

LESSON 2:

Applying the Belmont Principles

INTRODUCTION

In this lesson, students apply the principles outlined in the **Belmont Report** to complex case studies involving human participants as research subjects. Students analyze a case using the concept map they produced in *Lesson One*. They then work together in mixed-case groups to present their findings and evaluate each other's work using a peer evaluation process.

CLASS TIME

About one class period of 55 minutes.

KEY CONCEPTS

- Although the Belmont principles provide structure for **ethical** practices involving humans in research, complex real-world cases may not have clear answers and require a thoughtful balancing of **bioethical** principles.

LEARNING OBJECTIVES

Students will know:

- The complexities involved when conducting research with human participants require thoughtful and balanced consideration of the Belmont principles.

Students will be able to:

- Recognize and apply the Belmont principles in a variety of cases.
- Evaluate the work of other students in applying the Belmont principles.

Vocabulary words used in each lesson are in **bold**. Definitions can be found at the end of each lesson and in the *Master Glossary* in the *Appendix*.

MATERIALS

Materials	Quantity
Student Handout 2.1— <i>Applying the Belmont Principles—Case Studies A, B, C, and D</i>	1 case per student: A, B, C, or D
Student Handout 2.2— <i>Applying the Belmont Principles—Case Table</i>	1 per student
Possible Answers to Student Handout 2.2— <i>Applying the Belmont Principles—Case Table</i>	1 of each study: A, B, C, and D
Student Handout 2.3— <i>Peer Evaluation Procedure for Ethical Case Study Analysis</i>	1 per student
Student Handout 1.3— <i>Concept Mapping</i>	Reuse from <i>Lesson One</i>

NOTE TO THE TEACHER

The next lesson in this unit, *Lesson Three*, begins with a short skit performed by three student actors. It may be helpful to identify three willing actors and provide each of them with a copy of the script to review before *Lesson Three* (see the *STUDENT SCRIPT* in *Lesson Three*).

FRAMING THE LESSON

Tell students that *Lesson One* introduced the major ideas behind the **Belmont principles**. In this lesson, students will dig deeper into how to apply the Belmont principles by using them to analyze a challenging medical ethics case. They will explore the gray areas of ethical decision-making in a peer evaluation process. As with most ethical decision-making, students may find that there are several alternate solutions, and that no one solution satisfies all of the parties involved. For students frustrated that there is no “one right answer,” explain that in ethical decision-making there are “better or worse answers” based on well-reasoned justifications.

Students may also find that ideas within the three Belmont principles overlap. For example, some concepts covered under **Respect for Persons** are similar to those covered by **Justice**.

TEACHER PREPARATION

- Make copies of *Student Handouts*.
- Ask students to have available their concept maps from *Lesson One*.

PROCEDURE

Activity One: Putting the Principles into Practice

1. Have students review their notes on Student Handout 1.3—*Concept Mapping* from *Lesson One*. Ask students if they feel clear about the meaning of the **Belmont principles** and how they apply to human research cases.
2. Tell students that in this lesson they will be reading a short scenario that highlights the shades of gray (areas of ambiguity) found in applying the Belmont principles. In these cases, the principles are not easily supported and students will be challenged to find the best answer with only limited information.
3. Distribute to each student one of the cases (A, B, C, or D) from Student Handout 2.1—*Applying the Belmont Principles—Case Studies*, and a copy of Handout 2.2—*Applying the Belmont Principles—Case Table*.
4. Ask students to work individually to read and analyze their case using Handout 2.2—*Applying the Belmont Principles—Case Table* and their concept maps from *Lesson One* as a reference. Tell students that they will be sharing their case analysis in a small group. Walk around the room as students work, providing guidance as necessary.

Activity Two: Peer Evaluation

5. After students have completed their work, form mixed groups of four, with each team made up of students representing each one of the four cases.
6. Pass out one copy to each student of Student Handout 2.3—*Peer Evaluation Procedure for Ethical Case Study Analysis*. Walk through the basic format for peer review with the class. You may choose to have one group demonstrate the method for the class.

7. Using the *Peer Evaluation Procedure*, each student will take turns presenting his or her case by reading it to the rest of the group and sharing how they applied the Belmont principles. When they are finished, the group members give constructive feedback consisting of both warm and cool comments. The receiving student may take notes but should **refrain from responding verbally** until all feedback has been received. At this time, the student may respond through clarifying questions or by sharing new insights.
8. After all of the case studies have been shared and evaluated, tell students they may make changes to their original case analysis before turning in their work.

Activity Three: Debriefing

9. As a class, debrief the process:
 - a. What was that process like? Did the peer evaluation help clarify how you applied the Belmont principles to various cases?
 - b. How does Respect for Persons apply to any of the cases? **Beneficence**? Justice?
 - c. Was it easy or difficult to recognize and apply the Belmont principles in your analysis?
 - d. Did all of the principles apply equally in all cases? Did you find that some principles conflicted with others in a particular case? Which ones and how?
 - e. Was it easy or difficult to decide what to do? Why?
 - f. Is there something missing from the principles? What, if anything, still raised concerns for you even after you applied the principles?
10. Explain to students that, although the Belmont principles provide a solid ethical foundation, the ways in which they are applied can vary. In some cases other ethical models may be used, but for most biomedical research in the U.S., these are the main guiding principles.

Closure

11. Remind students that real-world cases involving humans in research can be complex. Although the Belmont principles provide structure for ethical practices, it is necessary to have a diverse group of people review and monitor studies involving human participants. This group, known as the **Institutional Review Board (IRB)**, or Ethics Committee, will be discussed in *Lesson Three*.

CONNECTION TO FORMATIVE ASSESSMENT

Revisit the statements students sorted for the *Formative Assessment*. After completing *Lesson Two*, students should understand that Statement E is not accurate.

ADAPTATIONS

- Have each student analyze all of the cases.
- Invite students to work in pairs when doing the initial case analysis. Pairs can then split up to create mixed groups of four (with one student knowledgeable about each of the four cases) for the peer evaluation.

GLOSSARY

Beneficence: Minimizing all potential harms and maximizing all potential benefits to the subject as well as to society.

Bioethics: A subfield of ethics applied to the life sciences; it looks at the ethical impacts of new scientific knowledge and how society makes policy decisions regarding medicines, treatments and human health.

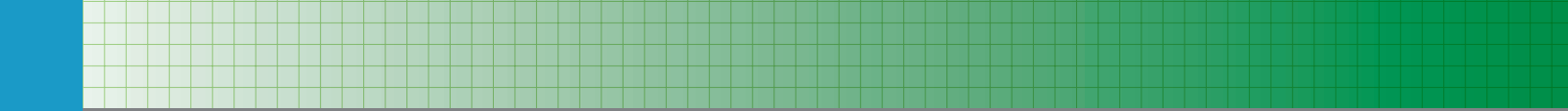
Clinical trials: Systematic research studies for health-related benefits that involve human participants.

Efficacy: Effectiveness as measured in a controlled clinical trial.

Ethics: A field of study that looks at the moral basis of human behavior and attempts to determine the best course of action in the face of conflicting choices.

SOURCES

The Critical Friends Group® Tuning Protocol is from National School Reform Faculty (n.d.). *Tuning Protocol: Overview*. Bloomington, Ind.: Harmony Education Center. Retrieved from: <http://www.nsrharmony.org/protocol/doc/tuning.pdf>.



STUDENT HANDOUT 2.1

Applying the Belmont Principles—Case Studies A, B, C, and D

These are fictional cases involving current ethical topics.



Case A: Saving Lives in a Heartbeat?

In cardiac arrest (heart attack) cases, it is critical to control and monitor body temperature. To increase the likelihood of survival, hospitals will quickly place the victim in an ice bath to produce hypothermia (a lowering of core body temperature), then gradually raise the body temperature. To ensure that the most accurate temperature is being recorded, researchers would like to perform a study on cardiac arrest patients in the emergency room at the county hospital. Temperatures will be taken using different methods for different patients, comparing results from forehead or fingertip thermometers to those from standard oral thermometers, to see which consistently offers the most accurate temperature reading. Because cardiac arrest patients are often unconscious upon arrival, and because the temperature reading must occur very quickly, the researchers would like to do the following:

1. If possible, speak to the next of kin to gain permission to enroll their family member in the study.
2. If next of kin cannot be located, record the patient's temperature, **and then** obtain permission to use the data once the next of kin arrive or after the patient regains consciousness (the data can be discarded if consent is not obtained).
3. If the next of kin or patient does not speak English, exclude them from the study (translators are difficult to obtain quickly).

Can the study proceed, obtaining informed consent as described?



Case B: A Gamble Worth Making?

Aggressive cancers can take a person's life in as little as three to six months. An experimental procedure called interleukin therapy is currently being studied in a **clinical trial**. In 7% of cases, the treatment has been highly effective. In one such case, a man with breast, kidney, and lung cancers with very little hope for survival agreed to participate to receive the experimental therapy. The experimental therapy effectively treated the tumors, and he has been cancer-free for five years. Unfortunately, the treatment has no effect for many people, and there is also a large risk involved: in some trials, the patients suffered immediate cardiac failure.

A woman diagnosed with aggressive cancer, who doctors estimate will live another six months, is interested in pursuing this therapy. In an intense informed consent process over a two-week period, she and her husband are given all the scientific background, the pros and cons, the risks and benefits, and more. After the informed consent process, the woman would like to pursue the treatment, but her husband is against it. The couple is from a cultural background in which the man of the family makes all of the important decisions and this couple is faithful to their cultural traditions. Should researchers enroll this woman in the study to receive the experimental therapy?

Clinical trials: Systematic research studies for health-related benefits that involve human participants.



These scenarios are modified from an activity developed by PATH in Seattle, Wash., and are used with permission.



Case C: Better Than Nothing?

Researchers want to test the effectiveness of a new formulation of insulin that will allow patients with diabetes to take a pill with every meal instead of injecting themselves with liquid insulin three times a day. Liquid insulin must be kept refrigerated, the injections can be painful, and sterile syringes have to be purchased regularly. With the insulin pill (which has an estimated future cost of \$5.00 a day for people with insurance), diabetics would be free of these burdens. Researchers discover that in a small, isolated, rural community, diabetes affects 45% of the residents (compared to 8.3% of the general population), and decide to run **clinical trials** of the drug there. Because there is no hospital or clinic nearby, researchers will set up a temporary clinic in the center of town for easy access. In addition to the experimental medication, participants will receive health screenings, check-ups, and basic medical care, plus compensation for lost time at work and transportation. After two years of gathering data, researchers will close the clinic and return to the laboratory to analyze the data and determine the **efficacy** of the pill.

Should the research proceed as described?

Clinical trials: Systematic research studies for health-related benefits that involve human participants.

Efficacy: Effectiveness as measured in a controlled clinical trial.



Case D – Text Me When You’re Ready!

In Zambia, one in seven adults is HIV positive (HIV+). Treatment is not readily available to all who need it, and researchers are interested in developing effective, low-cost treatment options for HIV+ patients. The study of a new medication for HIV faces a complication in that many Zambian people are mobile—they move from region to region because of jobs, political hostility, or to seek housing—making consistent contact with participants difficult. Furthermore, researchers worry that participants will send other family members to receive the experimental medication instead of coming in themselves in an effort to share the treatment. (This compromises both the study and the therapeutic value of the medicine, which must be taken consistently.)

Researchers propose using technology to solve several issues. They will scan the thumbprints of participants and add them to an electronic database so that participants can prove they are in the research study before receiving treatments. Researchers will also provide participants with cell phones, on which researchers can text reminders to participants about their study visits and reschedule appointments. Enabling the GPS tracking on the phones will also allow researchers to find participants when needed, so they can go to meet them in person.

Should the research proceed as described?



These scenarios are modified from an activity developed by PATH in Seattle, Wash., and are used with permission.

STUDENT HANDOUT 2.2

Applying the Belmont Principles—Case Table

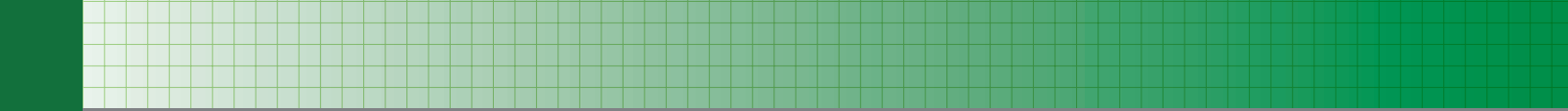
Name _____ Date _____ Period _____

Case Letter/Title:

Write a short summary of the main issues in the case (two to three sentences):

Principle and Elements	The study meets the elements of this principle because...	The study does not meet the elements of this principle because...
Respect for Persons <ul style="list-style-type: none">• Respect right to make choices, hold views, and take actions according to personal beliefs.• Protect those with reduced capacity to make their own choice.• Ensure voluntary participation.• Provide informed consent, explaining harms and benefits.		
Beneficence <ul style="list-style-type: none">• Minimize the harm/risks to the greatest extent possible.• Maximize the potential benefits.• Ensure that the rights and well-being of the patient take precedence over the needs of science.		
Justice <ul style="list-style-type: none">• Justly distribute benefits and burdens of the research.• Guard against using vulnerable populations.• Ensure fair selection of research participants.• Guard against coercion and undue influence.• Avoid potential financial or other conflicts of interest.		

What are some actions that could be taken to make this research better comply with ethical principles?



Possible Answers for STUDENT HANDOUT 2.2A

Applying the Belmont Principles—Case Table

Case A: Saving Lives in a Heartbeat?

Write a short summary of the main issues in the case (two to three sentences):

Researchers would like to study the most accurate method for taking the temperature of patients in cardiac arrest who may be unconscious. Since time is an issue and researchers can't always get consent from the patient, they would like to get permission from next of kin; if no next of kin, take the data and then ask the patient when consciousness is regained; or if next of kin or patient doesn't speak English, exclude them from the study.

Principle and Elements	The study meets the elements of this principle because...	The study does not meet the elements of this principle because...
Respect for Persons <ul style="list-style-type: none"> • Respect right to make choices, hold views, and take actions according to personal beliefs. • Protect those with reduced capacity to make their own choice. • Ensure voluntary participation. • Provide informed consent, explaining harms and benefits. 	<i>Researchers protect the unconscious patient by asking those who are closely related.</i> <i>Researchers only use data from patients who give permission.</i>	<i>Informed consent is not obtained until after the fact.</i> <i>If the patient does not give permission and the method used to collect temperature data is not as accurate as the other, the patient was not given a chance to accept the possible harms and could suffer.</i>
Beneficence <ul style="list-style-type: none"> • Minimize the harm/risks to the greatest extent possible. • Maximize the potential benefits. • Ensure that the rights and well-being of the patient take precedence over the needs of science. 	<i>All patients will receive emergency care.</i> <i>Non-English speakers are excluded so care of patient will take precedence over the needs of science to collect data.</i> <i>Research could benefit future cardiac patients.</i>	<i>Asking for permission from distraught family members might cause undue stress.</i>
Justice <ul style="list-style-type: none"> • Justly distribute benefits and burdens of the research. • Guard against using vulnerable populations. • Ensure fair selection of research participants. • Guard against coercion and undue influence. • Avoid potential financial or other conflicts of interest. 	<i>Populations who do not speak English will have a difficult time understanding the study; they will be excluded so they do not feel confused or coerced during a stressful time.</i>	<i>Populations excluded (non-English speakers) represent the diversity necessary for outcomes that accurately reflect all populations who may experience cardiac arrest.</i>

What are some actions that could be taken to make this research better comply with ethical principles?

Use both methods to collect patient temperatures to lessen the possible harms of one method being more accurate than the other.

Possible Answers for STUDENT HANDOUT 2.2B

Applying the Belmont Principles—Case Table

Case B: A Gamble Worth Making?

Write a short summary of the main issues in the case (two to three sentences):

Female cancer patient with six months to live would like to try an aggressive/risky procedure. In her culture, men make the decisions and her husband is against the procedure. Only 7% of the cases treated benefit, while most have no improvement and some suffer immediate cardiac failure.

Principle and Elements	The study meets the elements of this principle because...	The study does not meet the elements of this principle because...
Respect for Persons <ul style="list-style-type: none"> • Respect right to make choices, hold views, and take actions according to personal beliefs. • Protect those with reduced capacity to make their own choice. • Ensure voluntary participation. • Provide informed consent, explaining harms and benefits. 	<i>The two-week informed consent process explains the scientific background, pros and cons, risks and benefits.</i>	<i>If her husband's wishes are accepted, the patient isn't making the choice, but her traditions are being respected: conflict.</i>
Beneficence <ul style="list-style-type: none"> • Minimize the harm/risks to the greatest extent possible. • Maximize the potential benefits. • Ensure that the rights and well-being of the patient take precedence over the needs of science. 	<i>She is going to die soon; this might be her last chance.</i> <i>Information from the patient's outcome could benefit future cancer patients.</i>	<i>Treatment has only benefited 7% of cases treated so far.</i> <i>Risk of death by cardiac arrest.</i>
Justice <ul style="list-style-type: none"> • Justly distribute benefits and burdens of the research. • Guard against using vulnerable populations. • Ensure fair selection of research participants. • Guard against coercion and undue influence. • Avoid potential financial or other conflicts of interest. 		<i>Patient belongs to a vulnerable population since traditionally her husband makes the healthcare decisions.</i> <i>Risk of treatment means she will not likely benefit from her participation in the study.</i>

What are some actions that could be taken to make this research better comply with ethical principles?

Give private counseling to the patient to determine her true choice.

Give private counseling to the husband to determine why he is against treatment to see if a compromise can be reached.

Research treatment to see if there is a genetic component to successful outcomes to better target effective use.

Possible Answers for STUDENT HANDOUT 2.2C

Applying the Belmont Principles—Case Table

Case C: Better Than Nothing?

Write a short summary of the main issues in the case (two to three sentences):

Community with high percentage of patients with diabetes has been chosen for clinical trial of diabetes pill that would replace insulin shots. Community has no clinic but researchers would provide a temporary clinic with access to basic healthcare for those participating in the study along with compensation for travel and work missed. After two years, the clinic will close and researchers will go back to lab to analyze data.

Principle and Elements	The study meets the elements of this principle because...	The study does not meet the elements of this principle because...
Respect for Persons <ul style="list-style-type: none"> • Respect right to make choices, hold views, and take actions according to personal beliefs. • Protect those with reduced capacity to make their own choice. • Ensure voluntary participation. • Provide Informed consent, explaining harms and benefits. 	<p><i>Townpeople can choose whether to participate or not.</i></p>	<p><i>Participants might agree based on need for healthcare rather than genuine desire to volunteer.</i></p>
Beneficence <ul style="list-style-type: none"> • Minimize the harm/risks to the greatest extent possible. • Maximize the potential benefits. • Ensure that the rights and well-being of the patient take precedence over the needs of science. 	<p><i>It would provide needed healthcare to a community with high incidence of diabetes.</i></p> <p><i>Compensation is given for missed work and transportation.</i></p> <p><i>Community health might improve as a result of the research and the clinic.</i></p>	<p><i>Risks of pills are unclear compared to standard treatment for diabetes.</i></p>
Justice <ul style="list-style-type: none"> • Justly distribute benefits and burdens of the research. • Guard against using vulnerable populations. • Ensure fair selection of research participants. • Guard against coercion and undue influence. • Avoid potential financial or other conflicts of interest. 	<p><i>People of the community have a higher than average incidence of diabetes and would benefit greatly if a pill improved their quality of life.</i></p>	<p><i>Vulnerable population with few healthcare resources.</i></p> <p><i>Participants might feel undue influence since they need access to healthcare and the clinic would provide easy access.</i></p> <p><i>The community could suffer in the long term, since healthcare is only available during the two years of study—no long-term benefit.</i></p>

What are some actions that could be taken to make this research better comply with ethical principles?

Give participants access to information about the conclusion of the study and set up a foundation to help with continued healthcare access.

Educate participants about long-term diabetes care and lifestyle changes needed to reduce disease impact once clinic is gone.

Provide access to clinic to all community members during the trial regardless of their participation.

Possible Answers for STUDENT HANDOUT 2.2D

Applying the Belmont Principles—Case Table

Case D: Text Me When You're Ready!

Write a short summary of the main issues in the case (two to three sentences):

Study in Zambia on HIV-infected patients. Challenges include: mobility of patients makes consistent contact difficult, participants may send in family members to share treatments. Researchers want to use electronic database of participants' thumbprints to track and identify participants when they come to the clinics used in the study. They will also give cell phones with GPS to participants to text them for availability and track their location so they can more easily contact them.

Principle and Elements	The study meets the elements of this principle because...	The study does not meet the elements of this principle because...
Respect for Persons <ul style="list-style-type: none"> • Respect right to make choices, hold views, and take actions according to personal beliefs. • Protect those with reduced capacity to make their own choice. • Ensure voluntary participation. • Provide Informed consent, explaining harms and benefits. 	<i>Using cell phones to text participants might protect privacy more than other methods of contact.</i>	<i>Thumbprint and GPS tracking could intrude on participant privacy if used unethically.</i>
Beneficence <ul style="list-style-type: none"> • Minimize the harm/risks to the greatest extent possible. • Maximize the potential benefits. • Ensure that the rights and well-being of the patient take precedence over the needs of science. 	<i>Zambia has large HIV+ population so this research will be a major benefit if successful; could also be beneficial to other developing countries.</i>	<i>Participants known to be in the study or found out to be HIV+ could face negative social pressures and even physical harm that could outweigh potential benefits of participation.</i>
Justice <ul style="list-style-type: none"> • Justly distribute benefits and burdens of the research. • Guard against using vulnerable populations. • Ensure fair selection of research participants. • Guard against coercion and undue influence. • Avoid potential financial or other conflicts of interest. 	<i>Cell phones and HIV treatment are benefits to participants that help balance the burden of needing to be available for study.</i>	<i>Cell phone and medical treatment for a deadly disease might be undue influence in a setting where these are not readily available.</i> <i>HIV+ Zambians are considered to be a vulnerable population due to the stigma surrounding HIV and its transmission.</i>

What are some actions that could be taken to make this research better comply with ethical principles?

Enroll eligible family members to reduce possibility of a compromised study.

Educate participants about the importance of taking the medicine exactly as prescribed and not sharing doses with others because of the risk of creating drug-resistance.

Turn off GPS and destroy thumbprint database at the conclusion of the study.

To reduce coercive influence, provide only a limited number of minutes or text messages per month so that the phones are used for study purposes and not just for personal benefit.

STUDENT HANDOUT 2.3

Peer Evaluation Procedure for Ethical Case Study Analysis

Name _____ Date _____ Period _____

Use the following steps to share how you applied the Belmont principles to your case study and get feedback on your work. Use the “Providing Feedback” process to evaluate the work of others in your group. Getting feedback about each case study from the group will help you gain a greater understanding of how the principles are used in **clinical trials** involving human subjects.

How to Present Your Case

1. Read your summary of the main ideas presented in your case study.
2. Share your analysis by explaining how/if Respect for Persons, **Beneficence**, and Justice are addressed in the case. Are all three principles met, or are there elements missing from one or more of the principles?
3. Finally, describe the actions that you feel would make the research better comply with ethical principles.
4. Now it’s time for the rest of the group to provide you with feedback. Please do not make comments or ask questions until everyone has had a chance to give feedback (see *Reflection* in next column). Do take notes during the feedback period on Student Handout 2.2—*Applying the Belmont Principles—Case Table*.

How to Provide Feedback

1. Listen carefully as the presenter reads a summary of her case and shares her analysis of how the principles apply, and how she thinks the research could better comply with ethical principles. Take notes so you can provide specific examples when giving feedback.
2. Once the presenter is finished, group members will take turns sharing feedback to improve understanding of how the principles are applied. Use both “warm” and “cool” feedback in your evaluation:
 - o **Warm feedback:** Focus on a positive aspect of the analysis. Identify points the presenter explained clearly.
Example: “Your work is strong because...”
 - o **Cool feedback or clarifying questions:** Focus on areas the presenter needs to improve, and where he needs to improve his explanation of how the principles are used.
Examples: “I’m not sure if you explained...” or “Could you better define how...” or “I wonder if...”

Reflection

1. The presenter can now ask clarifying questions of the group, trying to do so without defending his work.

Repeat the process until each group member has presented a case, shared his or her analysis, and been evaluated. Once everyone has shared, students may make revisions to their analysis using the feedback provided by the group, and prepare for a class discussion about the cases and the evaluation process.

This peer evaluation format is based on a modified Critical Friends Group® Tuning Protocol.

Beneficence: Minimizing all potential harms and maximizing all potential benefits to the subject as well as to society.

Clinical trials: Systematic research studies for health-related benefits that involve human participants.

