

# **MEDICAL ETHICS: RIGHT, WRONG, & THE SPACE BETWEEN**

**PROMISE**

# WHAT ARE ETHICS?

Ethics are a system of moral principles that guide your decisions. They affect how you make decisions and live your life. They help you decide what is right or wrong.

# WHAT INFORMS YOUR ETHICS?

- Parents
- Individual conscience
- Personal experiences
- Religious community
- Teachers
- Media



# MEDICAL ETHICS

The medical/research community needs its own guidelines for what is right and wrong. Ethical decisions are typically made by a group of people who debate the topic and vote on their decision.

## **Examples:**

- Institutional Review Board (For research facilities)
- Supreme Court (Decides on laws)

## **Areas of Concern:**

- Animal research
- Treatment of humans
- Use of cells - Who owns cells?

# IMPORTANT VOCABULARY

- **Gene editing-** when DNA is inserted, deleted, or changed within the genome of an individual
- **Gene therapy-** the process of using a virus to get DNA inserted into cells of a patient
- **Pathogen-** something that causes disease like bacteria, viruses, and fungi
- **Virus-** a non-living pathogen that is able to inject DNA or RNA into a living cell to make more viruses
- **Antibody-** a protein that is created when a pathogen enters the immune system and tags pathogens to help white blood cells destroy them
- **Lysosomes-** vesicles inside a cell that recycle waste

# WHAT DO YOU THINK?

- There are 4 corners in the room labeled: Agree, Strongly Agree, Disagree, and Strongly Disagree.
- For each question, take 30 seconds to think and then move quietly to the area of the room that best fits your perspective.
- It is important to remain quiet so everyone can make their own decisions.
- Be respectful of others decisions. Ethics is not about being right but understanding differing views.

# ANIMAL RESEARCH

- In scientific research, scientists try to make treatments for humans who are sick.
- Animals test treatments before they are given to humans.
- Strict guidelines must be followed in order to use animals in research. For example, a treatment needs to prove to be effective in cells first.
- Typically two different animal models are needed to be used in research before a treatment can move into clinical trials. This is when human volunteers are used.

**This practice is fair and necessary. Move to the corner that represents your opinion on this statement.**

# GENE EDITING

- There are many diseases carried by mosquitos including: malaria, yellow fever, West-Nile virus, and Zika virus.
- It is the female mosquitos that bite and transfer disease.
- Scientists have developed gene-editing technology called CRISPR-CAS9 that would add a gene to male mosquitoes. The males mate with the native female mosquitoes.
- In the next generation, all the female mosquitoes would be infertile (can't reproduce). The males could still reproduce. This would make a large portion of the mosquito population die off.

**This practice is fair and necessary. Move to the corner that represents your opinion on this statement.**

# GENE THERAPY

- Batten Disease is a rare disease caused by a defect in a few genes. It prevents lysosomes from recycling waste in the cells.
- Children with Batten disease will forget important things, begin to lose their speech and motor skills, and develop seizures. The children usually do not survive into their teens.
- Scientists can put good genes into a virus and inject it into the children. The virus then injects the good gene into the cells.
- This gene therapy will stop the disease from getting worse and add years to their lives, but will not cure the disease.

**This practice is fair and necessary. Move to the corner that represents your opinion on this statement.**

# GENETIC MODIFICATION

- When new viruses break in a population, it is hard to respond quickly with antibody treatments for sick patients. Antibodies are produced by the immune system to identify and kill viruses.
- Scientists can genetically modify cows to have human immune systems. Antibodies from the cows can help sick humans.
- The cows live a normal life on a farm. When specific antibodies are needed, the cows are injected with a deactivated virus to create antibodies.
- Blood samples are drawn from the cows to collect the antibodies.

**This practice is fair and necessary. Move to the corner that represents your opinion on this statement.**

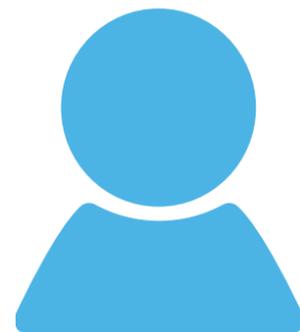
# ORGAN TRANSPLANT

- Each day, 20 people die from organ failure. There is a shortage of organs for transplants leaving many people in need of a new heart, liver, or kidney.
- Pig organs and tissues can be used to help humans. However, humans reject the organ because it is not recognized as its own.
- Gene editing can be used to engineer pigs to remove cell markers that trigger human immune responses. Pigs also have a virus in their genome that needs to be disabled.
- Once the pigs have been designed with these fixes, the pigs are killed and organs are given to hospitals where they are put into humans to help save their lives.

**This practice is fair and necessary. Move to the corner that represents your opinion on this statement.**

# WHAT DO YOU THINK?

- What surprised you about this activity?
- Did you ever feel like changing your opinion after you heard someone else's opinion?
- Did you feel pressured to move with your friends?



# USING MODELS IN RESEARCH

In order to understand a problem and develop a solution, researchers use models.



## Model Examples:

- Cells in culture
- 3-D models (tumor recreation)
- Zebrafish (have similar genes to humans and reproduce quickly)
- Mice (reproduce quickly, can be genetically modified)
- Pigs/Cows (similar to humans)

# USING MODELS IN RESEARCH

## **Humans may be used as test subjects under strict rules:**

- Must be tested in an animal model first and prove to be safe
- Must follow rules of the Belmont report (more on this later)

## **Phases of clinical trials:**

- PHASE 1-Did the treatment cause any harm to the patient?  
If not, may move on to PHASE 2.
- PHASE 2- Does the treatment work?
- PHASE 3- Prove that the treatment works better than standard treatments using randomized and blind testing to a large sample of patients.
- Review of results by governing bodies like the FDA.

# NEED FOR REGULATION

There have been many times in history where this order was not followed. Many humans have been subjected to cruel, unnecessary, and horrific experiments.

During Nazi occupation of Europe, millions of people were forced to be part of experiments while imprisoned.

- Mustard gas tests
- Removal of bones, muscles
- Injected with bacteria to test treatments
- Torture techniques

After World War 2, the scientists and officers were prosecuted in the Nuremberg Trials. Out of this came the Nuremberg code (1947).

# THE NUREMBERG CODE

- The patient has to agree to the experiment.
- The experiment should make society better.
- It should be tested on animals first to show it is safe.
- It shouldn't hurt the patient.
- The experiment should not be done at all if death is possible.
- The good needs to outweigh the risk.
- Test subjects should be kept in clean, safe places.
- The experiment should be done by an informed scientist.
- The patient should be able to stop and walk away.
- The scientist should stop immediately if it looks like the patient will be harmed or die.

# NEED FOR REGULATION

Between 1947 and 1978 there were many unethical studies done on humans. There was a need for a stricter code.

Belmont report was published in 1978.

# THREE CORE PRINCIPLES

## **Respect for Persons:**

- People have the right to make their own choices.
- People should be informed (at their education level) before consenting.
- Provide protections to vulnerable populations (children, prisoners, cognitively impaired.)

## **Beneficence:**

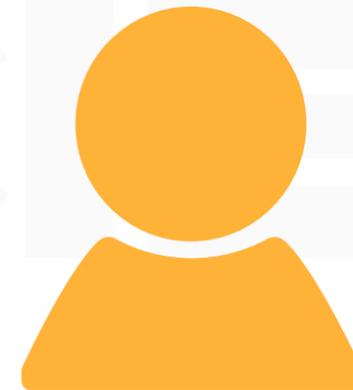
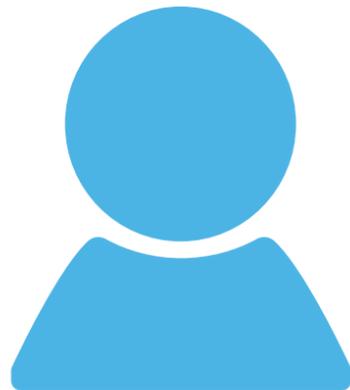
- Do no harm
- Maximize benefits and minimize risk

## **Justice:**

- Treat people fairly
- Will the group share in the benefit of this research?
- Equitable selection of subjects

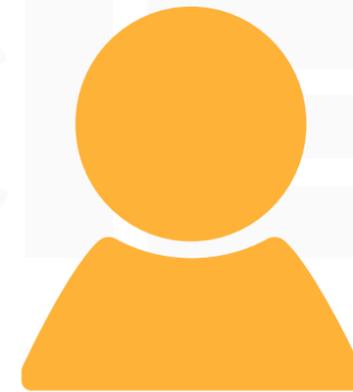
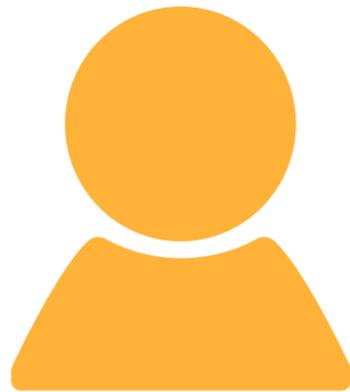
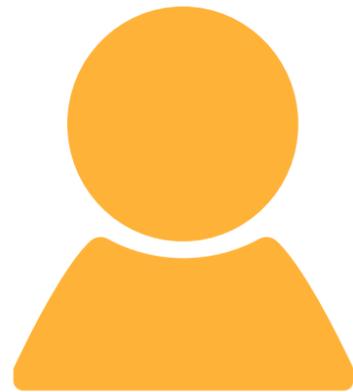
# CASE STUDY DISCUSSION

- Grab your Case Study Summaries.
- You will be assigned a color.
- Read the case study of your assigned color.
- Fill out the **READ** section of your lab notebook.



# CASE STUDY DISCUSSION

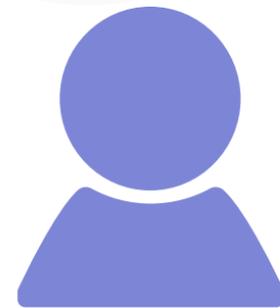
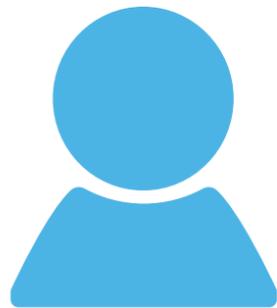
- Read the Group Work Norms section of your lab notebook, and meet with the other students assigned the same case study to discuss.
- Fill out the **MEET** section of your lab notebook.



# CASE STUDY DISCUSSION

Return to your original seat and discuss your case study with those around you.

- Give a specific example of how the ethics of the case are questionable.
- What are your opinions of the study?
- Which of the Belmont rules were not followed?

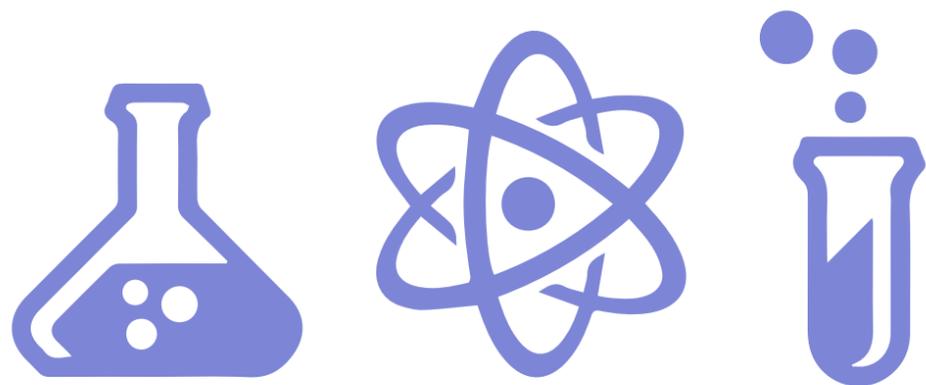


# CASE STUDY DISCUSSION

How do research facilities make sure unethical studies are not done?

Institutional Review Boards review all research plans before they are allowed to move forward. They use the Belmont Report as their guide.

# ANSWER THE REMAINING QUESTIONS IN YOUR LAB NOTEBOOK!



## SHARE YOUR CASE STUDY

Listen to your classmates share their case studies. Record the main idea and state which Belmont regulation was not followed and explain your reasoning.

### MAIN IDEA OF CASE

- 1.
- 2.
- 3.

### BELMONT REGULATION NOT FOLLOWED

- 1.
- 2.
- 3.



### Here's what I did today!

Today I visited the virtual PROMISE Lab at Sanford Research. I learned about the need for regulation in medical science and the history of how we developed today's ethical standards.