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
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 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

- 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

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.
The Six-Step Process of Ethical Decision Making

1. Gather Relevant Information
2. Identify the type of ethical problem
3. Use ethics theories or approaches 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.
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 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 Principals 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 Humans Services have additional resources for teachers that include detailed timelines of key events and studies the 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.


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.
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.

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.
The Belmont Report
Go to http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html to dissect the article on Ethics in Research. Summarize the article under the following headings.

- Ethical Principles and Guidelines for Research Involving Human Subjects

- Boundaries Between Practice and Research

- Basic Ethical Principles

  - Respect for Persons
Name:

- Beneficence

- Justice

  - Applications
    - Informed Consent
      - Information
      - Comprehension
○ Voluntariness

• Assessment of Risk and Benefits
  ○ The Nature and Scope of Risks and Benefits
  ○ The Systematic Assessment of Risks and Benefits

• Selection of Subjects
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?
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
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.
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.
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.
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.
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
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/clincialresearch/participants/index.html](http://www.cctr.vcu.edu/clincialresearch/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
3.39

Ethical Issues in Clinical Research

Human Rights and Experimentation

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 lead 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.
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.

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.

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.
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 National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was charged with:

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- Developing guidelines to assure that research is conducted in accordance with those principles.

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 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

- Respect for persons
  - Individuals should be treated as autonomous agents
  - Persons with diminished autonomy are entitled to protection

- Beneficence
  - Human subjects should not be harmed
  - Research should maximize possible benefits and minimize possible harms

- Justice
  - The benefits and risks of research must be distributed fairly

The Belmont Report

- Informed consent
  - 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:
    - Information
    - Comprehension
    - Voluntariness

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://biopsy.files.wordpress.com/2008/10/thalidomide.gif
  - http://i.dailymail.co.uk/i/pix/2009/02/08/article-1138955-002F8EF60000258941_233x423.jpg

- Slide 7 from the pregnant woman clockwise to molecular structures
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1966367/figure/F1/fig1.jpg
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1966367/figure/F1/fig1.jpg
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1966367/figure/F1/fig1.jpg

- Slide 10 from “Bad Blood” clockwise to hand
  - http://www.engagediversity.net/science/Tuskegee_Experiment.jpg
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
   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
   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=01ewAheYSXs
"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."
On Human Cloning: Three Views
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.

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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?”

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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.
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 times 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


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 bound by searching the topic “Bioethics in Science” on websites such as United Streaming, PBS.org, and NOVA.
Arctic Alive: Science Journal Rubric
This link opens a rubric that can be used to guide students as they create science journal entries.


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.
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: