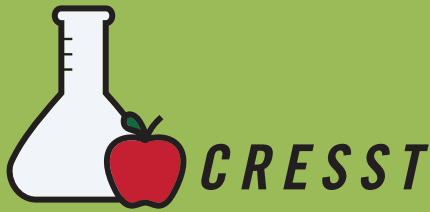


The Basics of Research



Overview

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Revised February 2016

The lessons included in this section will immerse students in the research process by engaging them in investigating factors associated with a healthy lifestyle. Students will explore the research process within each individual lesson to gain an in-depth understanding of each step of the scientific research process. The students will participate in a clinical research simulation and design their own research projects. Throughout these experiences, they will discuss the implications of living a healthy life and what they can do at home to make it a reality.

Section Objectives

At the end of this section, students will be able to:

- Compare and contrast the clinical research process with other types of research projects
- Describe the steps of the clinical research process
- Discuss the relationship between healthy lifestyle choices and maintaining a healthy weight

Topics

- Scientific research process
- Clinical research process
- Developing and implementing a research plan
- Collecting, recording, and analyzing data
- Constructing graphs, descriptive data analysis, and ANOVA data analysis (optional)

Activities

- The Science of Biology
- The Clinical Research Process
- It's All About You: A Clinical Research Simulation
- A Matter of Taste

Background Information and Resources

When reviewing reports or articles based on clinical research studies or when working with students to design a clinical research study, it is necessary to be familiar with the different types of study designs that are used in clinical research. Studies can be observational or experimental. Elements of design, such as decisions about the study population and the use of a control group, can contribute to the quality of the study and the overall confidence that we can place in the findings. Below are several resources that provide basic information about the clinical research process.

An overview of clinical research: The lay of the land, by David A. Grimes, Kenneth F. Schulz.

http://medicine.ucsf.edu/education/reesd/articles/Lancet5_anOverview.pdf

This resource is written for clinicians and is an overview of clinical research design. It discusses descriptive studies, cross sectional studies, cohort studies, case-control studies, and nonrandomized and randomized trials. It also reviews measurement of outcomes.

Overview of Study Designs in Clinical Research

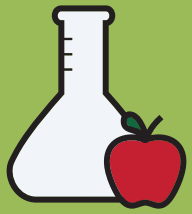
EBP@NUHS CH5 Study Design © Barbara M. Sullivan PhD, Jerrilyn A. Cambron DC PhD, Dept. of Research NUHS 2008.

<http://www.brainstrom.org/wp-content/uploads/2013/05/5.1bAppraiseOverviewofStudyDesignsLecture.pdf>

This resource is a presentation from the National University of Health Sciences. It reviews the hierarchy of clinical research evidence and the primary study designs used in clinical research studies.



The Basics of Research



CRESST

The Science of Biology

Revised February 2016

Introduction

The lesson provides students with a basic understanding of the research process that can be used to provide a foundation for or scaffolding for more complex content. The scientific process is introduced as a series of steps that a scientist goes through when attempting to answer a question, but it is important for students to understand that these steps are not a hard-and-fast rule to scientific research. Rather, they are a general guide that can extend in many directions depending on the nature of the question. With this lesson, students are exposed to the basics steps in the scientific process.

Purpose

This lesson will guide students through the process of developing a research plan.

Objectives

At the end of this lesson, students will be able to:

- Distinguish between qualitative and quantitative data
- Apply the methodology of the scientific process

Key Terms

- Control or control group: a group of research subjects or an experimental sample that remains unchanged during the experiment. The control provides an unchanged standard for comparison against the experimental groups.
- Constants: all factors that are purposely kept the same throughout the experiment in both the experimental and control groups
- Dependent or responding variable: the variable that is measured or observed during the experiment: the measurement that “depends” on what I change.
- Hypothesis: a testable prediction about the relationship between the variables.
- Independent or manipulated variable: the variable that is purposefully changed by the experimenter; “what I change”

- Inference: a logical interpretation based on prior knowledge or experience
- Observation: the process of gathering information about events or processes in a careful, orderly way
- Qualitative data: data that is descriptive, in written form, and involve characteristics that cannot usually be counted
- Quantitative data: data expressed as numbers, obtained by counting or measuring
- Repeated Trials: the number of experimental repetitions, objects, or individuals tested at each level of the independent variable
- Sample size: the number of observations in an experiment or study; for example, the participants that provide data in a survey
- Science: an organized way of using evidence to learn about the natural world

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 2

Science and Engineering Practices 1, 3, 5, 8

Nature of Science Understandings 1, 2, 4, 5, 7, 8

National Standards for Health: Standards 1, 2, 3, 4, 5, 6, 7, 8

National Standards for Physical Education: Standards 3, 4, 5

Virginia

Science LS.1 a–j, BIO.1 a–m

Health 6.1 b, c, 9.1 b, d, g, p, r, 9.3 a, b

Physical Education 7.3 a–f

Materials

Copies of student handout “The Research Process”

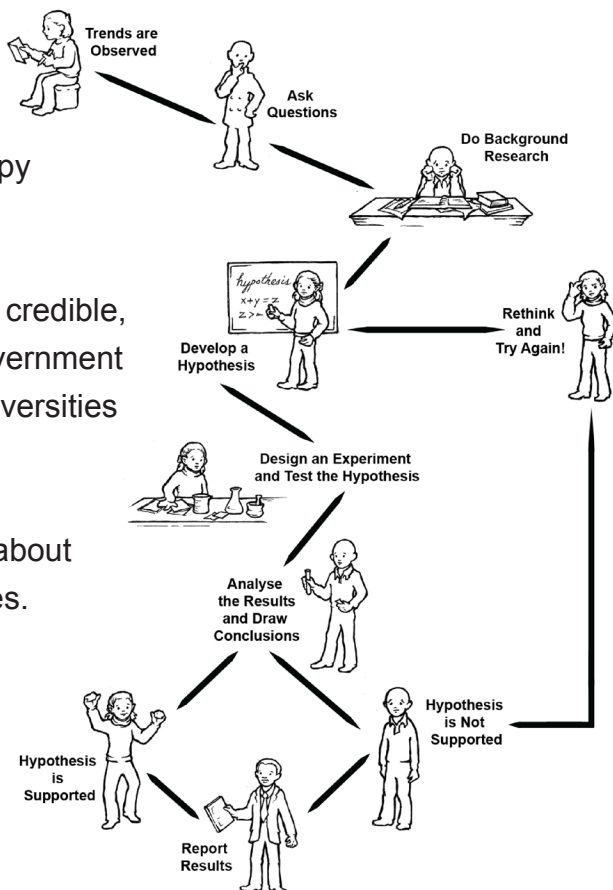
Copies of student handout “Design Your Experiment”



Procedures

1. Begin class with the question: “What does it mean to ‘do science’?” Have the class discuss what they think the word “science” means and what they consider to be “doing science.”
2. Explain to them that the goal of science is to investigate and understand the natural world, to explain events in the natural world, and to use those explanations to make useful predictions. In other words, science is an organized way of using evidence to learn about the natural world and scientific thinking usually begins with an observation.
3. Explain the difference between an observation and an inference:
 - a. Observing is the process of gathering information about events or processes in a careful, orderly way. An observation is anything we observe, measure, or record using our five senses or a device that augments our 5 senses.
 - b. An inference is a logical interpretation based on prior knowledge or experience.
 - c. An inference is when we use those observations to draw conclusions and propose explanations.
4. Share the diagram of the scientific process on the board and explain each step to the students. Note: There is a larger version of this diagram on page 2.4.

- a. Observe trends.
- b. Ask a question/state the problem you have observed.
Example: Do more students feel sleepy after lunch?
- c. Do background research.
- d. Choose sources that are reliable and credible, such as scientific journals, official government websites, and institutions such as universities and research facilities.
- e. Develop a hypothesis.
A hypothesis is a testable prediction about the relationship between the variables.
It is usually expressed as an “If..., then ...” statement.



- f. Design an experiment and test the hypothesis. Whenever possible, a hypothesis should be tested by an experiment in which only one variable is changed at a time (a controlled experiment), and the experiment should include more than one trial to help rule out error.

Example experiment: The effect of the amount of water on the height of plants

Possible Hypothesis: If a plant receives more water, it will grow taller.

Independent Variable (IV) = Amount of water

Levels (groups) of IV = 50mL, 100mL, 150mL

Dependent Variable (DV) = Height of the plant

Number of trials: Include 3 plants in Level of IV

- g. Analyze the data and draw conclusions

- i. For this step, graphs should be constructed when possible.

Example graph:

Title: The effect of (IV) on (DV)

Label the Axes- (including units!)

IV on the X-axis and DV on the Y-axis

Determine the scale for axes

(data w/in range, consistent interval, start at 0)

- ii. Data can be broken down into two categories:

Quantitative data (ex. distance, height, time)

Qualitative data (ex. color, location, tall/short)

- iii. Scientists use data from an experiment to evaluate the hypothesis and draw a valid conclusion. Their data can support or refute (not support) their hypothesis. If the hypothesis is supported, they prepare a report to share their methods, data, and conclusions so that other scientists can replicate the experiment or use the research for further study. If the hypothesis is not supported, scientists rethink their hypothesis and methods and develop a new experiment. Often they will also prepare a report that provides suggestions as to why the hypothesis was not supported and ideas for future experiments.

5. Separate the students into small groups and hand out the student worksheets. Have each group make an observation about the room around them, develop a question, and design a plan for investigating that question following the steps and questions on the handouts.

6. After each group has had ample time to develop a plan, have each group present the plan to the class. This will give you an opportunity to identify any confusion or misconceptions and address them with the whole class.

Observations and/or Data

Some possible observations that could be used to develop questions:

- Students seem to be less engaged in class after lunch.
- Students who sit near the window in class pay less attention.

Analysis and Conclusions

- What are essential steps in conducting an experiment?
- Why should you gather background information before you begin an experiment?
- How does one formulate a hypothesis?
- How does one analyze data from an experiment?

Critical Thinking Question

Why should we understand how research is conducted in real life?

Teacher Notes

When explaining the scientific process, it might help the students to see an example of each step before starting the process with their own questions.

Safety Notes

Make sure all students are following proper classroom safety guidelines.



Background Information & Resources

Science is an ongoing process - a process that involves asking questions, observing, making inferences, and testing hypotheses. Scientists continually revise and re-evaluate their ideas. For a conclusion to be valid, it must be based on logical interpretation of reliable data.

Repeating investigations

It should be possible for other scientists to replicate (repeat) an experiment, and the methods should be as rigorous as possible.

For example: Spallanzani tested Redi's findings with maggots on gravy to test the theory of biogenesis (<http://www.infoplease.com/cig/biology/spontaneous-generation.html>). The broth heated with the cover on did not grow the microorganisms while the uncovered broth did grow microbes. This experiment and Redi's work supported the hypothesis that new organisms are produced only by existing organisms.

When can something be called a theory?

As evidence from numerous investigations builds up, a particular hypothesis may become so well-supported that scientists consider it a theory (a well-tested explanation that unifies a broad range of observations). Several examples of well-accepted theories are biogenesis, plate tectonics, and evolution. Theories enable scientists to make predictions about new situations, but no theory is ever considered absolute truth. Theories are always reconsidered as new evidence is discovered.

An overview of clinical research: The lay of the land, by David A. Grimes, Kenneth F. Schulz.

http://medicine.ucsf.edu/education/resed/articles/Lancet5_anOverview.pdf

This resource is written for clinicians and is an overview of clinical research design. It discusses descriptive studies, cross-sectional studies, cohort studies, case-control studies, and nonrandomized and randomized trials. It also reviews measurement of outcomes.

Lesson 2: Inference from the Science Department of Clackamas Community College in Oregon City, Oregon

<http://dl.clackamas.edu/ch104-02/inference.htm>

This webpage gives a basic overview of observations and inferences. Using images and explanations, it guides the reader in distinguishing between observations and inferences.



Understanding Science: How Science Works

http://undsci.berkeley.edu/article/howscienceworks_01

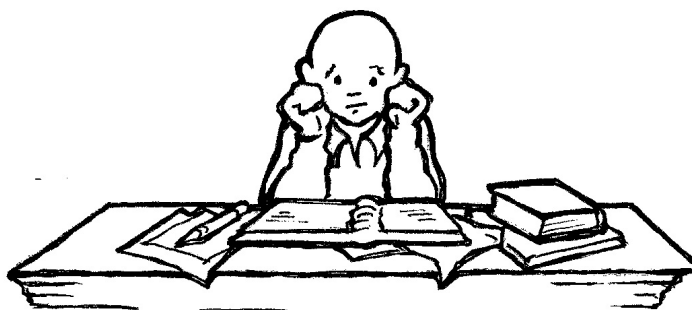
This website provides an interactive exploration of the process of science.

The website can also be downloaded as a PDF.

Infoplease: Origin of Life

<http://www.infoplease.com/cig/biology/spontaneous-generation.html>

This website gives a good overview of spontaneous generation and the experiments that were related to it.



Extensions

Classroom

As a class, select a research question and experimental design for a research study that the class can conduct. Have the students complete a lab report on what they did during the research study (from the question to the conclusion).

Cross-Curricular

Language Arts: In language arts class, the students can complete the formal scientific report as an exercise in technical writing.

Health and Physical Education: Coordinate with the Health and Physical Education teachers to allow the students to collect relevant data during their Health and Physical Education classes.

Name: _____

The Research Process

Directions: Use the questions below to design an experiment based on an observation that you make.

What is your observation?

Based on your observation, what is your question?

What kind of background information do you need to look up about your topic before developing your hypothesis and designing your experiment?

What is your hypothesis?

What kind of data will you collect in order to answer this question? Are they qualitative or quantitative?



Name: _____

Design Your Experiment

What is your independent variable?

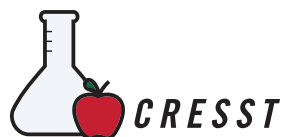
Will you have a control? If so, what will it be?

What are the constants in your experiment?

What is your dependent variable?

How many trials will you do?

Write out a step-by-step procedure explaining exactly how you will conduct your experiment.



Name: _____

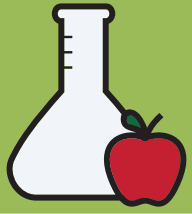
How will you analyze your data? Set up a graph that includes what you will label the x and y axes and the graph title. (It is always a good idea to know how you will graph your data before you begin the actual experiment.)

How do your data and your conclusions connect to current scientific knowledge? What resources will help you design your experiment, evaluate your data, and form your conclusions?

How will you communicate and justify your conclusions to your audience? Are your conclusions logical and supported by the data? Have you explained them in a clear and understandable manner for your audience?



The Basics of Research



The Clinical Research Process

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CRESST

Revised February 2016

Introduction

Scientists are continuously working on ways to improve daily life. One important approach to research is clinical research. Clinical research is research where humans participate as subjects in the research. The goal of clinical research is to improve public health by identifying better ways to treat, prevent, diagnose, and understand human disease. A clinical trial is one type of clinical research that follows a pre-defined plan or protocol (NICHD, 2013).

Currently, many scientists are conducting research that addresses the rising number of obese and overweight youth in America. As part of this lesson, students will learn the steps of clinical research and develop a research project investigating the influence of food choices on weight.

Purpose

This activity introduces the steps of the clinical research process and engages students in planning a clinical research project to investigate how food choices can influence weight.

Objectives

At the end of this lesson, students will be able to:

- Describe the different steps of clinical research
- Identify some of the causes of the rising rates of obesity in America
- Demonstrate knowledge by designing a research project exploring the link between food preferences and obesity



Key Terms

- **Calorie:** the amount of energy needed to raise the temperature of one gram of water by one degree Celsius at a pressure of one atmosphere. It is abbreviated as cal. It is also called a gram or small calorie. This unit is not the same as a nutritional Calorie. A nutritional Calorie is equal to 1 kilocalorie.
- **Clinical research:** research where humans participate as subjects in the research
- **Energy balance:** the relationship between “energy in” (Calories consumed) and “energy out” (Calories used by the body to meet the organism’s daily energy requirements). An energy imbalance will result in either weight gain or loss.
- **Nutritional Calorie:** a unit equal to one kilocalorie, used to express the heat output of an organism and the energy value of food. It is abbreviated as Kcal or Cal. It is also called a large Calorie.

National and State Standards

National

Next Generation Science Standards:

Disciplinary Core Ideas LS1.B

Crosscutting Concepts 1, 2, 5, 7

Science and Engineering Practices 1, 2, 3, 4, 5, 8

Nature of Science Understandings 1, 2, 3, 5, 6, 7, 8

Essential Features of Classroom Inquiry 1, 2, 3

National Standards for Health: Standards 1, 2, 3, 4, 5, 6, 7, 8

National Standards for Physical Education: Standards 3, 4, 5

Virginia

Science 6.1, LS.1, PS.1 k, BIO.1 b, e, j,

Health 6.1 g

Materials

- Microsoft PowerPoint®: Clinical Research Process
- Internet Access
- Computers

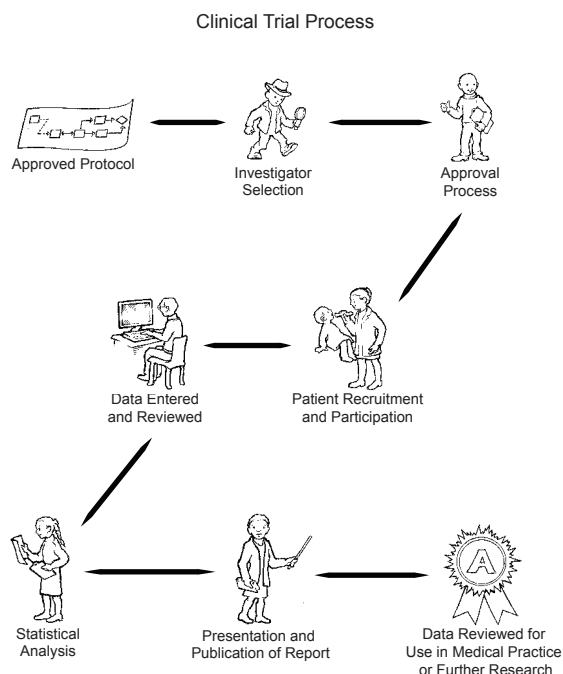


Procedures

1. In a class discussion, ask the students if they have ever heard of clinical research and what they think it is.
2. Present the “Clinical Research Process” PowerPoint and facilitate a discussion of clinical research.
 - a. Discuss the steps of the clinical research process and the importance of each.
 - b. Compare the clinical research process to the scientific method.

Note: There is a larger version of this diagram on page 1.32

3. Have the class develop a list of the foods they prefer, research the energy value (nutritional Calories) of these foods, and identify those that are high Calorie/low nutrition versus low Calorie/high nutrition. Be sure that the students understand the difference between the nutritional Calorie, also called a large or kilocalorie, and the small or gram calorie.
4. Have the class discuss the relationship among food preferences, nutrition, and weight.
5. As a class, design a research study investigating the relationship between food preferences and obesity.
 - a. Help the students ensure that their research project follows the clinical research process.
 - b. Guide the students in selecting the appropriate observations and data to collect in the research project.



Observations and/or Data

- How is the clinical research process similar to the scientific method? How is it different?
 - Why?
- How would you ensure appropriate protections for research participants?
- What types of data should be collected in this research project?
- What type of observations and research techniques should be used to collect these data?

Analysis and Conclusions

- What types of data analyses would be appropriate to use in this research project?
- How could you ensure the validity of the conclusions drawn from your research?

Critical Thinking Questions

- Why is clinical research important in people's lives?
- What factors might influence people's food preferences?
- How do high energy/low nutrient foods influence weight?

Teacher Notes

An example of a Microsoft PowerPoint® presentation is provided at the end of this lesson. This presentation can be used to provide background information to students and/or teachers about the steps in the clinical research process.

Review the differences and similarities of fact and opinion with the class.

When gathering and evaluating information, it is important that students be able to differentiate between what information is factual and what is opinion. Facts generally use concrete language or specific numbers and can be verified through reference sources, official records, or repeatable research. Opinions are usually attitudes, feelings, or beliefs that cannot be verified through reference sources, official records, or repeatable research. Often, opinions are expressed using adjectives and comparisons rather than concrete language and specific numbers.

Safety Notes

Make sure all students are following proper classroom safety guidelines.

Be conscious of student sensitivities about weight, food choices, and cultural differences.

CRESST Videos

The CRESST Videos are designed to be used in conjunction with the CRESST Curriculum. Each classroom-friendly video is approximately 4 minutes in length and can be used to generate discussion related to clinical research, healthy lifestyle choices, and student research into health-related topics.

In ***Clinical Research: Why Does It Matter to Me?***, researchers who study childhood health and wellness describe aspects of the clinical research process and the benefits of research to the individual and the community.

Background Information & Resources

These webpages provide a wide variety of information about the clinical research process, obesity, nutrition, and healthy lifestyles.

National Institutes of Health: Clinical Research Resources

<http://www.nih.gov/research-training/clinical-research-resources>

The NIH website includes a large database of articles on health and clinical trials.

The “NIH Clinical Research Trials and You” section is written for a general audience and provides information about the basics of clinical research as well as other excellent information, such as personal stories and how to find a clinical trial.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD): Clinical Trials & Clinical Research

<https://www.nichd.nih.gov/health/clinicalresearch/Pages/index.aspx>

This website provides concise definitions of clinical research and clinical trials as well as excellent background information, such as “Guidance for Clinical Researchers” and “What Else Should I Know About Clinical Research?”

The National Institute of Diabetes and Digestive and Kidney Diseases: Overweight and Obesity Statistics

<http://www.win.niddk.nih.gov/statistics/index.htm>

This website includes a variety of statistics related to obesity in the United States. It also provides information on age and ethnicity statistics, BMI, and physical activity levels. Links to additional health information and resources for community outreach and health fairs are available.

PBSKIDS: Food Smarts: Understanding Food Labels

<http://pbskids.org/itsmylife/body/foodsmarts/article4.html>

This PBS Kids website gives the students an easy to read explanation of food labels. Links to additional activities and resources, such as “Serving Size Surprises” and “Real World Tips and Tricks” are also useful. The Food Smarts Video (<http://pbskids.org/itsmylife/video/index.html?guid=e7f8bd80-3ad9-4304-801b-61c5ad9e2d84>) is an excellent complement to all of these topics.

Institute for Clinical Research Education

<http://www.icre.pitt.edu/>

The Institute for Clinical Research Education’s website gives you information on the clinical trials and research programs currently going on at the University of Pittsburgh’s clinical and translational research training programs.

US National Institutes of Health: ClinicalTrials.gov

<http://clinicaltrials.gov/>

This website, provided by the National Institutes of Health, is a registry of all private and publicly funded clinical trials currently being conducted in the United States.

Kid’s Health

<http://kidshealth.org/>

Kid’s Health is an award-winning interactive website for parents and children run by the nonprofit children’s health system, Nemours. It includes articles and activities related to health and other issues that contribute to children’s and teenagers’ health and well-being.

National Institute of Health

www.nih.gov

This website includes a large database of articles on health and clinical trials. The “Science Education” section under “Research and Training” includes links to a variety of resources and activities designed for K-12 students and teachers.

Extensions

Classroom

The 2008 Farm Bill defined a food desert as an “area in the United States with limited access to affordable and nutritious food, particularly such an area composed of predominantly lower income neighborhoods and communities.” Ask students to discuss how the availability and convenience of high Calorie/low nutrient versus low Calorie/high nutrient food can influence food choices and affect obesity levels.


Cross-Curricular

Social Studies: The USDA provides a searchable map identifying food deserts throughout the United States at: <http://www.ers.usda.gov/data/fooddesert>.

This map can be used to facilitate student investigations/discussions of the effect of socio-economic conditions on health and nutrition.

Language Arts: In language arts class, the students can complete the formal scientific report as an exercise in technical writing.





CRESST The Basics of Research

Clinical Research Process

This project was supported by the National Center for Research Resources and the Division of Program Coordination, Planning, and Strategic Initiatives of the National Institutes of Health through grant number 1P20RR020080-01.

What is Clinical Research?

- ❖ Research on or about humans
- ❖ Intended to improve human health
- ❖ Clinical research includes
 - ❖ Natural history (observational) studies
 - ❖ Clinical (experimental) trials
- ❖ Clinical Research provides information related to
 - ❖ Prevention
 - ❖ Screening
 - ❖ Diagnosis
 - ❖ Treatment
 - ❖ Quality of life

Step 1: Develop the Research Question

- ❖ Gather Background Information
 - ❖ What information is already known about your question?
 - ❖ What types of research have already been conducted?
 - ❖ What topics need more research?
- ❖ Benefits to Public Health
- ❖ Support the mission of the project sponsor

Step 1: Develop the Research Question

- ❖ Formulate the Hypothesis or Research Project Concept
 - ❖ Provide evidence of the need for the Research Project
 - ❖ Describe how the Research Project will add to what is already known
 - ❖ Submit the concept for the Research Project for expert view

Step 2: Project Funding

- ❖ Funding for Clinical Research comes from a variety of sources, including government, businesses, foundations, etc.
- ❖ Often funding comes from several sources

Step 3: Create a Project Protocol

A Project protocol is a detailed plan for conducting the Clinical Research Project

- ❖ The Protocol includes
 - ❖ The purpose and function of the Research Project
 - ❖ Information about the participants
 - ❖ Number of participants
 - ❖ How they will be recruited
 - ❖ Eligibility and exclusion criteria
 - ❖ How demographic data about the participants will be collected

Step 3: Create a Project Protocol

- ❖ The Project Protocol also includes
 - ❖ A complete and detailed description of what experiments, activities and/or treatments are involved in the Research Project (what, how much, when and how often)
 - ❖ Steps for clinical staff to carry out
 - ❖ The timeframe for the Research Project

Step 4: Protection of Participants

- ❖ Clinical Research Protocols must include safeguards to protect those who volunteer to take part in the study. Different types of studies require different levels of protection.
- ❖ Protections are provided through
 - ❖ General ethical guidelines, such as the Belmont Principles and the Declaration of Helsinki
 - ❖ Governmental Regulations
 - ❖ Sponsor Regulations

Step 5: Implement the Research Project

- ❖ Use the Research Protocol to develop and finalize the Research Procedures
- ❖ Implement the Research Project
 - ❖ Train the Research team
 - ❖ Recruit and enroll the participants

Step 6: Conduct and Monitor the Research Project

- ❖ Follow the Project Procedures to conduct the research and collect data
- ❖ Monitor the study to ensure that
 - ❖ The research participants are protected
 - ❖ The data is being collected appropriately and in accordance with the Research Protocols
- ❖ Conduct periodic reviews to ensure that the participants are protected and the Project Procedures are being correctly implemented

Step 7: Close the Research Project

- ❖ A Research Project will close (end) when the activities outlined in the Research Protocol are completed
- ❖ When a Research Project closes, the data are then checked for completeness
 - ❖ If the data are incomplete, the researcher may request that the project be reauthorized to collect additional data, or take into account the incomplete data during the analysis phase

Step 8: Data Analysis and Interpretation of the Results

- ❖ The analysis of the data is generally guided by the goals of the study and the question being asked
- ❖ The Project results must minimize bias and uncertainty. Some factors that can increase bias or uncertainty include
 - ❖ Incomplete data
 - ❖ Terminology that is not appropriately defined
 - ❖ High number of participants who leave the study before completion
 - ❖ Ambiguity in measurements

Step 9: Communicate the results

- ❖ **Benefits of Communication**
 - ❖ Participants can improve their health or make decisions related to their future health care
 - ❖ Health care providers can improve their clinical practices, which ultimately benefits patients and families
 - ❖ Other researchers can use the data to answer related scientific questions or develop new ones for further study
 - ❖ Information about specific health risks can encourage the general public adopt healthy lifestyles and behaviors

Step 9: Communicate the results

(Continued)

- ❖ Some ways that results can be communicated are
 - ❖ Publishing a report
 - ❖ Noting a finding in a community newsletter
 - ❖ Issuing a news release
 - ❖ Holding a news conference
 - ❖ Presenting at a meeting or conference
 - ❖ Publishing an abstract, or creating a brochure
- ❖ Peer reviewed communications are the highest standard for communicating results

Research Scenario

- ❖ We have received alarming information about the growing number of overweight and obese Americans.
- ❖ In a recent survey conducted in Virginia showed that 13% of our youth aged 10 -17 years old were overweight and 9% of our youth were obese.
- ❖ Discussion:
 - ❖ What do you think is causing Americans gaining so much weight?

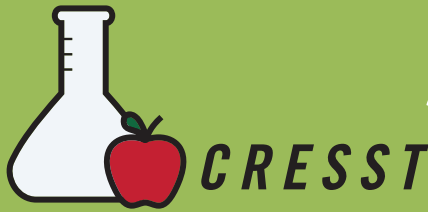
Research Scenario

- ❖ Many scientists think that the types of food that we are eating are contributing to the obesity issue.
 - ❖ As infants and young children, most people prefer foods that contain sugar and fat which provide energy (Calories) to help us grow.
 - ❖ Research suggests that some food additives, like added sugars and fats, encourage us to eat high calorie and low nutrient snack foods.
- ❖ Discussion:
 - ❖ What types of food are high energy/low nutrient?

Research Scenario

- ❖ Discuss ideas for a Clinical Research Project related to food choices and obesity.

The Basics of Research



It's All About You: A Clinical Research Simulation

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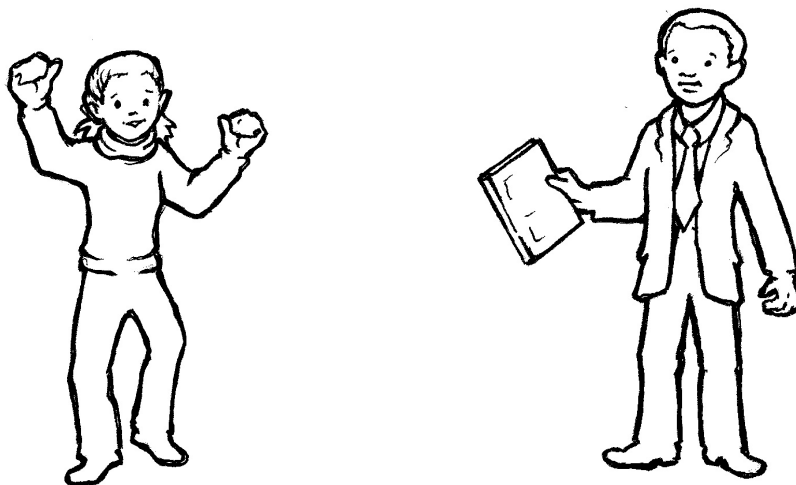
Revised February 2016

Introduction

Personal experience with participation in a clinical trial is one way to develop an understanding of the clinical research process. This lesson focuses on providing students with an authentic learning experience by simulating the process of a clinical research study. As part of the simulation, a variety of measurements are obtained and recorded by the students. These data can be used to discuss aspects of clinical research, such as measurement and statistics. Students have the opportunity to develop their own research questions related to health and wellness, develop hypotheses, analyze their own data, and graph results.

Purpose

This activity is designed to simulate participation in a clinical research study and provide data for use in a class exercise. The small group activity is designed to provide students experience in developing research questions, generating hypotheses, manipulating data, and graphing results within a group setting. This lesson can also encourage discussion of ethical issues. Students will gain experience in identifying ethical issues associated with the conduct of research in humans and challenges that can arise with conducting research, such as measurement issues and data integrity.



Objectives

At the end of this lesson, students will be able to:

- Describe their experience during the study simulation and identify how the data collected could be used to answer health-related questions
- Discuss ethical issues of clinical research and describe how some of these issues were addressed in this simulation
- Discuss ways to improve data collection and measurement when designing a clinical research study
- Compare and contrast the strengths and limitations of different types of data collection instruments
- Measure heart rate and other health-related indicators
- Develop research questions and hypotheses
- Collect and analyze data
- Use Microsoft® Excel to analyze data to test hypotheses
- Create graphs to represent data

Key Terms

- Heart rate: the number of a measure of cardiac activity usually expressed as number of beats per minute
(<http://www.merriam-webster.com/medical/heart%20rate>)

National and State Standards

National

Next Generation Science Standards:

Disciplinary Core Ideas LS1.B

Crosscutting Concepts 2, 7

Science and Engineering Practices 1, 3, 4, 6, 8

Nature of Science Understandings 1, 2, 3, 5, 7, 8

Essential Features of Classroom Inquiry 1, 2, 3, 4, 5

National Standards for Health: Standards 1, 2, 3, 4, 5, 6, 7, 8

National Standards for Physical Education: Standards 3, 4, 5

Virginia

Science 6.1 b, e, h, LS.1 e, h, PS.1 i-l, BIO.1 b-f, I, CH.1 f-h

Health 6.2 p, 6.3 b, 7.1 l, 7.2 j, 10.1 a

Physical Education 6.5 b, 7.3 d, 8.3 e, 8.5 a-h



Materials

- Printed forms for students
 - Pittsburgh Sleep Quality Index form:
<http://goodmedicine.org.uk/files/assessment,%20pittsburgh%20psqi.pdf>
 - Stress Screening Test:
<http://www.innerhealthstudio.com/support-files/stress-screening-test.pdf>
 - Stroke Risk Scorecard:
<http://www.stroke.org/sites/default/files/resources/stroke-risk-scorecard-engl-2015.pdf>
 - Student Handout to record data
- Student Internet access for
 - Calorie Goal Calculator:
<http://www.livestrong.com/thedailyplate/>
 - Walk Score:
<http://www.walkscore.com/cities-and-neighborhoods/>
- Stop watch or clock to aid in heart rate measurement
- Automated blood pressure monitor
- Hand grip strength meter
- Computer with Microsoft® Excel or other spreadsheet software
- Data Response Form (Either a spreadsheet or Google Form on a computer)

Procedures

1. The students will visit each of the eight measurement stations and record their data for each on the handout form provided. Please preview each of the measurement instruments to determine their suitability and usefulness in your educational setting. Measurement stations can be omitted or replaced if needed.
Measurement stations:
 - a. Blood Pressure
 - b. Heart rate at rest and after two minutes of running in place
 - c. Calorie Goal
 - d. Pittsburgh Sleep Quality Index
 - e. Stress Screening Test
 - f. Stroke Risk Scorecard
 - g. Grip Strength
 - h. Walk Score
2. Have the students enter their data into the Data Response Form at the reporting station.

3. Following the simulation exercise, lead a classroom discussion using the questions provided in the “Observations and/or Data,” “Analysis and Conclusions,” and “Critical Thinking Questions” sections of this lesson.
4. After the discussion, direct the students into small groups and have the students develop research questions and hypotheses, as well as analyze data, graph results, and provide explanations, conclusions, and future questions.
5. Small Group Tasks:
 - a. Develop one or two research question related to health and wellness.
 - b. Develop hypotheses.
 - c. Use the spreadsheet file to analyze the individual and combined data to test your hypotheses.
 - d. Graph your results.
6. What are your findings and possible explanations?
7. What additional or follow-up questions do you have?
8. What measures would need to be added to the simulation activity to answer these questions? Find some possible measurement tools you could use.
9. Each group will write a brief summary and/or prepare a presentation to share its work and conclusions with the class.

Observations and/or Data

Students should be prepared to answer the following questions after participating in the simulation:

- How did you feel participating in the study simulation?
- How did the experience compare to your expectations?
- Do you think the way that different aspects of health status were measured at each station were suitable for the study? Are they accurate? Do they measure what they are supposed to be measuring (sleep, etc.)?

Analysis and Conclusions

- Did you think you were provided enough information prior to participating in the “study”?
- What else would you have liked to know?
- Considering the research design, data collection measures, and ethical requirements:
 - What were the risks to participation?
 - Was your personal information/data protected?
 - Were ethical requirements violated?



- What would you share from your experience with a friend who was considering participating in a clinical research study?
- Do the data appear to have been recorded accurately in the data table by each of the participants? Why is this important? What could you do to improve the data recording process?

Critical Thinking Questions

- How would you improve the process if you were designing the study?
- What aspects of the study design or data collection may have contributed to error?
- What are the advantages and disadvantages of prospectively versus retrospectively collecting data? Is it more accurate to collect the data as they are happening or to use previously collected information or ask someone to remember what happened later?
- How do you think recording your behaviors over time may impact those behaviors? For example, if you are recording your entire food intake, will you change what and how much you eat?

Teacher Notes

Before the Activity:

- Set up the measurement stations and the reporting station so that the study subjects' confidentiality is maintained.
- Measurement stations can be omitted or replaced if needed. Exercise caution and sensitivity as needed.
- If you use the Stroke Risk Scorecard, review the information about Pediatric Stroke from the National Stroke Association and ScienceDaily: Young people are now at higher risk for stroke (see Background Information & Resources). You may want to discuss this information with your students as part of this activity.
- Create the Data Response Form as either a spreadsheet or a Google Form. This form serves as a collection point for each student's individual data and creates the combined class data set for analysis.
- Ensure that the necessary websites are accessible.
- Instruct students on how to accurately obtain their heart rate.
- Give thought to alternative options for students with physical disabilities.
- Review the background material and resources provided in the Ethical Issues in Clinical Research section for information related to human subjects protection.

Safety Notes

Make sure all students are following proper classroom safety guidelines.

CRESST Videos

The CRESST Videos are designed to be used in conjunction with the CRESST Curriculum. Each classroom-friendly video is approximately 4 minutes in length and can be used to generate discussion related to clinical research, healthy lifestyle choices, and student research into health-related topics.

Several of the physical measurements that are demonstrated in ***Clinical Research: Why Does It Matter to Me?*** are used to collect data in this lesson. The video can be used to show the link between the classroom activities and actual clinical measures.

Background Information & Resources

Pediatric Stroke

<http://www.stroke.org/understand-stroke/impact-stroke/pediatric-stroke>

Stroke can affect people of all ages, and the incidence of stroke among adolescents is rising. This website includes information about pediatric stroke, including risk factors, symptoms and treatment.

ScienceDaily: Young people now at higher risk for stroke

<http://www.sciencedaily.com/releases/2013/09/130903112916.htm>

An increasing number of adolescents and young adults are demonstrating risk factors for adults. This article discusses these risk factors and raises questions about the economic long-term impact of an increased number of strokes among young people.

How to use Excel to analyze data:

Mean

1. Go to the Insert tab and select Function
2. Click on the cell where you want to display the mean
3. Select the AVERAGE function and enter the cell range (e.g., A1:J1), click OK

Standard deviation

1. Go to the Insert tab and select Function
2. Click on the cell where you want to display the standard deviation
3. Select the STDEV function and enter the cell range (e.g., A1:J1), click OK



Correlation

1. Go to the Insert tab and select Function
2. Click on the cell where you want to display the standard deviation
3. Select the CORREL function and enter the cell range of the two data columns or arrays, click OK
4. Use scatterplot option to graph the correlation

Generating A Research Hypothesis

<https://people.uwec.edu/piercech/ResearchMethods/Generating%20a%20research%20hypothesis/generating%20a%20research%20hypothesis%20index.htm>

This website provides useful information to help guide students through the process of generating a research hypothesis.

Cleveland Clinic Children's Health Essentials: Diseases & Conditions

http://my.clevelandclinic.org/disorders/sleep_disorders/hic_sleep_in_adolescents.aspx

This website provides information regarding sleep in adolescents and teenagers, including signs of sleep deprivation and ways to improve their sleep.

Extensions

Classroom

The data from this exercise can be used to discuss measurement and statistics in research.

Cross-Curricular

Mathematics: Coordinate with the mathematics teachers so that the statistical analysis and graphing of the data can be completed in mathematics class, demonstrating the links between research, science and mathematics.

Health and Physical Education: Discuss appropriate Calorie goals, physical activity goals, energy balance, heart rate, healthy sleep habits, and screen time. Develop personal plans to meet goals for appropriate Calorie intake, physical activity, energy balance, heart rate, healthy sleep habits, and screen time.

Name: _____

Study Simulation

This activity is designed to simulate participation in a clinical research study and provide data for use in an exercise for class. This and any other forms you complete related to this project are strictly confidential. You are asked to provide a personal code so that your responses will not be linked with your name in any data base.

Personal Code:

Circle first letter of mother's first name:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Circle first letter of mother's maiden name:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Circle first letter in the city of your birth:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Circle first letter in state of your birth:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Personal Code: _____

Instructions: Visit each of eight measurement stations. Record your data for each of the eight measurement stations on the back side of this form. Enter your data in the Data Response Form for the study.

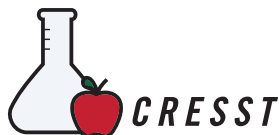
Measurement stations:

Sitting blood pressure using automated blood pressure monitor

Heart rate at rest and after two minutes of running in place

Calorie Goal (<http://www.livestrong.com/thedailyplate/>)Pittsburgh Sleep Quality Index (<http://goodmedicine.org.uk/files/assessment,%20pittsburgh%20psqi.pdf>)Stress Level (<http://www.innerhealthstudio.com/support-files/stress-screening-test.pdf>)Stroke Risk Scorecard (<http://www.stroke.org/sites/default/files/resources/stroke-risk-scorecard-engl-2015.pdf>)

Grip Strength

Walk Score (<http://www.walkscore.com/cities-and-neighborhoods/>)

Name: _____

Data Reporting

Measurement Station #1:

Sitting Systolic Blood Pressure _____ mmHg

Sitting Diastolic Blood Pressure _____ mmHg

Measurement Station #2:

Heart rate at rest _____ beats per minute

Heart rate after two minutes running in place _____ beats per minute

Measurement Station #3:

Calorie Goal to maintain your current weight _____ daily caloric intake

Measurement Station #4

Global Sleep Score _____

Measurement Station #5

Total Stress Screening Score _____

Measurement Station #6

Number of points in high risk category _____

Measurement Station #7

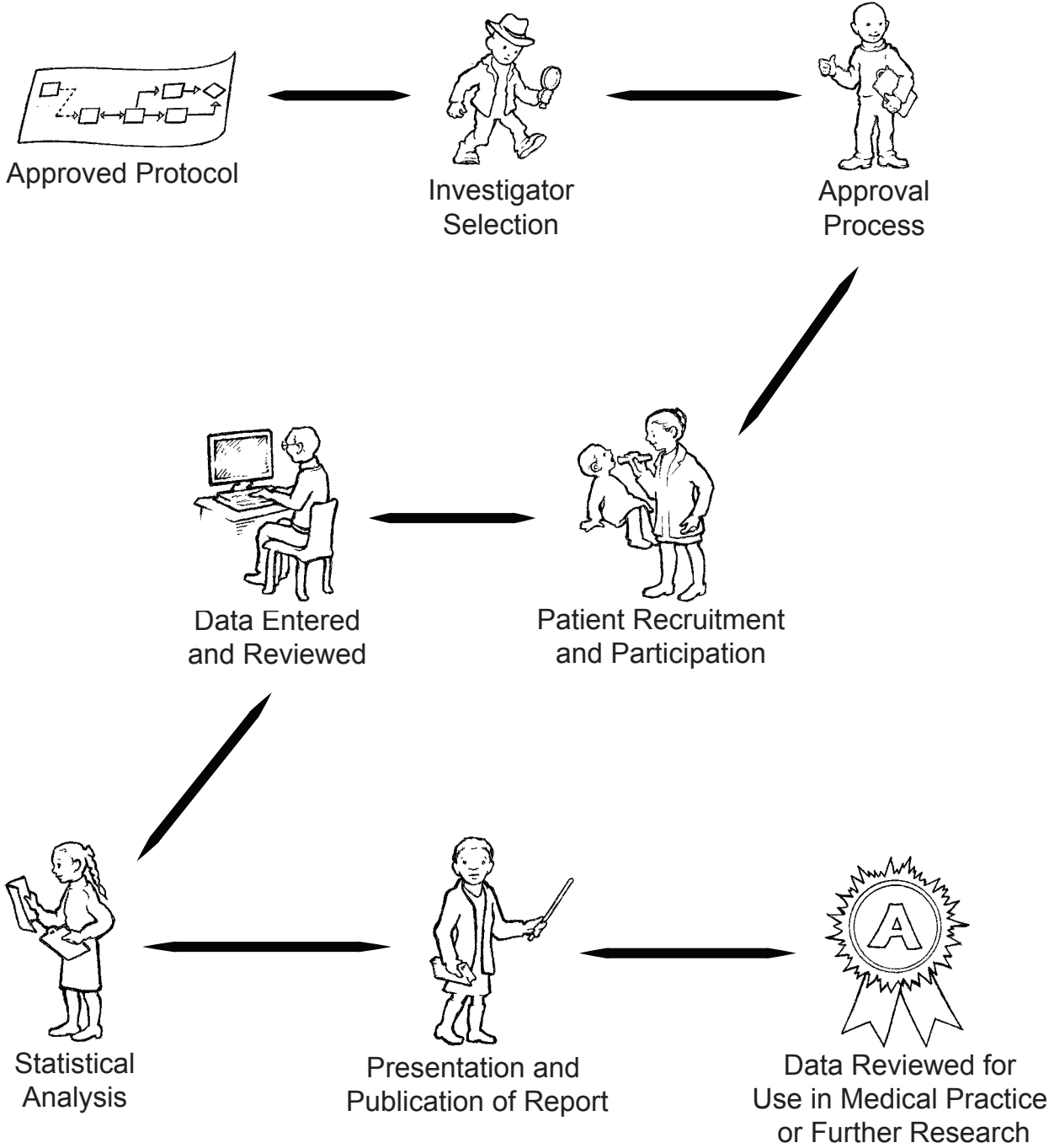
Grip Strength _____

Measurement Station #8

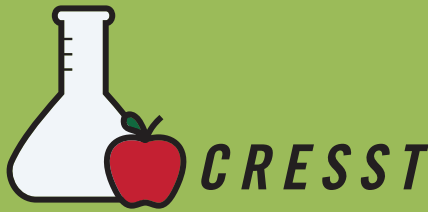
Walk Score _____



Clinical Trial Process



The Basics of Research



A Matter of Taste

© Virginia Commonwealth University 2013

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Introduction

There are many factors that influence what people eat, including a genetic variation in the ability to taste bitter foods. The research on this genetic trait has provided new insights into food preferences. These insights also influence our understanding of the complex issues related to childhood and adult health, nutrition and obesity. As part of this lesson, students will develop and conduct a research project exploring the link between genetics and food preferences.

Purpose

The purpose of this activity is to research some of the factors that influence food choices and to conduct a clinical research project that investigates the link between the genetics of food preferences and actual food choices.

Objectives

At the end of this lesson, students will be able to:

- Describe the different steps of the clinical research process
- Conduct research on how genetics can influence food preferences
- Identify some of the causes of the rising rates of obesity in America
- Demonstrate knowledge by designing a research project related to food preferences

Key Terms

- Clinical research: research where humans participate as subjects in the research
- Nutritional Calorie: a unit equal to one kilocalorie, used to express the heat output of an organism and the energy value of food. It is abbreviated as Kcal or Cal. It is also called a large Calorie.

National and State Standards

National

Next Generation Science Standards:

Disciplinary Core Ideas LS1.C, LS1.D, LS3.A, LS3.B

Crosscutting Concepts 2, 4, 6

Science and Engineering Practices 3, 6, 8

Nature of Science Understandings 1, 5, 7, 8

Essential Features of Classroom Inquiry 1, 2

National Standards for Health: Standards 1, 2, 3, 4, 5, 6, 7, 8

National Standards for Physical Education: Standards 3, 4, 5

Virginia

Science 6.1, LS.1, PS.1 k, BIO.1 b, e, j

Health 6.1 g

Materials

- Videos
- Supertasters Taste Buds: http://youtu.be/2Fhc0t_QNhs
- Taste Buds and Weight <http://www.doctoroz.com/videos/taste-buds-and-weight>

Per class:

- 1 bottle blue food color

Per group

- 1 index card, cut in quarters
- 1 hole punch
- 1 hand lens
- 1 mirror

Per person

- 1 PTC test strip
- 1 control test strip
- 1 thiourea test strip
- 1 cotton swab

Note: A version of the “A Matter of Taste: Food Preference Questionnaire” that does not use the test strips is included in the Student Handouts.

Procedures

1. Show the “Supertasters Taste Buds” and “Taste Buds and Weight” videos.
2. Facilitate a class discussion on the relationship between taste ability, food preferences, and weight.
3. Create a list of foods that the class feels are bitter. Some example may be Brussels sprouts, black coffee, olives, grapefruit, etc.
4. Design a questionnaire to record the students’ preferences related to the list of food generated by the class. (Note: you may use the Student Handouts as a template for this questionnaire.)
5. Provide a space on the questionnaire for students’ response to the test strip activity.
6. Provide a space on the questionnaire for students to record the number of taste buds observed.
7. Working in small groups, each student will complete the food preference questionnaire.
 - a. Taste the control strip.
 - b. Taste the PTC strip and record his or her taste response on the food preference questionnaire.
 - c. Taste the thiourea strip and record his or her taste response on the food preference questionnaire.
 - d. Apply blue food color to his or her tongue.
 - e. Use a hole punch to make hole in an index card. The student should place the index card on his or her tongue. Use the mirror to count the number of taste bud within the circle. Record the number of taste buds on the food preference questionnaire.
 - f. Based on the responses to the questionnaire, the student will determine if he or she is a non-taster, taster, or supertaster.
8. Discuss the relationship between:
 - a. The number of taste buds and the response to the test strips.
 - b. Food preferences and the number of taste buds.
 - c. Food preferences and the response to the test strips.
9. Students will work in small groups to design a clinical trial investigating the relationship between food preferences and genetic tasting ability.
10. Each group will present a clinical trial, and the class will choose one to develop into a class clinical trial.

Observations and/or Data

- Is there are relationship between the number of taste buds and the response to the test strips?
- Is there a relationship between the response to the number of tastes buds and food preferences?
- What percentage of the class were non-tasters, tasters, and supertasters?
- Guide the students to make observations and collect data appropriate to the research project.

Analysis and Conclusions

- Have students summarize the data that was collected during the research project and draw conclusions about their results.

Critical Thinking Questions

- Why is clinical research important in people's lives?
- Did the student's genetic tasting ability completely determine his or her food preferences?
- Why or why not?

Teacher Notes

Before the Activity:

- Preview the recommended videos for the lesson.
- Discuss the differences and similarities between fact and opinion with the class before viewing the video clips.

Safety Notes

Supertasters may have a strong reaction to the test strips and the blue food color will temporarily stain the teeth and mouth. It is best to have water available so that the students can rinse their mouths after the experiment.

Make sure all students are following proper classroom safety guidelines.

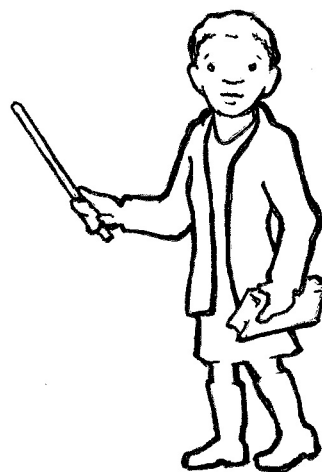
Some school systems do not allow PTC and/or thiourea test strips to be used. Both chemicals can be toxic if consumed in large amounts, so be aware of your school's policies and exercise appropriate safety measures during the experiment. More information related to the safety of PTC and thiourea test strips can be found at:

<http://www.carolina.com/teacher-resources/Document/msds-ptc-papers/tr-msds-ptcpapersghs.tr>

<http://www.carolina.com/teacher-resources/Document/msds-thiourea-taste-test-strips/tr-msds-thioureattstrpghs.tr>

A version of the “A Matter of Taste: Food Preference Questionnaire” that does not use the test strips is also provided.

Be conscious of the potential for germ transmission. Have the students properly dispose of used test strips and cotton swabs and sanitize their hands after the experiment. Make sure that you have parent approval for this activity. When students prepare the worksheet that will be filled in, be sure that a signature line for parents is included.



CRESST Videos

The CRESST Videos are designed to be used in conjunction with the CRESST Curriculum. Each classroom-friendly video is approximately 4 minutes in length and can be used to generate discussion related to clinical research, healthy lifestyle choices, and student research into health-related topics.

The questions related to genetics and food choices in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** can lead to more in-depth research questions related to why we eat what we eat and how that influences our health.

Background Information & Resources

These webpages provide a wide variety of information about the clinical research process, obesity, nutrition, and healthy lifestyles.

National Institutes of Health: Clinical Research Resources

<http://www.nih.gov/research-training/clinical-research-resources>

The NIH website includes a large database of articles on health and clinical trials. The “NIH Clinical Research Trials and You” section is written for a general audience and provides information about the basics of clinical research as well as other excellent information such as personal stories and how to find a clinical trial.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD): Clinical Trials & Clinical Research

<https://www.nichd.nih.gov/health/clinicalresearch/Pages/index.aspx>

This website provides concise definitions of clinical research and clinical trials as well as excellent background information, such as “Guidance for Clinical Researchers” and “What Else Should I Know About Clinical Research.”

The National Institute of Diabetes and Digestive and Kidney Diseases: Overweight and Obesity Statistics

<http://www.win.niddk.nih.gov/statistics/index.htm>

This website includes a variety of statistics related to obesity in the United States. It also provides information on age and ethnicity statistics, BMI, and physical activity levels. Links to additional health information and resources for community outreach and health fairs are available.

US National Institutes of Health: ClinicalTrials.gov

<http://clinicaltrials.gov/>

This website, provided by the National Institutes of Health, is a registry of all private and publically funded clinical trials currently being conducted in the United States.

Kid’s Health

<http://kidshealth.org/>

Kid’s Health is an award-winning interactive website for parents and children run by the nonprofit children’s health system, Nemours. It includes articles and activities related to health and other issues that contribute to children’s and teenagers’ health and well-being.



National Institute of Health

www.nih.gov

This website includes a large database of articles on health and clinical trials. The “Science Education” section under “Research and Training” includes links to a variety of resources and activities designed for K-12 students and teachers.

BBC, Science and Nature, Human Mind and Body. Science of supertasters.

<http://www.bbc.co.uk/science/humanbody/body/articles/senses/supertaster.shtml>

This website includes background information related to our ability to taste bitter compounds and a brief discussion of how this may influence food preferences.

Extensions

Classroom

Expand the Food Preference Questionnaire to include “favorite foods.” Discuss these “favorite foods,” and create a list of common characteristics, such as sweet, salty, creamy, etc. Have the students research the nutritional value for these foods and identify those that are high Calorie/low nutrition versus low Calorie/high nutrition. Discuss how food preferences and food characteristics relate to nutritional value and may contribute to increases in obesity rates.

Cross-Curricular

Social Studies: Investigate how cultural influences and food availability complements and/or modifies genetic tendencies related to food preferences.

Language Arts: Have students complete a formal scientific write-up as an exercise in technical writing.



Name: _____

A Matter of Taste: Food Preference Questionnaire

(test strip version)

Bitter Foods

Food Type	Like	Neutral	Dislike
Cabbage			
Grapefruit juice			
Broccoli			
Cauliflower			
Black coffee			
Brussels sprouts			
Green tea			
Baker's chocolate			
Black olives			

My food preferences,
suggest that I am a:

non-taster taster supertaster

Test Strip Results

PTC test strip: no taste bitter very bitter

Thiourea test strip: no taste bitter very bitter

My response to the test strips
suggests that I am a

non-taster taster supertaster

I counted _____ taste buds in the circle.

The number of taste buds in the circle,
suggests that I am a

non-taster taster supertaster

I believe that I am a

non-taster taster supertaster



Name: _____

A Matter of Taste: Food Preference Questionnaire

(taste test version)

Bitter Foods

Food Type	Like	Neutral	Dislike
Cabbage			
Grapefruit juice			
Broccoli			
Cauliflower			
Black coffee			
Brussels sprouts			
Green tea			
Baker's chocolate			
Black olives			

My food preferences,
suggest that I am a:

non-taster

taster

supertaster

Taste Test Results

On a scale of 0 to 5, indicate how bitter each food tastes to you by marking your choice on the scales below:

Broccoli

0 1 2 3 4 5
Not Bitter Very Bitter

Baker's chocolate

0 1 2 3 4 5
Not Bitter Very Bitter

My response to the taste test

suggests that I am a

non-taster

taster

supertaster

I counted _____ taste buds in the circle.

The number of taste buds in the circle,

suggests that I am a

non-taster

taster

supertaster

I believe that I am a

non-taster

taster

supertaster



