

LESSON 3:

Institutional Review Boards—The Nitty Gritty

INTRODUCTION

Students are introduced to the concept of an **Institutional Review Board** (IRB) and perform a skit to learn about the regulations and membership requirements of an IRB. Students use the information learned from the skit to further discuss the rationale for having IRBs evaluate research studies involving humans. In small groups, students visit different stations to perform three activities typical of the work of IRBs. They work together to 1) simplify the language of a section of an informed consent document to be more easily understood, 2) analyze three advertisements made for fictional clinical trials to assess whether they are accurate and/or coercive, and 3) examine a segment of a research proposal written by an investigator describing the process for obtaining informed consent. Students report back to the class on their experience and discuss the benefits and limitations of the rigorous IRB process. Lastly, students read an article in which bioethicists encourage shorter, easier to understand consent forms.

CLASS TIME

About one class period of 55 minutes.

KEY CONCEPTS

- Institutional Review Boards (IRBs) oversee, monitor, and review research studies involving humans to protect the safety, rights, and welfare of human participants.
- Any research institution that receives U.S. federal funding (in the country or abroad) requires IRB regulation. The IRB may approve a study to proceed, stop a study from going ahead, or request changes the board must approve before researchers may move forward.
- IRBs are required to include a diverse group of people with differing views, backgrounds, and areas of expertise.
- Informed consent documents can be fairly lengthy and complex due to extensive content regulations.

Before class: This lesson incorporates a short play. Teachers may wish to identify three actors and provide each with a copy of the script.

LEARNING OBJECTIVES

Students will know:

- The purpose and function of an Institutional Review Board (IRB).
- There are many considerations involving science and ethics that the IRB must weigh to determine appropriate protection of human participants in research.

Students will be able to:

- Carry out sample activities that an IRB might perform.
- State the membership requirements for an IRB.

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

Activity One: What is an IRB and who is on it?

Materials	Quantity
STUDENT SCRIPT for <i>Reader's Theater: IRB Membership</i>	3 copies—one per actor
TEACHER TRANSCRIPT— <i>Video Transcript for IRB Membership Video</i> (similar to student script, with answers)	1
Student Handout 3.1— <i>IRB Membership Chart</i>	1 per student
<i>Possible Answers to Student Handout 3.1—IRB Membership Chart</i>	1
Optional: Computer and internet access to show video	1
<p>Optional: Video: <i>IRB Membership</i> from the Office of Human Research Protections (OHRP)</p> <p>[Note: You may choose to show the video instead of performing the skit. To correspond to Student Handout 3.2—<i>IRB Membership Chart</i>, follow these segments:</p> <ul style="list-style-type: none"> From beginning of video to 5:13 From 13:18 to 13:47 <p>Teachers may also choose to show the entire 16-minute video: http://www.youtube.com/watch?v=GHTlbdLkSwU.]</p>	Access via the internet

Activity Two: What does an IRB do?

Materials	Quantity
<p>Station A</p> <p>Student Handout 3.2a—<i>Say WHAT? Translating Informed Consent Language</i></p> <p>Computer with Microsoft® Word</p> <p><i>Readability Instructions, Strategies, and Reminders</i></p>	1 per group
<p>Station B</p> <p>Student Handout 3.2b—<i>False Advertising? Interpreting Study Advertisements</i></p> <p>[Note: Each group can choose one or more of the three advertisements to interpret, depending on time.]</p>	1 per group [Note: Copy in color if possible.]
<p>Station C</p> <p>Student Handout 3.2c—<i>Are You Sure? Becoming Informed</i></p> <p><i>Possible Answers to Student Handouts 3.2a, 3.2b, and 3.2c</i></p>	1 per group
	1 of each

FRAMING THE LESSON

Now that students have an understanding of the **Belmont principles** and their applications, this lesson will focus on the IRB—the group of people responsible for enacting the Belmont principles and protecting the safety, rights, and welfare of humans participating in research. Students will learn about IRBs from the inside out by stepping into the shoes of IRB members to make decisions about medical form language, research study advertisements, and informed consent.

Any research institution that receives U.S. federal funding (in the country or abroad) requires IRB regulation. An IRB may approve a study to proceed, stop a study from going ahead, or request changes the board must approve before researchers may move forward.

TEACHER PREPARATION

- Make copies of *Student Handouts*.
- Provide students in skit with STUDENT SCRIPT **before the lesson**.
- Clear an area where the students can perform the skit.
- If showing the video instead of doing the skit, prepare computer and projection unit.
- Set up three stations (A, B, and C) through which groups of students will rotate. Each group will share one corresponding *Student Handout* at each station. Depending on space, more than one student group may occupy a station at the same time.

PROCEDURE

Activity One: What is an IRB and who is on it?

1. Tell students that the purpose of an Institutional Review Board (IRB) is to monitor and review studies involving human participants so that the safety, rights, and welfare of the human participants are protected. An IRB may approve a study to proceed, stop a study from going ahead, or request changes the board must approve before researchers may move forward. In this lesson an informational skit will illustrate the types of people who are IRB members.

[Note: If showing the video, recommended video segments are: the beginning of video to 5:13, and from 13:18 to 13:47.]

2. **The Skit:** Introduce the STUDENT SKIT about IRB membership. [**Note:** The script is based on a video about IRB Membership from the federal Office for Human Research Protections (OHRP).] The skit details some of the regulations that ensure that IRBs consist of a diverse group of people with various views, backgrounds, and areas of expertise. Alternately, students may watch the OHRP video at: <http://www.youtube.com/watch?v=GHTlbdLkSwU>.
3. Give students Student Handout 3.1—*IRB Membership Chart*.
4. As students watch the skit or video, have them fill out the second column of the *Student Handout*. (The first column has already been filled out with the corresponding regulations.) Stop the skit or video as necessary for students to finish their notes.
5. After the skit or video, have students work in small groups to fill out the third column of the chart.
6. Once students complete the chart, lead a class discussion asking these questions:
 - a. How do IRB membership requirements help ensure that the Belmont principles are applied? [**Note:** Review the Belmont principles if necessary.]
 - b. If an institution observes all the regulations, do you think that everyone who should be on an IRB is on it? Who, if anyone, is not represented?
 - c. How would you change the regulations to improve research ethics and accountability?
 - d. How does the IRB protect participants? How does the IRB protect the institution?

Activity Two: What does an IRB do?

7. Remind students that the IRB's role is to ensure protection of human participants in research, as outlined in federal regulations and in the Belmont principles.
8. Divide students into small groups. Direct each group to Station A, B, or C. (More than one group may occupy a station at the same time.) Have each group fill out the *Student Handout* found at the corresponding station:
 - Station A:** Student Handout 3.2a—*Say What? Translating Informed Consent Language*
 - Station B:** Student Handout 3.2b—*False Advertising? Interpreting Study Advertisements*
 - Station C:** Student Handout 3.2c—*Are You Sure? Becoming Informed*

Ask students to follow the instructions on their *Student Handout* and perform the tasks listed.

9. When students have finished at one station, have them move as a group to the next station.
10. After all groups have had a turn at each station, discuss the following questions as a class:
 - a. What was it like to do some of the tasks an IRB is asked to do?
 - b. Was it easy or difficult to keep all of the materials and processes true to the requirements of the Belmont principles? What challenges did you face in following the principles? Why?
 - c. What are the benefits of having an IRB review all of the details related to a clinical research study?
 - d. What are the limitations of such a detailed process?
11. Invite students to think about how they would change or improve the process so that studies are kept to high **ethical standards**, participants' rights are protected, and important research can progress at an efficient pace. As important as this system is, it is imperfect. Explain to students that:
 - Though the IRB has the right to visit the labs and clinics of any of the investigations they have reviewed, they often do not.
 - Because of the many regulations surrounding informed consent, most consent forms are 20 or more pages long (a sample informed consent form can be found at <http://www.nwabr.org>).
 - Institutions have different standards and requirements for what they will review. Some institutions, for example, will review the informed consent form but not the informed consent process.

Closure

12. Ask students to work in pairs and write in their notebooks three to four answers to the question, "In what ways does the IRB ensure protection of human participants in research?"
13. Have two pairs combine to make a group of four students. Invite the groups to compare their answers and add any new ideas to their notes.
14. Now ask two groups of four to work together as a group of eight students. Again, have students compare answers and add any new information.
15. Bring the class back together and compare the answers from each large group. Make sure that the answers reflect the **Key Concepts** outlined at the beginning of this lesson, and ask the students to add any missing ideas.

CONNECTION TO FORMATIVE ASSESSMENT

Revisit the statements students sorted for the *Formative Assessment*. After completing this lesson detailing the role and function of an IRB, students should understand that Statement C is accurate and reconfirm that Statement E is not accurate.

HOMEWORK

Teachers may choose from two relevant and accessible articles to assign for homework, if desired. They are:

- *Informed Consent Forms Should be Shortened, Simplified, Bioethicists Say*, found at: <http://www.sciencedaily.com/releases/2011/07/110715135325.htm>.
- *Informed Consent on Trial: Lengthy, complicated documents leave many clinical-trial participants in the dark about the risks they face*, found at: <http://www.nature.com/news/informed-consent-on-trial-1.9933>.

EXTENSION

Have students look at the University of Washington *Human Subjects Review Application* and consider how this institution's IRB members are asked to think about the research studies they review. The form can be found at: <http://www.washington.edu/research/hsd/docs/3>. Looking at the questions that researchers have to answer on this form, ask students to list three of them and the Belmont principles they address.

GLOSSARY

Belmont Report (Belmont principles): Created in 1978 by the U.S. Department of Health, this report established three basic ethical principles to be considered when humans participate in research.

Ethical standards: Rules governing the conduct of a person or the conduct of the members of a profession.

Institutional Review Board (IRB): A group made up of a diverse group of people (with varying views, backgrounds, and areas of expertise) who oversee, monitor, and review research studies to protect the safety, rights, and welfare of human participants.

Placebo: A pill or liquid that is made to look like the treatment being researched but has no active ingredients (e.g., “sugar pill” or saline solution).

Randomization (randomized): The process of assigning study participants to two or more alternative treatments by chance, such as by flipping a coin or rolling a die.

RESOURCES

Washington State University IRB Checklist
http://www.irb.wsu.edu/documents/forms/pdf/Application_Review_Checklist.pdf

University of Washington IRB Review Form
<http://www.washington.edu/research/hds/docs/3>

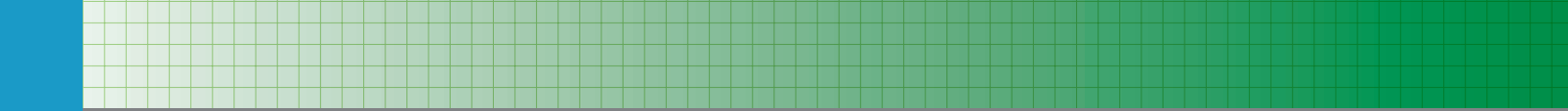
Seattle Children’s Hospital IRB-related Forms
<http://www.seattlechildrens.org/research/forms-policies/irb/application-forms/>
<http://www.uab.edu/irb/forms/sample-consent-form.doc>

SOURCES

The activities found in *Activity Two* are modified from lessons developed by the HIV Vaccine Trials Network (HVTN) Leadership and Operations Center, Seattle, Wash., and are used with permission.

Images are from <http://www.fotolia.com>.

The *ScienceDaily* article is based on: Johns Hopkins Medical Institutions (2011, July 20). Informed-consent forms should be shortened, simplified, bioethicists say.



STUDENT SCRIPT

Reader's Theater: IRB Membership

Setting:

An office at an institution that would like to establish an Institutional Review Board (IRB).

Characters:

Dr. Quinn (Dr. Q)—Official with Mock University responsible for making sure the institution follows through on its IRB commitments.

Ms. Hobbs (Ms. H)—Humans Protection Administrator

Dr. Resner (Dr. R)—Medical Director of Mock University

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- Dr. Quinn (Dr. Q):** Ms. Hobbs, Dr. Resner, thank you for joining me today. I understand that establishing an Institutional Review Board at Mock University would be in our best interest. Ms. Hobbs, can you tell me a little about who would serve as a member of the IRB?
- Ms. Hobbs (Ms. H):** Sure. We will need to appoint at least five members to serve on the IRB, although it may be to our advantage to have eight to 10 members, since there is no limit on how many people we can appoint to the IRB.
- Dr. Q:** To demonstrate my commitment to the IRB, I would like to be an IRB member.
- Ms. H:** Since your primary concern is the welfare of Mock U, I recommend against you serving as an IRB member, but you can demonstrate your support to the IRB in other ways.
- Dr. Q:** OK, so I won't appoint myself as an IRB member. I can ask each department head to identify a physician to serve on the IRB. That will fulfill the required numbers.
- Ms. H:** Well, Dr. Quinn, it's a great idea to have several physicians on the IRB, however, the members need to come from a variety of backgrounds so there is a complete and adequate review of each research project. And the regulations do not allow an IRB to be comprised of members from only one profession. Also, our IRB should reflect our community. It should have diversity in gender, race, and cultural backgrounds.
- Dr. Resner (Dr. R):** What considerations about gender? Do half the members need to be female?
- Ms. H:** No, there isn't a required set percentage for male and female members in the regulations, but we don't want to discriminate when selecting IRB members, and it would be best if the board is not made up entirely of men or of women.
- Dr. Q:** Does the type of research that we currently conduct have any bearing on who should serve as an IRB member?
- Ms. H:** Yes. We need to have IRB members with the ability to review the specific research activities that are submitted to our IRB. Since we conduct both biomedical and social/behavioral research studies, we'll need to have experts in both of these areas.

- Dr. R:** Occasionally, we conduct very complex studies by a specialist. Do we need to have members from every specialty?
- Ms. H:** No, we should look for IRB members with expertise in the types of studies that we typically conduct. We can supplement our IRB's review scope by bringing in consultants to review areas of study that are uncommon for Mock U.
- Dr. R:** We conduct a lot of cancer and cardiac studies at this institution. I think it would be wise to have a cardiologist and an oncologist sit on the IRB.
- Ms. H:** I agree. We also do a lot of research with children and prisoners, so we need to have IRB members with expertise in these areas as well.
- Dr. Q:** I understand why it's important to have an expert in pediatric research, but why have an expert in prisoner issues?
- Ms. H:** This person is actually called the prisoner representative. Their role is to serve as an advocate for the rights and welfare of research subjects who are prisoners.
- Dr. Q:** I happen to know the state prison warden and can ask her if she would be willing to be an IRB member.
- Ms. H:** Well, although the warden should have a close working knowledge and understanding of the prison conditions, she probably wouldn't be viewing the conditions from a prisoner's perspective. It may be better to identify someone else to serve in this capacity.
- Dr. R:** Do you have someone in mind?
- Ms. H:** A suitable prisoner representative could be a present or former prisoner, a prison chaplain, a prison psychologist, or a prison social worker. I happen to know a member of the clergy who routinely visits the state prison. I think he would have the appropriate background to represent the rights and welfare of prisoners.
- Dr. Q:** Okay. So far we have come up with a plan to ask a couple of physicians and a minister to join our IRB. You said eight to 10 members. Who else were you thinking we should ask to be a Mock University IRB member?
- Ms. H:** We need to have at least one scientist, one nonscientist, and one member with no connection to Mock University. The physicians are considered to be scientists and the clergy member is considered to be a nonscientist.
- Dr. R:** I could see the value of the nonscientist's role in reviewing research studies through the eyes of anyone in our community, and reviewing the informed consent language and reading level.
- Ms. H:** You are correct. In addition, there needs to be a nonscientist present at all times for official business to be carried out.
- Dr. R:** What happens if the nonscientist needs to leave the room temporarily?
- Ms. H:** The meeting cannot continue in the absence of the nonscientist. The nonscientist must be present for the IRB to conduct study review and approval.
- Dr. R:** Are IRB members required to have special training?

Ms. H: No, there is no regulatory requirement for training, but because we receive federal funding for our clinical trials involving humans, the Office of Human Research Protections strongly recommends that we provide a training program for our IRB members.

Dr. Q: What would you want to include in the training?

Ms. H: I would want to include a review of the ethical principles identified in the Belmont Report, and both a review of the Human Health Services and Food and the Drug Administration regulations, and the Office of Human Research Protections guidance documents.

Dr. Q: Ms. Hobbs and Dr. Resner, thank you both very much for your time today. With your dedication and knowledge, I believe that we are much closer to establishing an effective and appropriate IRB at this institution.

Script is modified from the video *IRB Membership* produced by the Office of Human Research Protections and used with permission.

TEACHER TRANSCRIPT

Video Transcript for IRB Membership Video

Similar to student script; includes answers.

[**Note:** This is a direct transcript from the OHRP video available at: <http://www.youtube.com/watch?v=GHTlbdLkSwU>.]

The STUDENT SCRIPT was modified for student use. The regulations found in brackets on this transcript correspond to the STUDENT SCRIPT. Student Handout 3.1—*IRB Membership Chart* can be used as a key to the handout.

Setting:

An office at an institution that would like to establish an Institutional Review Board (IRB).

Characters:

Dr. Quinn (Dr. Q)—Official with Mock University responsible for making sure the institution follows through on its IRB commitments.

Ms. Hobbs (Ms. H)—Humans Protection Administrator

Dr. Resner (Dr. R)—Medical Director of Mock University

Dr. Quinn (Dr. Q): Ms. Hobbs, Dr. Resner, thank you for joining me today. I understand that establishing an IRB at this institution would be in our best interest. Ms. Hobbs, can you tell me a little about who would serve as a member of the IRB?

Ms. Hobbs (Ms. H): Sure. We will need to appoint at least five members to serve on the IRB, although it may be to our advantage to have eight to 10 members, since there is no limit on how many members we can appoint to the IRB. [IRB MEMBERSHIP AT LEAST FIVE MEMBERS]

Dr. Q: To demonstrate my commitment to the IRB, I would like to be an IRB member.

Ms. H: As signatory official, your primary concern is the welfare of the institution. I recommend against you serving as an IRB member, but believe that you can demonstrate your support to the IRB in other ways.

Dr. Q: Okay, so I won't appoint myself as an IRB member. I can ask each department head to identify a physician to serve on the IRB. That will fulfill the required numbers.

Ms. H: Well, Dr. Quinn, it's a great idea to have multiple physicians on the IRB, however, the members need to have varying backgrounds so there is a complete and adequate review of each research project. And the regulations do not allow an IRB to be comprised of members from only one profession. [VARYING BACKGROUNDS; MORE THAN ONE PROFESSION MUST BE ON IRB]

Also, in appointing our IRB, we should try to give consideration to getting an IRB with diversity in terms of gender, race, and cultural backgrounds, especially given the demographic makeup of the community in which we reside. [QUALIFIED THROUGH EXPERIENCE, EXPERTISE, AND DIVERSITY]

Dr. Resner (Dr. R): What considerations about gender? Do fifty percent of the members need to be female?

- Ms. H:** No, there's no regulatory requirement for the percent of members that must be a certain gender. However, we need to be careful that we don't discriminate when selecting IRB members, including making selections based on gender. We should also try to ensure that our IRB doesn't consist entirely of men or of women. [EVERY EFFORT MADE TO AVOID GENDER DISCRIMINATION AND PROMOTE GENDER DIVERSITY]
- Dr. Q:** Does the type of research that we currently conduct have a bearing on who should serve as an IRB member?
- Ms. H:** Yes. We need to have IRB members with the professional competence necessary to review the specific research activities that are submitted to our IRB. Since we conduct both biomedical and social/behavioral research studies, we'll need to have experts in both of these areas. [PROFESSIONAL COMPETENCY]
- Dr. R:** Occasionally we conduct very complex studies by a specialist. Do we need to have members from every specialty?
- Ms. H:** No, we should have IRB members with expertise in the type of studies that we typically conduct. We can supplement our IRB's review by bringing in a consultant to provide a review for other types of studies which we don't typically conduct. [USE OF EXPERTS TO ASSIST REVIEW]
- Dr. R:** We seem to conduct a lot of cancer and cardiac studies at this institution. I think it would be wise to have a cardiologist and an oncologist sit on the IRB.
- Ms. H:** I agree. We also do a lot of research with children and prisoners, so we need to have IRB members with this expertise as well.
- Dr. Q:** I understand why it would be important to have an expert on children's research, but why have an expert in prisoner issues?
- Ms. H:** This person is actually called the prisoner representative. This person's role is to serve as an advocate for the rights and welfare of the subjects who are prisoners. [PRISONER REPRESENTATIVE]
- Dr. Q:** I happen to know the state prison warden and can ask her if she would be willing to be an IRB member.
- Ms. H:** Well, although the warden should have a close working knowledge and understanding of the prison conditions, she probably wouldn't be viewing the conditions from the prisoner's perspective. It may be better to identify someone else to serve in this capacity.
- Dr. R:** Do you have someone in mind?
- Ms. H:** A suitable individual to serve as a prisoner representative may include a present or former prisoner, a prison chaplain, a prison psychologist, or prison social worker. I happen to know a member of the clergy who routinely visits the state prison. I think that he would have the appropriate background to represent the rights and welfare of prisoners.
- Dr. Q:** Okay. So we have a couple of physicians and a minister on the IRB. You said eight to 10 members. Who else were you thinking that we should ask to be an IRB member?

Ms. H: We need to have at least one scientist, one nonscientist, and one nonaffiliated member on the IRB. The physicians are considered to be scientists and the clergy member is considered to be a nonscientist.
[SCIENTIFIC AND NONSCIENTIFIC MEMBERS]

Dr. R: I could see the value of nonscientists' roles in reviewing research studies through the eyes of a layperson and reviewing the informed consent language and reading level.

Ms. H: You are correct. In addition, there needs to be a nonscientist present to meet quorum requirements.
[NONSCIENTIST PRESENCE]

Dr. R: What happens if the nonscientist needs to leave the room temporarily?

Ms. H: The meeting cannot continue in the absence of the nonscientist. The nonscientist must be present for the IRB to conduct its review and approval of studies.

Video reference 13:18

Dr. R: Are IRB members required to have special training?

Ms. H: No, there is no regulatory requirement for training although the terms of our federal-wide assurance with OHRP strongly recommend that we establish an educational training program.

Dr. Q: What would you want to include in the training?

Ms. H: I would want to include a review of the ethical principles identified in the Belmont Report, a review of both the HHS and FDA regulations, as well as the OHRP guidance documents. I would also recommend the IRB members review the Human Subject Assurance Training modules available through the OHRP website.

Dr. Q: Ms. Hobbs and Dr. Resner, thank you both very much for your time today. With your dedication and knowledge, I believe that we are much closer to establishing an effective and appropriate IRB at this institution.

STUDENT HANDOUT 3.1

IRB Membership Chart

Name _____ Date _____ Period _____

Regulation	What does it mean?	Why is it important?
IRB membership, at least five members		
Varying backgrounds, more than one profession must be on the IRB		
Qualified through experience, expertise, and diversity		
Every nondiscriminatory effort made for gender diversity		
Professional competency		

Regulation	What does it mean?	Why is it important?
Use of experts to assist review		
Prisoner representative		
Scientific and nonscientific members		
Nonscientist presence		
Training for IRB members		

Possible Answers for STUDENT HANDOUT 3.1

IRB Membership Chart

Regulation	What does it mean?	Why is it important?
IRB membership, at least five members	<i>At least five people, better to have eight to 10; no limit.</i>	<i>Lots of people to help make important decisions, more representative of the community at large.</i>
Varying backgrounds, more than one profession must be on the IRB	<i>Not all doctors, not all researchers; different professions and kinds of people.</i>	<i>People who may have different perspectives.</i>
Qualified through experience, expertise, and diversity	<i>People with good experience, knowledge, or from diverse backgrounds.</i>	<i>People who know what they're talking about, different perspectives.</i>
Every nondiscriminatory effort made for gender diversity	<i>Not all men or not all women. Not necessarily 50/50, but trying to achieve balance. For groups conducting social/behavioral research, it might also be beneficial to have diversity of sexual orientations.</i>	<i>Difference of perspectives along the gender identity spectrum and from different sexual orientations.</i>
Professional competency	<i>People with expertise in the kinds of studies the institution regularly performs.</i>	<i>The right people with the right expertise making decisions on topics they are familiar with.</i>

Regulation	What does it mean?	Why is it important?
Use of experts to assist review	<i>Bringing in people with expertise if it doesn't exist in the group.</i>	<i>People are well informed before they make decisions.</i>
Prisoner representative	<i>Former prisoner, prison chaplain, psychologist, social worker, etc., who can provide prisoner's perspective.</i>	<i>Someone needs to look out for prisoners so that they won't be taken advantage of.</i>
Scientific and nonscientific members	<i>Scientists and nonscientists (people whose professions are not in the sciences).</i>	<i>A nonscientist can help to ensure that research is not pushed forward only because it may be scientifically noteworthy.</i>
Nonscientist presence	<i>The nonscientist must be at the meeting for decisions to be made.</i>	<i>The nonscientist perspective should be shared at every decision point to help make sure the research is being handled ethically from a citizen's viewpoint.</i>
Training for IRB members	<i>No regulatory requirement, but recommend members review Belmont Report, Code of Federal Regulations, FDA regulations and others.</i>	<i>Knowing the history and background of the Belmont Report and FDA regulations will help IRB members understand the importance of their role.</i>

STUDENT HANDOUT 3.2a

Say WHAT? Translating Informed Consent Language

Name _____ Date _____ Period _____

Instructions: The Belmont Report stresses that research participants must be fully informed in an adequate manner. It is therefore common practice that informed consent forms are written at about an eighth grade reading level (or below). Translate the following excerpt from an informed consent form into language that somebody with an eighth grade reading level (or below) would understand.

Original Text A

Any medical data that is obtained in connection with this study will be utilized only for this study, with exception by consent. If you give us your permission by signing this document, we plan to submit medical data to the University database. All information will be made anonymous.

Current Flesch-Kincaid Grade Level ("readability" score): 13.9

Your Version:

Readability Score Text A: _____

Original Text B

Drawing blood may cause brief discomfort, bleeding, and discoloration where the needle enters the body, and in a few cases inflammation at the site of entry. Rarely, loss of consciousness and infection can occur. There also may be other unforeseen side effects or discomforts that we cannot predict, thus it is important to advocate with your clinician when unusual symptoms occur.

Current Flesch-Kincaid Grade Level ("readability" score): 12.2

Your Version:

Readability Score Text B: _____

This activity is modified from a lesson developed by the HIV Vaccine Trials Network's (HVTN) Leadership and Operations Center, Seattle, Wash., and is used with permission.

STATION A – READABILITY INSTRUCTIONS, STRATEGIES, AND REMINDERS

Instructions for finding the Flesch-Kincaid Grade Level (“readability” score):

If using an older version of Microsoft® Word:

1. Choose **Tools** then **Options**.
2. Click the **Spelling & Grammar** tab.
3. Check both **Check grammar with spelling** and **Show readability statistics**.
4. Readability is displayed after you run a spell check; anything above grade 12 indicates a college-level education is necessary to ensure understanding.

If using a newer version of Word:

1. Click the **Office** button in the upper left corner.
2. Choose **Word Options** at the bottom.
3. Click on **Proofing**.
4. Check the box **Show readability statistics** under the **Spelling & Grammar** section.
5. Readability is displayed after you run a spell check; anything above grade 12 indicates a college-level education is necessary to ensure understanding.

If using a Mac:

1. Choose **Tools** then **Spelling & Grammar**.
2. Click on **Options**.
3. Check the box **Show readability statistics** under the **Grammar** section.
4. Readability is displayed after you run a spell check; anything above grade 12 indicates a college-level education is necessary to ensure understanding.

Strategies for decreasing the “readability” score of a passage

Follow these principles for writing in plain language:

1. Use shorter sentences.
2. Use the active voice. (“Run!” instead of “I told her to run.”)
3. Avoid text in parentheses or in phrases that are set off with commas.
4. Use shorter words.
5. Avoid words that could be interpreted differently based on context. (For example, the word “trial” could mean different things depending on whether it is used in a legal sense or in a biomedical research sense.)
6. Use simple punctuation and grammar.

Reminders of your responsibility

While it is important to lower the readability score, it is your responsibility to convey the same information and messages. Make sure you don’t simplify the text to the point where the meaning is lost. Remember, the goal is **informed** consent.

Possible Answers for STUDENT HANDOUT 3.2a

Say WHAT? Translating Informed Consent Language

Instructions: The Belmont Report stresses that research participants must be fully informed in an adequate manner. It is therefore common practice that informed consent forms are written at about an eighth grade reading level (or below). Translate the following excerpt from an informed consent form into language that somebody with an eighth grade reading level (or below) would understand.

Original Text A

Any medical data that is obtained in connection with this study will be utilized only for this study, with exception by consent. If you give us your permission by signing this document, we plan to submit medical data to the University database. All information will be made anonymous.

Current Flesch-Kincaid Grade Level ("readability" score): 11.3

Your Version:

We will use medical information we get only for this study. If you give us permission by signing below, we will share this information with the University. We will take your name off any records so no one can link the information to you.

Readability Score Text A: 8.0

Original Text B

Drawing blood may cause brief discomfort, bleeding, and discoloration where the needle enters the body, and in a few cases inflammation at the site of entry. Rarely, loss of consciousness and infection can occur. There also may be other unforeseen side effects or discomforts that we cannot predict, thus it is important to advocate with your clinician when unusual symptoms occur.

Current Flesch-Kincaid Grade Level ("readability" score): 12.2

Your Version:

Taking blood from you with a needle may be uncomfortable. Sometimes your skin may turn a different color where the needle enters the body. Sometimes you may bleed where the needle enters the body. Sometimes the area may swell. It is not common, but you may faint, or the place where the needle enters the body may become infected. Other things may happen that we cannot guess about. If something weird or not expected happens to you, you should tell us and see the doctor.

Readability Score Text B: 6.3

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STUDENT HANDOUT 3.2b

False Advertising? Interpreting Study Advertisements

Name _____ Date _____ Period _____

Instructions: The Belmont Report stresses that we need to recruit participants fairly, guard against using vulnerable populations, guard against undue influence, and avoid potential financial and other conflicts of interest. Review these advertisements seeking participants for a clinical trial. Analyze each of them for strong and weak elements. You may approve the advertisements for use, make recommendations for changes before they can be used, or prohibit their use.

Advertisement One

Advertisement strengths	Advertisement weaknesses (and suggested changes)

Advertisement Two

Advertisement strengths	Advertisement weaknesses (and suggested changes)

Advertisement Three

Advertisement strengths	Advertisement weaknesses (and suggested changes)

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Possible Answers for STUDENT HANDOUT 3.2b

False Advertising? Interpreting Study Advertisements

Instructions: The Belmont Report stresses that we need to recruit participants fairly, guard against using vulnerable populations, guard against undue influence, and avoid potential financial and other conflicts of interest. Review these advertisements seeking participants for a clinical trial. Analyze each of them for strong and weak elements. You may approve the advertisements for use, make recommendations for changes before they can be used, or prohibit their use.

Advertisement One

Advertisement strengths	Advertisement weaknesses (and suggested changes)
<p>Colorful and eye-catching. Clear contact information.</p> <p>Time commitment for participants stated clearly.</p> <p>Benefits to participants clearly stated (reimbursement for time and transportation, etc.). Except for title, benefits not overstated.</p>	<p>The study title (“Want Healthier Babies?”) implies that your baby will directly benefit from your participation in the trial, which cannot be guaranteed.</p> <p>The important information about the study is difficult to read because of the colored background.</p> <p>The picture shows a homogenous group of women, but the study is seeking women of diverse ages, races, ethnicities, and backgrounds.</p> <p>Additional criteria for qualification would be helpful (i.e., how far along in pregnancy, is woman taking any other medications, etc.).</p>

Advertisement Two

Advertisement strengths	Advertisement weaknesses (and suggested changes)
<p>Colorful and eye-catching. Clear contact information.</p> <p>Shows diversity of ages, backgrounds, and genders in potential participants.</p> <p>Benefits to participants clearly stated (compensation for time and transportation, etc.).</p>	<p>Statement “You will not get malaria in the study” cannot be guaranteed. Participants may still contract malaria while in the study (while traveling internationally, for example), even though their participation in the study will not give them malaria.</p> <p>Overstatement of heroic nature of study participants makes it seem that this study will directly lead to cures and/or treatments.</p> <p>“Your participation can save lives” overstates the outcome of participation. The vaccine being testing may still be decades away from use.</p>

Advertisement Three

Advertisement strengths	Advertisement weaknesses (and suggested changes)
<p>Colorful and eye-catching. Clear contact information.</p> <p>Criteria for participation clearly stated.</p>	<p>Focus on money may unduly influence potential participants.</p> <p>Promise of “quick” cash may not be straightforward. Research is not fast, and the study may last for months or even years.</p> <p>Picture of Pandora’s box misrepresents the biomedical research process (i.e., It’s magical! It’s mysterious!).</p>

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Want Healthier Babies?

A doctor in your area is looking for volunteers for a pre-labor research study.

A research drug is being evaluated for its ability to prevent premature births. You will be asked to come in for a day and a half for treatment and common tests administered to pregnant women. We will cover all costs of treatments and tests, and you will also be reimbursed for your time and transportation costs. We are seeking pregnant women from a diverse range of ages, races, ethnicities, and backgrounds.



**For more information, contact:
Faux University
Department of Pediatric Research
(056) 099-7614**

Not All Heroes Wear Masks and Capes



Volunteer for a malaria vaccine research study!

Shambhala Clinical Research Center is seeking 2000 participants of all ages, genders, races, and backgrounds to test the effectiveness of a malaria vaccine. You will not get malaria in the study. All visits are free of charge, and you will be compensated for travel and your time.

**Your participation can save lives. Be a hero!
Call (321) 987-6543 today!**



**Earn
\$200
Fast!**

For more information,
call 1-800-485-1614.

Do you have Type I Diabetes?

A clinical research study is available.

You may qualify if:

- You are between the ages of 18-70
- You have been diagnosed with Type I Diabetes more than 2 years ago
- You have been on a stable insulin regimen for the last 6 months or more
- You meet other study criteria

Find out if you may qualify!

STUDENT HANDOUT 3.2c

Are You Sure? Becoming Informed

Name _____ Date _____ Period _____

Instructions: The Belmont Report stresses that participants must enter into research voluntarily, must be informed in an adequate manner, and must genuinely give consent with full knowledge of benefits and harms. An investigator proposed the following procedure for obtaining informed consent from volunteers interested in enrolling in the study:

Procedure

The prospective participant will meet with the principal investigator (PI) for a few minutes in a private waiting room. The PI will give a brief overview of the study, and flip through the informed consent form to point out the major elements. The PI will then exit the room, leaving the prospective participant to read the form. Because it is a 10-page form, the PI will return after 30 minutes to give adequate time for the prospective participant to read the form. After 30 minutes, the PI will re-enter the room and ask the prospective participant if she has any questions. If there are no questions, the PI will then ask the prospective participant if she will sign up to be in the study. If yes, the participant will sign the appropriate lines on the consent form and then will be escorted into the next room to receive the first treatment. Combining the informed consent and first treatment will reduce the number of times the participant has to come into the clinic.

Do you see any problems with this method? If so, what are they?

An IRB can require changes before the study is approved. Are there changes you believe need to be made to the investigator's informed consent process described above?

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Possible Answers for STUDENT HANDOUT 3.2c

Are You Sure? Becoming Informed

Instructions: The Belmont Report stresses that participants must enter into research voluntarily, must be informed in an adequate manner, and must genuinely give consent with full knowledge of benefits and harms. An investigator proposed the following procedure for obtaining informed consent from volunteers interested in enrolling in the study:

Procedure

The prospective participant will meet with the principal investigator (PI) for a few minutes in a private waiting room. The PI will give a brief overview of the study, and flip through the informed consent form to point out the major elements. The PI will then exit the room, leaving the prospective participant to read the form. Because it is a 10-page form, the PI will return after 30 minutes to give adequate time for the prospective participant to read the form. After 30 minutes, the PI will re-enter the room and ask the prospective participant if she has any questions. If there are no questions, the PI will then ask the prospective participant if she will sign up to be in the study. If yes, the participant will sign the appropriate lines on the consent form and then will be escorted into the next room to receive the first treatment. Combining the informed consent and first treatment will reduce the number of times the participant has to come into the clinic.

Do you see any problems with this method? If so, what are they?

Problems could include:

- *That amount of time may be too long, or too short, for different people.*
- *Not best way to communicate information to people who don't read well. Other visual or spoken methods should be included.*
- *Relying on the prospective participant to ask questions about what she does not understand is problematic.*
- *There should be time built in to review the form with the participant and assess her understanding.*
- *The prospective participant should have time between signing the consent form and receiving the first treatment to think more about the study, ask her own personal doctor about the pros and cons of participation, or consult with family members.*
- *It should be very clear that the prospective participant may withdraw from the study at any time without any penalty.*

An IRB can require changes before the study is approved. Are there changes you believe need to be made to the investigator's informed consent process described above?

- *The PI (or doctor) should not get consent from prospective participants. Participants may be influenced by the authority and importance of the PI or doctor (i.e., "white coat syndrome" makes the PI or doctor too persuasive).*
- *It is acceptable to have another trained staff person who is able to spend as much time as needed with the participant go over the consent form, a nurse or counselor could be a good choice.*
- *The staff person should stay the entire time and read through the consent form with the participant.*
- *The staff person should also provide visual aids such as graphic books, videos, or flip charts for those with limited literacy.*
- *The staff person should ask the participant periodically about her understanding of the study rather than wait for the participant to ask questions.*
- *There could be a short "quiz" to make sure the prospective volunteer has understood all the key elements of the study.*
- *The appointment during which the consent form is signed should not be the same appointment as the first clinical appointment.*

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