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:

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.

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. Itcatalogues useful and reputable health resources as well as provides criteria for evaluating health information websites.
The Science Research Process

1. Trends are Observed
2. Ask Questions
3. Do Background Research
4. Develop a Hypothesis
5. Design an Experiment and Test the Hypothesis
6. Analyse the Results and Draw Conclusions
7. Hypothesis is Supported
8. Report Results
9. Hypothesis is Not Supported
10. Rethink and Try Again!
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.

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
Procedures
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:
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

LIVESTRONG.com: Problems With BMI
NIH National Heart, Lung, and Blood Institute (NHLBI)
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.
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.

\[
\text{BMI} = \frac{\text{Weight (kg)}}{\text{Height}^2 (m^2)}
\]

**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?

\[
\begin{align*}
5 \text{ feet} & \times (12 \text{ inches/foot}) = 60 \text{ inches} \\
60 \text{ inches} + 2 \text{ inches} & = 62 \text{ inches}
\end{align*}
\]

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

\[
62 \text{ inches} \times (2.54 \text{ cm/inch}) = 157 \text{ cm}
\]

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

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

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?

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

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

\[
47.72 \text{ kg} / 2.46 \text{ m}^2 = 19.3 \text{ kg/m}^2
\]

**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)?

\[
65 \text{ inches} \times (2.54 \text{ cm/inch}) = 165 \text{ cm}
\]

What is Terry’s height in meters (m)?

\[
165 \text{ cm} \times (1 \text{ m/100cm}) = 1.65 \text{ m}
\]

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

\[
1.65 \text{ m} \times 1.65 \text{ m} = 2.70 \text{ m}^2
\]

What is Terry’s weight in lbs?

\[
135 \text{ lbs}
\]

Divide by 2.2 to get the weight in kilograms (kg)
What is Terry’s weight in kg?

\[
135 \text{ lbs} \times (1 \text{ kg/2.2 lbs}) = 61.36 \text{ kg}
\]

What is Terry’s BMI?
We use the formula: BMI = Weight (kg)/Height² (m²)

\[
61.36 \text{ kg} / 2.70 \text{ m}^2 = 22.72 \text{ kg/m}^2
\]

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.
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?
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.
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:
- 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

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/](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 (dH₂O) - 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.


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

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.
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.

   ![Chart]

   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 (dH₂O). 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 dH₂O. 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 dH₂O. 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 dH₂O. 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 dH₂O. 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.
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?
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, l, 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/](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

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.
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.
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.
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?
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.
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/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.
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

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.acesscable.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.
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.