Understanding Clinical Trials:
A science class for high school students

Teacher Prep:
1. Purchase regular size Oreo cookies (mini-Oreos don’t work as well; Chips and chitos are more difficult to see); Approximately 2 cookies per student.
2. Purchase mini-carrots; At least one carrot for every 2 students.
3. Photocopy score sheets; Approximately 2 per student.
4. Have a Summary Score Sheet – ideally for overhead projector, if possible; Alternative is an Excel Spreadsheet on a computer screen.

Class outline:
1. Theory behind all clinical trials – discussion and exploration with class;
2. Look to students for examples of what has been studied by clinical trial
   • Tylenol, antibiotics, chemotherapy
   • MRI machines
   • Weight-loss programs, and smoking-cessation programs
3. Prepare class for tooth experiment: “Dental hygienists and dentists often tell parents of toddlers to give them a crunchy food after they’ve eaten cookies or chips, to help clean their teeth. There is no evidence that this really works, however”.
4. Perform the experiment:

<table>
<thead>
<tr>
<th>EXPERIMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hypothesis:</strong> Carrots help to clean teeth of mushy foods.</td>
</tr>
<tr>
<td><strong>Scientific background:</strong> Foods stuck to teeth promote dental decay. Children, especially young ones, do not clean their teeth with their tongues after eating, as do older people.</td>
</tr>
<tr>
<td><strong>Research steps:</strong></td>
</tr>
<tr>
<td>1. Give each student one score sheet and one full-size oreo.</td>
</tr>
<tr>
<td>2. Divide students into pairs. Have each eat a cookie and then let the pairs score one another. (Students with diabetes or food allergies should not eat cookie, and should later be assigned as “researchers”, not “human subjects”.)</td>
</tr>
<tr>
<td>3. Ask all students to clean their teeth with their tongue.</td>
</tr>
<tr>
<td>4. Divide class into 1/3 “researchers” and 2/3 “human subjects” (also known as “research participants”).</td>
</tr>
<tr>
<td>5. Ask researchers to leave the room and to take two score sheets with them (they can also read the Consent Form that remaining students will be signing). Reinforce the importance of now asking which student ate only a cookie and which student also ate a carrot, when they re-enter the room.</td>
</tr>
<tr>
<td>6. Ask remaining students to read and sign the consent form</td>
</tr>
<tr>
<td>7. Students call out a number…. (“1,2, 3, etc..) and remember that number. Give all odd numbers a cookie; Give all even numbers a cookie and a carrot. All students eat the cookie at same time. Even eat the carrot immediately AFTER the cookie.</td>
</tr>
<tr>
<td>8. Explain importance of keeping Researchers “blinded” to who got carrot, when they re-enter room.</td>
</tr>
<tr>
<td>9. Immediately after all is eaten, invite “researchers” back into room. Each “researcher” chooses any two “human subjects”. Record the assigned number on the sheet. Score their sheets, including putting the “code number”,</td>
</tr>
<tr>
<td>10. Put a Summary Score Sheet on the Overhead Projector. Write in results and calculate average score for “even” and average score for “odd”. Alternatively, an Excel Sheet on a computer could work.</td>
</tr>
</tbody>
</table>

COMMUNITY PROGRAMS OF SAN DIEGO CLINICAL & TRANSLATIONAL RESEARCH INSTITUTE [CTRI]  
CONTACT: htaras@ucsd.edu  
December 2009
5. Discuss why was it important to have the researcher “blinded” as to who was “intervention” (carrot) versus “control” (no carrot)?
6. Why do we use numbers, not “human subjects” real names? Why might a human subject in a drug trial or a trial of a weight-loss program want to have their name replaced with a number?
7. Discuss the ethics behind doing research and how a control group can still be ethical
   - What is a Placebo, and why is a Placebo sometimes ethical? Why sometimes not ethical?
   - How does a Placebo sometimes work to improve symptoms?
   - “Control” : Compare two interventions, rather than having a placebo
   - Concept of an “Institutional Review Board” to review all experiments involving human subjects. Why is this important?** (see box, bottom of second page, below)
   - Why do human subjects have to sign “informed consent” forms?
8. Ask each student to “design” their own clinical research experiment (on paper). Start with a Hypothesis (what are we trying to prove or disprove); Then decide on how many groups will be needed to compare (one intervention and one control?) How many people in each group?

Things teachers can discuss with students (seniors +) as they present their research experimental design.

a. Why did the student choose the number of subjects in each group?
   [Note: if the number of subjects chosen is too small, even a real difference between “intervention” and “control” group may be incorrect. If the number is too big, researchers may not get their study funded, or will be wasting time and money; For experiments where researchers expect a big measurable difference between the intervention condition and the control condition (eg, comparing response of Tylenol/acetaminophen to nothing for people with high fevers), small numbers are usually okay. For experiments where researchers expect only a subtle measurable difference, large numbers are usually required (like effects of taking Tylenol/acetaminophen on a full stomach versus an empty stomach).]

b. How did students find their control group?
   [Note: Were “control” and “intervention” randomly divided from a large pool? Did they identify their intervention group and then look for “matched controls” who had similar characteristics (same age, same height, same language, or whatever...) Demonstrate importance of not building in any bias, so that you don’t expect the people in the Control and Intervention groups to be different.

**Historical Importance for an Institutional Review Board

“The Tuskegee Study of Untreated Syphilis in the African American Male” began in 1932 in Tuskegee, Alabama by the U.S. Public Health Service (USPHS), a government agency. The study was designed to determine the natural course of untreated syphilis, a sexually-transmitted disease. 400 African American men who already had syphilis were followed, along with 200 uninfected subjects who served as a control group.

Problems:
1. The subjects were recruited with misleading promises of “special free treatment,” in truth, they got no free treatment. Many thought that a spinal tap (a study of fluid in their spinal column) was treatment, but it was not.
2. When antibiotic therapy (penicillin) became widely available in the 1950s, these human subjects were not told that an effective treatment was available. The USPHS actually sought to prevent some subjects from getting it.

When this terrible experiment was published in the media in the 1970s, only 74 of the 400 human subjects were still alive; At least 28, but perhaps more than 100, had died directly from advanced syphilis.
What is Clinical Research?

• It’s an experiment involving people
• Does a new treatment or cure work?
• Does a new lab test work?
• It may work, but is it safe?
• Clinical research leads to better ways to prevent, diagnose and treat disease
WHO PARTICIPATES?

- Volunteer are called “human subjects”
- Sometimes volunteers have a disease that is being studied
- Sometimes volunteers just help find new cures
Is It Safe?

• Strict rules protect the safety of research volunteers

• Experiments must follow safety rules, or they are not approved.

• Since what is being studied is new, there might be unexpected side effects

• Volunteers are closely monitored to make sure they are not harmed.
**What is "Informed Consent"**

- Researchers must explain to volunteers any risks and use language that the volunteer understands.
- Volunteers are then asked to sign a form (Informed Consent Form) to show they understand the experiment and risks.
- Never sign up for a study, unless you understand.
- Volunteers can always ask questions if they don’t understand.
What is a “Control Group”?

- The group that does not get the new treatment or test being studied
- In this experiment, that is the group eating only the cookie
What is an “Experimental Group”? 

- The group that gets the new treatment or test being studied
- In our experiment, that’s the group eating the carrot after the cookie
What is a “Blind Study”? It’s a blind study...

• when the volunteers do not know who got the new treatment, and who was in the control group

- OR -

• when the researcher does not know who got the new treatment, and who was in the control group

If volunteers and researchers don’t know who got the treatment and who is in the control group, it’s called a “Double Blind Study”
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, chips, crackers and chitos often stick to teeth. Most people cannot brush their teeth in the middle of the day to clean food out. Toddlers 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 Clinical Trial 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 by a “researcher”

The benefits of being in this study are:

- You will be helping dentists know if crunchy foods really help clean teeth.
- This knowledge will help dentists teach patients about reducing tooth decay.

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 the condition of your teeth could possibly be leaked.

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. You have a right to keep a copy of this Consent Form.

By signing this form, you agree to participate.

_____________________________  __________________
Signature                      Date

_____________________________
Printed Name
Score Sheet

Score on Practice Oreo cookie: 0 1 2 3 4

Subject # _________ [no names of subject, please]
Score after second Oreo cookie: 0 1 2 3 4

Name of Researcher is: __________________
Date: __________________

Score = 0

Criteria
- No food is stuck to the tooth.
- Tooth is clean.

Score = 1

Criteria
- About 1/4 of grooves are covered by food.

Score = 2

Criteria
- About 1/2 of the grooves are covered by food.

Score = 3

Criteria
- About 3/4 or most of the grooves are covered by food.

Score = 4

Criteria
- All of the grooves are covered by food.
- Food may also be stuck to other parts of the tooth.

COMMUNITY PROGRAMS; SAN DIEGO CLINICAL & TRANSLATIONAL RESEARCH INSTITUTE [CTRI]
CONTACT: htaras@ucsd.edu

December 2009