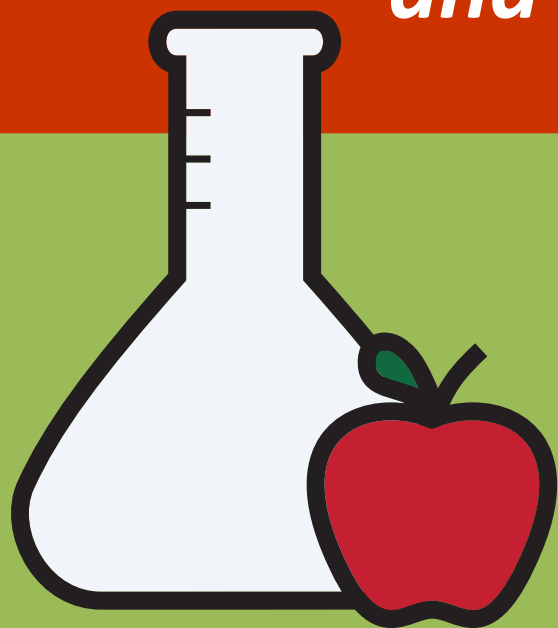


*Clinical Research Education
for
Secondary Students
and Teachers*



CRESST

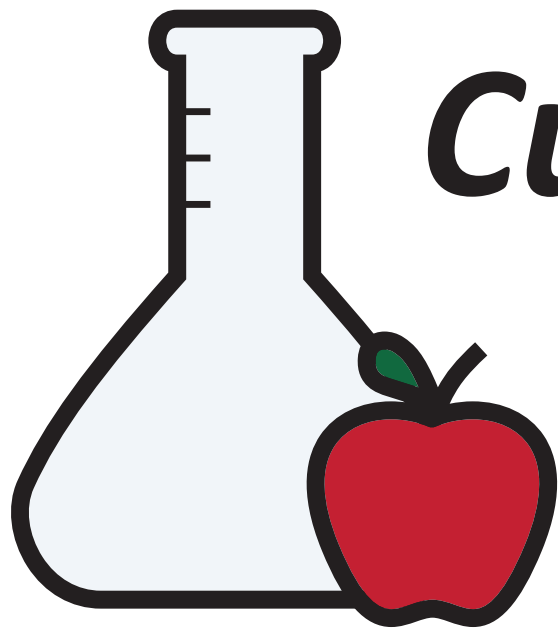
Curriculum



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CRESST

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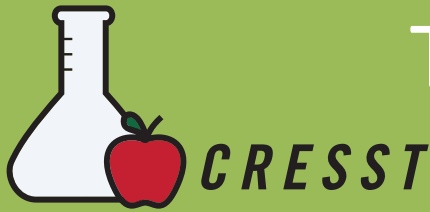


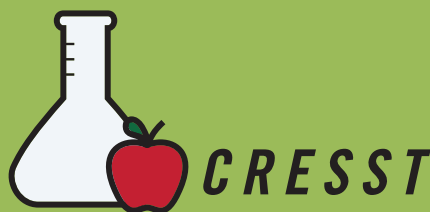
TABLE OF CONTENTS

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INTRODUCTION	iii
PROJECT CRESST TEAMS	v
1. <u>THE BASICS OF RESEARCH</u>	
OVERVIEW	1.1
THE SCIENCE OF BIOLOGY	1.3
THE CLINICAL RESEARCH PROCESS	1.13
IT'S ALL ABOUT YOU: A CLINICAL RESEARCH SIMULATION	1.23
A MATTER OF TASTE	1.33
2. <u>INFORMATION GATHERING AND SYNTHESIS</u>	
OVERVIEW	2.1
FIT OR FAT? FIT AND FAT?	2.5
AM I FULL YET?	2.13
TEAM SCIENCE: INQUIRY INTO HEALTHY HABITS	2.25
WALKABLE COMMUNITIES (EXTENSION ACTIVITY)	2.39
ATTACKING THE ASTHMA ATTACK! (EXTENSION ACTIVITY)	2.41
RETHINK YOUR DRINK (EXTENSION ACTIVITY)	2.43
3. <u>ETHICAL ISSUES IN CLINICAL RESEARCH</u>	
OVERVIEW	3.1
ETHICAL SCENARIOS CAROUSEL	3.3
HISTORY OF ETHICAL GUIDELINES AND REQUIREMENTS	3.11
ETHICAL CONTROVERSIES: DEBATING THE PROS AND CONS	3.43
BIOETHICS: STANDARDS FOR SCIENTISTS	3.49

4. <u>COLLECTING AND ANALYZING DATA</u>	
OVERVIEW	4.1
NUMBERS CAN TALK: EXPLORING STATISTICAL DATA	4.3
LET’S WORK IT OUT	4.13
WALKABLE COMMUNITIES: EXPLORING MEASUREMENT, RELIABILITY AND VALIDITY	4.21
WHAT’S ON YOUR PLATE	4.29
APPENDIX A: NATIONAL STANDARDS MATRIX	A.1
APPENDIX B: VIRGINIA STANDARDS OF LEARNING MATRIX	B.1
APPENDIX C: CRESST VIDEO GUIDE	
OVERVIEW	C.1
CLINICAL RESEARCH: WHY DOES IT MATTER TO ME?	C.3
CRESST KIDS AND HEALTH: FROM CLASSROOM TO COMMUNITY – HOW RESEARCH CAN IMPROVE OUR HEALTH?	C.7



Introduction

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Project CRESST: *Enhancing Clinical Research Education for Secondary Students and Teachers* was designed to support secondary teachers' classroom instruction in areas related to designing, conducting, and interpreting research using a childhood health and wellness content framework. The following instructional lessons and student activities were designed to assist teachers in their use of inquiry-based instructional approaches to deliver research and health-related content.

The CRESST curriculum integrates three main topics: research content, childhood-health and wellness content, and inquiry-based instructional strategies. In an effort to provide high-quality curricular tools that promote inquiry-based teaching, the curriculum was developed by a team of exemplary middle and high school science teachers, and reviewed by K-12 professionals and university faculty with significant expertise in lesson topics and the instructional approach. The development process ensures that the curriculum is aligned with the Virginia Standards of Learning (SOL) for Science (2010), Health (2015), and Physical Education (2015); it is also aligned with the Next Generation Science Standards (2013), and the National Health Education Standards (2007), and Physical Education Standards (2013). The curriculum is designed to enhance students' research literacy knowledge and skills as described in the state and national standards. Matrices that link each lesson to the state and national standards are provided in the appendices (see Appendices).

The curriculum has been organized into four main content areas that mirror steps in the research process:

- The Basics of Research
- Information Gathering and Synthesis
- Ethical Issues in Clinical Research
- Collecting and Analyzing Data

These units were developed so that they can be used in their entirety, or teachers can select stand-alone lessons to target specific content areas or skills. The lessons are accompanied by ideas for how to extend or differentiate the strategies for varied groups of students and to encourage cross-curricular collaboration with colleagues who teach other subject areas. Two short videos were developed to accompany the lessons.

Clinical Research: Why Does It Matter to Me? introduces students to the concept of clinical research and what it means to be a research participant; ***CRESST Kids and Health: From Classroom to Community – How Research Can Improve Our Health*** explores how clinical research can be used to address health issues prevalent in the local community. A video guide for classroom suggestions and accompanying CRESST lessons can be found in the appendices.

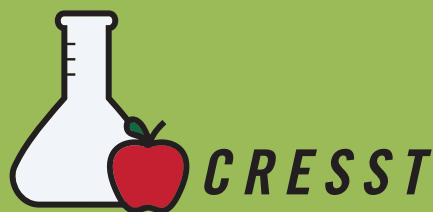
In addition to engaging students in the conduct of research, the CRESST curriculum also strives to promote general health and wellness knowledge among adolescent learners. According to the Virginia Foundation for Healthy Youth, roughly one out of every four students between the ages of 10 and 17 is obese.¹ Statistics collected by the Centers for Disease Control and Prevention indicate that the rate of childhood obesity has more than tripled among adolescents aged 12-19 since the late 1970s and early 1980s, from 5.0% to 20.5% in 2011-2012.² Consequently, similar to the goals of clinical research studies in childhood health and wellness, the overarching goal of the CRESST curriculum is to engage students and teachers in learning about a significant public health issue through an inquiry-based instructional approach. Through this process, we hope that teachers, students, families, and community members develop an appreciation for the important role clinical research plays in improving the human condition.

Project CRESST was supported by the Office of The Director, National Institutes of Health, under award number R25 OD010984. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

¹ Source: <http://www.vfhy.org/>

² Source: <http://www.cdc.gov/obesity/data/childhood.html>

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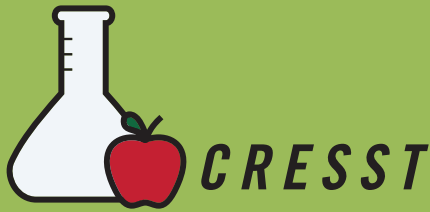
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The Basics of Research



Overview

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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/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.

Overview of Study Designs in Clinical Research

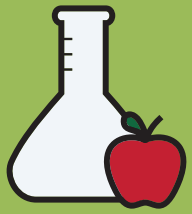
EBP@NUHS CH5 Study Design © Barbara M. Sullivan PhD, Jerrilyn A. Cambron DC PhD, Dept. of Research NUHS 2008.

<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”

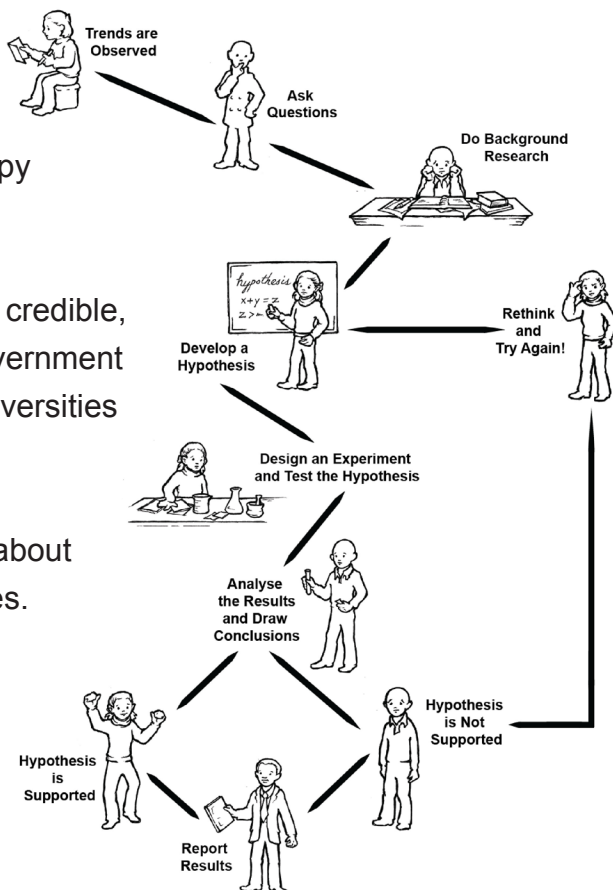


Procedures

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

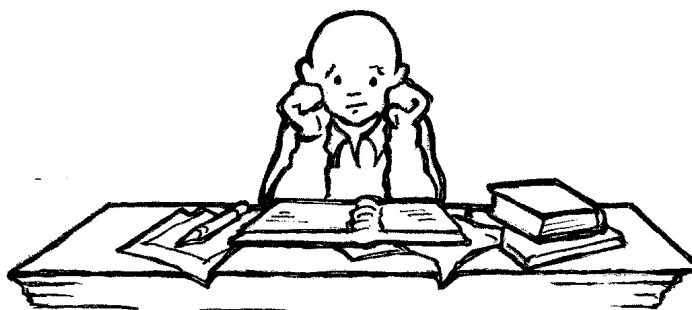
This website provides an interactive exploration of the process of science.

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: _____

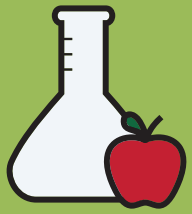
How will you analyze your data? Set up a graph that includes what you will label the x and y axes and the graph title. (It is always a good idea to know how you will graph your data before you begin the actual experiment.)

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

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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

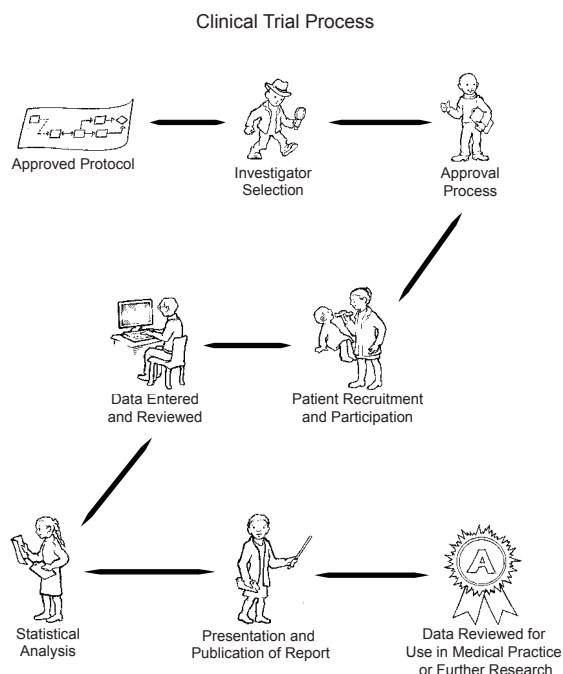


Procedures

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?

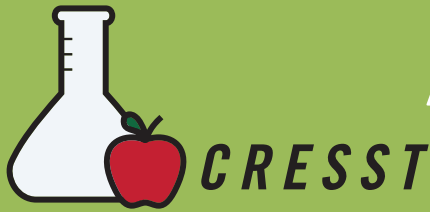
Research Scenario

- ❖ 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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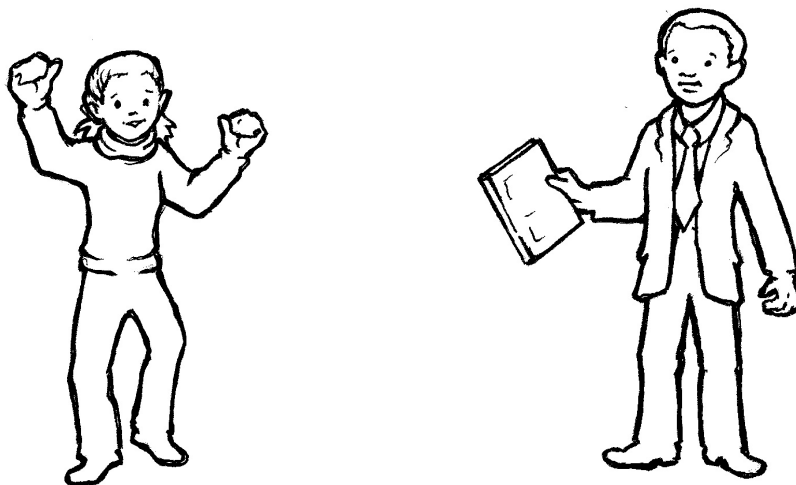
Revised February 2016

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

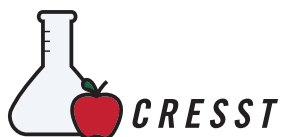
Number of points in high risk category _____

Measurement Station #7

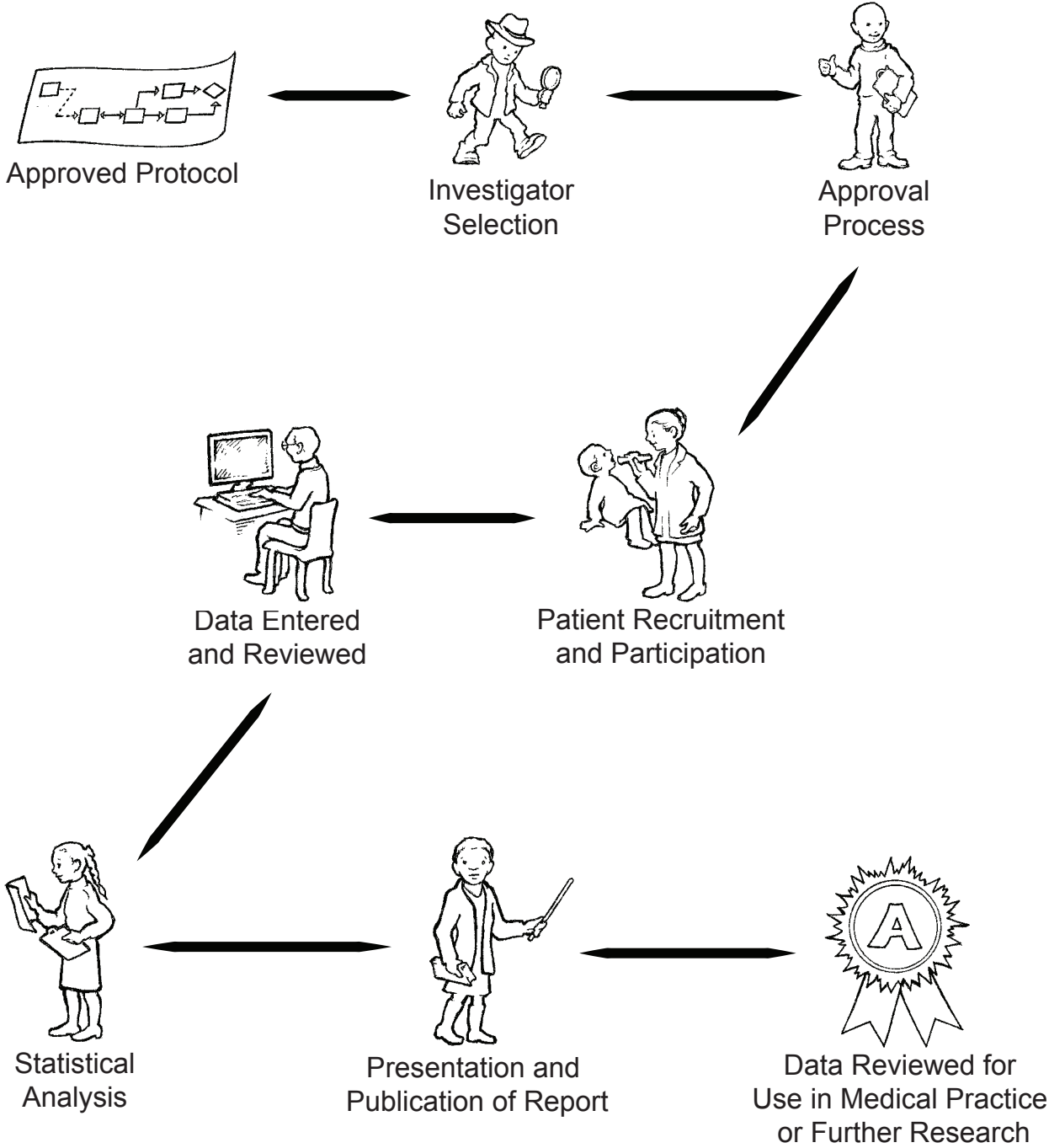
Grip Strength _____

Measurement Station #8

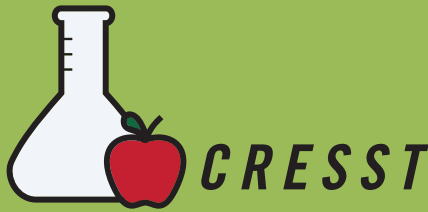
Walk Score _____



Clinical Trial Process



The Basics of Research



A Matter of Taste

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Revised February 2016

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.

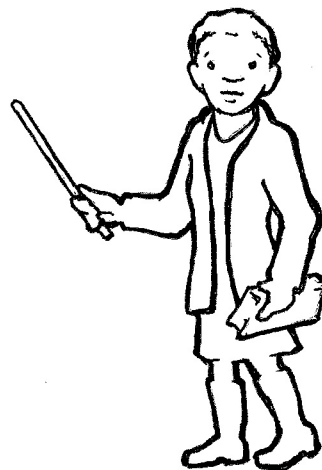
Some school systems do not allow PTC and/or thiourea test strips to be used. Both chemicals can be toxic if consumed in large amounts, so be aware of your school's policies and exercise appropriate safety measures during the experiment. More information related to the safety of PTC and thiourea test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

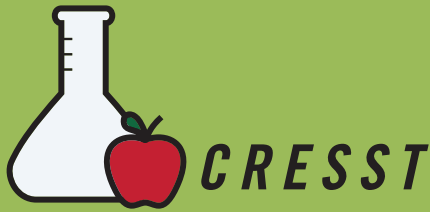
non-taster taster supertaster

I believe that I am a

non-taster taster supertaster



Information Gathering and Synthesis



Overview

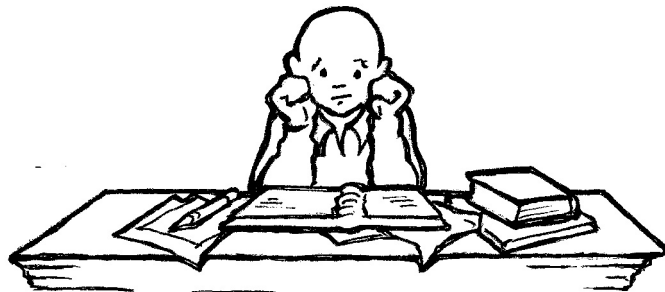
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Gathering background information is essential for the success of clinical research studies. Understanding current issues and findings from research on related topics can inform the focus and design of clinical research studies. However, simply gathering information without any direction or purpose will not lead to a well-informed study. Information can come from many sources, including experts, the internet, direct interviews, surveys, and scientific papers. An important step in all research studies is to locate, read, and evaluate information and literature that will be used to help develop not only the study's research questions and hypotheses, but also the methods that will be used to answer the research questions and test the hypotheses.

Clinical researchers gather information when developing a research question. They evaluate the existing medical literature, identify topics that remain unknown, and design a study or series of studies to try to answer the question they've developed. The design of a clinical study starts with researching what has already been published and evaluating it critically.

With the wide array of health information available on the internet and in medical literature, it can be challenging to determine which sources of information are reliable and credible. To help students become more knowledgeable and skilled in evaluating health



information, this section provides lessons that place the students in the role of researchers investigating issues related to obesity and general health and wellness. As "researchers" selecting research questions and designing the research study, students will identify sources that provide background information to support their methods and conclusions.

Section Objectives

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

- Demonstrate the skills needed to evaluate and identify credible sources of information
- Gather their own information through interviews and surveys, and record data from sample trials and experiments
- Synthesize information from different sources and summarize it into tables and graphs that can be analyzed to test hypotheses and support or refute conclusions

Topics

- Causes of obesity
- Characteristics of credible information sources
- Definitions of obesity and calculation of BMI (Body Mass Index)
- Leptin and energy balance
- Conducting interviews and presenting information

Activities

- Fit or Fat? Fit and Fat?
- Am I Full Yet?
- Team Science: Inquiry into Healthy Habits
- Extension Activity: Walkable Communities
- Extension Activity: Attacking the Asthma Attack
- Extension Activity: Rethink Your Drink

Background and Resources

Some excellent resources available to guide students as they locate and evaluate resource literature include:

Science Buddies' Resources for Finding and Accessing Scientific Papers.

http://www.sciencebuddies.org/science-fair-projects/top_science-fair_finding_scientific_papers.shtml

This resource provides a table containing free, online academic search engines for various science disciplines. It also reviews how to obtain a copy of a scientific paper, including a list of databases containing free, full-text scientific papers and data sets.

Science Buddies' How to Read a Scientific Paper.

http://www.sciencebuddies.org/science-fair-projects/top_science-fair_how_to_read_a_scientific_paper.shtml

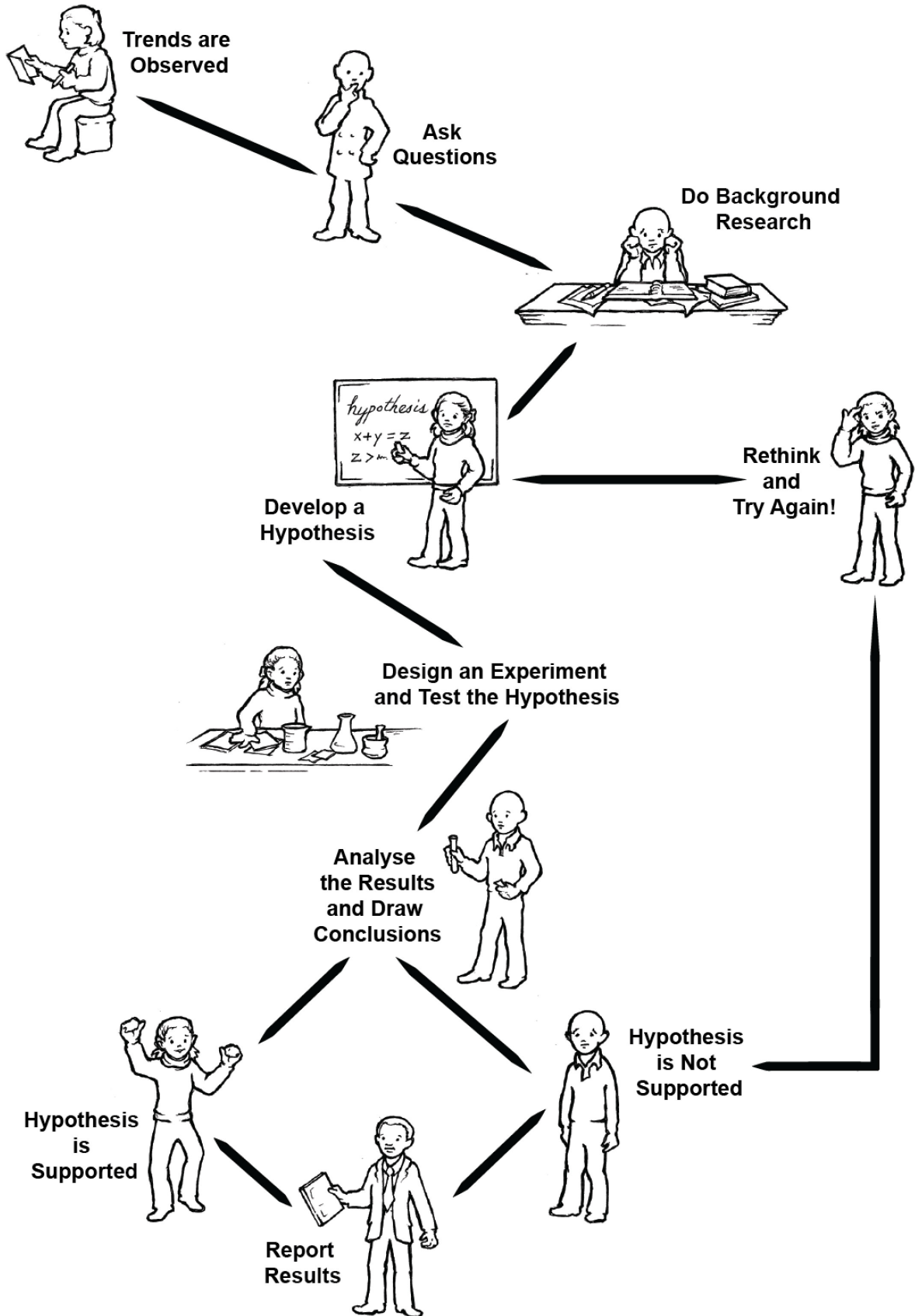
This resource is targeted to high school students and reviews the basic steps of how to read a scientific paper in a student friendly way.

The Medical Library Association's User's Guide to Finding and Evaluating Health Information on the Web.

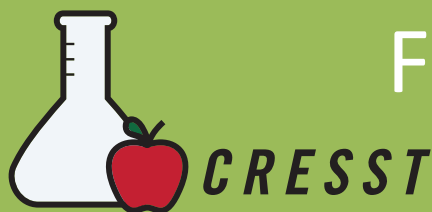
<http://www.mlanet.org/resources/userguide.html>

This resource provides guidance to the general public on how to find and evaluate health information available on the web. It catalogues useful and reputable health resources as well as provides criteria for evaluating health information websites.

The Science Research Process



Information Gathering and Synthesis



Fit or Fat? Fit and Fat?

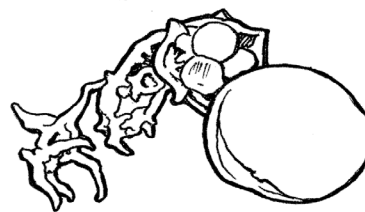
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Introduction

The balance between energy input, energy expenditure, and energy storage is termed energy homeostasis or energy balance. Energy intake is the food and beverages consumed; the definition of energy expenditure is a little more complex. Energy expenditure includes our physical activity, how our body produces energy, and all of the chemical reactions that take place in our body.

When more energy is consumed than is expended, the excess energy is stored in the form of fat. This can lead to obesity.



An adipocyte (fat cell) gaining droplets of fat as an individual's body weight increases.

Purpose

Students will learn about the Body Mass Index (BMI) and why it can be a useful tool for identifying a person's weight category. They will also investigate the limitations of BMI as an indicator of weight and nutritional health. During this activity, students will investigate other factors that contribute to obesity and develop skills to identify credible sources of information.

Objectives

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

- Calculate BMI (Body Mass Index) to determine an individual's weight category
- Explain why BMI is not always an accurate indicator of a person's weight category
- Discuss the factors that contribute to obesity and find credible information about these factors
- Develop skills to identify credible sources of information

Key Terms

- **BMI:** (Body Mass Index) an index used to indicate a person's weight category; it is obtained by dividing a person's weight in kilograms by the square of his or her height in meters
- **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.
- **Homeostasis:** the tendency of an organism or system to maintain internal stability, through the coordinated response of its parts to any situation or stimulus that would disturb its normal condition or function
- **Obesity:** a condition characterized by an abnormal or excessive amount of fat stored in the body

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 2

Science and Engineering Practices 1, 4, 5, 8

Nature of Science Understandings 1, 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, LS.1, BIO.1

Health 6.1 b, c, 6.2 a, 6.3 d, s, 7.1 d, e, 7.2 a, e-h, 7.3 e, 8.1 d, 8.2 c, f, 8.3 d, e, 9.2 b, d, 10.1 a, b

Physical Education 6.3 d, e, h, 6.5 c, 7.3 d, 7.5 a-h, 8.3 a, e, 8.5 a-h, 9.5 b, c, 10.5 a-g

Materials

- Computer lab
- Student data sheets
- Copies of "A Good Way to Measure Obesity? Fat Chance", Carl Bialik, The Wall Street Journal, January 12, 2013 (<http://www.wsj.com/articles/SB10001424127887324581504578233950347117088>) for each student or group



Procedures

1. Introduce the Body Mass Index and have the students read the article: 'A Good Way to Measure Obesity? Fat Chance', Carl Bialik, The Wall Street Journal, January 12, 2013
2. Discuss the limitations and concerns that the article raises related to BMI.
3. Using the Student Handout, have each student calculate the BMI from the information provided.
4. Have the students discuss the results of their calculations, any patterns in the BMIs, and their conclusions.
5. Working in small groups and using the resources in the background information section of this activity, have the students present the pros and cons of BMI as a diagnostic tool for obesity. Encourage them to use other resources to support their arguments.
6. After each group has shared its presentation, have group members discuss how they selected their sources of information and how they know that the sources were credible.

Observations and/or Data

- Does a high BMI always indicate unhealthy weight and habits?
- Does a low BMI always indicate healthy weight and habits?
- Is the health information available to the public always accurate and reliable?

Analysis and Conclusions

- Why might BMI not always be a good indicator of weight category?
- What other factors should be considered when assessing a person's weight, nutrition, fitness, and health?
- How can you ensure that information is accurate and reliable or credible?

Critical Thinking Questions

- What are some of the limitations of using BMI as the indicator of obesity?
- What are the sources of experimental error in calculating BMI?

Teacher Notes

Exercise caution and sensitivity in discussing BMI.



Safety Notes

Make sure all students are following proper classroom safety guidelines.

Background Information and Resources

Obesity has become a worldwide problem. In the U.S., there are more obese adults (33.8 %) than adults who smoke (20.6%), and childhood obesity is considered an epidemic (CDC, 2008). Some factors that may contribute to the rising obesity rates are portion sizes, unhealthy food choices, and lack of exercise. According to the CDC, for children and adolescents:

- Overweight = BMI at or above the 85th percentile and lower than the 95th percentile for children of the same age and sex.
- Obesity = BMI at or above the 95th percentile for children of the same age and sex.

We calculate overweight and obesity by using a person's height and weight to calculate BMI (Body Mass Index). In some cases, such as with athletes, a person's BMI may be high, but his or her body's fat content is not high; therefore, there are limitations to the use of BMI as a measure of overweight and obesity.

For a comprehensive review of the issues in measuring and using BMI as an indicator of childhood obesity, see Himes, JH. "Challenges of Accurately Measuring and Using BMI and Other Indicators of Obesity in Children". (Pediatrics, 2009;124:S3-S22).

http://pediatrics.aappublications.org/content/pediatrics/124/Supplement_1/S3.full.pdf

Additional resources to support a discussion of the limitations of using BMI in children and adolescents to measure obesity can be found at:

"A Good Way to Measure Obesity? Fat Chance", Carl Bialik, *The Wall Street Journal*, January 12, 2013

<http://www.wsj.com/articles/SB10001424127887324581504578233950347117088>

WebMD: What Your BMI Doesn't Tell You

<http://www.webmd.com/diet/bmi-drawbacks-and-other-measurements>

NIH National Heart, Lungs, and Blood Institute: Assessing Weight and Health Risk

http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm

LIVESTRONG.com: Problems With BMI

<http://www.livestrong.com/article/387703-limitations-of-bmi/>



NIH National Heart, Lung, and Blood Institute (NHLBI)

http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/index.htm

The National Heart, Lung, and Blood Institute provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

The Centers for Disease Control and Prevention

<http://www.cdc.gov/nccdphp/dnpao/growthcharts/resources/index.htm>

The CDC provides a Microsoft® PowerPoint presentation focusing on growth charts and BMI-for-age charts, including advantages of using these charts and calculating BMI. This webpage includes links to a variety of tools, including BMI calculators and growth charts.

Extensions

Classroom

Engage students in a discussion or debate regarding the use of BMI as a measure of obesity. What are the advantages and disadvantages of using BMI for a research study? What are the limitations? What alternatives are available? Are they practical?

Cross-Curricular

Health and Physical Education: Coordinate with the Health and Physical Education teachers so that the discussion of BMI, obesity and healthy choices are presented collaboratively.



Name: _____

One way that we define overweight and obesity is by using a person's height and weight to calculate BMI (Body Mass Index). For most people, BMI indicates the amount of body fat content. We will learn how to calculate BMI and then find out the value of your BMI.

$$\text{BMI} = \text{Weight (kg)} / \text{Height}^2 \text{ (m}^2\text{)}$$

Example:

Chris is 5 feet 2 inches and weighs 105 lbs.
What is Chris' BMI?

Take a person's height and convert it to inches
What is Chris' height in inches?

$$5 \text{ feet} \times (12 \text{ inches} / 1 \text{ foot}) = 60 \text{ inches}$$

$$60 \text{ inches} + 2 \text{ inches} = 62 \text{ inches}$$

Multiply by 2.54 to get the height in centimeters
What is Chris' height in centimeters (cm)?

$$62 \text{ inches} \times (2.54 \text{ cm} / 1 \text{ inch}) = 157 \text{ cm}$$

Divide by 100 to get the height in meters
What is Chris' height in meters (m)?

$$157 \text{ cm} \times (1 \text{ m} / 100 \text{ cm}) = 1.57 \text{ m}$$

Square it (multiply by itself)
What is the square of Chris' height (m²)?

$$1.57 \text{ m} \times 1.57 \text{ m} = 2.46 \text{ m}^2$$

Take the person's weight in pounds (lbs.)
What is Chris' weight in lbs?

$$105 \text{ lbs}$$

Divide by 2.2 to get the weight in kilograms (kg)
What is Chris' weight in kg?

$$105 \text{ lbs} \times (1 \text{ kg} / 2.2 \text{ lbs}) = 47.72 \text{ kg}$$

What is Chris' BMI?
We use the formula: BMI = Weight (kg)/Height² (m²)

$$47.7 \text{ kg} / 2.46 \text{ m}^2 = 19.3 \text{ kg/m}^2$$

Now Calculate Terry's BMI:

Terry is 5 ft 5 in tall and weighs 135 lbs.
What is Terry's BMI? (Show Your Work)

What is Terry's height in inches?

What is Terry's height in centimeters (cm)?

What is Terry's height in meters (m)?

What is the square of Terry's Height (m²)?

What is Terry's weight in lbs?

What is Terry's weight in kg?

What is Terry's BMI?
Use the formula: BMI = Weight (kg)/Height² (m²)



Name: _____

What is Terry's weight category?

What other factors could influence Terry's fitness and nutritional health?

Student Data:

Student 1: Male, 5ft 6in, 170 lbs, exercised daily, running and weight training, eats a well-balanced diet.

Student 2: Male, 5ft 8 in, 130 lbs, sedentary with no exercise, eats a lot of fast food and snacks, usually skips breakfast and lunch.

Student 3: Female, 5ft 2in, 100 lbs, exercises 3 times per week, including running, eats a lot of fast food and snacks

Student 4: Female, 5ft 4in, 110 lbs, sedentary, eats a well-balanced diet

Based on the information above, do you think that any of these students are overweight? Who and why?

Based on the information above, which students do you think are healthiest? Who and why?

Name: _____

Now calculate the BMI and weight category for these students:

Student 1: BMI = _____

Weight Category = _____

Student 2: BMI = _____

Weight Category = _____

Student 3: BMI = _____

Weight Category = _____

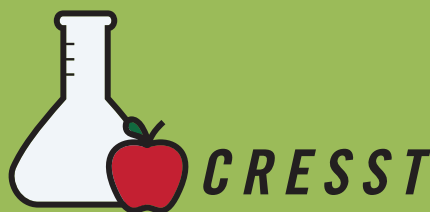
Student 4: BMI = _____

Weight Category = _____

Did the BMI and weight category of any of these students surprise you? Explain.

Have you changed your opinion about the students' health? Explain.

Information Gathering and Synthesis



Am I Full Yet?

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Revised February 2016

Introduction

In organisms, energy balance, or homeostasis, is the relationship between energy input, energy expenditure, and energy storage. Energy input is the number of Calories consumed. Energy output is the number of Calories used by an organism through metabolic functions and physical activity. Excess energy is stored as fat.

This energy balance is regulated by chemical signals (hormones) that are received in our brain centers (hypothalamus, brainstem, and reward centers). When this system is functioning properly, energy input, or feeding, is generally equal to energy expenditure. Leptin is one of the important signals for energy homeostasis. It is produced in fat cells and provides the brain with information that allows the brain to balance energy input (feeding) with energy expenditure. Leptin affects our appetite and makes us feel full or satiated.

Some obese people have high amounts of circulating leptin, but their brain does not respond to the presence of leptin by signaling that they are full. Over time, these increased leptin levels have desensitized the brain to the presence of leptin, and it takes higher and higher levels of leptin to trigger the satiation signal. This is called leptin resistance. In some individuals, there is also a genetic mutation that causes the receptor molecule to not recognize leptin. This is called leptin receptor deficiency.

Purpose

Students will learn about the signal molecule leptin, which helps control energy usage in our bodies. Students will create models of the cell communication of leptin and a nerve cell. Students will then conduct a chemical test to simulate an ELISA used to determine the amount of leptin present in the subjects' samples.

Objectives

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

- Explain cell signaling
- Discuss the importance of the leptin molecule to obesity
- Demonstrate the lab skills required to perform an ELISA
- Discuss the factors that contribute to obesity and find credible information about these factors

Key Terms

- Cell signaling: transfer of information from one cell to another, often by one cell releasing substances that transmit information to other cells
- ELISA: (Enzyme Linked Immunosorbent Assay) a laboratory technique using antibodies and enzymes to indicate the presence of antigens
- 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.
- Homeostasis: the tendency of an organism or system to maintain internal stability through the coordinated response of its parts to any situation or stimulus that would disturb its normal condition or function
- Leptin: a hormone that is thought to suppress appetite and speed up metabolism
- Obesity: a condition characterized by an abnormal or excessive amount of fat stored in the body

National and State Standards

National

Next Generation Science Standards:

Disciplinary Core Ideas LS1.A, LSA1.B, LS1.D, LS3.B

Crosscutting Concepts 2, 3, 4, 5, 7

Science and Engineering Practices 2, 3, 4, 6, 7, 8

Nature of Science Understandings 1, 2, 3, 4, 5, 6, 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, LS.1, LS.3, BIO.1



Materials (per group)

- 1 spot plate or microtiter plate
- 2 micropipettes
- 1 permanent marker
- 1 100ml beaker
- 1 bottle of red cabbage indicator–labeled substrate (G)
- 3 bottles of distilled water (dH₂O)
- 1 labeled rabbit anti-human leptin antigen (A)
- 1 labeled secondary antibody (F)
- 1 labeled distilled water
- 2 bottles of baking soda solution
- 1 labeled negative control (B)
- 1 labeled subject 1 sample (D)
- 2 bottles of lemon juice solution
- 1 labeled positive control (C)
- 1 labeled subject 2 sample (E)

Procedures

1. Introduce or review cell signaling (see Resources) and discuss the process of cell signaling.
2. Show the NOVA scienceNOW Obesity video: (<http://video.pbs.org/video/1506746269/>) and/or provide background information for leptin resistance and leptin deficiency.
3. Explain that the class will be conducting a simulated clinical procedure. In this simulation experiment, each group of students will be testing samples from two adolescents participating in a research study investigating leptin resistance in obese adolescents. Leptin levels will be tested using a simulated ELISA (Enzyme-Linked Immunosorbent Assay) procedure.
4. Their role as a researcher is to:
 - a. determine if either subject is leptin resistant
 - b. decide how to share this information with the research study participants
 - c. recommend several behaviors that would help these subjects prevent or combat obesity
5. Students will conduct the leptin ELISA simulation as outlined in the Student Handout.
6. Each group will prepare a short report to share with the “subjects” that includes conclusions, with supporting evidence, and recommendations.



7. Have the groups share and discuss their reports with the class.
8. After all of the groups have shared their reports, have the class discuss some or all of the questions in the following sections.

Observations and/or Data

Students should be prepared to answer the following questions:

- Why is it important to follow the ELISA procedure exactly as it is written?
- What are the factors that contribute to obesity in our society?
- What is leptin and what role does it play in obesity?
- If someone asked you if obesity is genetic, how would you respond?

Analysis and Conclusions

- How do you feel about getting tested for leptin as modeled in this simulation?
- Have your feelings about obesity changed after completing these activities?

Critical Thinking Questions

- What are some behaviors that would help prevent or combat obesity?
- How did the models demonstrate how obesity can occur?

Teacher Notes

Before the Activity:

For the simulation, you will need a source of water and a container for the purpose of emptying soiled water. We are simulating the activity using a red cabbage juice indicator, distilled water, and mild acid and base solutions. You will need to prepare and label the various solutions and bottles prior to the lab.

You will need containers for the seven reagents. Microfuge tubes or small cups can be used for the reagents: one set of seven per lab group.

- 1 bottle of distilled water (dH_2O) - labeled rabbit anti-human leptin antigen (A)
- 1 bottle of baking soda solution - labeled negative control (B)
- 1 bottle of lemon juice solution - labeled positive control (C)
- 1 bottle of baking soda solution - labeled subject 1 sample (D)
- 1 bottle of lemon juice solution - labeled subject 2 sample (E)
- 1 bottle of red cabbage indicator - labeled substrate (G)
- 1 bottle of distilled water - labeled secondary antibody (F)



Safety Notes

Make sure all students are following proper classroom safety guidelines. Students must practice safe lab procedures, including wearing goggles.

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.

Both researchers and the research participant interviewed in ***Clinical Research: Why Does It Matter to Me?*** discuss how learning more about healthy lifestyle choices can empower research participants to better manage their health.

Background Information and Resources

Overview of the Role of Leptin in Energy Balance and Obesity:

The human nervous system regulates energy balance in the body by continuously adjusting energy intake, expenditure, and storage. Our understanding of the neural control of metabolism has increased significantly in recent years. One major milestone was the cloning of the gene *ob*, which encodes the protein leptin, in 1994. Leptin is a hormone produced and secreted by white adipose tissue and acts in the central nervous system to regulate body weight, feeding, energy expenditure, and glucose metabolism as part of a complex system interacting with other hormones and regulatory mechanisms. Circulating levels of leptin are closely related to body fat mass. Mice deficient in leptin due to a mutant *ob* gene suffer from severe obesity, diabetes, and other abnormalities. If the leptin is replaced, food intake decreases, energy expenditure increases, and glucose homeostasis normalizes. This has been observed in humans as well. A number of variants in the genes for leptin and the leptin receptor have been identified.



To avoid starvation, mammals developed complex mechanisms to conserve energy and respond to low levels of energy availability. Starvation leads to a rapid decrease in leptin levels, which may be the signal that initiates these mechanisms to conserve energy. Rare genetic disorders can also result in decreased leptin levels. On the other hand, the over-nutrition that is becoming increasingly common is the major cause of obesity. As a consequence of increased fat mass, obese individuals show elevated leptin levels. However, for reasons not entirely understood, these increased leptin levels do not seem to result in decreased appetite or increased energy expenditure as would be expected. This observation led scientists to the concept of leptin resistance, where obese individuals are unable to respond to leptin that is produced in their own body or administered to them. Some individuals may also experience leptin resistance due to genetic variations in the leptin receptor itself.

Much of what we know about leptin comes from animal research, and there is still much that we have to learn. Researchers continue working to develop leptin-based therapeutics to treat diseases such as type I diabetes. Gut peptides such as ghrelin may interact with leptin additively to regulate energy balance. Combination therapies are being studied to enhance leptin sensitivity in obese individuals. Studies also suggest that leptin may be helpful in maintaining weight loss. Exciting therapies are being explored based on what we have learned about leptin and may help to address the problems of obesity and related health problems.

Reference: Gautron L and Elmquist JK. "Sixteen years and counting: an update in leptin in energy balance". J Clin Invest 2011;121:2087-2093. Available online at: <http://www.jci.org/articles/view/45888>

For more information about leptin and obesity see: Gade W., Gade J., Collins M. et al., "Failures of Feedback: Rush Hour Along the Highway to Obesity". Clin Lab Sci 2010; 23:39-50.

NOVA scienceNOW: Obesity video: <http://video.pbs.org/video/1506746269/>.

NOVA scienceNOW: Obesity Teacher's Guide at: http://www.pbs.org/wgbh/nova/teachers/programs/3313_03_nsn.html

General information about the leptin molecule can be found on the video clip "Leptin Feedback Control" found at <http://www.hhmi.org/biointeractive/leptin-feedback-control-system>



Extensions

Classroom

Students can read the following scientific article on obesity:

The Science of Childhood Obesity, Health Affairs, 29, no.3 (2010):393-397

<http://content.healthaffairs.org/content/29/3/393.full>

Ask students to identify and define 10 new biology terms, summarize the article, and describe what additional research these findings could prompt.

Cross-Curricular

Health and Physical Education: Coordinate with the Health and Physical Education teachers so that the discussion of BMI, obesity, and healthy choices are presented collaboratively.

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

What Causes Obesity?

Introduction and Background Information

Obesity occurs when there is an imbalance between the amount of energy taken in (food eaten) and the amount of energy consumed (activity). There are many factors that play a role in the development of obesity. These include lifestyle, environmental factors, and sometimes genetics.

There is a signal molecule called leptin that is produced by fat cells. Leptin is received by brain cells and is an important signal for maintaining the correct energy balance. In order for leptin to be received by brain cells, the correct cell membrane receptor must be present and functioning normally. High levels of leptin are present when the receptors do not function properly. We call this condition leptin resistance.

In this simulation experiment, you will be a researcher testing samples from two adolescents participating in a research study investigating leptin resistance in obese adolescents. Leptin levels will be tested using a simulated ELISA (Enzyme-Linked Immunosorbent Assay) procedure.

Your role as a researcher is to:

- determine if either subject is leptin resistant
- decide how to share this information with the research study participants
- recommend some behaviors that would help these subjects prevent or combat obesity

Your group will prepare a short report to share with the “subjects” that includes conclusions, with supporting evidence, and recommendations.

In this case, rabbit antibodies specific to human leptin are first added to the reaction wells. The antibodies are allowed to bind to the plastic wells. Excess antibodies are washed off. Samples containing leptin are added to the wells. Leptin will bind to the antibodies. Washing is performed to remove unbound material. Enzyme-linked anti-leptin antibodies are added, which will bind to the bound leptin. Again, washing is performed to remove unbound material. Substrate is added and color is detected which is proportional to the amount of leptin in the sample. A color change from colorless to red will indicate the presence of leptin.

Name: _____

Safety Note:

- Use gloves and eye protection.
- Follow all chemical safety rules!

Procedure

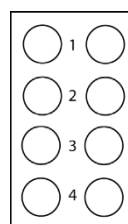
1. Label the bottom of wells of the microtiter or spot plate according to the chart below.

Well 1 = negative control

Well 2 = positive controls

Well 3 = subject 1

Well 4 = subject 2



2. Rinse a micropipette in a beaker of distilled water (dH_2O). Practice squeezing the pipet slowly to get one drop at a time. When you are comfortable with using the pipet, remove any remaining water before starting the experiment.
3. Carefully place two (2) drops of rabbit anti-human leptin antigen (A) into each of the eight wells of the microtiter strip. Replace unused sample back into the tube from the pipet. Flush and rinse the pipet several times in dH_2O . Discard and replace the water used for washing the pipet.
4. Incubate the plate for 2 minutes at room temperature.
5. Place two (2) drops of the negative control (B) sample into each of the two negative control wells (1). Replace unused sample back into the tube from the pipet. Flush and rinse the pipet several times in dH_2O . Discard and replace the water used for washing the pipet.
6. Place two drops (2) of the positive control (C) sample into each of the two positive control wells (2). Replace unused sample back into the tube from the pipet. Flush and rinse the pipet several times in dH_2O . Discard and replace the water used for washing the pipet.
7. Place two drops (2) of the subject 1 sample (D) into each of the two subject 1 wells (3). Replace unused sample back into the tube from the pipet. Flush and rinse the pipet several times in dH_2O . Discard and replace the water used for washing the pipet.
8. Place two (2) drops of the subject 2 sample (E) into the subject 2 wells (4). Replace unused sample back into the tube from the pipet. Discard this pipet.
9. Incubate the plate for 2 minutes at room temperature. This is a simplified version and we will not wash off any unbound antibodies.

Name: _____

- 10. Using a new pipet, place two (2) drops of the secondary antibody (F) into all wells. Replace unused sample back into the tube. Flush and rinse the pipet several times in dH₂O. Discard and replace the water used for washing the pipet.
- 11. Incubate the plate for 2 minutes at room temperature.
- 12. Place two (2) drops of substrate (G) into all wells.
- 13. Observe and record results.

color for negative control _____

color for positive control _____

color for subject 1 _____

color for subject 2 _____

14. Interpretation of results:

Key: blue = normal leptin pink = high leptin

Subject 1 has _____ leptin.

Subject 2 has _____ leptin.

Analysis Questions:

What would you tell the parents?

What are some behaviors that would help these subjects prevent or combat obesity?

Name: _____

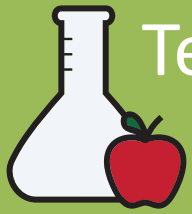
How do you feel about conducting such testing on subjects?

Do you think that this would help the subject? Why, or why not?

What is the difference between subject care and clinical research? Which best describes this activity?

How might this test be useful in a clinical research study?

Information Gathering and Synthesis



Team Science: Inquiry into Healthy Habits

© Virginia Commonwealth University 2013

CRESST

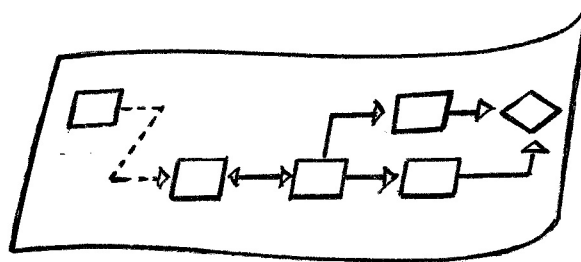
Revised February 2016

Introduction

Research is often conducted by teams, with each individual on the team serving a specific role or function. Having teams of individuals with different expertise and responsibilities helps to ensure the success of the research study. As a team designs a research study, it is important to identify the appropriate study design needed to evaluate the hypothesis and determine the best methods to measure the outcome. Once the data are collected, the researchers analyze the data to test the hypothesis, form their conclusions, and identify future research directions. In student research, as in clinical research, there are key roles that support the research study and facilitate the design, implementation, and data collection and analysis. This activity uses cooperative learning strategies to mirror the structure of a clinical research team as the students design and implement a small-scale research study. The information gathered is used to help the students make informed decisions about their health-related behaviors.

Purpose

By designing and implementing a small-scale research study on health-related behaviors, students will correctly identify what data are and understand how data can be used to draw conclusions and make informed decisions. They will translate that information into graphs and figures in order to enhance their analysis and effectively communicate their findings.



Objectives

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

- Explain what data are and how they can be used to tell a story
- Explain the roles of the various research team members and why each role is important
- Design a small-scale research study, including:
 - Identifying relevant data to collect
 - Recruiting volunteers
 - Identifying credible sources of information
 - Gathering and synthesizing data
 - Presenting study results in an organized and persuasive manner

Key Terms

- Clinical research: research where humans participate as subjects in the research
- Clinical trial: one type of clinical research that follows a pre-defined plan or protocol (NICHD, 2013).
- Data: individual facts, statistics, or items of information
- 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.

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 2

Science and Engineering Practices 3, 4, 5, 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, LS.1, LS.3, BIO.1, BIO.2

Health 6.1 b, c, g, 6.2 a, 6.3 b, d, j, 7.1 d, q, r, 7.2 a, b, e, g, k, 7.3 j, k, m, t, 8.2 c, f, 8.3 h, i, 9.2 c, f, h, v, y, 10.1 b, l, 10.2 u, 10.3 g, l

Physical Education 6.3 a, b, 6.5 b, c, 7.3 d, 7.5 a–h, 8.5 a–h, 9.5 a–d, 10.5 a–g



Materials

- Computer lab
- Clipboards
- Calculators
- Log books
- A role card for each team member
- Small incentives for study participants (optional)

Procedures

Research Questions

1. Begin a classroom discussion related to healthy habits by posing these questions:
 - a. What are some healthy and unhealthy habits that you and your peers may perform in school?
 - b. What factors do you believe will be most related to performance on physical fitness and academic tests?
2. Have the class generate a list of research topics based on the class discussion. Some suggestions are provided in this activity, but other ideas may be added or substituted. For example, students may be interested in the healthy and unhealthy behaviors they see exhibited in their school.
 - a. Research Question: How do you believe these habits affect performance on physical fitness and academic tests?
 - b. Hypothesis: A hypothesis can be generated by students' anticipated answer(s) to the research questions.
3. The class can choose one question to be investigated by all teams, or each team may choose its own. All research questions must be approved by the teacher.

Study Design

4. Introduce or review clinical trials and research studies, discuss:
 - a. team roles
 - b. research protocols
 - c. privacy and ethical concerns
5. Students will determine their individual roles for the research study and a timeline of how they wish to proceed.
6. Each team will develop a protocol for its study. The Key Investigator will have the protocol approved by the project teacher.
7. In each team, the student will perform his or her role and coordinate with the Key Investigator to design and implement the research study.

8. Students will analyze results within their teams and prepare a report of the data and findings.
9. Students will present their findings to the class and administration.
10. Each group should select a role for each group member:

- Key Investigator

- Coordinate team roles.
- Coordinate with the project teacher and administration about any concerns and obtain clearance for all aspects of the study.



- Statistician

- Synthesize all data from the Key Interviewer in tables.
- Conduct statistical analysis on the data to identify trends.
- Check progress and results with math teachers.



- Quality Control Officer

- Bring any safety or procedural concerns to the attention of the Key Investigator.
- Ensure the validity of the data collected.

For example:

- Match the volunteers' cafeteria consumption with the day's menu.
- Check with teachers on volunteers' performance if brought into question on dates of assessments for comparisons.



- Interviewer

- Compile the list of questions selected for the research study and design the survey form. Possible items for inclusion are health-related habits such as
 - hours of sleep per night,
 - healthy or unhealthy food choices,
 - amount of daily exercise.
- Poll volunteers.
- Conduct interviews and gather accurate information.
- Note: A minimum of 25 interviews should be conducted.



Study Implementation, Analysis and Reporting:

11. Recruit 100 (adjust as appropriate for school size) volunteer students in either grades 6-8 or 9-12. Do not write down any names or identifying information. (Small incentives may be offered to help recruit volunteers, if necessary).
12. If participants cannot provide exact figures, ask them to provide estimates.
13. The Interviewer should take no longer than two weeks to compile interviews.
14. Statistician will compile
 - a. all data into a spreadsheet and make at least 2 graphic representations of the data. For example:
 - i. Bar graphs showing total number of students following healthy habits and unhealthy habits
 - ii. Bar graphs showing number of students, broken down by gender, who follow healthy habits (at least 8 hours/night of sleep, healthy food choices, 30 minutes/ day exercise) and unhealthy habits
 - iii. Scatterplots of each lifestyle choice matched with physical fitness test results (Example: hours of sleep matched with physical fitness test results)
 - b. Determine statistical significance of each comparison to determine which lifestyle choice had the largest effect on performance.
 - c. Discuss results within the team and with a math teacher.
15. Quality Control Officer will confirm with the teachers the dates of the physical fitness tests. He or she will also determine if performance numbers match the class' overall performance. He or she will also verify that the food choices recorded were available in the cafeteria on that day, if applicable.
16. Key Investigator will confirm the results with the teacher and administration (if applicable).

Observations and/or Data

- What was the biggest surprise encountered when interviewing volunteers?
- What were the biggest challenges to analyzing the data obtained?
- Was there any data that needed to be discarded and why?
- Make a series of graphs that illustrate the connections between the data and the outcomes.

Analysis and Conclusions

- What factors had the greatest effect on the study outcomes?
- What factors had the least effect on study outcomes?
- Discuss recommendations that you would like to present to the administration based on your findings.

Critical Thinking Questions

- What were your challenges in collecting data?
- What are the issues you encountered when recruiting volunteers?
- Why is “sample size” important in research?
- Is it appropriate to use these findings to suggest changes in school procedures or policies?
- Can we make recommendations based on our findings? Is the data valid?

Teacher Notes

Coordination among the Mathematics, Science, and Health and Physical Education Departments will help provide the students with the necessary skills and data to successfully complete their research studies.

Prior to the research study, students should be familiar with gathering data, practice clinical trial information gathering (surveys and/or consent forms), and be able to identify valid data within the data collected.

A master for the role cards is provided. Make enough copies so that each student has the appropriate card.

Approve any suggested trial and clear it with administration, other teachers, students, and parents.

Have students practice interviewing techniques and receive feedback from the teacher.



Safety Notes

All students should follow proper classroom safety guidelines. All studies must be carefully considered and approved before implementation. The studies should be based on normal day-to-day activities, and all school rules and procedures should be followed.

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.

Clinical Research: Why Does It Matter to Me? includes a variety of researchers and research locations, and helps to illustrate the team nature of clinical research. It also demonstrates the wide variety of data that can be collected in a health-related research study.

The questions generated by the students in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** can help shape and expand research questions for the student-designed research projects.

Background Information and Resources

Several CRESST activities include useful information about the research process:

- The Basics of Research: The Science of Biology
- The Basics of Research: The Clinical Research Process

Institute for Clinical Research Education

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

The Institute for Clinical Research Education's website provides 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.

KidsHealth

<http://kidshealth.org/>

KidsHealth 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

Coordinate with other teachers to conduct several research studies throughout the school year. Compare and contrast the studies to identify common and unique factors. Coordinate with teachers at other schools to conduct simultaneous trials and compare results.

Cross-Curricular

Coordination among the Mathematics, Science and Health and Physical Education Departments will help provide the students with the necessary skills and data to successfully complete their research studies.

Mathematics: Graphing and calculations for data analysis can be performed in mathematics class.

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

Health and Physical Education: Coordinate with the Health and Physical Education teachers to collect fitness and health data in class. Fitness and obesity content can be presented and discussed in health and physical education classes.

Role Cards

Key Investigator



Interviewer



Statistician



Quality Control Officer



Name: _____

Clinical Trial: _____

Purpose of information gathering and synthesis:

Observations: What are some healthy and unhealthy habits that you and your peers may exhibit in school?

Hypothesis: Develop a hypothesis based on the research question: (For example: What factors do you believe will be most related to performance on physical fitness tests?)

Procedure:

1. Each group should select a role for each team member:

Key Investigator

- Coordinate team roles.
- Coordinate with the project teacher and administration about any concerns and obtain clearance for all aspects of the study.

Name: _____

Statistician

- Synthesize all data from the Key Interviewer in tables.
- Conduct statistical analysis on the data to identify trends.
- Make a series of graphs that illustrate the connections between the data and the outcomes.
- Check progress and results with math teachers.

Quality Control Officer

- Bring any safety or procedural concerns to the attention of the Key Investigator.
- Ensure the validity of the data collected. For example:
 - Match the volunteers' cafeteria consumption with the day's menu.
 - Check with teachers on volunteers' performance if brought into question on dates of assessments for comparisons.

Interviewer

- Compile the list of questions selected for the research study and design the survey form. Possible items for inclusion are health-related habits such as
 - hours of sleep per night,
 - healthy or unhealthy food choices,
 - amount of daily exercise.
 - Poll volunteers.
 - Conduct interviews and gather accurate information.
 - Note: A minimum of 25 interviews should be conducted
2. Recruit 100 (adjust as appropriate for school size) volunteer students.
- a. Do not write down any names or identifying information. (Small incentives may be offered to help recruit volunteers if necessary).
 - b. If participants cannot provide exact figures, ask them to provide estimates.
 - c. Interviews should be completed after HPE physical fitness tests have been performed.
 - d. The Interviewer should take no longer than two weeks to compile interviews.

Name: _____

3. The Statistician will compile all data into a spreadsheet and make at least 2 graphic representations of the data.
For example:
 - Bar graphs showing total number of students following healthy habits (at least 8 hours/night of sleep, healthy food choices, 30 minutes/day exercise) and unhealthy habits.
 - Bar graphs showing number of students, broken down by gender, who follow healthy habits (at least 8 hours/night of sleep, healthy food choices, 30 minutes/day exercise) and unhealthy habits.
 - Scatterplots of each lifestyle choice matched with physical fitness test results (Example: Hours of sleep matched with physical fitness test results).
4. Determine statistical significance with each comparison to determine which lifestyle choice had the largest effect on performance.
5. Discuss results within the team and with a math teacher.
6. The Quality Control Officer will confirm with the various teachers the dates of tests and physical fitness tests. He or she will also determine if performance numbers match with class overall performance. He or she will also verify that the food choices recorded were available in the cafeteria on that day, if applicable.
7. The Key Investigator will confirm the results with the teacher and administration.

What was the biggest surprise encountered when interviewing volunteers?

What were the biggest challenges to analyzing the data obtained?

Name: _____

Were there any data that needed to be discarded and why?

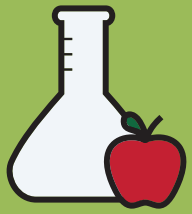
What factors had the greatest effect on performance?

Based on your results, what factors had the least effect on performance?

Conclusions:

Discuss recommendations that you would like to present to the administration based on your findings.

Information Gathering and Synthesis



CRESST

Extension Activity

Walkable Communities: How Does Neighborhood Design and Recreation Environment Affect Physical Activity?

© Virginia Commonwealth University 2013

Revised February 2016

Introduction

“Walkable Community” is a construct indicating how friendly a community or neighborhood is to walking. Communities around the world are considering ways to increase walkability as a way to improve the health and well-being of the community (www.walkscore.com). Some of the factors that influence the walkability of a neighborhood include availability of sidewalks, level of traffic, and safety. Dr. James Sallis at San Diego State University maintains a video lecture library on his website at http://sallis.ucsd.edu/publications_slides.html.

One of the lectures is entitled “How Neighborhood Design and Recreation Environments Affect Physical Activity in Youth” and can be used to introduce the idea of “walkability.” It can be accessed directly at <http://videos.med.wisc.edu/videos/1689>.

Dr. Sallis has also developed a measurement tool, specifically for use by adolescents, to assess walkability of a neighborhood: Neighborhood Environment Walkability Scale – Youth (NEWS-Y) at http://sallis.ucsd.edu/Documents/Measures_documents/NEWS_Y_adolescent.pdf.

Activity

Students complete the Neighborhood Environment Walkability Scale for the neighborhood where they live. They then discuss the possible impact of “walkability” on community health. Compare walkability in students’ hometown to other cities (<http://www.walkscore.com/>) or countries. The 10 most walkable cities are described at <http://www.frommers.com/slideshows/819366-the-world-s-most-walkable-cities>.

- How could walkability in students’ communities be improved?
- What are other sources of physical activity in your community?
- Why is it important to have a scale like the NEWS-Y if you wanted to do a clinical study about community health and physical activity?

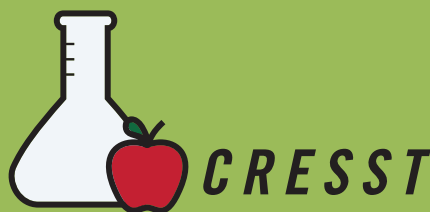
Background Information and Resources

Virginia Safe Routes to School Program

http://www.virginiadot.org/programs/led_Rt2_school_pro.asp

This website, from the Virginia Department of Transportation (VDOT), provides resources to help schools and communities create and maintain Safe Routes to School (SRTS) programs. These programs are designed to encourage children and youth to increase physical activity by providing safe routes for walking and biking.

Information Gathering and Synthesis



Extension Activity Attacking the Asthma Attack!

© Virginia Commonwealth University 2013

Revised February 2016

Introduction

According to the American Lung Association, an estimated 26 million Americans have asthma, 8.6 million of whom are under the age of 18. Obesity increases the risk of developing asthma. Obese asthma patients have more severe asthma and worse asthma control. Weight reduction may improve asthma symptoms (Lugogo NL, Kraft M Dixon AE. Does obesity produce a distinct asthma phenotype? J Appl Physiol 2009;108:729-734).

The CBS News clip: (<http://www.cbsnews.com/video/watch/?id=6769851n>) provides a nice overview of the nature and nurture aspects of asthma. It also discusses the results of a recent clinical trial implicating acetaminophen as an influence in the onset of asthma.

Activity

Students will design and conduct a survey of classmates, family, neighbors, and others to find out how prevalent asthma is in their community. The survey can track how many people have the illness and/or how many people know someone with asthma. Students will compile and present their survey results using appropriate graphs and charts to illustrate their findings.

Background Information and Resources

The National Institute of Environmental Health Science

<http://www.niehs.nih.gov/health/topics/conditions/asthma/>

This website is an excellent resource for asthma related information.

Breaking the Mold

<http://enviromysteries.thinkport.org/breakingthemold/lessonplans/asthma.asp>

The activity can be used to help your students learn about asthma and develop their survey.

Types of Surveys

<http://www.stat.wmich.edu/s216/book/node29.html>

This website explains a variety of survey types and provides an overview of the advantages and disadvantages of each format.

InfoPoll: How to Write a Good Survey

<http://www.accessible.net/~infopoll/tips.htm>

This website provides guidelines and suggestions for writing and conducting surveys.

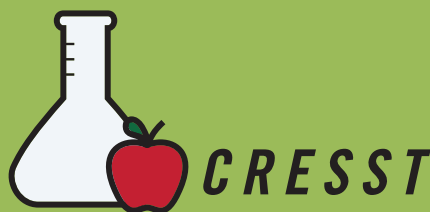
Teacher Notes

Data tables will vary based on how many questions and respondents you intend to have. Microsoft® Excel or LoggerPro® are the resources most widely used in science and math as tools to translate data into graphs.

If you already have a website or web account, or you plan on creating one, you can publish a survey (<http://www.quia.com/web>, for example) on your site. This would be a great opportunity to compile the survey questions created in class and send the survey “link” out to the school faculty and staff via email. Online surveys will generally give you an option to export your results to a spreadsheet.

If you plan to have each student take his or her results and transfer them into a spreadsheet format, use the “number” of each row to identify each respondent and each column to organize the question. Column A would represent the responses to the first surveyed question.

Information Gathering and Synthesis



Extension Activity Rethink Your Drink

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Revised February 2016

Introduction

Sugar's primary role in the body is to provide energy (Calories). To get the nutrients you need, eat a diet that's rich in fruits, vegetables, whole grains, lean meats, fish, poultry, and low-fat or fat-free dairy products. Typically, foods high in added sugars do not have the nutrients the body needs and only contain extra Calories.

The American Heart Association (AHA) defines "daily discretionary Calorie allowance" as Calories available for consumption after meeting nutrient needs—these Calories don't contribute to weight gain. The AHA recommends that no more than half of your daily discretionary Calorie allowance come from added sugars. For most American women, this is no more than 100 Calories per day and no more than 150 per day for men (or about 6 teaspoons a day for women and 9 teaspoons a day for men).

The U.S. Department of Agriculture has warned that the major sources of added sugars in American diets are sugar-sweetened beverages, like sodas, sports drinks, and energy drinks. These types of drinks account for 36% of the Calories we get from added sugars. They also have little to no nutritional value, and unfortunately, studies have shown that high levels of sugar consumption are linked to increased risk for obesity, diabetes, and other chronic diseases like heart disease and cancer.

Materials

- Sugar
- Small containers for holding sugar (specimen cups, baggies, etc.)
- Several drinks (or empty drink containers) that are popular with your students
- Food scale

Activity

1. Read the labels for each of the sugar containers and determine the amount of sugar in the entire container.
2. For each beverage, measure out the amount of sugar in the drink and put it in a container. Label each container with a letter or number. Make a key matching the letter or number with the beverage.
3. Once each beverage has a corresponding container of sugar, display the drink containers and the sugar containers (in no particular order). Have students work in groups to guess which sugar container matches the beverage.
4. Students will then examine the beverage labels to determine what else is in the drink (amount of caffeine, etc.).

Teacher Notes

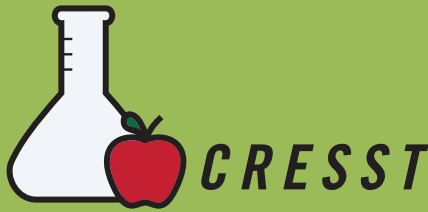
This activity work best when there is some variation in the amount of sugar in the drinks. If the examples are all soft drinks, the sugar containers will be filled with almost identical amounts. Adding water, juice, or other options will create more variation in the levels of sugar in the containers.

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.

Since this lesson is one of the classroom lessons in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** the video can be used to engage students in discussion of the impact of added sugar in their diet.

Ethical Issues in Clinical Research



Overview

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Revised February 2016

Conducting research designed to address important societal and medical issues is critical to improving the human condition, quality, and effectiveness of health care and medical treatment, and understanding how other factors influence health-related outcomes. Since 1974, research involving human subjects or participants has been governed by federal legislative requirements to ensure the ethical treatment of those who participate in research studies. The activities included in this section are designed to introduce students to the history of human subjects research and events leading to the passage of the 1974 National Research Act. The lessons and activities will engage students in identifying and applying the guiding principles that inform the design and conduct of research studies involving human subjects.

Section Objectives

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

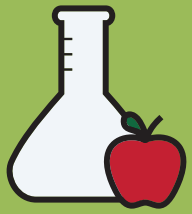
- Distinguish between ethical and unethical practices in scientific research
- Evaluate the ethical implications of the use of human subjects in the research process
- Weigh the pros and cons of future biomedical discoveries and their role in the use/disuse of new technology
- Answer questions about how research should be conducted and understand the history and advances within the field of medicine

Topics

- Ethics in the scientific process: “The Six-Step Process of Ethical Decision Making”
- History of ethics legislation: Belmont Report, critical historical events and research incidents
- Ethical issues and controversies
- Conducting research that is ethically sound

Activities

- Ethical Scenarios Carousel
- History of Ethical Guidelines and Requirements
- Ethical Controversies: Debating the Pros and Cons
- Bioethics: Standards for Scientists



Ethical Scenarios Carousel

Introduction

Ethical decisions are not to be made lightly, and there are many stakeholders and perspectives involved in these decisions. Often different viewpoints are needed to arrive at a decision that guides behavior and action. This lesson introduces students to the concepts of ethics by presenting a series of social dilemmas that require students to consider morals, values, and social expectations and norms. Examining and responding to ethical dilemmas requires critical thinking, which can be challenging due to the influence of long-held beliefs and assumptions. Open discussion in small groups can lead toward greater understanding of multiple perspectives and decision-making that is mutually acceptable.

Purpose

Students will be able to present well-informed arguments in response to the different sides of difficult ethical decisions. Students will be able to compare and contrast past scenarios and apply them to potential ethical dilemmas in the medical field.

Objectives

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

- Successfully present different sides of arguments
- Work in groups to present cohesive ideas
- Practice using critical-thinking skills in decision-making



Key Terms

- Ethics: refers to concepts of right and wrong. These concepts are reflected in social and moral standards that guide our actions, behaviors, and decision-making.
- Ethical dilemma: occurs when individuals are faced with a question or situation that involves more than one ethical principle. In order to respond to an ethical dilemma, individuals have to weigh the value of different principles to decide on an action. For example, sometimes researches may have to reveal the name of a student participant and breach the ethical principle of confidentiality in order to respond to a medical diagnosis discovered during the course of a research study.
- Ethical distress: this can occur when you have made a decision about how to respond to an ethical dilemma and the actions you decided to take are blocked or you experience barriers that limit your ability to respond. For example, peer pressure may influence a student's decision to tell a teacher about cheating that occurred on a test. In this case, the pressure put on the student by his or her peers to not inform the teacher may cause the student distress such as anxiety and worry about how he or she will be treated by his or her peers.
- Locus of authority: the one with the final say in making a decision that involves an ethical dilemma

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 2

Science and Engineering Practices 3, 6, 7, 8

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

Essential Features of Classroom Inquiry 3, 4, 5

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

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

Virginia

Science: LS.1 j

Health 8.1 b, f, g, h, 8.2 l, 8.3 a–g, p

Physical Education 7.4 a–c, e, g

Materials

- “The Six-Step Process of Ethical Decision Making” Microsoft® PowerPoint
- Butcher block paper or larger sheets on which students can write their responses
- markers

Procedures

1. Introduce the steps in making an ethical decision.
2. Use the PowerPoint (“The Six-Step Process of Ethical Decision Making”) to introduce the concept so students are able to apply the steps while completing the “Ethical Scenarios Carousel.” On slide #2, click on each box to be linked to the description slide. Then, click the “return” symbol to return to slide #2.

Directions for students:

3. In groups of three, you will travel around the room visiting seven different stations. At each station, you will be presented with a situation involving an ethical dilemma. As a group, you must decide what to do. Follow the guidelines we have discussed for decision making. Come to a group decision and be prepared to explain why you selected your solution.
 - a. Scenario 1: You and your friends are on the cross country team. During the “big” district meet, one of your best friends finishes second. He finishes in second place because he cheats and cuts through the woods to get ahead of three other runners. The move should have disqualified your friend. You saw him cheat. What should you do?
 - b. Scenario 2: You attend a school dance and are at an after-party with your date. He or she has decided to drink and is now intoxicated. He or she is also the driver. When it is time to leave, he or she refuses to give you the keys. What should you do?
 - c. Scenario 3: Your health and physical education class has decided to host a huge marathon volleyball tournament. All students in the class are required to participate. Students must be in teams of six. As you view the team lists, you notice that three students do not have a team. The same three students are constantly left out. You are a leader in the 8th grade class. What should you do?
 - d. Scenario 4: In the locker room, you have heard rumors of a special needs student being bullied by two other students. Today you actually see these two bullies force the student to give them all of his money. What should you do?

- e. Scenario 5: While standing in the lunch line with your friends, you see one of your friends stuffing cookies in his or her pockets. What should you do?
 - f. Scenario 6: You go to Best Buy to get a new iPod Touch. While looking at the different models, you overhear an older adult talking about buying a new TV. You begin to watch the adult and notice that she is counting her cash to make sure she has enough for the TV and the warranty. As she heads toward the checkout line, her cash falls out of her purse. What should you do?
 - g. Scenario 7: One of your good friends is trying to lose weight to fit into a dress she wants to purchase. She is dropping weight consistently and in a healthy manner. She still needs to lose ten more pounds in three weeks. You notice she is becoming irritable and nervous. You find out she is taking diet pills and forcing herself to vomit. What should you do?
4. Once all groups have gone to all seven stations, have each group respond to the following questions.

Observations and/or Data

- How much discussion was involved with each scenario?
- Did anyone have problems arguing for or against any options in any of the situations?
- Did everyone participate?

Analysis and Conclusions

- What scenario had the most discussion associated with it?
- What was your rationale in the choices you made?
- What role do ethics and morals have in the decisions we make?

Critical Thinking Questions

- How would you feel if you were put in this situation? Respond to this question for each scenario.
- What scenarios would you come up with if this activity were to be repeated again?
- Describe at least three scenarios.

Teacher Notes

Depending on class dynamics, you may want to assign groups in order to have the best level of continuity within each group to maximize its level of decision making. Be sure to include enough large paper and markers. The content of the lesson will be created by student responses to each scenario presented.

Safety Notes

Be sure all students are following proper classroom safety guidelines. Plan for any sensitivity that students may feel if they can directly relate in a negative way to any of the scenarios presented.

Background and Resources

“The Six-Step Process of Ethical Decision Making” Microsoft® PowerPoint
Purtilo, R. (1999). Ethical dimensions in the health professions. (3rd edition). Philadelphia, PA: W. B. Saunders.

Extensions

Classroom


Students will be required to choose one scenario and write a five-paragraph essay presenting their position on resolving a particular problem.

Cross-Curricular

Language Arts: In language arts class, the students can complete the scenario critical thinking essay as an exercise in technical and/or persuasive writing.

Physical Education: Collaborate with the Health and Physical Education teachers to coordinate the ethical decision with related health topics.

History and Social Studies: Collaborate with history and social studies teachers to present ethics in decision making in the broader context of world history.



Ethical Issues in Clinical Research

The Six-Step Process of Ethical Decision Making

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 5R01RR020494-04

The Six-Step Process of Ethical Decision Making

- ❖ Get the story straight: Gather relevant information
- ❖ Identify the type of ethical problem
- ❖ Use ethics theories or approaches to analyze the problem
- ❖ Explore the practical alternatives
- ❖ Complete the action
- ❖ Evaluate the process and outcome

6 Steps of Ethical Decision Making

1. Gather Relevant Information
- ↓
2. Identify the type of ethical problem
- ↓
3. Use ethics theories to analyze the problem
- ↓
4. Explore the practical alternatives
- ↓
5. Complete the action
- ↓
6. Evaluate the process and outcome

Gather Relevant Information

- ❖ Clinical indications
- ❖ Preference of the person
- ❖ Quality of life
- ❖ Contextual factors

Identify the Type of Ethical Problem

- ❖ Ethical distress
- ❖ Ethical dilemma
- ❖ Locus of Authority Problem

Theoretical Approaches

- ❖ Utilitarian
 - ❖ Considers actions based on the balance of good compared to harm, values the greatest good
- ❖ Rights
 - ❖ Considers the basic rights of individuals and ability to choose freely
- ❖ Fairness or Justice
 - ❖ Based on treating everyone equally or the same
- ❖ Common Good
 - ❖ Considers conditions that are in the best interest of everyone's welfare
- ❖ Virtue
 - ❖ Focuses on personal character and considers if the action is consistent with one's character or how the action will impact character

Explore the Practical Alternatives

- ❖ What can be done in the situation?
- ❖ Avoid oversimplifying the range of options.
- ❖ Try out some of the more far-fetched alternatives with a colleague whom you trust.



Complete the Action

- ❖ After completing the first four steps, failure to act reduces the entire process to a inconsequential philosophical exercise or may result in harm to parties involved.
- ❖ Completing the action often requires strength of will, knowing there may be risks or backlashes.

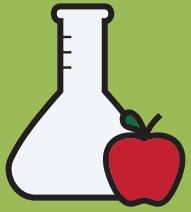


Evaluate the Process and Outcome

- ❖ Once you have acted, pause and engage in a careful retrospective examination of the situation.
- ❖ This evaluation is important to your growth as an ethical professional.



Ethical Issues in Clinical Research



History of Ethical Guidelines and Requirements

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CRESST

Revised February 2016

Introduction

Federal regulations have changed greatly over the past century. Prior to 1974, clinical research studies were conducted with little regulation and many times without participants' full knowledge or permission. The following activities are intended to introduce the events that led to the creation of federal regulations that govern the conduct of research with human subjects.

Purpose

Students will engage with the specific report findings that led to the federal laws as well as analyze actual consent documents associated with a study on healthy eating habits.

Objectives

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

- Understand the past history of ethics legislation
- Examine and understand the application of the Belmont Report to ethical decision making
- Explain how consent forms provide legal grounds within medical trials



Key Terms

- **Assent:** a type of consent process used with children under the age of 18. The process involves obtaining “assent” from potential child participants who cannot “consent” to participation since they are not legal adults. The process involves informing the child and his or her parents/guardians about what participation in the study involves, and then both groups decide whether the child can participate; an assent process typically accompanies a parental consent/permission process.
- **Beneficence:** an obligation to promote benefits, to prevent and minimize harms, and to weigh and balance the possible benefits against the costs and possible harms of participating in research
- **Informed consent:** the process by which study participants or parents are fully informed by investigators about what participation in the research study involves; consent means participants and/or parents agree to participate or give permission for their child to participate in the research
- **Justice:** the equitable distribution of benefits and burdens of research
- **Respect for persons:** reflects the idea that individuals are independent, autonomous, and are entitled to make their own decisions about their actions

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 2

Science and Engineering Practices 3, 6, 7, 8

Nature of Science Understandings 1, 3, 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 j

Health 8.1 b, f, g, h, 8.2 c, 8.3 i, p, q

Physical Education 7.4 a, b, c

Materials

- Microsoft® PowerPoint “Human Rights and Experimentation”
- Handout for the impact of the Belmont Report activity
- Handouts on consent and assent documents

Procedures

1. Introduce the history of ethics legislation: This activity is focused on the misuse of humans in scientific experiments and legislation resulting from those experiments.
2. Use the Microsoft® PowerPoint “Human Rights and Experimentation” and the material from the Background Information section of this activity to begin the discussion. It is suggested that teachers show only the slides with pictures to students and use the slides with text as background information to explain the pictures.
3. Impact of the Belmont Report:
 - a. Organize students into small groups to complete this “mini” project (30 minutes suggested) to dissect and evaluate the importance of the Belmont Report: <http://www.hhs.gov/ohrp/policy/belmont.html>
 - b. See student handouts.
4. Follow up with a discussion that includes a review of the key principles.
 - a. How are ethical principles applied?
 - b. What is informed consent?
5. Review the attached example Parental Consent and Child Assent documents from a study about promoting healthy eating.
 - a. The student and his or her parent/guardian should complete the activity about the risk and benefits of participation in the study and why informed consent is important in research.
 - b. Ask students about their parents’ views. Would they allow them to participate in the study? Why or why not?

Observations and/or Data

- How did the students react to the presentation of historical views in ethics?
- What proportion of students was given parental consent?

Analysis and Conclusions

The following questions can be used throughout many of the activities to engage students in a discussion of the ethical conduct of research.

- What do you have to take into account before you start any research study?
- What ethical issues may arise before or during a research study?
- What are essential components of conducting a proper research study?
- What are some things we have learned from history about proper conduct concerning humans in research?
- What are some of the “rules” about conducting experiments on humans?
- What are some ethical issues that we may have to decide upon in the next 20 years?

Critical Thinking Question

- If you were very confident in the potential of a drug that you were developing to improve people’s lives, would you try it on yourself if you were not given permission to do human trials?

Teacher Notes

Be sure that all Internet links work and are not blocked by a school filter.

Safety Notes

Make sure all students are following proper classroom safety guidelines. Plan for any sensitivity or negative emotions that students may experience during the lesson.

Background Information & Resources

This material has been adapted from a chapter on ethics written for a textbook on educational research. For the full chapter, see Abrams, L.M. & McMillan, J.H., “Ethical Issues, Principles and Practices”. In McMillan, J. H. (2016) Educational Research Fundamentals for the Consumer (7th ed). New York: Pearson.

This section describes the history of ethical rules and regulations in the United States, discusses the core ethical principles that govern all research with human subjects, and depicts historical examples of actual studies to illustrate the application of the principle to the practice of conducting research.

Guiding Questions:

- Why do we need laws to govern research that involves the participation of people?
- What are researchers' ethical obligations to the individuals who participate in studies?



Ethics are standards and principles that are used to guide how people behave and to determine what is or is not wrong. Ethics are related to our morals or values. In research, ethics guide researchers' decisions about how to study a problem or important question. Ethics suggest that research needs to be conducted in ways that are fair, protect study participants from harm, and ensure that the benefits that may result from the study are outweighed by any potential risks associated with an individual's participation in the research. Most of the ethical standards for conducting research are concerned with how researchers interact with and treat participants throughout the study. Ethical principles and standards are relevant to all aspects of how research is conducted. Researchers are required to adhere to a code of ethics, but this was not always the case. It wasn't until 1974 that legislation was passed in the United States that established laws intended to protect those who participated in research.

History of Ethics Codes in the United States

Research with human subjects has had a troubled history. One of the most egregious examples of unethical research was the Tuskegee Study of Untreated Syphilis in the Negro Male study, conducted by the U.S. Public Health Service over a 40 year period (1932-1972). This research was conducted to document and record the naturally occurring history of syphilis to investigate differences in the effects of the disease and to develop treatment programs. When the study started in 1933, there were no known effective treatments for the disease. The researchers enrolled 600 men; 399 with syphilis and 201 who did not have the disease – most of whom were illiterate and poor sharecroppers. All the men were told they were going to be treated for “bad blood,” a common term at the time that was used to describe a variety of ailments including syphilis, general fatigue, and anemia. However, what was told to the participants about the purpose of the research was different from the real goals of the researchers. By participating, the men received free medical exams, transportation to and from the clinics, free meals, medical treatment for minor complaints, and burial insurance. In 1972, the Associated Press published a story condemning the Tuskegee Study. The story described how the 40-year study did not treat the study participants for the

disease, even though penicillin was widely accepted as the standard treatment as early as 1945. The withholding of penicillin from the study participants resulted in numerous unnecessary deaths and the needless infection of countless numbers of other individuals. The uproar that resulted from the AP story set into motion several actions that resulted in federal laws that codified ethical principles and practice for research that involves human subjects. The Tuskegee Study was just one of numerous examples of flagrant violations of ethical principles in the United States and internationally.¹

Federal Research Regulations

Public outcry about the Tuskegee Study demonstrated the need to change research practices so that the mistakes evident in the Tuskegee Study were not repeated. There was a compelling need for ethical rules and regulations for the conduct of research involving humans. The National Research Act was passed in 1974 and established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was responsible for creating a code of ethics for research involving human subjects conducted in the U.S. In 1979, the National Commission published a report “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” commonly known as the Belmont Report or the Belmont principles. These principles are the foundation for current ethical laws – The Code of Federal Regulations (CFR) Title 45 Part 46: Protection of Human Subjects. The ethical guidelines and requirements in the federal code apply to both social-behavioral research, which educational research is most often considered, and biomedical research. In 1991, Subpart A, the section of these regulations on the protection of human research subjects, was adopted by 15 federal agencies and became known as “the Common Rule.” It is now the primary doctrine governing all research with human subjects.

Recent Federal Efforts to ensure Ethical Standards and Conduct

Since the aforementioned regulations were adopted, other national commissions have continued the work of studying and promoting the highest ethical standards as technology, research methods and expertise have advanced. Consider the technological advances of the last decades and the influence technology has had on how research is conducted. As approaches to research have changed, so have

¹ The National Institutes of Health and the Department of Health and Human Services have additional resources for teachers that include detailed timelines of key events and studies that have informed ethical guidelines and legislations.

ethical guidelines. For example, when the National Commission was formed, the use of the Internet for data collection and use of personal computers for research management, data storage, and analysis was not widespread. The National Bioethics Advisory Committee (1996-2001) examined topics such as cloning, human stem cell research, and other emerging research. This commission was succeeded by the President's Council on Bioethics (2001-2009), which reported on stem cell research and reproductive technologies, among other topics. More recently, in 2009, the President's Commission for the study of Bioethical Issues was created. Each presidential administration has continued to explore ethical issues in science, medical, technology, and research with human subjects to ensure that current ethical legislation is keeping pace with scientific advances and that researchers continue to be sensitive to ethical issues associated with the rapidly changing fields.

Research Ethics in Practice

The Belmont Report identified three core principles that should govern all research and researcher-participant interactions: Respect for Persons, Beneficence, and Justice. These principles are ethical values that, when carried out or reflected in actions, demonstrate adherence to the Common Rule and current ethical codes and values.

Respect for Persons

The principle of respect for persons reflects the idea that individuals are independent, autonomous and are entitled to make their own decisions about their actions. A key feature of this principle is in the voluntary nature of research. That is, individuals should be free to decide for themselves if they want to participate in a study and if they want to end their participation for any reason. Respect for persons is most clearly demonstrated in the informed consent requirement and process. The informed consent process usually takes the form of a written consent document that the researcher discusses with each potential study participant prior to his or her involvement in the research. The idea is that each individual, once fully aware of what the study is about and what his or her involvement means, has the opportunity to carefully consider participation and to make an independent decision about if they want to be involved. Federal regulation requires that informed consent include the following essential characteristics:

- Disclose to potential research participants all of the information needed to make an educated decision about participation
- Ensure that the potential participants understand the information that describes the study and what participation will involve
- Support the voluntary nature of the decision to participate

A consent document is important for both the researcher and participant because it reflects a contract designed to protect participants. It also requires that the researchers describe their study in ways that are clear, easily understandable, and transparent. The federal Office of Human Research Subjects Protections (OHRP) provides a useful informed consent checklist to ensure that the required information is included. The following list includes all of the information that should appear in consent documents and be explained to potential research participants:

- A statement that the study involves research
- A description of the purpose of the research study
- The expected duration of participation – how long will participation in the study take to complete?
- A description of the procedures to be followed – what does participation involve?
- Identification of any procedures which are experimental – where not all participants receive the intervention or degree of the intervention
- A description of any reasonably foreseeable risks or discomforts to the participant
- A description of any benefits to the participants or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures, if any, that might be beneficial for the participant
- A description of how the confidentiality of data and identifying information will be protected and any circumstances where confidentiality may not be maintained (e.g., participant describes wanting to hurt themselves or others)
- Information about whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury
- A statement that participation is voluntary, refusal to participate will involve no consequences, and the subject may choose to discontinue his or her participation at any time without consequences.

Beneficence

According to the principle of beneficence, researchers are obligated to protect study participants from harm, and to act in ways in the best interest of the participants' welfare. Two key guidelines or rules illustrate the principle of beneficence: (1) do not harm and (2) maximize the possible benefits and minimize the possible harms.

Do not harm

One historical example that illustrates this principle is a series of studies on obedience conducted by Stanley Milgram in the 1960's. In a series of experiments, Milgram used what are now clearly recognized as unethical procedures to understanding how willingly participants ("teachers") would apply electrical shocks to "learners" (confederates, who volunteered to appear to be shocked), as encouraged by an authority figure. The purpose of the study was to explore why average, everyday individuals may act or behave in socially unacceptable ways and cause physical harm to others just because an authority figure said it was ok. In Milgram's studies, when the "learner" failed to answer a question correctly, the "teacher" was to administer shocks and were encouraged to do so by the lab assistant. The "teacher" participants were to continue delivering greater amounts of shock treatments for wrong answers, despite protests from the learners. The teachers could only hear and not see the learners, and believed that they were experiencing pain and suffering as a result of the continued and increasing severity of the shocks. The results showed that many of the "teachers" were willing to obey, believing that it was in the best interests of the learners to be given increasingly painful shots of electricity. An important outcome of Milgram's studies was much greater sensitivity to the psychological damage studies can have on participants. In this case, there was evidence that some participants in Milgram's study did suffer psychological distress and became less trusting of others, once they understood the actual purpose of the study. It was one of several studies that led to the essential ethical principle that it is of utmost importance to inflict no harm and minimize risks of harm on participants.

Another notable characteristic of Milgram's study was the use of deception to accomplish the research goals. As noted previously, research participants should be aware of the purpose and nature of the study they are being asked to participate in. In other words, full disclosure is required to allow participants to make an informed decision about participation. Sometimes, though, if participants know the purpose it makes the findings of the study less credible. If Milgram's participants knew the study was about obedience they most likely would not have administered the shocks. In some research, then, the only way to provide credible results is to essentially deceive the participants about the purpose. Deception, while strongly discouraged, is sometimes the only way to conduct valid research. If deception is used, it is necessary to debrief participants. Debriefing is a process of fully informing the participants about the actual nature of the study and why deception was necessary, and allows them to ask questions and discuss any concerns. This process should occur either immediately following

data collection or the participant's completion of the study requirements. Debriefing is essential to minimize any potential negative consequences or harm that may have resulted from participation.

Another notorious study that demonstrated the risk of psychological harm was the Stanford Prison Experiment. This landmark 1971 study, conducted by Philip Zimbardo, was designed to examine human reaction to captivity and how individuals assume "roles" during this captivity. As part of the study, male undergraduate students were paid to assume the role of either a prison guard or prisoner (Haney, Banks & Zimbardo, 1973). A fake prison was constructed in the basement of a university building, and volunteers assumed their roles in the study setting. "Guards" received uniforms, night sticks, and mirrored sunglasses as part of their role. "Prisoners" were dressed in prison uniforms. The research became very intense and unpredictable with physical and psychological outcomes escalating as the "guard" participants became further engaged in the role. Less than two days after the study began, participants reported feeling distressed. The experiment was intended to last approximately two weeks but was stopped after six days to prevent further risk of harm to participants.

Minimizing Risk and Maximizing Benefit

It is important to note that the risks associated with social behavioral and educational research are different from those of biomedical research. Biomedical research could involve the study of a new drug treatment, the effectiveness of a new medical device such as those used to deliver insulin, or involve an intervention where a participant is exposed to common cold germs or deprived of sleep. Think of the sleep and cold studies that are common on many college campuses. These examples suggest some physical risk or potential for injury associated with study participation. In contrast, educational research, by nature, is rarely physically risky. As noted earlier, the types of risk most common in educational research are psychological, social, and reputational. So, researchers have to weigh the potential risks involved with the study against the potential benefits of the knowledge gained. In order for research to be ethical, the benefits must be greater than any potential risk involved with participation.

One way researchers minimize risk is to ensure confidentiality to study participants. This means that all aspects of an individual's involvement of the study would be confidential or not publicly disclosed. A breach in confidentiality or accidental disclosure

of a participant's name or his or her personally identifiable study information (e.g., responses on a survey or test scores) could have a detrimental impact on students' self-perceptions or school personnel professional or community standing for example. In order to ensure the validity of research and the credibility of the study findings, participants need to feel free to accurately and honestly communicate their views, perceptions or thoughts. Protecting the confidentiality of participation and the privacy of personal information are essential to minimizing risk. In addition to providing assurances of confidentiality, researchers need to carefully consider how data are collected, stored, analyzed and reported to ensure privacy. One common way to do this is to assign each study participant an ID code so that he or she does not have to use participant's names on data collection forms or in databases. If a study is conducted so that no names or identifiable information at all are collected, the data will be anonymous. Whether confidential or anonymous, the level of detail in reporting of study findings should be sufficiently general or in summary form to protect the confidentiality of the participants and locations, in order to avoid possible identification in the future.

Justice

The final main ethical principle is justice, which is really about fairness. The following question was posed in the Belmont Report, "Who ought to receive the benefits of research and bear its burdens?" The justice principle requires that the benefits and burdens of research are distributed equitably. This means that in research intended to benefit a specific segment of the population, study participants should be obtained from this same group. This principle guards against using samples of convenience, such as institutionalized or incarcerated individuals, for research that is not of direct benefit to them. The Nazi experiments on those held in concentration camps during WWII are an example of this, as are several studies conducted in state institutions for mentally disabled children. For instance, the Willowbrook Hepatitis Experiment involved a long-term study of hepatitis to study mode of infection, the course of the disease, and the effectiveness of inoculation. As part of the study, over 700 mentally disabled children were studied and some were intentionally injected with the disease over a 15 year period (1955-1970). Figure 3.1 is the letter parents received from researchers in the Willowbrook Hepatitis Study. In this letter to parents, there is no disclosure of the possible risks involved with the study, and the information about the study procedures and what might happen to their child as a result of being in the study are not clear or understandable to children with cognitive impairments. Further, there is some evidence that parents may have felt coerced to sign the permission form. The school was closed to new enrollment in 1964 due to overcrowding; however, spots were available for

children who could participate in the study. Public outcry about the study was directed towards the perception that parents had little choice about allowing their child to participate in the study.

Figure 3.1

November 15, 1958 Willowbrook Study

Staten Island, New York

Dear Mrs.

We are studying the possibility of preventing epidemics of hepatitis on a new principle. Virus is introduced and gamma globulin given later to some, so that either no attack or only a mild attack of hepatitis is expected to follow. This may give the children immunity against this disease for life. We should like to give your child this new form of prevention with the hope that it will afford protection.

Permission form is enclosed for your consideration. If you wish to have your children given the benefit of this new preventive, will you so signify by signing the form.

Source: Rothman, D., and Rothman, S. 1984. The Willowbrook Wars.
Cambridge: HarperCollins, pages 265–266.

Another appalling example was a study conducted on mentally disabled boys institutionalized at the State Residential School in Massachusetts, where they were intentionally fed radioactive iron and calcium in breakfast cereal to study nutrition and metabolism. In both of these studies, there was no compelling reason to study children compared to adults. In both instances, children bore the brunt of the research, but were not necessarily the group intended to benefit from the findings. Researchers are not allowed to involve captive populations, like prisoners, in research unless the research findings are intended to directly benefit these populations.

Cherry, Kendra. "What is informed consent?" About.com Guide http://psychology.about.com/od/iindex/g/def_informedcon.htm

This webpage provides a brief overview of informed consent.

University of Nevada, Las Vegas: History of Research Ethics: <http://www.unlv.edu/research/ORI-HSR/history-ethics>

This website provides a brief description of the development of human subjects' regulations and requirements in the United States.

The University of British Columbia: Research Ethics and Research Involving Humans PowerPoint presentation on ethics:

<http://grad-postdoc.med.ubc.ca/files/2014/04/Research-Ethics-and-Research-Involving-Humans.ppt>

This link opens a Microsoft®PowerPoint presentation that provides background information on the development of human subjects' regulations and requirements.

Extensions

Classroom

Choose one of the topics from above and complete a research paper on how it came to be, what the implications are, and whether it was the blueprint for other events or by what was it replaced.

Cross-Curricular

Language Arts: Write short fictional stories in which the student puts himself or herself in the different time periods of these events and writes a narration of how his or her life might be affected. Use historical events related to research ethics to reinforce sequencing of events in writing.

History and Social Studies: Produce a research paper, poster, or presentation on one of the events discussed in this lesson.

Physical Education: Collaborate with the Health and Physical Education teachers to coordinate the ethical decision with related health topics.

Name: _____

- Beneficence

- Justice

- Applications
 - Informed Consent

 - Information

 - Comprehension

Name: _____

Informed Consent

Informed consent is a legal procedure to ensure that a patient or client knows all of the risks and costs involved in a treatment. The elements of informed consent include informing the potential participant of the nature of his or her involvement, possible alternatives to participation, and the potential risks and benefits of participation in the research.

What is the purpose of the NOURISH study?

What does participation in the study involve for children? What are youth participants being asked to do?

What information is being collected about or from the youth participants?

Name: _____

How is this information being protected or kept confidential?

How will youth participants benefit from being in the study?

Will anyone else other than the youth participants benefit from the results of the study?

Are there any risks due to participation? If yes, what are they?

Name: _____

Are the risks justified when you think about the potential benefits? Why, or why not?

Why are there two consents documents (e.g., parental consent form and youth assent form)? Do you think it is important that the parents and the child give their permission for the child to participate in the study?

Name: _____

**Student and Parent/Guardian Discussion
Benefits and Risks of Participation in NOURISH**

Note to Parents: The attached consent and assent forms are used strictly for educational purposes and your child in no way will be participating in this study described in this form as a result of this activity.

Student – What are two reasons for children/youth to participate in the study?

Reason #1

Reason #2

Parent – What are two reasons for parents to participate in the study?

Reason #1

Reason #2

Name: _____

Student – Why should you not participate?

Reason #1

Reason #2

Parent – Why should you or your child not participate?

Reason #1

Reason #2

Name: _____

Would you choose to participate in this study if applicable?

Student: Why or why not?

Parent: Why or why not?

Why is “informed consent” an important part of ethics in the research process?

Sample Consent Form

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: NOURISHing Families to Promote Healthy Eating and Exercise in Overweight Children

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this research study is to teach parents/caregivers skills that will help prevent and reduce the problems of obesity and eating disorders in children. You are invited to participate in this study because you have identified yourself as someone who has a child between the ages of 5 and 11 with a Body Mass Index (BMI) > the 85th percentile, which is considered overweight.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study, you will have the opportunity to participate in one of two groups in which many issues that may concern you will be addressed. Parents in both groups will learn about ways of becoming more healthy. One group will meet for 1.5 hours weekly (over a 6-week period) with other parents in sessions led by NOURISH+ staff. They will also participate in two, 30-minute individual nutrition sessions during which they can discuss their families' specific dietary challenges. Three weeks after the program's completion, parents in this group will be contacted via phone to participate in a brief, personalized booster session. The other group will meet one time for a "Family Wellness Night" and will receive mailings about the healthy lifestyle behaviors at five different times over the course of nine weeks. This will allow us to see which group format is more effective at helping families make healthy lifestyle changes.

Name: _____

All group sessions will be videotaped. The purpose of taping the sessions is to ensure that all groups are receiving the same information, and to help train future group leaders. Families will be randomly assigned to their group. This randomization process is done using a computer program; everyone has an equal (50/50) chance of being in either group.

Finally, parents in both groups will come to the NOURISH clinic to fill out a set of questionnaires at four different time points: before the intervention (i.e., today), at the end of the intervention, four months after the intervention, and ten months after the intervention.

Some questions will be about your behaviors, and some will be about your child's behaviors. You and your child will be given a pedometer to measure and record your steps. Also, research staff will measure your height; weight; and abdominal, hip, and waist circumferences. Percent body fat will be determined by bioelectrical impedance, which will require you to lay on a couch and have stickers attached to your hand and foot. In addition, your child's height; weight; and abdominal, hip, and waist circumferences and body fat will be measured in the same way by research staff (with a parent or another adult present). Finally, your child will be asked to complete a few questionnaires (research staff will interview younger children and older children will complete their own). Children eight and older will also complete a self-assessment of pubertal status. For children under eight, we will ask parents to report children's pubertal status. This questionnaire is important because puberty significantly influences weight gain.

If you become pregnant during the intervention, please notify us immediately. Because we want to minimize the risks associated with changes in exercise and diet during pregnancy, you will no longer be permitted to continue participating in the NOURISH program. However, you will not be financially penalized if this occurs.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

Name: _____

RISKS AND DISCOMFORTS

Possible risks and inconveniences associated with participation in this study include feeling concerned or embarrassed after thinking about your current or past health behaviors and having measurements taken. However, you do not have to talk about any subjects you do not want to talk about, and you may leave the study at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

BENEFITS TO YOU AND OTHERS

There are several benefits that you may gain from participating in this intervention. First, you will learn about healthy lifestyle behaviors. Second, you will learn skills that may help you improve both your own and your child's well-being. Lastly, the information from this research study may lead to better treatment in the future for people with a history of eating problems and obesity.

COSTS

There are no costs for participating in this study other than the time you will spend in the groups and filling out questionnaires.

PAYMENT FOR PARTICIPATION

You and your child will receive a pedometer to use in the study and to keep following the study. All participants (i.e., those in both groups) will be given gift cards for completing all questionnaires and body measurements (\$50 gift cards for completing the pretest, \$70 for completing post testing, \$90 for completing the 4-month follow-up testing, and \$100 for 10-month follow-up). You will receive payment once we receive your completed questionnaire. Also, for those who are in the group that meets in-person on a weekly basis, we will conduct weekly raffles for "door prizes" (small items costing approximately \$5 or less). Participants who attend the final session will be given Certificates of Completion. Finally, childcare will be available for those participants attending the weekly group sessions.

ALTERNATIVES

If you do not wish to complete this study, your alternative is to not participate.



Name: _____

CONFIDENTIALITY

Potentially identifiable information about you will consist of surveys, body measurements, and recordings of group sessions. Data are being collected only for research purposes. Your data will be identified by ID numbers, not names, and stored in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted after the completion of this study. Video recordings will be kept in a locked file cabinet for three months after the study ends and will be destroyed at that time. Information gathered in this study will be maintained in a manner consistent with federal and state laws and regulations. This means that all information you provide to us, and all of your answers to our surveys, will be kept confidential. No one outside the research team will have access to your records. There are limits to confidentiality where the clinician is required by law to reveal information without your consent. These situations may involve the following: 1) If a court of law subpoenas your records, 2) If you are judged to be of immediate danger to yourself or to another person, and 3) If there is reason to suspect abuse or neglect of a child or adult. Videotapes and surveys will be kept in Dr. Mazzeo's locked laboratory office. Tapes will be destroyed immediately after the completion of this study.

We will not tell anyone the answers you or your child give us; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. What we find from this study may be presented at meetings or published in papers, but you or your child's name will not ever be used in these presentations or papers.

We will not tell anyone the answers your child gives us. But, if your child tells us that someone is hurting her or him or that she or he might hurt herself, himself or someone else, the law says that we have to let people in authority know so they can protect your child.

The group sessions will be audio taped, but no full names will be recorded. At the beginning of the session, all members will be asked to use their first names only. The tapes and the notes will be stored in a locked cabinet. After the information from the tapes is typed up, the tapes will be destroyed.



Name: _____

IF AN INJURY OR ILLNESS HAPPENS

Virginia Commonwealth University and the VCU Health System (formerly known as MCV Hospital) do not have a plan to give long-term care or money if you are injured because you are in the study. If you are injured because of being in this study, contact Dr. Suzanne Mazzeo right away. She will arrange for short-term emergency care or referral if it is needed. Fees for such treatment may be billed to you or to appropriate third party insurance. Bills for treatment may be sent to you or your insurance. Your insurance may or may not pay for taking care of injuries that happen because of being in this study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include: the study staff thinks it necessary for your health or safety; you have not followed study instructions; or administrative reasons require your withdrawal.

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Principal Investigator

Address

Phone Number

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research

Sponsoring Organization

Address

Phone Number



Name: _____

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at <http://www.cctr.vcu.edu/clinicalresearch/participants/index.html>.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed

Participant signature

Date

Name of Person Conducting Informed Consent Discussion / Witness
(Printed)

Signature of Person Conducting Informed Consent Discussion / Witness

Date

Principal Investigator Signature (if different from above)

Date



Ethical Issues in Clinical Research

Human Rights and Experimentation

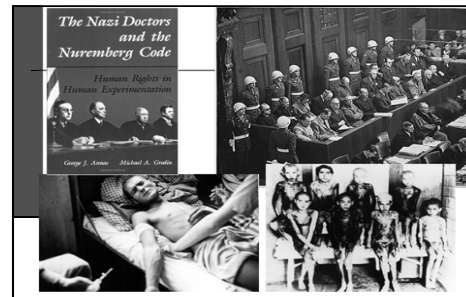
This project was supported by the National Center for Research Resources and the Division of Program Coordination, Planning, and Strategic Initiatives of the National Institutes of Health through grant number 5Z05GM008833-03

Nuremberg Code

- ❖ On December 9, 1946 an American military tribunal began criminal proceedings against 23 leading German physicians and administrators for war crimes and crimes against humanity for conducting medical experiments on thousands of concentration camp prisoners without their consent. In most cases, these experiments resulted in death or permanent disabilities.

Nuremberg Code

- ❖ This trial led to the adoption of the Nuremberg Code in 1948.
- ❖ The Nuremberg Code states
 - ❖ that "The voluntary consent of the human subject is absolutely essential,"
 - ❖ and that the benefits of research must outweigh the risks
- ❖ While the Nuremberg Code does not carry the force of law, it was the first international document advocating voluntary participation and informed consent.

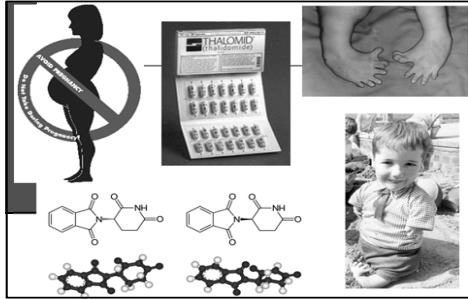


Thalidomide

- ❖ In the late 1950s, thalidomide, which was approved as a sedative in Europe but not in the United States, was prescribed to control sleep and nausea throughout pregnancy.
- ❖ If taken during pregnancy, thalidomide causes severe deformities in the fetus.
- ❖ Approximately 12,000 babies were born with severe deformities due to thalidomide usage.
- ❖ Many patients were not informed that thalidomide was not approved by the FDA, nor did they give informed consent.

Thalidomide

- ❖ U.S. Senate held hearings and, in 1962, the Kefauver-Harris Drug Amendments to the Food, Drug and Cosmetic Act were passed.
- ❖ These amendments require that, prior to marketing, drug manufacturers must prove to the FDA that their products are both safe and effective for the product's intended use.



Tuskegee Syphilis Study

- ❖ The Tuskegee Syphilis Study was a research project conducted by the U.S. Public Health Service between the years of 1932 and 1972
- ❖ Six hundred low-income African-American males were included in the study
 - ❖ 400 of the subjects were infected with syphilis
 - ❖ Monitoring continued for 40 years
- ❖ Free medical examinations were provided
 - ❖ subjects were not told about their disease
 - ❖ Penicillin, a proven cure for Syphilis became available in the 1950s; however the study continued and participants were denied treatment until 1972

Tuskegee Syphilis Study

- ❖ In some cases, when other physicians diagnosed the subjects' illness, researchers intervened to prevent treatment
- ❖ Many subjects died of syphilis during the study
- ❖ The study was stopped in 1973 by the U.S. Department of Health, Education, and Welfare only after its existence was publicized and it became a political embarrassment
- ❖ In 1997, continuing public pressure lead to President Clinton's apology to the study subjects and their families



Declaration of Helsinki

- ❖ In 1964, the World Medical Association established recommendations to guide medical doctors in biomedical research involving human subjects. These recommendations govern international research ethics and define rules for "research combined with clinical care" and "non-therapeutic research."
- ❖ The Declaration of Helsinki was revised in 1975, 1983, 1989 and 1996 and is the basis for Good Clinical Practices used today.

Declaration of Helsinki

- ❖ The Declaration of Helsinki guidelines relate to the following issues:
 - ❖ Research with humans should be based on the results from laboratory and animal experimentation
 - ❖ Research protocols should be reviewed by an independent committee prior to initiation
 - ❖ Informed consent from research participants is necessary
 - ❖ Research should be conducted by medically/scientifically qualified individuals
 - ❖ Risks should not exceed benefits

National Research Act

- ❖ Due to the publicity surrounding the Tuskegee Syphilis Study, the National Research Act of 1974 was passed.
- ❖ The National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was charged with:
 - ❖ Identifying basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects
 - ❖ Developing guidelines to assure that research is conducted in accordance with those principles

The Belmont Report

- ❖ In 1978, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issues the Belmont Report which:
 - ❖ Summarize the basic ethical principles identified by the Commission in the course of its deliberations
 - ❖ Outlines ethical principles and guidelines for human subjects protection in the United States

The Belmont Report

- ❖ The Belmont Report established three basic ethical principles – respect for persons, beneficence, and justice – which are the foundation of regulations for research involving human subjects

The Belmont Report

Principle	Application
<ul style="list-style-type: none">❖ Respect for persons<ul style="list-style-type: none">❖ Individuals should be treated as autonomous agents❖ Persons with diminished autonomy are entitled to protection	<ul style="list-style-type: none">❖ Informed consent<ul style="list-style-type: none">❖ Subjects, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them❖ The consent process must include three elements:<ul style="list-style-type: none">❖ Information❖ Comprehension❖ Voluntariness

The Belmont Report

Principle	Application
<ul style="list-style-type: none">❖ Beneficence<ul style="list-style-type: none">❖ Human subjects should not be harmed❖ Research should maximize possible benefits and minimize possible harms❖ Justice<ul style="list-style-type: none">❖ The benefits and risks of research must be distributed fairly	<ul style="list-style-type: none">❖ Assessment of risks and benefits<ul style="list-style-type: none">❖ The nature and scope of risks and benefits must be assessed in a systematic manner❖ Selection of subjects<ul style="list-style-type: none">❖ There must be fair procedures and outcomes in the selection of research subjects

CURRENT REGULATIONS

- ❖ In 1981, the Department of Health and Human Services and the Food and Drug Administration issued regulations based on the Belmont Report
- ❖ These regulations addressed issues related to
 - ❖ Public welfare
 - ❖ Protection of human subjects
 - ❖ Research related to food and drugs
 - ❖ Institutional Review Boards (IRBs)

CURRENT REGULATIONS

- ❖ In 1991, the Federal Policy for the Protection of Human Subjects, or "Common Rule" was adopted by more than a dozen federal departments and agencies that conduct or fund human subjects research
- ❖ Today, the 1991 Federal Policy is used by most, but not all, of the federal departments and agencies that sponsor human-subjects research
- ❖ Some federally sponsored and many privately sponsored research programs are subject to additional Food and Drug Administration regulations

Common Rule

- ❖ The main elements of the Common Rule include :
 - ❖ Requirements for assuring compliance by research institutions
 - ❖ Requirements for obtaining and documenting informed consent
 - ❖ Requirements for Institutional Review Board membership, function, operations, review of research, and record keeping.
 - ❖ Additional protections for certain vulnerable research subjects
 - ❖ Pregnant women
 - ❖ Prisoners
 - ❖ Children

Photo References

- ❖ Slide 4 from "The Nazi Doctors" clockwise to person laying in bed
 - ❖ <http://www.bookapex.com/images/The-Nazi-Doctors-and-the-Nuremberg-Code-Human-Rights-in-Human-Experimentation-0195101065-1.jpg>
 - ❖ http://www.uncp.edu/home/rwb/nuremberg_trials.gif
 - ❖ <http://standwell.org/wp-content/uploads/2008/06/children-experiments.gif>
 - ❖ <http://static.technorati.com/11/03/01/28261/Patient.jpg>

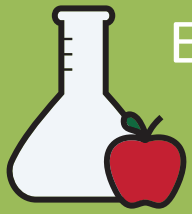
Photo References

- ❖ Slide 7 from the pregnant woman clockwise to molecular structures
 - ❖ <http://biopsy.files.wordpress.com/2008/10/thalidomide.gif>
 - ❖ http://barnesworld.blogspot.com/barnes_world/images/thalid4.jpg
 - ❖ <http://www.digitaljournal.com/img/4/2/0/9/3/9/1/6/1/1/ol/thalidomide.jpg>
 - ❖ http://1.dailymail.co.uk//pix/2009/02/08/article-1138955-0024381F00000258-341_233423.jpg
 - ❖ <http://toxipedia.org/download/attachments/1322/thalidomide.png>

Photo References

- ❖ Slide 10 from "Bad Blood" clockwise to hand
 - ❖ <http://t2.gstatic.com/images?q=tbn:ANd9GcRCv5ik1zhQBvYcv28MzLErO2VtLW3mkddUiy1voHC1evMIKRRFA>
 - ❖ <http://t1.gstatic.com/images?q=tbn:ANd9GcTF-qC0HwrgtHMA4FKWQlU5t5l98C337Cip8FP6oBrS2S9Tvrq>
 - ❖ http://t1.gstatic.com/images?q=tbn:ANd9GcToO2-vmV0zL93jMavesd03KmanSt-wQL_5n-eM56THp-f8jBg
 - ❖ http://www.engagediversity.net/science/Tuskegee_Experiment2.jpg

Ethical Issues in Clinical Research



Ethical Controversies: Debating the Pros and Cons

© Virginia Commonwealth University 2013

CRESST

Revised February 2016

Introduction

With advances in technology come new challenges regarding how those advances are incorporated into society. This is especially the case when this new technology challenges long-established barriers to medical advances and brings into question religious and moral values. These technologies include issues such as gene manipulation and cloning. In this country and many others, there is little legislation to address concerns that accompany new technologies. In order to establish legislation, a great deal of debate will be necessary.

Purpose

This activity is designed to encourage students to apply the process of ethical decision making and essential principles to current controversial topics in research.

Objective

At the end of this lesson, students will be able to research different topics to make informed arguments.

Key Terms

- Cloning: producing an organism with the same genetic makeup from another organism
- Gene: a segment of DNA that codes for a particular trait (ex. hair color)
- Regenerative: having the ability to grow back a segment of an organism's cellular organization
- Scientific Integrity: a commitment to intellectual honesty and personal responsibility for one's actions and practices that characterize the responsible conduct of research; for example, adhering to the scientific method, ensuring unbiased testing, respecting human subjects, and accurately reporting research results

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 2

Science and Engineering Practices 3, 6, 7, 8

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

Essential Features of Classroom Inquiry 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: LS.1 a, b, e-g, i, j, BIO.1 c, e, f, h-m

Health 9.1 g, p, r, 9.2 h, s, v, y, 9.3 e, k, l, m

Physical Education 7.4 a, b, c

Materials

- Use the “Structured Academic Controversy” as a guide for structuring the student discussion of various ethical topics. The guide can be found at the following link: <https://www.nwabr.org/sites/default/files/StructuredAcademicControversy.pdf>

Procedures

Use a think-pair-share approach to discuss the following current ethical issues.

Topics:

1. Regenerative Body Parts. Would You?

<https://www.youtube.com/watch?v=o1ewAheYSXs>

“Morley Safer reports on the emerging technology of growing body parts from human cells taken directly from patients, providing new hope for amputees and patients on organ transplant lists.”

2. On Human Cloning: Three Views

<http://www.pbslearningmedia.org/resource/tdc02.sci.life.cell.humcloning/on-human-cloning/>

This website presents three points of view on this highly controversial issue. The three scientists are experts in the field and are basing their opinions on the same facts, yet they have very different opinions.

3. Personalized Genetic Testing

<http://www.pbs.org/wnet/religionandethics/2010/06/11/june-11-2010-personal-genetic-testing/6444/>

This video raises a host of both ethical and public policy concerns. “What difference should this make in the way you behave, in the health care you get, in your relationships with loved ones, your plans for your future? ... What should you do with that information?”

4. CIA’s Secret Experiments (from National Geographic)

<http://channel.nationalgeographic.com/channel/videos/cia-secret-experiments/>

“This powerful National Geographic video documents how for decades, top secret government projects worked virtually non-stop to perfect means of controlling the human mind. Though for many years the government denied that these projects even existed, the details have long been preserved in thousands of pages of now declassified government documents reluctantly released through the Freedom of Information Act. LSD and electroshock therapy in huge doses given to unsuspecting citizens are only a part of this unbelievable program.”

5. Office of Research Integrity (ORI): “The Lab: Avoiding Research Misconduct”

<http://ori.hhs.gov/TheLab/>

In “The Lab: Avoiding Research Misconduct,” you become the lead characters in an interactive movie and make decisions about integrity in research that can have long- term consequences. The simulation addresses Responsible Conduct of Research topics such as avoiding research misconduct, mentorship responsibilities, handling of data, responsible authorship, and questionable research practices.



Observations and/or Data

- Which topics elicited the greatest level of discussion?
- Which topic did the class find least interesting?
- Were there further questions generated by this activity?

Analysis and Conclusions

- In the cloning argument, which side did most students choose?
- What were the emotional reactions of students when learning about either CIA experiments or technology they may not have known existed?
- Would students be willing to participate in any of these situations?

Critical Thinking Questions

- Many major agricultural products, such as corn, have been or are considered to be genetically altered. With animals being cloned, would you eat cloned animal products?
- If you knew there were genetic diseases in your family, would you be willing to be screened to determine if you have those traits?
- Who should have the authority to determine what can be cloned and whose genes can be altered and how?

Teacher Notes

Make sure that Internet sites are accessible from individual classrooms.

Safety Notes

Make sure all students are following proper classroom safety guidelines. Plan for any sensitivity that students may feel if they can directly relate to assignments given.

Background Information and Resources

Use these guides and links to develop further understanding of discussion topics.

Regenerative Body Parts. Would You?

<https://www.youtube.com/watch?v=o1ewAheYSXs>

“Morley Safer reports on the emerging technology of growing body parts from human cells taken directly from patients, providing new hope for amputees and patients on organ transplant lists.”

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“This powerful National Geographic video documents how for decades, top secret government projects worked virtually non-stop to perfect means of controlling the human mind. Though for many years the government denied that these projects even existed, the details have long been preserved in thousands of pages of now declassified government documents reluctantly released through the Freedom of Information Act. LSD and electroshock therapy in huge doses given to unsuspecting citizens are only a part of this unbelievable program.”

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Extensions

Classroom

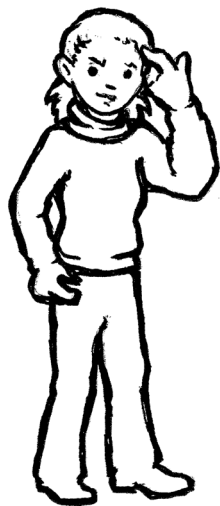
Choose one of the topics discussed in class. Complete additional research and prepare a poster, presentation, or research paper.

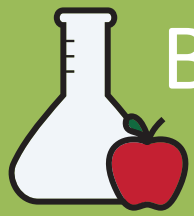
Cross-Curricular

Language Arts: In language arts class, the students can complete a paper or presentation on one of these topics as an exercise in technical and/or persuasive writing.

Physical Education: Collaborate with the Health and Physical Education teachers to coordinate the discussion of these topics with related health topics.

History and Social Studies: Collaborate with history and social studies teachers to present an investigation into the technological developments that led to these advances.





Bioethics: Standards for Scientists

CRESST

Revised February 2016

Introduction

Scientists are often on the cutting-edge of research and discovery. Sometimes, there are situations in which companies or individuals invest large amounts of money and resources to support research that may yield unique discoveries and treatments. In these situations, there can be tremendous pressure to produce results in a short time line which can lead to taking short cuts in the research process and even falsifying information. These types of actions can lead to multiple forms of harm for individuals, consumers, patients and researchers. The following activities are designed to encourage students to engage in best practices in science and research by keeping a science journal and understanding the importance of honesty and integrity in scientific reporting.

Purpose

Students will become more familiar with scientific research that has ethical considerations and how to follow correct scientific reporting and procedures.

Objectives

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

- Read, summarize, and react to current scientific articles in a journal that deals with ethics
- Simulate laboratory procedures in which proper reporting of scientific findings would be required

Key Terms

- Ethics: refers to concepts of right and wrong. These concepts are reflected in social and moral standards that guide our actions, behaviors, and decision-making.
- Ethical dilemma: occurs when individuals are faced with a question or situation that involves more than one ethical principle. In order to respond to an ethical dilemma, individuals have to weigh the value of different principles to decide on an action. For example, sometimes researchers may have to reveal the name of a student participant and breach the ethical principle of confidentiality in order to respond to a medical diagnosis discovered during the course of a research study.
- Ethical distress: this can occur when you have made a decision about how to respond to an ethical dilemma, and the actions you decided to take are blocked or you experience barriers that limit your ability to respond. For example, peer pressure may influence a student's decision to tell a teacher about cheating that occurred on a test. In this case, the pressure put on the student by his or her peers to not inform the teacher may cause the student distress such as anxiety and worry about how he or she will be treated by his or her peers.
- Locus of authority: the one with the final say in making a decision that involves an ethical dilemma

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 2

Science and Engineering Practices 3, 6, 7, 8

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

Essential Features of Classroom Inquiry 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: LS.1 a, b, e-g, i, j, BIO.1 c, e, f, h-m

Health 9.1 g, p, r, 9.2 h, s, v, y, 9.3 e, k, l, m

Physical Education 7.4 a-c

Materials

- Scientific journals articles
- “The Six-Step Process of Ethical Decision Making” Microsoft® PowerPoint
- NOVA: Do Scientists Cheat? (see Background Information and Resources section for more information)

Procedures

Science Events Journal

1. As a class, collect articles from newspapers and magazines that deal with science related issues. Article topics will vary, depending on the course (e.g., biology, chemistry, earth sciences, and physics).
2. Each student will be assigned or select an article for his or her report. He or she will also be provided with guiding questions that focus on the ethical issues rather than on specific scientific facts (although getting clear about the ethical questions usually requires getting clear about some of the scientific facts).
3. A journal entry consists of a summary of the main points of an article and some discussion of the ethical and value issues raised by the article. Teachers might assist the discussion of ethical and value issues by adding specific questions for students to answer. For example, “What kinds of questions should scientists ask about possible areas of research before they undertake them?” and “Is science ‘value-neutral?’” It would be useful to encourage students to develop their own questions, as well.
 - Here is a possible format for the assignment rubric:
Each assignment will be graded on the basis of a possible 10 points.
 - 3 points: Brief summary of article
 - 3 points: Reaction to article
 - 2 points: Answer to a specific question
 - 2 points: Quality of writing (spelling, sentence structure, etc.)
4. Journal entries can be turned in for teacher evaluation and grading or they can provide the basis for class discussion.
5. Discussion
 - a. Use journal entries to connect science studies with current events, as well as historically significant events that involve science.
 - b. Discuss science in the news to connect the relevance of science studies to events outside the classroom.

Honesty in Reporting Research

1. View and discuss “The Six-Step Process of Ethical Decision Making” Microsoft® PowerPoint (see Ethical Issues in Clinical Research: [Ethical Scenarios Carousel](#)).
2. Discuss the importance of laboratory honesty, especially in research that has a direct impact on human health and welfare. This discussion should include a general description of the requirements of laboratory honesty and whether manipulating data to appear more favorable is ethical behavior.
3. View the segment (approximately 9 minutes) of the NOVA video, “Do Scientists Cheat?” which emphasizes the importance of honesty in data reporting.
4. Discuss the class’ opinions of the issues raised by the NOVA video.
5. As a homework assignment, apply this discussion to household products that have resulted from scientific research, considering what dangers these products might pose if the research behind them had been falsified or misrepresented.
6. Discuss the homework assignment during the next class period. Consider how the well-being of the general public and the reputations and careers of scientists can be impacted when data is fabricated, falsified, or misrepresented.

Observations and/or Data

- What types of ethical issues were raised in the video?
- What were the consequences of the scientists’ actions?

Analysis and Conclusions

- Did you consider the actions of the scientists unreasonable? Did you agree with some of their decisions? Explain.
- How do you feel you would act if put in these positions?

Critical Thinking Questions

- If you were a medical researcher and some of your experiments to cure a major disease worked while others failed, would you manipulate your results in the hope of helping others?
- It can be difficult to support clinical research studies that will help to determine effective treatments of rare diseases. Should the government fund research studies where the results may only affect a small percentage of the population, or instead fund research on treatments for diseases that affect more people, such as cancer? What is the government's responsibility in how federal tax dollars are used to support research that can help cure rare and common diseases?

Teacher Notes

Plan for sensitivity or negative emotions students may experience related to the assignment.

Safety Notes

Make sure all students are following proper classroom safety guidelines.

Background Information and Resources

Honesty in research is a critical factor in ethical behavior. Science is a process of discovery where researchers test hypotheses. Researchers should not begin a research study by anticipating what they expect to find and then alter their observations to match their preconceived notions. The peer review process and experimental replication are two methods of ensuring the honesty in research.

“NOVA: Do Scientists Cheat?”

Produced by WGBH, Boston in 1988

This video explores the issues and consequences of cheating in science.

Like most NOVA videos that are more than three years old, it is no longer available for purchase. It is in the collection of many libraries, academic institutions, and other video archives from which it may be borrowed. You may be able to request the video (video #VT0113) through interlibrary loan at your local library. It can also be found at:

<https://www.youtube.com/watch?v=VooaLRqTSPi>

Other Videos on ethics in research can be found by searching the topic “Bioethics in Science” on websites such as United Streaming, PBS.org, and NOVA.



Arctic Alive: Science Journal Rubric

<http://archive.arcus.org/arcticalive/downloads/Rubric%20-Sci%20Journal.pdf>

This link opens a rubric that can be used to guide students as they create science journal entries.

Purtilo, R. (1999). Ethical dimensions in the health professions. (3rd edition).

Philadelphia, PA: W. B. Saunders.

Extensions

Classroom

Have students create fictitious scenarios for possible data manipulation. Use examples from labs and other experiments done during the school year and discuss where data could have been manipulated.

Cross-Curricular

Language Arts: Coordinate with the language arts teachers to use the science journal assignments as exercises in technical writing.

Physical Education: Collaborate with the Health and Physical Education teachers to coordinate the honesty in research decision with related health topics.



Name: _____

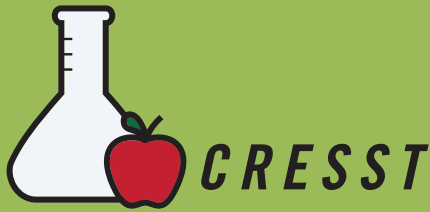
Do Scientists Cheat

Watch the video “Do Scientists Cheat?”

While watching the video, examine the ethical considerations that scientists would have to consider or ignore.

Write down 10 complete thoughts/sentences that you will be able to use as possible talking points for class discussion:

Collecting and Analyzing Data



Overview

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Revised February 2016

In recent years, the increase in obesity levels in our population, especially among youth, has been the focus of a great deal of research and study. This section includes lessons that help students learn more about how research processes and experimental studies are implemented in clinical research while conducting their own investigations about health and wellness. An important aspect of clinical research studies is the selection of the outcome that will be measured in the study. Examples of study outcomes include body mass index (BMI), level of physical activity, food choices, or having a diagnosis of diabetes. In order to accurately measure these outcomes, appropriate tools must be chosen. In clinical research, measurement tools include things like surveys and questionnaires as well as devices like blood pressure meters and pedometers. Some of the important considerations when selecting a measurement tool are the validity, reliability, and feasibility of the measure for a study. Choosing an outcome measure and considering the validity, reliability, and feasibility of how it is measured is an essential part of designing a successful study. Gathering and synthesizing information about the outcome and the possible ways to measure it is one way researchers become more knowledgeable about clinical research and identify ways to strengthen their own studies.

Section Objectives

In this section, students will:

- Investigate and understand how the research process and experimental design are implemented in clinical research
- Analyze data using graphs and statistics
- Understand how reliability and validity may relate to various health measurement tools, such as pedometers and Calorie counting resources

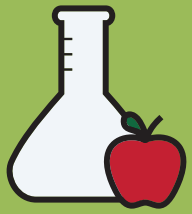
Topics

- Implementing the research process and experimental design in clinical research
- Analyzing data using graphs and statistics
- Evaluating the effects and benefits of physical activity and healthy food choices on health
- Examining the validity and reliability of measurements

Activities

- Numbers Can Talk: Exploring Statistical Data
- Let's Work It Out
- Walkable Communities: Exploring Measurement Reliability and Validity
- What's On Your Plate?

Collecting and Analyzing Data



Numbers Can Talk: Exploring Statistical Data

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CRESST

Revised February 2016

Introduction

In the clinical research community, special attention has been given to the rise in obesity levels among our youth population. The Data Resource Center for Child and Adolescent Health (DRC) uses surveys and medical records to monitor trends and changes in rates of obesity. The goal of the DRC is to provide accurate, freely available data related to children's health concerns and assist in improving children's health and health-related services for youth and families throughout the United States. Analyzing this data and the survey methods used to collect it will help students learn to identify important types of data and improve their study design skills.

Purpose

In this lesson, students will investigate and learn how the research process and experimental design are implemented in clinical research. Students will then analyze existing survey data using graphs and descriptive statistics in order to make inferences and draw conclusions.

Objectives

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

- Apply analysis skills to existing data
- Graph data to illustrate comparisons
- Draw conclusions and inferences based on data analysis
- Discuss factors that contribute to the increase in childhood obesity
- Discuss the strengths and limitations of using existing data or survey data in research

Key Terms

- Accuracy: the closeness with which an observation or a measurement of a variable approximates its true value; an accurate test implies freedom from both random and systematic error

- Constants: all factors that are purposely kept the same throughout the experiment in both the experimental and control groups
- 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.
- Dependent or responding variable: the variable that is measured or observed during the experiment; the measurement that “depends” on what I change
- Hypothesis: a prediction about the relationship between the variables that can be tested
- Independent or manipulated variable: the variable that is purposefully changed by the experimenter; “what I change”
- Precision: in statistics, the extent to which a measurement procedure gives the same results each time it is repeated under identical conditions
- Qualitative data: data that are descriptive, in written form, and involve characteristics that cannot usually be counted
- Quantitative data: data expressed as numbers, obtained by counting or measuring
- Statistical significance: the criterion for the decision that the results of an experiment did not happen by chance but were the result of the treatment/ experiment
- Statistics: the branch of mathematics involving the probability-based procedures to analyze data for interpretation

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 1, 2

Science and Engineering Practices 4, 5, 6, 8

Nature of Science Understandings 1, 2, 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

Virginia

Science: BIO.1, BIO.2, BIO.3, BIO.4

Health: 7.3 j, 9.1 b, r, 9.2 c, h, 9.3 e; 10.1 a–c, f; 10.2 c

Physical Education: 9.2 a, b, 9.3 a, d, e, 9.5 a, b, c, 10.2 a, b, 10.3 a, b, 10.5 b, c



Materials

- Copies of Student Handouts
- LCD projector
- One computer per pair of students

Procedures

1. As students come into the classroom, project the 2007 Childhood Obesity State Report Card (<http://www.childhealthdata.org/browse/data-snapshots/obesity-2007>) on the board.
2. Conduct a class discussion using the following teacher prompts.
3. Teacher prompts to elicit participation:
 - a. “I’m curious...what percent of our children, in the state of ____, are obese? What do you think?” Ask students to justify the percent they have predicted: “Why do you think that?”
 - b. “Let’s see the results. Click on your home state and view the percentages and relative data.” Read the key points aloud.
 - c. “Let’s look at this map of the USA showing the percent of children ages 10-17 classified as overweight or obese, by state, in 2007. What trends can you see?” When developing experimental or other types of studies, researchers usually start with an observed phenomenon or trend to inform their research questions. This phenomenon or trend should strike up more questions, and that is when the statistical analysis begins.
 - d. “Can you hypothesize a reason for these trends?”
 - e. “Why might these trends exist?”
 - f. “As a class, let’s research the Obesity Report Card for a couple different states and try to make connections as to why children might struggle with their weight.”
 - g. “When conducting this study, what sampling method do you believe scientists used to collect the information provided on this website?”
 - h. “I’m going to send you on a web hunt to find out more!” (distribute the Numbers Can Talk student worksheets)

Observations and/or Data

- Find the state average (% overweight/obese) from the data you collected.
- What is the national average for overweight and obese children?
- How close does the calculated average compare to the website's quoted average?

Analysis and Conclusions

- What factors influence childhood obesity?
 - Why?
- How do you think that these factors influence the child's health?
 - Why?

Critical Thinking Questions

In a short paragraph (minimum of 5 sentences), compare the data from household income and state obesity percentage with physical activity and state percentage. Which factor appears to have the most influence on childhood obesity? Why do you think this is the case? Justify your answer with specific examples.

Teacher Notes

Be sure there is at least one computer with Internet access available for every two students. Check to make sure the following webpages are not blocked by school administration. If they are, ask permission to access the site.

<http://www.childhealthdata.org/browse/data-snapshots/obesity-2007> and http://childhealthdata.org/learn/NSCH/topics_questions/2007-nsch
http://childhealthdata.org/docs/nsch-docs/2007_nsch_sampling_and_administration_508-pdf.pdf?sfvrsn=2

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.

Comparing the survey data used in this lesson with the data collected through physical measurements shown in ***Clinical Research: Why Does It Matter to Me?*** illustrates the importance of choosing the appropriate data and data collection tools for a research project.

Background Information and Resources

These resources can be used to provide background information and to guide students in the research process.

Cothron, Julia H., Ronald N. Giese and Richard J. Rezba. *Students and Research: Practical Strategies for Science Classrooms and Competitions*, Iowa: Kendall/Hunt Publishing Company, 2000, Third Edition.

Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition. © 2003 by Saunders, an imprint of Elsevier, Inc.

Extensions

Classroom

Choose either income level or physical activity level, and develop a scenario in which either of these groups could improve its situation. Examples could be ways of acquiring healthier foods or increasing physical activities.

Cross-Curricular

Language Arts: In a short paragraph (minimum of 5 sentences), compare the data from household income and state obesity percentage with physical activity and state percentage. Which factor appears to have the most influence on childhood obesity? Why do you think this is the case? Justify your answer with specific examples.

Name: _____

Numbers Can Talk: Exploring Statistical Data

Using the 2007 Childhood Obesity State Report Card and other statistical data, let's make connections between the numbers and lifestyle choices!

Visit The National Survey for Children's Health at <http://www.childhealthdata.org/browse/data-snapshots/obesity-2007> to complete the following web search.

View state report cards based on geographic location. After recording your state's data, select five other states of differing geographic location, and record the data below.

Review of your state's report card: In which state do you reside? _____

Your State: % Overweight or Obese	_____	National Rank: _____
State in Northeast: % Overweight or Obese	_____	National Rank: _____
State in Southeast: % Overweight or Obese	_____	National Rank: _____
State in Northwest: % Overweight or Obese	_____	National Rank: _____
State in Southwest: % Overweight or Obese	_____	National Rank: _____
State in Central US: % Overweight or Obese	_____	National Rank: _____

Find the state average (% overweight/obese) from the data you collected. Show your work.

What is the national average for overweight and obese children?

How close does the average of the five states that you calculated compare to the website's quoted average?

Name: _____

Visit the 2007 NSCH Sampling & Administration Process at http://childhealthdata.org/docs/nrch-docs/2007_nrch_sampling_and_administration_508-pdf.pdf?sfvrsn=2

- Draw a flow chart in the space below to explain the process researchers used in this study.

- How many people were interviewed nationally?

- How many people were interviewed from each state?

- Which statement best fits the description of proper research? Explain.
 - The number of participants or trials does not influence the validity of the research.
 - The larger the number of participants or trials, the more valid the research becomes.
 - Less is more!

Name: _____

Go to **Indicator 1.4: What is the weight status of children based on Body Mass Index (BMI) for age?**, on the 2007 National Survey of Children’s Health at

<http://childhealthdata.org/browse/survey/results?q=226&r=1>

- What are these numbers saying about childhood obesity?

Go to **Indicator 1.5: Physical activity, age 6-17**, on the 2007 National Survey of Children’s Health at: <http://childhealthdata.org/browse/survey/results?q=228&r=1>

- Describe what you think the graph is telling you.

- Record the Nationwide data:

Percentage (%) engaged in physical activity

Nationwide: _____ 0 days _____ 1-3 days _____ 4-6 days _____ Everyday

- In the **Edit Search Criteria** box, select your state in the state dropdown menu. Compare your state’s percentage (%) of children engaged in physical activity to the nationwide results for each category.

Percentage (%) engaged in physical activity

Your State: _____ 0 days _____ 1-3 days _____ 4-6 days _____ Everyday

- After recording your state’s data, select five other states of differing geographic locations and record the data below.

Percentage (%) engaged in physical activity

0 days 1-3 days 4-6 days Everyday

State in Northeast: _____ _____ _____ _____

State in Southeast: _____ _____ _____ _____

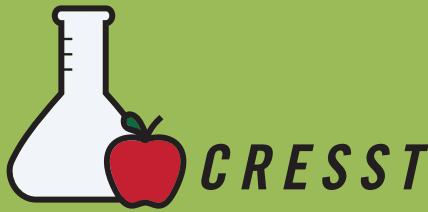
State in Northwest: _____ _____ _____ _____

State in Southwest: _____ _____ _____ _____

State in Central US: _____ _____ _____ _____



Collecting and Analyzing Data



Let's Work it Out

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Revised February 2016

Introduction

The relationship between Calories consumed and the Calories used by an individual to meet his or her daily energy requirement is referred to as energy balance. When energy is out of balance, the individual will either lose or gain weight. This relationship is key to healthy weight maintenance. To successfully lose weight, individuals must increase physical activity and reduce Calorie consumption. To sustain that weight loss, one's diet and physical activity plan needs to be maintained as a natural part of his or her daily schedule. Individuals who personalize their diet and physical activity plan, and incorporate it into their everyday life, generally have a better chance of maintaining a healthy weight than those who adopt overly intense plans or ones that include specialized foods or equipment.

Purpose

In this lesson, students will study the benefits of being physically active while comparing information from a variety of websites to examine the accuracy and validity of health information. They will explore what “physically active” means to them and find at least three ways they can be active.

Objectives

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

- Demonstrate the ability to access valid information and use goal-setting skills to enhance health
- Demonstrate the knowledge and skills to achieve and maintain a health-enhancing level of physical activity and fitness
- Develop a personal plan to stay active on a regular basis
- Use Microsoft® Excel or other spreadsheet to graph their findings using bar graphs

- Develop hypotheses or questions and gather information from relevant sources
- Use the information gathered to determine three of the best ways to burn Calories throughout the school day

Key Terms

- Accuracy: the closeness with which an observation or a measurement of a variable approximates its true value; an accurate test implies freedom from both random and systematic error
- Aerobic exercise: exercise that increases your heart rate, works your muscles, and raises your breathing rate
- 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.
- Flexibility exercise (stretching): exercise that helps keep your joints flexible and reduces your chance of injury during other activities
- 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.
- Reliability: the extent to which a test, device, or tool gives the same results in repeated measures under similar circumstances
- Strength training (resistance training): exercise that helps build strong bones and muscles
- Validity: the extent to which inferences based on scores are appropriate and meaningful

National and State Standards

National

Next Generation Science Standards:

Disciplinary Core Ideas LS1.C

Crosscutting Concepts 2, 3, 5

Science and Engineering Practices 5, 8

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

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

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

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



Virginia

Science 6.1 b, e, f, LS.1 h, PS.1 g–k BIO.1 a, e

Health: 6.2 a, 6.3 b, c, d, f, 7.1 b, 7.2 a, b, c, e, n, o, 7.3 b, k, t, 8.1 b, 8.2 c–g, 8.3 a, c, 9.1 b, g, p, 9.2 b, d, f, h, , 9.3 a, 10.1 a, b, c, f, 10.2 a, b, 10.3 a, g, l

Physical Education: 6.2 a–d, 6.3 a, b, 6.5, 7.2 b, 7.3 a–e , 7.5 a, b , 8.3 a, b, 8.4 a–e, 8.5 b, 9.2 a, b, 9.3 a–e, 9.5 a–c, 10.2 a, b, 10.3 a, b, 10.5 a–c, 11/12.2 a, b, 11/12.3 a–d, 11/12.5

Materials

- Internet access to Calorie counting websites
- At least one computer per 2 students

Procedures

1. As a class, discuss energy balance and the relationship between Calorie intake and physical activity.
2. Brainstorm ways to be physically active. Encourage the students to consider any activity where they are moving (walking, going up/down stairs, and housecleaning).
3. Write the ideas on the board/Smart Board and have each student choose at least ten activities he or she would enjoy.
4. Using the Internet, the students will look up each of their activities and determine how many Calories are burned in 30 minutes.
5. Students will then use another spreadsheet program to graph their findings using a bar graph.
6. The students will use the information gathered to determine three of the best ways to burn Calories throughout the school day.



Observations and/or Data

- Ask students the following questions when reviewing the activities and the amount of Calories burned in 30 minutes:
 - What are some activities that you think burn a lot of Calories?
 - What are some activities that you would enjoy doing at least twice a week for one month?
 - Did you accurately identify Calorie-burning activities?
 - Which activities will you perform in order to complete your plan?

Analysis and Conclusions

- Were there differences between websites in the number of Calories burned for the various activities? What explanations can you suggest for any differences?
- After completing your research and class discussion of the findings, write a short report about which three activities you would do most often. Develop a plan for doing these activities two to three times a week.

Critical Thinking Questions

- Burning Calories is considered synonymous with weight loss. Based on the activities you have examined, which activities would burn more Calories?
 - Why?
- Would strength training burn more Calories than aerobic activities?
 - Why?
- What would be the benefit of combining strength training and aerobic activities?

Teacher Notes

Check the classroom Internet access to be certain that students can access a variety of Calorie counting and physical activity websites. These websites should include the range of Calories consumed for different body types.

Students should have a basic understanding of the definition of physical activity and Calories, potential versus kinetic energy, mechanical energy, and energy conversions within the body that cause the utilization of Calories.

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.

The Health class in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** is completing this lesson. The video can help students make connections between physical activities, energy balance, and healthy choices. This lesson is one of the lessons highlighted in this video.

Background Information and Resources

Students should use different search engines in order to find different websites that will assist them in determining common daily activities and the approximate amount of Calories burned. Below are some websites that may provide students with this information.

Calorie Count

www.caloriecount.com

This site provides Calorie values from a large variety of food. It can be used without signing up; however, there are more resources available to those who sign up.

Health Status Calories Burned Calculator

www.healthstatus.com/calculate/cbc

This site includes a calculator that determines the number of calories burned for a variety of physical activities.

Livestrong.com: MyPlate

www.livestrong.com/myplate

This site provides Calorie values for a large variety of food, as well as a large variety of health and wellness resources. It can be used without signing up; however, there are more resources available to those who sign up.

Livestrong.com: Fitness and Exercise Directory

www.livestrong.com/thedailyplate/fitness/directory/

This site includes a directory of common physical activities and includes the number of calories burned for each activity.



Extensions

Classroom

Physical science energy topics can be discussed when introducing Calories and food energy. A chemistry experiment could be designed and conducted to determine the Calories in various foods. This experiment will also illustrate the difference between a calorie and a nutritional Calorie.

Cross-Curricular

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

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

Name: _____

Let's Work It Out Sample Rubric

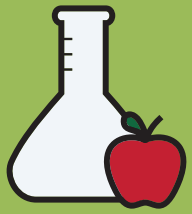
Your plan must include the following: received	Possible points	Points
1. The identification of at least four activities that will be performed at least twice a week (5 points per activity)	20	
2. A paragraph (5 to 7 sentences) about the four activities chosen	20	
3. A spreadsheet graph of the Calories burned while doing at least ten different activities	20	
4. Time schedule and calendar for performing the activities (should span over at least a month)	20	
5. Two witness letters, photographs, or other approved documentation of activity participation	20	

Possible Grade = 100

Grade =

#2 and #3 will be completed in class prior to the development of your activity plan, but must be turned in at the end of the unit along with your plan.

Collecting and Analyzing Data



Walkable Communities: Exploring Measurement, Reliability and Validity

CRESST

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Revised February 2016

Introduction

The ease with which regular exercise can be incorporated into daily life is being studied as one factor that may be related to rates of obesity within a community. Walking is recommended by many public health organizations to promote fitness and wellness. In some neighborhoods, it is easier than in others to walk as part of accomplishing the usual tasks of the day. Researchers have developed a variety of methods to measure the walkability of a neighborhood, such as using pedometers to measure how far people walk per day or completing rating scales that incorporate factors such as availability of sidewalks and safety in the neighborhood. This lesson uses the outcome of walkability of a community to investigate the important concepts of reliability, validity, and feasibility of outcome measures in clinical studies.

Purpose

The purpose of this lesson is to explore reliability, validity, and feasibility of an outcome measure for a clinical study by considering how to measure the concept of a “walkable community.”

Objectives

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

- Define reliability and validity
- Explain why reliability, validity, and feasibility of the outcome measure is important in a clinical study
- Analyze data collected from a pedometer to assess reliability of the pedometer measurement
- Correlate the walkability checklist score of the community with physical activity level as measured by pedometers
- Debate the pros and cons of using the walkability checklist and pedometers as a measure of a “walkable community”

Key Terms

- **Construct:** an idea or theory, especially one that is complex and formed from a number of other elements (e.g., intelligence)
- **Pedometer:** a device that measures the distance walked by recording the number of steps taken
- **Reliability:** the extent to which a test, device, or tool gives the same results in repeated measures under similar circumstances
- **Validity:** the extent to which inferences based on scores are appropriate and meaningful
- **Walkability:** a measure of how easy it is to walk around in an area, neighborhood, or community

National and State Standards

National

Next Generation Science Standards:

Crosscutting Concepts 3, 5

Science and Engineering Practices 3, 4, 5, 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

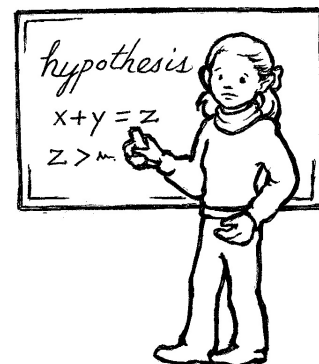
National Standards for Physical Education: Standards 2, 3, 4

Virginia

Science 6.1 f, LS.1 e, l, j, PS.1 f–k, BIO.1 a–g, l, m

Health: 6.1 g, 6.2 a, 6.3 b, c, j, 7.1 b, c, k, n, 7.2 a–c, t, u, v, 7.3 b, c, e, k–m, t, 8.1 b, 8.2 c, r, 8.3 b, c, p, q, 9.1 b, g, p, r, 9.2 b, d–f, h, v, y, 9.3 a, e, 10.1 a, f, i, 10.2 b, c, f, o, u, x, 10.3 a, g, m,

Physical Education: 6.4 a, b, 6.5 b, 7.2 d, 7.3 b, 7.4 a–c, e, 7.5 a, b, 8.2 d, 8.5 c; 9.1 d, 9.2 a, c, 9.5 a, 10.1 a, b, 10.2 d, 10.4 b, 10.5 d, e,



Materials

- Pedometers
- Copies of the Walkability Checklist (<http://www.walkableamerica.org/checklist-walkability.pdf>) for the class
- Copies of the Neighborhood Environment Walkability Scale – Youth (NEWS-Y) (http://sallis.ucsd.edu/Documents/Measures_documents/NEWS_Y_adolescent.pdf) for the class
- A spreadsheet program for data recording, graphing, and calculations
- As an alternative, data can be recorded and graphed on paper
- Computer and LCD projector

Procedures

1. Engage students in a discussion of walking as a form of exercise and its relationship to health and wellness. What opportunities do students have to walk during the day? What are some of the things that make walking difficult or easy within the community? If we were to conduct a study to compare communities or neighborhoods on how easy it is to walk while carrying out daily activities, how could we measure “walkability”?
2. Introduce three methods that have been used to measure walkability: the pedometer, the walkability scale, and the NEWS-Y.
3. Define reliability, validity, and feasibility, and review the importance of these concepts when measuring a study outcome such as walkability.
4. To illustrate the concept of reliability:
 - a. Students walk a defined distance (such as 1 lap around the school track) at a comfortable pace wearing a pedometer on their right arm. Record the total steps walked.
 - b. Repeat the walk for the same distance wearing the pedometer on the left arm. Record the total steps walked. Alternatively, the pedometer can be used to measure the total steps when walking the same distance on two different days.
 - c. Create a graph, plotting measurement 1 versus measurement 2. Using a spreadsheet program, calculate the correlation coefficient. The more highly

correlated the two measures are, the more reliable the measure.

5. To illustrate the concept of validity:
 - a. Have students work in groups to complete the NEWS-Y for the neighborhood around the school. This is a validated measurement tool. Discuss the neighborhood characteristics that are being evaluated in the NEWS-Y.
 - b. One way to show that a measurement tool is valid is to show that it measures the same thing that a “gold standard” validated tool measures. Have students work in groups to complete the walkability checklist, another measure of walkability, for the neighborhood around the school. What are the similarities and differences?

Observations and/or Data

- Reliability exercise:
Enter the two pedometer recordings for each student in an Excel spreadsheet. The spreadsheet should have three columns (student ID, total steps for 1st measurement, and total steps for 2nd measurement) and a row for each student.
- Validity exercise:
Does the walkability checklist appear to assess the same factors as the NEWS-Y? What are the similarities and differences?

Analysis and Conclusions

- Reliability exercise:
Create a graph, plotting measurement 1 versus measurement 2. Using Excel, calculate the correlation coefficient. The more highly correlated the two measures are, the more reliable the measure. What are some reasons that the two measures might not be exactly the same?
- Validity exercise:
What are the advantages and disadvantages of using the NEWS-Y versus the walkability checklist?

Critical Thinking Questions

- What are some ways that the reliability of a measurement tool can be improved? Is training of the individuals who will be making the measurements important?
- Discuss how the walkability checklist could be validated by comparing walkability checklist scores to the NEWS-Y scores in various communities. What kinds of

communities would you want to study (similar or different communities)?

- Based on what you considered about your community when completing the NEWS-Y and the walkability checklist, what things could be changed in your community to improve its walkability? Do you think people would walk more if these changes were made?

Teacher Notes

You can calculate the score on the NEWS-Y using instructions available at http://sallis.ucsd.edu/Documents/Measures_documents/NEWS_Y_scoring.pdf. This calculation is rather complicated but would definitely illustrate the point of how complex validated clinical trial measures can be.

Safety Notes

Make sure all students are following proper classroom safety guidelines. When walking outside of the classroom, follow guidelines appropriate for physical education safety.

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 physical activities presented in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** can be used to create a community plan to improve walkability and provide options for increased physical activity.

Background Information and Resources

An important aspect of clinical research studies is the selection of the outcome (also called the study endpoint) that will be measured in the study. The outcome is the construct that the study is attempting to understand or affect. Examples of study outcomes include body mass index (BMI), level of physical activity, food choices, or having a diagnosis of diabetes. In the process of designing a clinical study, the method that will be used to measure the outcome must be selected from measures already reported in the scientific literature, or a new method must be developed.

Some of the important considerations in the selection of a measurement tool are the validity, reliability, and feasibility of the measure for a study. Reliability, or consistency of the measure, refers to whether using the measurement tool generates the same results when used under similar circumstances. Validity refers to whether the measurement tool actually measures what it intends to measure. A measurement tool can be valid (measures what we think it measures), but not reliable. It can also be reliable (measures consistently), but not valid. The reliability and validity of existing measures are often published in the scientific literature. If a new method of measurement of an outcome is proposed, then it is important to establish this measure's reliability and validity. Feasibility of a measure indicates whether it is practical (easy to use, affordable, etc.) to use in a particular study population or setting. Choosing an outcome measure and considering its validity, reliability, and feasibility is part of the information gathering and synthesis needed to design a clinical study.

“Walkable community” is a concept indicating how friendly a community or neighborhood is to walking. Communities around the world are considering ways to increase walkability as a way to improve the health and well-being of the community (www.walkscore.com). Some of the factors that influence the walkability of a neighborhood include availability of sidewalks, level of traffic, and safety. Several tools or processes have been used to measure walkability. Some of these include counting the number of people walking in a given area during a period of time, using a standard scoring process such as the Walkability Checklist (<http://www.walkableamerica.org/checklist-walkability.pdf>), or using a validated rating scale such as the Neighborhood Environment Walkability Scale – Youth (NEWS-Y) (http://sallis.ucsd.edu/Documents/Measures_documents/NEWS_Y_adolescent.pdf).

Walkability has been shown to correlate with BMI and measures of physical activity as well (Frank et al. 2005). The Center for Disease Control (<http://www.cdc.gov/physicalactivity/basics/adults/>) advises at least 2.5 hours of walking per week for adults to reduce the risk of obesity and the resulting health conditions such as cardiovascular disease, diabetes, hypertension, high cholesterol, stroke, cancer, and depression. Children and adolescents should have one hour or more of physical activity per day. In a walkable community, it is easier to accumulate the recommended minutes of walking per week while carrying out daily tasks such as going to and from school or running errands.

University of California, San Diego: James F. Sallis, Ph.D.

<http://sallis.ucsd.edu/index.html>

Dr. Sallis maintains a number of resources related to walkability and physical activity on his website. His current projects can be accessed via the links at the bottom of the page.

“How Neighborhood Design and Recreation Environments Affect Physical Activity in Youth”

<http://videos.med.wisc.edu/videos/1689>

This presentation by Dr. James F. Sallis can be used to introduce “walkability.”

Neighborhood Environment Walkability Scale – Youth (NEWS-Y)

http://sallis.ucsd.edu/Documents/Measures_documents/NEWS_Y_adolescent.pdf

This validated rating scale was developed by Dr. Sallis to measure community walkability from an adolescent perspective.

Center for Disease Control and Prevention: How much physical activity do you need?

<http://www.cdc.gov/physicalactivity/everyone/guidelines/>

This site provides recommendations for physical activity that are based on the 2008 Physical Activity Guidelines for Americans. Recommendations are provided for different age categories.

Walk Score

www.walkscore.com

This site provides information about neighborhood walkability and a directory of scores for various cities and communities throughout the United States.

Frommers: World’s Most Walkable Cities

<http://www.frommers.com/slideshows/819366-the-world-s-most-walkable-cities#sthash.uOnzTCEJ.dpbs>

This site provides information about the most walkable communities around the world.

Virginia Safe Routes to School Program

http://www.virginiadot.org/programs/ted_Rt2_school_pro.asp

This website, from the Virginia Department of Transportation (VDOT), provides resources to help schools and communities create and maintain Safe Routes to School (SRTS) programs. These programs are designed to encourage children and youth to increase physical activity by providing safe routes for walking and biking.

Extensions

Classroom

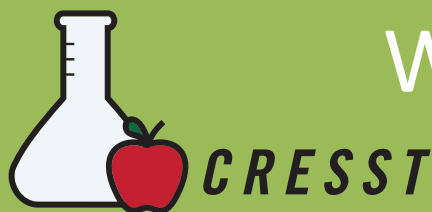
For additional data collection and analysis experience, have each student complete the walkability checklist for the neighborhood around his or her home. Next, have students wear a pedometer for a whole day to count the steps that they walk. Each student enters his or her data into a class spreadsheet in Excel (Column 1 = student ID, Column 2 = walkability checklist score, Column 3 = pedometer number of steps in a day, with one row for each student). Use Excel to plot the checklist score versus number of steps. Are they correlated? How might the measures of walkability be similar and different from one another?

Cross-Curricular

Mathematics: Coordinate with mathematics teachers so that the students can complete the graphs and graph analyses in mathematics class.

Language Arts: In language arts class, the students can complete a report or presentation of suggestions to improve walkability in the school community.

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.



What's On Your Plate?

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Revised February 2016

Introduction

Energy balance, the relationship between Calories consumed and the Calories used by an individual to meet his or her daily energy requirement, is critical to healthy weight maintenance. To successfully lose weight, individuals must increase physical activity and reduce Calorie consumption. Many online Calorie counting sites use data provided by users. In some cases, this data is inaccurate or misleading. It is important that Calorie estimates from credible resources are used to create and maintain a sustainable dietary plan.

Purpose

In this lesson, students will study the benefits of using credible resources to assist with monitoring food intake, setting realistic goals, and improving healthy eating habits. They will explore interactive websites and resources in order to create a healthier meal plan and monitor food intake. Students will discuss concepts associated with the reliability and validity of their measurements.

Objectives

In this lesson, students will:

- Monitor food intake over a specified period of time
- Analyze nutritional values of their food intake
- Distinguish between scales of measurement
- Understand concepts relating to the credibility of measurement, specifically reliability and validity
- Develop a plan to enhance healthy eating habits

Key Terms

- 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.
- Interval scale: level of measurement in which there are equal intervals between numbers, the “zero point” is arbitrary and negative numbers can be used (e.g., temperature)
- Nominal scale: level of measurement, with no implied order, in which names or labels are used for certain characteristics (e.g., male and female)
- Ordinal scale: level of measurement in which categories are ordered, but there is no measure of the degree of difference between categories (e.g., the results of a horse race: first place, second place, third place, etc.)
- Ratio scale: level of measurement in which ratios can be used in comparing scores, and it is possible to measure a true zero point (e.g., weight)
- Reliability: The extent to which a test, device, or tool gives the same results in repeated measures under similar circumstances
- Validity: the extent to which inferences based on scores are appropriate and meaningful

National and State Standards

National

Next Generation Science Standards:

Disciplinary Core Ideas LS1.C

Crosscutting Concepts 2, 3, 4, 5

Science and Engineering Practices 4, 5, 6, 8

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

Essential Features of Classroom Inquiry 2

National Standards for Health: Standards 1, 2, 3, 4, 6

Virginia

Science 6.1 b, e, f, LS.1 e PS.1g–k BIO.1 a, e, f

Health: 6.1 b, 6.2 a, 6.3 a, 7.1 e, 7.2 e, 8.3 e, 9.1 b, c, 9.2 c, f, 9.3 a, b, 10.1 b, 10.2 b, 10.3 a, b

Physical Education: 7.3 d, 7.5 a, 8.4 a, b, c, 8.5 b, 9.3 a, 10.5 a



Materials

- Internet access
- Laptop LCD projector

Procedures

Day 1:

1. Visit www.choosemyplate.gov and review the new USDA “Choose My Plate” guidelines with the students.
2. Explain procedures for itemizing today’s food consumption using the attached Food Intake Record.
 - a. Direct students to write down what they have eaten so far during Day 1 and continue through the end of the day.
 - b. Remind students to bring their completed Food Intake Record to the next class.

Day 2:

1. Explain how to access Food-A-Pedia (<https://www.supertracker.usda.gov/foodapedia.aspx>) or a similar website.
2. Ask students to look up and record the caloric values for the food items in their logs.
3. Create a sample meal description (for example: a peanut butter and jelly sandwich with a glass of milk) that you will describe to the class. This description should not include specific details about serving size, food brands, etc. Have all students calculate the total caloric value of this meal.
4. Ask students to share the total caloric value they calculated for the sample meal described in step 3.
5. Prompt a classroom discussion about reasons for differences in the students’ total values by asking them why they think they might have calculated different caloric values for the same meal. Consider different interpretations of portion size, type of bread, etc.

Day 3:

1. Explain how to access the USDA SuperTracker Food Tracker (<https://www.supertracker.usda.gov/foodtracker.aspx>).
2. Have the students enter food items from Day 1’s Food Intake Record in the Food Tracker and click on the “Nutrient Intake Report” link to compare their nutrient and caloric intake to the target values in the report.

3. Ask students to write a summary of their personal findings related to their eating habits including three healthy suggestions to improve their own food choices.
4. Assign homework: The students will write a personal meal plan based on the USDA SuperTracker Food Tracker recommendations using a blank Food Intake Record.
5. Collect the revised meal plan and summary.
6. Assess summary and provide feedback as needed.

Observations and/or Data

- Observed eating habits will be recorded using the Food Intake Record sheets.

Analysis and Conclusions

- Did everyone calculate the same values for the sample meal?
- What factors may have contributed to any differences?
 - How might these differences influence an individual's health?
- How could we redesign this activity to improve the reliability of our results?
- What are the basic food groups?
- What are some of the features or characteristics of a healthy meal plan?
- Which food group(s) should be eaten in moderation?

Critical Thinking Question

- Which is more important, validity or reliability? (Hint: This is a challenging question. Scores must be reliable in order to be valid.)

Teacher Notes

When discussing healthy eating, it is important to gather information from students about their preconceived ideas of healthy habits. The students should have a general understanding of the basic food groups. Background information about basic food groups and the USDA's "Choose My Plate" guidelines are available at www.choosemyplate.gov.

The students should also be familiar with serving size. Serving size is a standardized amount of a food used to compare similar foods. It is usually listed in common measurements, such as 1 cup or 1 ounce. Often, the serving size differs from the contents of the food package. For example, one serving of soda equals one cup (eight fluid ounces); however, the typical can of soda contains 12 fluid ounces. Thus, a can of soda is usually 1.5 serving sizes.



Preview the YouTube video (<http://www.youtube.com/watch?v=dZ49FuUpxnE>) and written guide (<https://www.supertracker.usda.gov/userguide.aspx>), and familiarize students with Food-A-Pedia at <https://www.supertracker.usda.gov/foodapedia.aspx>.

Safety Notes

Make sure all students are following proper classroom safety guidelines.

Background Information and Resources

Every five years, U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) publish the Dietary Guidelines for Americans. The 2015-2020 Dietary Guidelines for Americans is the 8th edition. Building on the previous editions, these guidelines focus on eating patterns in addition to Calorie and nutrition recommendations and emphasize the importance of physical activity. The new guidelines are found at www.choosemyplate.gov.

USDA SuperTracker Help

<https://www.supertracker.usda.gov/help.aspx>

This webpage provides a user guide and site video tours to help you and your students navigate and use the SuperTracker tools.

USDA: Choose My Plate

<http://www.choosemyplate.gov>

This site provides a wealth of information, tools, and background information related to the current USDA Dietary Guidelines for Americans.

USDA Choose My Plate: Printable Materials

<http://www.choosemyplate.gov/printable-materials>

This website includes a number of printable resources and activities to support nutrition instructions. Some recommended items from this list are:

Getting Started with My Plate

Calorie Balance Handout

Recipes from Create Healthy, Active Celebrations

SuperTracker and other tools, this includes a SuperTracker Scavenger Hunt to help introduce the students SuperTracker tool

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.

Extensions

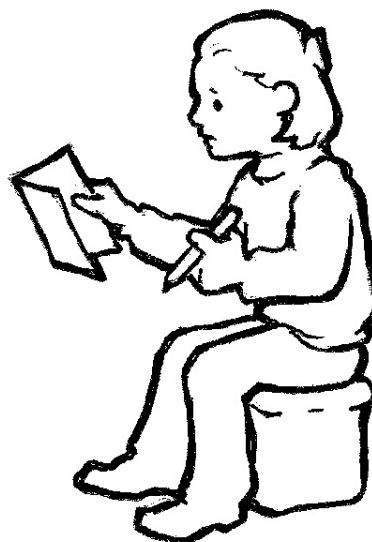
Classroom

Students can utilize the two worksheets in this lesson, as well as visit PBSKIDS: Food Smarts: Understanding Food Labels (<http://pbskids.org/itsmylife/body/foodsmarts/article4.html>) to learn about food labels and use a Calorie counting site to determine the caloric/nutritional values of the foods they have at home. Then, they can then make a daily/weekly food plan, possibly discussing the exercise with their parents and choosing healthy substitutes for future grocery shopping.

Cross-Curricular

Language Arts: In language arts class, students can complete a report or presentation highlighting the benefits of including certain types of food in a daily meal plan.

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



Name: _____

Food Intake Record

For (date): _____

Record the food that you have eaten today, starting with breakfast, then continue to record what you eat for the rest of the day. Try to be as accurate as possible with the type of food eaten and the amounts. List each food separately.

For example: a peanut butter and jelly sandwich would be listed as follows:

Meal	Food	Amount	Food Group	Servings
Lunch	<i>Peanut Butter</i>	<i>2 tablespoons</i>	<i>Meat</i>	<i>2</i>
	<i>Jelly</i>	<i>2 tablespoons</i>	<i>FOF</i>	<i>2</i>
	<i>Bread-white</i>	<i>2 slices</i>	<i>Breads, Cereals, Pasta</i>	<i>2</i>
	<i>Milk</i>	<i>1 cup</i>	<i>Dairy</i>	<i>1</i>
	<i>Apple</i>	<i>1 medium</i>	<i>Fruit</i>	<i>1</i>

Meal	Food	Amount	Food Group	Servings
Breakfast				
Lunch				
Dinner				
Snack				



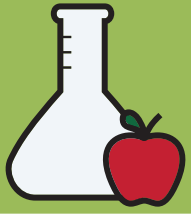
Name: _____

Peer Review Checklist

Record your nutrient intake in the column title “Yours” using the SuperTracker Food Tracker Nutrient Intake Report page.

Have your partner place a checkmark in the column title “Minimum Requirements” if you met the minimum requirements.

Nutrient	Recommended	Yours	Minimum Requirements
Calories (kcal)	2200		
Protein (g)	50 g		
Carbohydrates (g)	300 g		
Dietary Fiber(g)	25 g		
Total Fat(g)	No more than 30% of total calories		
Saturated Fat (g)	No more than 10% of total calories		
Cholesterol (mg)	300 mg		
Vitamin A (RE)	700 RE		
Vitamin C (mg)	75 mg		
Calcium (mg)	1200 mg		
Iron (mg)	8 mg		
Sodium (mg)	<=2400 mg		



Appendix A: National Standards

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Science

The Next Generation Science Standards (NGSS)

<http://ngss.nsta.org/AccessStandardsByTopic.aspx>

The NGSS integrate three dimensions within each standard. These dimensions are Practices, Disciplinary Core Ideas, and Crosscutting Concepts.

Disciplinary Core Ideas in the Life Sciences

<http://ngss.nsta.org/DisciplinaryCoreIdeasMid.aspx?id=2>

Based on the National Research Council's Framework for K–12 Science Education Disciplinary Core Ideas are important, central concepts in each of four domains: physical sciences, life sciences, Earth and space sciences, and engineering, technology, and applications of science. The CRESST Curriculum aligns with the life science domain.

LS1: From Molecules to Organisms: Structures and Processes

LS1.A: Structure and Function

LS1.B: Growth and Development of Organisms

LS1.C: Organization for Matter and Energy Flow in Organisms

LS1.D: Information Processing

LS2: Ecosystems: Interactions, Energy, and Dynamics

LS2.A: Interdependent Relationships in Ecosystems

LS2.B: Cycles of Matter and Energy Transfer in Ecosystems

LS2.C: Ecosystem Dynamics, Functioning, and Resilience

LS2.D: Social Interactions and Group Behavior

LS3: Heredity: Inheritance and Variation of Traits

LS3.A: Inheritance of Traits

LS3.B: Variation of Traits

LS4: Biological Evolution: Unity and Diversity

LS4.A: Evidence of Common Ancestry and Diversity

LS4.B: Natural Selection

LS4.C: Adaptation

Crosscutting Concepts <http://ngss.nsta.org/CrosscuttingConceptsFull.aspx>

These concepts help the students understand and connect scientific and engineering knowledge across disciplines and grade levels. They also provide a structure for interrelating knowledge from various science fields into a coherent and scientifically based view of the world.

CC1. Patterns: Observed patterns in nature guide organization and classification and prompt questions about relationships and causes underlying them.

CC2. Cause and Effect: Events have causes, sometimes simple, sometimes multifaceted. Deciphering causal relationships, and the mechanisms by which they are mediated, is a major activity of science and engineering.

CC3. Scale, Proportion, and Quantity: In considering phenomena, it is critical to recognize what is relevant at different size, time, and energy scales, and to recognize proportional relationships between different quantities as scales change.

CC4. Systems and System Models: A system is an organized group of related objects or components; models can be used for understanding and predicting the behavior of systems.

CC5. Energy and Matter: Tracking energy and matter flows, into, out of, and within systems helps one understand their system's behavior.

CC6. Structure and Function: The way an object is shaped or structured determines many of its properties and functions.

CC7. Stability and Change: For both designed and natural systems, conditions that affect stability and factors that control rates of change are critical elements to consider and understand.

Science and Engineering Practices

http://instahosted.org/pdfs/ngss/20130509/AppendixF-ScienceAndEngineeringPracticesInTheNGSS_0.pdf

These statements are grouped into the eight categories and explain the science and engineering practices that are important at each grade level. These practices help students develop a better understanding of how knowledge develops in science and engineering. They also help students understand that science and engineering are not limited to one approach.

SEP1. Asking questions (science) and defining problems (engineering)

SEP2. Developing and using models

SEP3. Planning and carrying out investigations

SEP4. Analyzing and interpreting data

SEP5. Using mathematics and computational thinking

SEP6. Constructing explanations (science) and designing solutions (engineering)

SEP7. Engaging in argument from evidence

SEP8. Obtaining, evaluating, and communicating information

Nature of Science <http://ngss.nsta.org/NSConnectionsFull.aspx>

The NGSS also recognizes the important of the Nature of Science, the characteristics of science that should be understood by all citizens. The NGSS includes eight statements related to the Nature of Science that support a great understanding of “how science is done.”

NOS1. Scientific Investigations Use a Variety of Methods

NOS2. Scientific Knowledge is Based on Empirical Evidence

NOS3. Scientific Knowledge is Open to Revision in Light of New Evidence

NOS4. Scientific Models, Laws, Mechanisms, and Theories Explain
Natural Phenomena

NOS5. Science is a Way of Knowing

NOS6. Scientific Knowledge Assumes an Order and Consistency in
Natural Systems

NOS7. Science is a Human Endeavor

NOS8. Science Addresses Questions About the Natural and Material World

Essential Features of Classroom Inquiry

<http://www.nap.edu/read/9596/chapter/3#29>

The National Science Education Standards (NSES) developed by the National Research Council and published in 1996, included inquiry as both a learning goal and as a teaching method. The NSES emphasized five essential features of classroom inquiry that apply across all grade levels and continue to be a valuable tool to engage students in authentic science experiences.

EFCI1. Learner engages in scientifically oriented questions

EFCI2. Learner gives priority to evidence in responding to questions

EFCI3. Learner formulates explanations from evidence

EFCI4. Learner connects explanations to scientific knowledge

EFCI5. Learner communicates and justifies explanations



Health and Physical Education

The National Health Education Standards (NHES)

<http://www.shapeamerica.org/standards/health/>

The NHES, developed by the Joint Committee on National Health Education Standards, are designed to provide students with the knowledge and skills to make informed health-related decisions for themselves and their community.

NHES1: Students will comprehend concepts related to health promotion and disease prevention to enhance health.

NHES2: Students will analyze the influence of family, peers, culture, media, technology, and other factors on health behaviors.

NHES3: Students will demonstrate the ability to access valid information and products and services to enhance health.

NHES4: Students will demonstrate the ability to use interpersonal communication skills to enhance health and avoid or reduce health risks.

NHES5: Students will demonstrate the ability to use decision-making skills to enhance health.

NHES6: Students will demonstrate the ability to use goal-setting skills to enhance health.

NHES7: Students will demonstrate the ability to practice health-enhancing behaviors and avoid or reduce health risks.

NHES8: Students will demonstrate the ability to advocate for personal, family, and community health.

The National Physical Education Standards (NPES)

<http://www.shapeamerica.org/standards/pe/index.cfm>

SHAPE America's NPES provide guidelines to assist schools and school systems in developing quality physical education programs. The goal of these standards is to provide individuals with the knowledge and skills to engage in healthy and safe physical activity throughout their lives.

NPES1 The physically literate individual demonstrates competency in a variety of motor skills and movement patterns.

NPES2 The physically literate individual applies knowledge of concepts, principles, strategies and tactics related to movement and performance.

NPES3 The physically literate individual demonstrates the knowledge and skills to achieve and maintain a health-enhancing level of physical activity and fitness.

NPES4 The physically literate individual exhibits responsible personal and social behavior that respects self and others.

NPES5 The physically literate individual recognizes the value of physical activity for health, enjoyment, challenge, self-expression and/or social interaction.

The charts on the following pages identify how each of the CRESST Curriculum activities aligns with these national standards.

The Next Generation Science Standards

Disciplinary Core Ideas

Activity Title	LS1.A	LS1.B	LS1.C	LS1.D	LS3.A	LS3.B
THE BASICS OF RESEARCH						
The Science of Biology						
The Clinical Research Process		X				
It's All About You: A Clinical Research Simulation		X				
A Matter of Taste			X	X	X	X
INFORMATION GATHERING AND SYNTHESIS						
Fit or Fat? Fit and Fat?						
Am I Full Yet?	X	X		X		X
Team Science: Inquiry into Healthy Habits						
ETHICAL ISSUES IN CLINICAL RESEARCH						
Ethical Scenarios Carousel						
History of Ethical Guidelines and Requirements						
Ethical Controversies: Debating the Pros and Cons						
Bioethics: Standards for Scientists						
COLLECTING AND ANALYZING DATA						
Numbers Can Talk: Measuring and Exploring Statistical Data						
Let's Work It Out			X			
Walkable Communities: Exploring Measurement, Reliability and Validity						
What's On Your Plate?			X			

The Next Generation Science Standards

Crosscutting Concepts

Activity Title	CC1	CC2	CC3	CC4	CC5	CC6	CC7
THE BASICS OF RESEARCH							
The Science of Biology		X					
The Clinical Research Process		X			X		X
It's All About You: A Clinical Research Simulation		X					X
A Matter of Taste		X		X		X	
INFORMATION GATHERING AND SYNTHESIS							
Fit or Fat? Fit and Fat?		X					
Am I Full Yet?		X	X	X	X		X
Team Science: Inquiry into Healthy Habits		X					
ETHICAL ISSUES IN CLINICAL RESEARCH							
Ethical Scenarios Carousel		X					
History of Ethical Guidelines and Requirements		X					
Ethical Controversies: Debating the Pros and Cons		X					
Bioethics: Standards for Scientists		X					
COLLECTING AND ANALYZING DATA							
Numbers Can Talk: Measuring and Exploring Statistical Data	X	X					
Let's Work It Out		X	X		X		
Walkable Communities: Exploring Measurement, Reliability and Validity			X		X		
What's On Your Plate?		X	X	X	X		

The Next Generation Science Standards

Science and Engineering Practices

<i>Activity Title</i>	SEP1	SEP2	SEP3	SEP4	SEP5	SEP6	SEP7	SEP8
THE BASICS OF RESEARCH								
The Science of Biology	X		X		X			X
The Clinical Research Process	X	X	X	X	X			X
It's All About You: A Clinical Research Simulation	X		X	X		X		X
A Matter of Taste			X			X		X
INFORMATION GATHERING AND SYNTHESIS								
Fit or Fat? Fit and Fat?	X			X	X			X
Am I Full Yet?		X	X	X		X	X	X
Team Science: Inquiry into Healthy Habits			X	X	X	X		X
ETHICAL ISSUES IN CLINICAL RESEARCH								
Ethical Scenarios Carousel			X			X	X	X
History of Ethical Guidelines and Requirements			X			X	X	X
Ethical Controversies: Debating the Pros and Cons			X			X	X	X
Bioethics: Standards for Scientists			X			X	X	X
COLLECTING AND ANALYZING DATA								
Numbers Can Talk: Measuring and Exploring Statistical Data				X	X	X		X
Let's Work It Out					X			X
Walkable Communities: Exploring Measurement, Reliability and Validity			X	X	X	X		X
What's On Your Plate?				X	X	X		X

The Next Generation Science Standards

The Nature of Science

<i>Activity Title</i>	NOS1	NOS2	NOS3	NOS4	NOS5	NOS6	NOS7	NOS8
THE BASICS OF RESEARCH								
The Science of Biology	X	X		X	X		X	X
The Clinical Research Process	X	X	X		X	X	X	X
It's All About You: A Clinical Research Simulation	X	X	X		X		X	X
A Matter of Taste	X				X		X	X
INFORMATION GATHERING AND SYNTHESIS								
Fit or Fat? Fit and Fat?	X		X		X		X	X
Am I Full Yet?	X	X	X	X	X	X	X	X
Team Science: Inquiry into Healthy Habits	X	X	X		X		X	X
ETHICAL ISSUES IN CLINICAL RESEARCH								
Ethical Scenarios Carousel	X		X		X		X	X
History of Ethical Guidelines and Requirements	X		X		X		X	X
Ethical Controversies: Debating the Pros and Cons	X		X		X		X	X
Bioethics: Standards for Scientists	X		X		X		X	X
COLLECTING AND ANALYZING DATA								
Numbers Can Talk: Measuring and Exploring Statistical Data	X	X			X		X	X
Let's Work It Out	X		X		X		X	X
Walkable Communities: Exploring Measurement, Reliability and Validity	X	X	X		X		X	X
What's On Your Plate?	X	X	X		X	X	X	X

The Essential Features of Inquiry

<i>Activity Title</i>	EF/C1	EF/C2	EF/C3	EF/C4	EF/C5
THE BASICS OF RESEARCH					
The Science of Biology					
The Clinical Research Process	X	X	X		
It's All About You: A Clinical Research Simulation	X	X	X	X	X
A Matter of Taste	X	X			
INFORMATION GATHERING AND SYNTHESIS					
Fit or Fat? Fit and Fat?	X	X	X	X	X
Am I Full Yet?	X	X	X	X	X
Team Science: Inquiry into Healthy Habits	X	X	X	X	X
ETHICAL ISSUES IN CLINICAL RESEARCH					
Ethical Scenarios Carousel			X	X	X
History of Ethical Guidelines and Requirements					
Ethical Controversies: Debating the Pros and Cons			X	X	X
Bioethics: Standards for Scientists			X	X	X
COLLECTING AND ANALYZING DATA					
Numbers Can Talk: Measuring and Exploring Statistical Data	X	X	X	X	X
Let's Work It Out	X	X	X		X
Walkable Communities: Exploring Measurement, Reliability and Validity	X	X	X	X	X
What's On Your Plate?		X			

National Health Education Standards

Activity Title	NHES1	NHES2	NHES3	NHES4	NHES5	NHES6	NHES7	NHES8
THE BASICS OF RESEARCH								
The Science of Biology	X	X	X	X	X	X	X	X
The Clinical Research Process	X	X	X	X	X	X	X	X
It's All About You: A Clinical Research Simulation	X	X	X	X	X	X	X	X
A Matter of Taste	X	X	X	X	X	X	X	X
INFORMATION GATHERING AND SYNTHESIS								
Fit or Fat? Fit and Fat?	X	X	X	X	X	X	X	X
Am I Full Yet?	X	X	X	X	X	X	X	X
Team Science: Inquiry into Healthy Habits	X	X	X	X	X	X	X	X
ETHICAL ISSUES IN CLINICAL RESEARCH								
Ethical Scenarios Carousel	X	X	X	X	X	X	X	
History of Ethical Guidelines and Requirements	X	X	X	X	X	X	X	X
Ethical Controversies: Debating the Pros and Cons	X	X	X	X	X	X	X	X
Bioethics: Standards for Scientists	X	X	X	X	X	X	X	X
COLLECTING AND ANALYZING DATA								
Numbers Can Talk: Measuring and Exploring Statistical Data	X	X	X	X	X	X	X	X
Let's Work It Out	X	X	X	X	X	X	X	
Walkable Communities: Exploring Measurement, Reliability and Validity	X	X	X	X	X	X	X	X
What's On Your Plate?	X	X	X	X		X		

National Physical Education Standards

Activity Title	NPES3	NPES4	NPES5
THE BASICS OF RESEARCH			
The Science of Biology	X	X	X
The Clinical Research Process	X	X	X
It's All About You: A Clinical Research Simulation	X	X	X
A Matter of Taste	X	X	X
INFORMATION GATHERING AND SYNTHESIS			
Fit or Fat? Fit and Fat?	X	X	X
Am I Full Yet?	X	X	X
Team Science: Inquiry into Healthy Habits	X	X	X
ETHICAL ISSUES IN CLINICAL RESEARCH			
Ethical Scenarios Carousel	X	X	X
History of Ethical Guidelines and Requirements	X	X	X
Ethical Controversies: Debating the Pros and Cons	X	X	X
Bioethics: Standards for Scientists	X	X	X
COLLECTING AND ANALYZING DATA			
Numbers Can Talk: Measuring and Exploring Statistical Data			
Let's Work It Out	X	X	X
Walkable Communities: Exploring Measurement, Reliability and Validity	X	X	
What's On Your Plate?			

CRESST Curriculum Standards Alignment



Appendix B: Virginia Standards of Learning

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Revised February 2016

The Standards of Learning for Virginia Public Schools provide knowledge and performance expectations for each course or grade level. These standards are periodically reviewed and revised.

The charts on the following pages identify how each of the CRESST Curriculum activities aligns with the following standards:

Science Standards of Learning, Adopted January 2010

http://www.doe.virginia.gov/testing/sol/standards_docs/science/2010/complete/stds_all_science.pdf

Health Education Standards of Learning, Adopted January 2015

http://www.doe.virginia.gov/testing/sol/standards_docs/health/2015/stds_2015_health.pdf

Physical Education Standards of Learning, Adopted January 2015

http://www.doe.virginia.gov/testing/sol/standards_docs/physical_education/2015/stds_2015_physed.pdf

Virginia Standards of Learning

Middle and High School Science

Activity Title	6.1	LS.1	LS.3	PS.1	BIO.1	BIO.2	BIO.3	BIO.4	CH.1
THE BASICS OF RESEARCH									
The Science of Biology		X			X				
The Clinical Research Process	X	X		X	X				
It's All About You: A Clinical Research Simulation	X	X		X	X				X
A Matter of Taste	X	X		X	X				
INFORMATION GATHERING AND SYNTHESIS									
Fit or Fat? Fit and Fat?	X	X			X				
Am I Full Yet?	X	X	X		X				
Team Science: Inquiry into Healthy Habits	X	X	X		X	X			
ETHICAL ISSUES IN CLINICAL RESEARCH									
Ethical Scenarios Carousel		X							
History of Ethical Guidelines and Requirements		X							
Ethical Controversies: Debating the Pros and Cons		X			X				
Bioethics: Standards for Scientists		X			X				
COLLECTING AND ANALYZING DATA									
Numbers Can Talk: Measuring and Exploring Statistical Data					X	X	X	X	
Let's Work It Out	X	X		X	X				
Walkable Communities: Exploring Measurement Reliability and Validity	X	X		X	X				
What's On Your Plate?	X	X		X	X				

Virginia Standards of Learning

Middle School Health

Activity Title	6.1	6.2	6.3	7.1	7.2	7.3	8.1	8.2	8.3
THE BASICS OF RESEARCH									
The Science of Biology	X								
The Clinical Research Process	X								
It's All About You: A Clinical Research Simulation		X	X	X	X				
A Matter of Taste	X								
INFORMATION GATHERING AND SYNTHESIS									
Fit or Fat? Fit and Fat?	X	X	X	X	X	X	X	X	X
Am I Full Yet?									
Team Science: Inquiry into Healthy Habits	X	X	X	X	X	X		X	X
ETHICAL ISSUES IN CLINICAL RESEARCH									
Ethical Scenarios Carousel							X	X	X
History of Ethical Guidelines and Requirements							X	X	X
Ethical Controversies: Debating the Pros and Cons									
Bioethics: Standards for Scientists									
COLLECTING AND ANALYZING DATA									
Numbers Can Talk: Measuring and Exploring Statistical Data						X			
Let's Work It Out		X	X	X	X	X	X	X	X
Walkable Communities: Exploring Measurement Reliability and Validity	X	X	X	X	X	X	X	X	X
What's On Your Plate?	X	X	X	X	X				X

Virginia Standards of Learning

High School Health

Activity Title	9.1	9.2	9.3	10.1	10.2	10.3
THE BASICS OF RESEARCH						
The Science of Biology	X		X			
The Clinical Research Process						
It's All About You: A Clinical Research Simulation				X		
A Matter of Taste						
INFORMATION GATHERING AND SYNTHESIS						
Fit or Fat? Fit and Fat?		X		X		
Am I Full Yet?						
Team Science: Inquiry into Healthy Habits		X		X	X	X
ETHICAL ISSUES IN CLINICAL RESEARCH						
Ethical Scenarios Carousel						
History of Ethical Guidelines and Requirements						
Ethical Controversies: Debating the Pros and Cons	X	X	X			
Bioethics: Standards for Scientists	X	X	X			
COLLECTING AND ANALYZING DATA						
Numbers Can Talk: Measuring and Exploring Statistical Data	X	X	X	X	X	
Let's Work It Out	X	X	X	X	X	X
Walkable Communities: Exploring Measurement Reliability and Validity	X	X	X	X	X	X
What's On Your Plate?	X	X	X	X	X	X

Virginia Standards of Learning

Middle School Physical Education

Activity Title	6.2	6.3	6.4	6.5	7.2	7.3	7.4	7.5
THE BASICS OF RESEARCH								
The Science of Biology						X		
The Clinical Research Process								
It's All About You: A Clinical Research Simulation				X		X		
A Matter of Taste								
INFORMATION GATHERING AND SYNTHESIS								
Fit or Fat? Fit and Fat?		X		X		X		X
Am I Full Yet?								
Team Science: Inquiry into Healthy Habits		X		X		X		X
ETHICAL ISSUES IN CLINICAL RESEARCH								
Ethical Scenarios Carousel							X	
History of Ethical Guidelines and Requirements							X	
Ethical Controversies: Debating the Pros and Cons							X	
Bioethics: Standards for Scientists							X	
COLLECTING AND ANALYZING DATA								
Numbers Can Talk: Measuring and Exploring Statistical Data								
Let's Work It Out	X	X		X	X	X		X
Walkable Communities: Exploring Measurement Reliability and Validity			X	X	X	X	X	X
What's On Your Plate?						X		X

Virginia Standards of Learning Middle School Physical Education (continued)

Activity Title	8.2	8.3	8.4	8.5
THE BASICS OF RESEARCH				
The Science of Biology				
The Clinical Research Process				
It's All About You: A Clinical Research Simulation		X		X
A Matter of Taste				
INFORMATION GATHERING AND SYNTHESIS				
Fit or Fat? Fit and Fat?		X		X
Am I Full Yet?				
Team Science: Inquiry into Healthy Habits				X
ETHICAL ISSUES IN CLINICAL RESEARCH				
Ethical Scenarios Carousel				
History of Ethical Guidelines and Requirements				
Ethical Controversies: Debating the Pros and Cons				
Bioethics: Standards for Scientists				
COLLECTING AND ANALYZING DATA				
Numbers Can Talk: Measuring and Exploring Statistical Data				
Let's Work It Out		X	X	X
Walkable Communities: Exploring Measurement Reliability and Validity	X			X
What's On Your Plate?			X	X

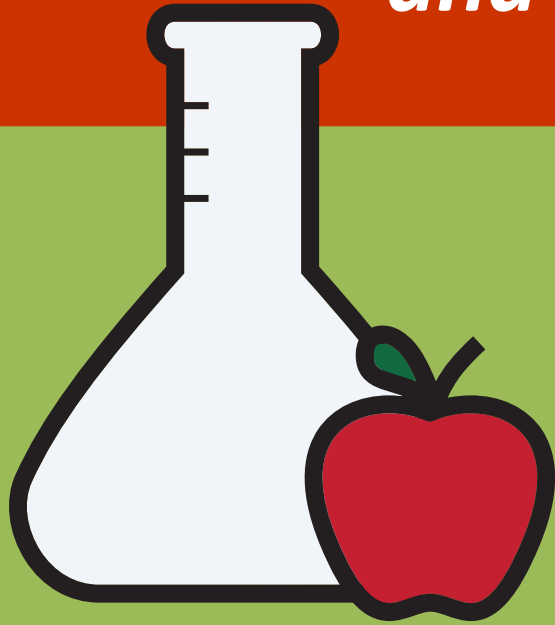
Virginia Standards of Learning High School Physical Education

Activity Title	9.1	9.2	9.3	9.5	10.1	10.2	10.3	10.4	10.5
THE BASICS OF RESEARCH									
The Science of Biology									
The Clinical Research Process									
It's All About You: A Clinical Research Simulation									
A Matter of Taste									
INFORMATION GATHERING AND SYNTHESIS									
Fit or Fat? Fit and Fat?				X					X
Am I Full Yet?									
Team Science: Inquiry into Healthy Habits				X					X
ETHICAL ISSUES IN CLINICAL RESEARCH									
Ethical Scenarios Carousel									
History of Ethical Guidelines and Requirements									
Ethical Controversies: Debating the Pros and Cons									
Bioethics: Standards for Scientists									
COLLECTING AND ANALYZING DATA									
Numbers Can Talk: Measuring and Exploring Statistical Data		X	X	X		X	X		X
Let's Work It Out		X	X	X		X	X		X
Walkable Communities: Exploring Measurement Reliability and Validity	X	X		X	X	X		X	X
What's On Your Plate?			X						X

Virginia Standards of Learning High School Physical Education (continued)

Activity Title	11/12.2	11/12.3	11/12.5
THE BASICS OF RESEARCH			
The Science of Biology			
The Clinical Research Process			
It's All About You: A Clinical Research Simulation			
A Matter of Taste			
INFORMATION GATHERING AND SYNTHESIS			
Fit or Fat? Fit and Fat?			
Am I Full Yet?			
Team Science: Inquiry into Healthy Habits			
ETHICAL ISSUES IN CLINICAL RESEARCH			
Ethical Scenarios Carousel			
History of Ethical Guidelines and Requirements			
Ethical Controversies: Debating the Pros and Cons			
Bioethics: Standards for Scientists			
COLLECTING AND ANALYZING DATA			
Numbers Can Talk: Measuring and Exploring Statistical Data			
Let's Work It Out	X	X	X
Walkable Communities: Exploring Measurement Reliability and Validity		X	X
What's On Your Plate?			

*Clinical Research Education
for
Secondary Students
and Teachers*



CRESST

Video Guide



VCU

Make it real.

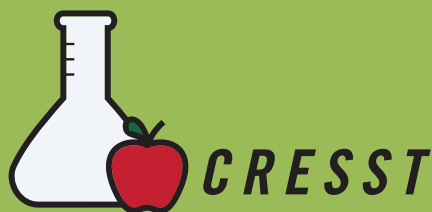
VIRGINIA COMMONWEALTH UNIVERSITY

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Overview

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CRESST supports science and health/physical education instruction by using inquiry and authentic instructional strategies to promote student-directed research and general health and wellness knowledge among adolescent learners. The CRESST Curriculum provides extensive curricular materials designed to translate CRESST concepts and approaches to the classroom in ways that engage students and the local community. The CRESST Videos are designed to be used in conjunction with the CRESST Curriculum, to introduce CRESST or to support individual CRESST activities. They can also be used to generate discussion related to clinical research, healthy lifestyle choices, and student research into health-related topics.

***Clinical Research:
Why Does It Matter to Me?***

<http://bit.do/CRESST-Clinical-Research>

(Duration: 3m 29s)

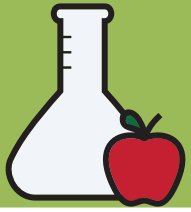
How does clinical research differ from other types of research? Why is it important? Researchers and study participants from the Children's Hospital of Richmond at VCU's T.E.E.N.S. Weight Management Program discuss how clinical research can benefit the individual and the broader community by improving knowledge related to healthy lifestyle choices and effective interventions. Discover how this knowledge can empower individuals to improve their health-related choices and provide communities with the data needed to support the health of all its citizens.

***CRESST Kids and Health:
From Classroom to Community –
How Research Can Improve Our Health***

<http://bit.do/CRESST-Kids-and-Health>

(Duration: 4m 22s)

How can clinical research address questions regarding personal, school, and community public health concerns? Join students in science, health, and family and consumer science classes as they use CRESST Curriculum activities to generate questions and research solutions. A researcher from Virginia Commonwealth University's School of Medicine discusses the benefits of involving young people in research, both to the young person and the community. The questions raised in this video can be used to inspire student-led research projects and community health awareness events.



Clinical Research: Why Does It Matter to Me?

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CRESST

Discussion Questions

These discussion questions can be used to help guide student attention while viewing the video or to encourage and structure discussion after viewing the video.

What is clinical research?

Clinical research is research where humans participate as subjects in the research.

How does clinical research differ from other forms of research, such as basic science research?

Basic science research is conducted to increase our knowledge of the world around us and can be conducted in any of the areas of science. It can be theoretical or it can be conducted for practical reasons. Clinical research usually focuses on human related problems and seeks to answer questions related to the effectiveness of treatments, medications, preventative measures, etc.



How can clinical research help to improve community health?

Clinical research involves people as both the researchers and the subjects. The goal is to identify better ways to treat, prevent, diagnose, and understand human disease and improve human health. As students generate health-related questions, they can also discuss how answering these questions can lead to improvements in community health.

Curriculum Connections

Clinical Research: Why Does It Matter to Me? can be used to introduce clinical research or to reinforce concepts already discussed. It can also be used to introduce and support the CRESST Curriculum activities. Several activities that are particularly appropriate are:

The Basics of Research: The Clinical Research Process

In this lesson, students will learn the process of clinical research and design a clinical research project of their own to investigate how food choices can influence weight. In ***Clinical Research: Why Does It Matter to Me?*** researchers describe aspects of the clinical research process and the benefits of research to the individual and the community.

The Basics of Research: It's All About You: A Clinical Research Simulation

This lesson is designed to simulate participation in a clinical research study and provide data for use in a class exercise. The small group activity provides students experience in developing research questions, generating hypotheses, manipulating data, and graphing results. Students will also 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. 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.

Information Gathering and Synthesis: Team Science: Inquiry into Healthy Habits

By designing and implementing a small-scale research study on health-related behaviors, students will learn to identify what data is and understand how it can be used to draw conclusions and make informed decisions. They will also investigate the importance of diverse teams in research with specific roles that help to coordinate the research and ensure the success of the project.

Clinical Research: Why Does It Matter to Me? introduces a variety of researchers and research locations and helps to illustrate the team nature of clinical research. It also demonstrates the wide variety of data that can be collected in a health-related research study.

Information Gathering and Synthesis: Am I Full Yet?

In this lesson, students investigate how the hormone leptin helps to maintain the body's energy balance. Assuming the role of clinical researcher, the students will conduct a simulated ELISA procedure to identify leptin resistance/deficiency and discuss recommendations to help the patient manage his/her weight. Both researchers and the research participant interviewed in ***Clinical Research: Why Does It Matter to Me?*** discuss how learning more about healthy lifestyle choices empowers individuals to better manage their health.

Collecting and Analyzing Data: Numbers Can Talk: Exploring Statistical Data

Using data from the 2007 Childhood Obesity State Report Card, students will investigate survey design and data collection. They will then analyze data using graphing trends and statistics. Comparing the survey data used in this lesson with the data collected through physical measurements shown in ***Clinical Research: Why Does It Matter to Me?*** illustrates the importance of choosing the appropriate data collection tools for a research project.



Clinical Research: Why Does It Matter to Me?

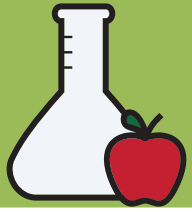
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CRESST: Video Guide



CRESST Kids and Health: From Classroom to Community – How Research Can Improve Our Health?

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Discussion Questions

These discussion questions can be used to help guide student attention while viewing the video or to encourage and structure discussion after viewing the video.

How can clinical research help to improve community health and inform healthy lifestyles?

Clinical research is research that involves people as both the researchers and the subjects. The goal is to identify better ways to treat, prevent, diagnose, and understand human disease and health. As students generate health-related questions, they can also discuss how answering these questions can lead to improvements in community health.

Why is it important to be able to understand health information that we find on television and internet?

There are many sources of information related to health and wellness available today. Unfortunately, much of this information is incomplete, misleading, and sometimes wrong. In order to be certain that the information we use is credible, we must be critical of our sources, consult a variety of reputable sources, and be certain that we understand the concepts presented.

How can different kinds of physical activity influence your health?

Physical activity is an important part of an organism's energy balance and helps to maintain healthy weight, as well as improve overall health. Different types of physical activity can provide a variety of health benefits, such as weight management, muscle strengthening, and sports training. By understanding the various types of physical activity, students can make informed decisions related to their health and fitness.

What do you want to investigate?

Use the questions generated by the students in the video to encourage your students to generate their own questions for research.

Curriculum Connections

CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health can be used to introduce clinical research and student research projects by identifying topics of interest to students and generating research questions. It can also be used to introduce and support the CRESST Curriculum activities. Several activities that are particularly appropriate are:

The Basics of Research: A Matter of Taste

There are many factors that influence what people eat. In this lesson, students will research some of the factors that influence food choices and conduct a clinical research project to investigate the link between the genetics of food preferences and actual food choices. The question 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.

Information Gathering and Synthesis: Team Science: Inquiry into Healthy Habits

By designing and implementing a small-scale research study on health-related behaviors, students will learn to identify what data is and understand how it can be used to draw conclusions and make informed decisions. They will also investigate the importance of diverse teams in research with specific roles that help to coordinate the research and ensure the success of the project. The questions generated by the students in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** can help shape and expand research questions for student-designed research projects.

Information Gathering and Synthesis: Rethink Your Drink (Extension Activity)

In this lesson, students will generate a list of their favorite beverages and research the amount of sugar in one serving of each beverage. They will then create a graphic display to educate their classmates or the community about the amount of sugar and the nutritional value of each beverage. Since this lesson is one of the classroom lessons in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** the video can be used to engage students in discussion about the impact of added sugar in their diet.



Collecting and Analyzing Data: Let's Work It Out

In this lesson, students will research the benefits of being physically active. After learning about these benefits, they will use a variety of resources to create a personal physical activity plan. The health class in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** is completing this lesson. The video can help students make connections between physical activities, energy balance, and healthy choices.

Collecting and Analyzing Results: Walkable Communities: Exploring Measurement, Reliability, and Validity

Walkability is a measure of how easy it is to walk around in an area, neighborhood, or community to carry out our daily activities. Using the Walkability Checklist and online tools, students will investigate the walkability of their community and discuss how this can impact the health of the community. They will also make recommendations to improve the walkability of the community. The physical activities presented in ***CRESST Kids and Health: From Classroom to Community - How Research Can Improve Our Health*** can be used to create a community plan to improve walkability and provide options for increased physical activity.



***CRESST Kids and Health: From Classroom to Community –
How Research Can Improve Our Health***

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