results, and that is safe, fair and ethical to the people who volunteer for the study.

THIS WORKSHEET IS COMPLETED USING CHICKEN SOUP FOR COLDS AS AN EXAMPLE. THESE ANSWERS ARE EXAMPLES ONLY.

What is your study question?
This is the question that you are trying to answer with your study.
"Does chicken soup really make people with colds get healthy faster?"

What is your study type?
Is it intervention or observational? Intervention studies are not always possible, but they produce stronger results.
"We will have an interventional study because we will be asking participants to eat the chicken soup or the placebo."

How will you be able to measure your results to answer your question?
"We will have participants have a nose swab each morning, which will be tested for presence of cold viruses. We will also have participants fill out a symptom journal three times daily."

Will you be able to have blinding in your study? If so, how?
Can you set up a study in which the participants, or the researchers, or both, cannot tell who is taking which treatment?
"For blinding, you would have to create a placebo that looks and tastes exactly like chicken soup, but isn't, so that the people eating and observing can't tell the difference between the real chicken soup and the placebo. This would be difficult."

What kinds of people will be eligible to participate in your study?
Certain ages, genders, etc.? Do they have to have a certain health condition? Is there anyone that would not be eligible because participating would have too much risk?
"Participants would have to be people who have a cold. All participants would have to be at the same stage of their cold, so we would need to recruit people at the very beginning of their cold. They would be screened to be sure they do have a cold, and do not have other conditions like influenza. People who are allergic to any ingredient in chicken soup or in the 'fake' chicken soup would not be eligible."
Are you able to randomize your participants?

*Randomization* makes the results of the study stronger.

"Yes, the chicken soup study can be randomized."

How will you recruit your participants?

Is it possible to find and recruit enough people into this study? Where will you find people and ask them to join?

"We would have to find people who are just beginning to feel sick. An idea for recruiting participants is pharmacies, because people may go there earlier than they go to their doctor's offices."

Where will your study take place?

Will your study need to be somewhere that has specialized equipment or staff? Is it feasible for the study volunteers to get to that location?

"We would have participants come to a location such as a clinic to be served their soup or placebo. Study staff would be needed to monitor participants to be sure they follow the protocols (eat the correct amount, eat at standardized times, etc."

What are the possible benefits to people that participate in the study?

These could be direct or indirect benefits.

"One possible benefit is getting healthy from a cold more quickly. Also, participants' health will be monitored, so any complications from their cold might be caught earlier than if they hadn't joined the study. They will also be compensated with free cookbooks."

What are the possible risks of being in the study?

If a study has *minimal risk*, it means that the risks of participating in the study are not higher than those of normal day-to-day life.

"One possible risk is that the participants develop an allergy to one of the ingredients of the chicken soup or the placebo. Another risk is that either chicken soup or the placebo actually has a negative effect – making the cold worse, or causing side effects. In general, for this study, the risks are low."

In your opinion, do the potential benefits outweigh the risks?

"Because the risks are probably minimal for most participants, and the possible benefit is recovering from a cold more quickly, it looks like the potential benefit may outweigh the risks."

How will you protect the participants’ confidentiality?

"Study records will be locked in a safe place. Participants will be given identification numbers, and their names will not be connected to their study information."
### Appendix 8: Study Design Table

|------------|------------------|----------|-------------|------------|-------------|-----------|-------------------|-----------------|

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Clinical & Translational Research Institute
858-657-5139 ctri-community@ucsd.edu
## Appendix 9: Study Design Table Instructor Guide

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<tbody>
<tr>
<td>Measure Results?</td>
<td>Yes, with:</td>
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<td></td>
<td>- Diaries</td>
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<td></td>
<td>- Nose swab</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Yes, with placebo</td>
</tr>
<tr>
<td></td>
<td>- Difficult</td>
</tr>
<tr>
<td>Eligibility</td>
<td>Beginning of cold</td>
</tr>
<tr>
<td>Randomize?</td>
<td>Yes</td>
</tr>
<tr>
<td>Recruitment</td>
<td>In pharmacies</td>
</tr>
<tr>
<td>Location?</td>
<td>In Clinic</td>
</tr>
<tr>
<td>Benefits &gt; Risks?</td>
<td>Yes</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>Yes</td>
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Appendix 10: Case Study Sheets (4 pages)

CASE #1

A company wants to test a new sunscreen. They hope their new sunscreen is better than sunscreens already being sold in drug stores. They team up with a professor at a local university and start a double-blind study. The study will ask people who work outdoors (e.g., farmers, postal workers, construction crews) and people who spend time outdoors on weekends (e.g., children who play outside, joggers) to use either the new sunscreen or a regular sunscreen. This is how the study will work: Each person will get a bottle with sunscreen in side. The bottle is marked with an “A” or a “B”. The participants do not know if A is the new sunscreen and the other is the old sunscreen, or if it is the other way around. They also have to keep a log of all the time they spent outdoors. All research volunteers needs to go to a special clinic once a month to get their skin checked by a dermatologist and to get more free sunscreen cream. The dermatologist doesn’t know which people are using which sunscreen. In their appointments with the dermatologists, participants also hand in their logs of how much time they spent outside during the sunlight hours. They get $25 gift certificates every time they go to these check-ups. This will go on for 2 years.

Your job for this study: You need to try to find people who agree to volunteer for this study. Once these people are recruited into the study, you are no longer involved.

You know many people in this community (through church, family friends, people you know from the clinic) and you ask many of them to join the study. Also, since you work at a health clinic 2 days a week, you recruit some volunteers when you are there. Many people you meet there volunteer. You find 100 volunteers!

The problem is that after the first clinic visit, most were not interested in continuing with this. In fact, of the 100 volunteers, 73 are no longer showing up at the clinic, may not be keeping records of time spent outside, and are not using their sunscreen.

Questions:

1) Why is this called a double-blind study?
2) Why did so many participants drop out of the study?
3) Why did they sign up in the first place?
4) Is there a way to predict who is likely to stay in the study and who is likely to drop out?
5) What would you do differently next time?
CASE #2

Someone is starting a study in your community. This study is trying to get a representative sample of people in the county so the recruiters try to get every 10th home as they walk down the street in your town (for example, they try for every address that ends with a “9”). The purpose of this study is to find out how many people in the county have been diagnosed with diabetes. They also want to know what is different about families with someone with diabetes. You are a research worker who is assigned to collect information in home visits.

Every 4 months, you go into each home and ask questions: “Does anyone in this house have diabetes? How many people live in this household right now and what are their ages? What is your total household income right now? How much does each person here exercise?” You also get permission to open the refrigerator and cupboards in the kitchen and write down what you see. For example, does the family drink milk? Is it regular or low fat? Are there bottles of soda, and if so, are they regular or diet? Are there fruits in the fridge, and if so, how much? Are there vegetables? Lastly, you are supposed to write down your overall impression of the home and family. All of these answers become part of the study record for that family, and will be analyzed by the researchers in charge of the study.

After following these families for 3 years, with three visits to the home (total of nine visits), the researchers will look at all the data to answer these questions: What percentage of households in this community has someone with diabetes? Are health habits changing over time? Are they getting better or worse? Are households with low exercise and high fat foods in their fridge more likely to have someone with diabetes?

Questions:

1) An observational study only looks at something that is happening or has happened, but does not change anything; while an interventional study makes some change to see what happens. Is this an observational study or an interventional study? Why?
2) When you go to one home, you notice that a family with a member with diabetes has a lot of cookies in their cupboards, but doesn’t have any fruits or vegetables at all. You also see that the family uses a lot of lard to prepare their food. Should you show the members of the family how to choose healthier foods? Why or why not?
3) Why don’t the researchers just ask for volunteers to be in the study through a local church or newspaper, and then choose one out of ten volunteers?
4) In this study, the person that observes the home is the same person who finds out whether people in the household have diabetes. Do you think that knowing whether somebody has diabetes affects the way the research assistant does the observations? Why or why not?
CASE #3

You and your friend work at the front desk of a clinic. Apart from your normal work of checking patients in, you also begin helping out with a research study that is happening at the clinic. Your job is to walk around your clinic’s waiting room and ask people if they want to answer a survey. If somebody is interested, you have several steps that you have to complete with him or her: you go over a consent form and have them sign it, you write in an ID number on the survey, you make sure they fill out their whole survey, and you make sure put their survey into a locked box. You also have to make sure nobody else looks at the survey and that the signed consent forms are locked in a file. It takes quite a while to go through all of these steps, just for people to answer a few questions! However, you have learned from the people that are running the study that it is very important to be sure that everything is done correctly.

One day, your supervisor has a meeting and tells you that your clinic is giving another survey to all of their patients. She tells you that the reason for this survey is for “internal evaluation to improve customer service”. Just like in the mental health survey, patients are asked to fill out a questionnaire. However, there are some big differences with this survey. All that people have to do for this one is fill it out and turn it in! No consent forms, no ID numbers, nobody monitoring how people fill out the questionnaires.

After the meeting, you talk with your co-worker about the new surveys. She says she does not understand why these two surveys are so different. “Why should we have to do all that extra work for one survey, and nothing for the other?” she asks. “That first survey seems like a waste of time”.

Questions:

1) What is the difference between the two types of surveys?
2) Why do you have to take all of those steps for one survey and not the other?
3) Confidentiality in a research study means that participants’ personal information is kept secret from as many people as possible. What steps are being taken in the first survey to make it confidential?
4) Informed consent is the process of being sure people participating in a research study understand what they are being asked to do, and agree to participate. What steps are being taken in the first survey to have informed consent?
CASE #4

You work for a clinical study testing how well a new medicine works to relieve depression. The participants in this study are randomized into two groups: One group receives the new medication, and the other group receives the same medication that they have been taking for depression. The study is double-blind, so neither the participants nor the staff at the clinic knows which person is getting which medication. All participants have the same routine while they are in the study: They go to the clinic twice a week to have their blood drawn and answer questions about how they are feeling.

Your job is to see the participants when they come in for their weekly appointment. You ask them questions from a questionnaire, and then somebody comes in to take a blood sample. You do not know who is taking which medication, so you do the same thing for everyone. One day, when one of the participants is in your clinic, he begins to talk to you about the study. He says he noticed that he is feeling much better since the study began. He is sure that he is taking the new medicine, and that it is working.

You remind him that there is a 50/50 chance that he is not taking the new medicine. He could be taking the same medicine he has always been taking. When he hears this, he is upset. “If I am taking the same medicine that I always take, why do I have to keep coming here to get my blood drawn? I never had to get my blood drawn before this study, even though I have been taking this medicine for over a year! Does that mean the usual medicine isn’t safe?”

Questions:

1) Why do you, as the staff at the study, have to be blinded, too?
2) Why do participants who are taking the same medicine they have been taking have to come in for blood tests and questionnaires?
3) Do you think this participant is taking the new medication, or his usual medication? Why?
4) Why did you have to remind the participant that he might be taking the old medication? Why not just let him think he is taking the new one, if it makes him feel better?
5) How should things have been done differently, to avoid this confusion?
**CASE #3: Instructor Guide**

1) **What is the difference between the two types of surveys?**
   - The first survey is **human subjects research** because the researchers for this study are hoping to share their results with others to advance the public’s understanding. That means they might publish the results or talk about them in public.
   - The other survey is for “internal evaluation”, like the supervisor said. The clinic just wants to know if it is doing a good job. They will not use this information for anything general or publishable – it is for their own information.

2) **Why do you have to take all of those steps for one survey and not the other?**
   - **Human subjects research** has so many more rules to follow because the results may be published or shared. The results may end up in a public place like a journal or even on the news. So, the investigators need to take extra precaution to protect the people who give that information.

3) **Confidentiality in a research study** means that participants’ personal information is kept secret from as many people as possible. What steps are being taken in the first survey to make it confidential?
   - An ID number is used on the surveys instead of a name
   - The surveys are turned in to a locked box
   - The employees have to make sure the nobody else looks at the surveys
   - The employees make sure the survey and consent forms are kept locked up

4) **Informed consent** is the process of being sure that people participating in a research study understand what they are being asked to do, and agree to participate. What steps are being taken in the first survey to have informed consent?
   - The employees explain the consent form and make sure people understand it
   - People sign the consent form before they begin filling out the questionnaire