APPENDIX

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MASTER GLOSSARY

- **Albinism:** A condition characterized by a lack of pigmentation, resulting in very light skin coloring, white hair, and light blue or red eyes.
- **Animal trial:** A medical research trial using non-human animals. Together with cell and tissue cultures, also known as pre-clinical trials.
- **Antibody:** A substance made by the body as an immune response that attacks and destroys foreign agents, such as viruses and bacteria.
- **Assent:** A process in which the parent or guardian of a minor agrees to the minor's participation in a research study. The participant is still required to give informed consent.
- **Autonomy:** A person's freedom and ability to make his or her own decisions.
- **Autopsy:** An examination conducted on a dead body to determine the cause of death.
- **Autosomal recessive trait**: A trait both parents must carry for a child to inherit the syndrome.
- **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.
- **Beneficence:** Minimizing all potential harms and maximizing all potential benefits to the subject as well as to society.
- **Biobank:** A storage facility for biological materials used in medical research.
- **Bioethics:** A sub-field 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.
- **Bleeding disorder:** A medical disorder that leads to poor blood clotting and continuous bleeding.

- **Blinded study:** A study in which participants do not know whether they are receiving the treatment being researched or a placebo.
- **Cell and tissue cultures:** Biological samples used in a preliminary study stage (that precedes animal and human clinical trials) to evaluate whether a new treatment is a good candidate for further study. Together with animal trials, also known as pre-clinical trials.
- **Cervical cancer:** Cancer of the cervix, which is the lower, narrow end of the uterus.
- **Clinical research:** Medical research involving human participants to test new medications, treatments, methods of prevention, and therapies.
- **Clinical trials:** Systematic research studies for health-related benefits that involve human participants.
- **Clinical trial phases:** Clinical trials are conducted in three or four phases. Each phase has a different purpose to help researchers answer different questions. Following is an overview of each phase:
 - *Phase I*—An experimental drug or treatment is tried on a small group of people (fewer than 100). The purpose is to evaluate its safety and identify any side effects.
 - *Phase II*—The experimental drug or treatment is administered to a larger group of people (several hundred) to further assess safety, and to assess questions such as optimal dosing and frequency of dose administration.
 - *Phase III*—The experimental drug or treatment is administered to large groups of people (several thousand) to determine its effectiveness, further monitor safety, and compare it with standard or equivalent treatments.
 - *Phase IV*—After a drug is licensed by the FDA, researchers track its safety, seeking more information about its risks, benefits, and best use in "real world" settings.

- **Coercion:** The act of pressuring someone to do something using force, intimidation, or threats without respect for individual choice. This includes the idea that a person with few choices may find participation in a study to be so appealing that they feel they cannot decline, even if being in the study is not a good decision for other reasons.
- **Computer simulation:** A technique used in preliminary research that precedes animal and human clinical trials. Computer simulations can help scientists evaluate whether a new treatment is a good candidate for further study.
- **Conflict of interest:** A situation in which someone is responsible for making a decision in an official capacity (e.g., someone holding public office) that could benefit them personally.
- **De-identify:** To remove personal information such as name, medical record number, or study code from a genetic sample so that the sample cannot be linked to a specific individual.
- **Diuretic:** A drug that promotes the production of urine; a common treatment for hypertension.
- **Double-blind study:** A study in which neither the participants *nor the researchers* know which participants are receiving the treatment being researched and which are receiving a placebo. This information is not available to anyone working with study participants.
- Efficacy: Effectiveness as measured in a controlled clinical trial.
- **Ethical standards:** Rules governing the conduct of a person or the conduct of the members of a profession.
- **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.
- **Exclusion criteria:** Any of the conditions that would disqualify someone from participating in a study (see inclusion criteria).
- **FDA (Food and Drug Administration):** The U.S. national authority ultimately responsible for the licensure of new drugs and treatments, as well as supervision of clinical trials.
- **Futility:** Uselessness or pointlessness; reason for stopping a clinical trial if interim data show that the treatment group is unlikely to see any more improvement than the control group.

- **Genetic predisposition:** A greater likelihood of expressing a certain trait based on a person's genetic material (e.g., someone may carry a gene that is known to be related to an increased chance of breast cancer).
- **Genome:** The complete genetic material of an organism.
- **Hepatitis:** Inflammation of the liver caused most frequently by viruses.
- Hermansky-Pudlak Syndrome (HPS): A rare genetic disorder characterized by albinism, bleeding problems, and fatal pulmonary fibrosis.
- **Human cell line:** A continuously dividing set of cells used in medical research that are derived from a single human cell.
- Hypertension: Abnormally high blood pressure.
- **Idiopathic pulmonary fibrosis:** Pulmonary fibrosis that occurs in otherwise healthy people without a known cause.
- **Inbreeding:** When closely related people have children together, generation after generation.
- **Incidence:** The percentage of newly diagnosed cases of a disease in a population.
- **Inclusion criteria:** All of the conditions that must be met for someone to participate in a study (see exclusion criteria).
- **Inclusion/exclusion criteria:** Factors that allow someone to participate in a clinical trial are inclusion criteria. Those that exclude or do not allow participation are exclusion criteria.
- **Informed consent:** A process that outlines required elements of research participation, including its risks and potential benefits, to help someone decide whether to participate. An informed consent form is used to convey essential information and is signed by the participant if he or she decides to join the study.
- **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.
- **Lysosomal disorder:** A disorder that affects the function of lysosomes in cells.

Lysosomes: The part of a cell responsible for breaking down waste materials and other debris.

Metabolize: To break down or synthesize within the body.

Multicenter: Conducted through more than one research center.

Open label: The term for a study in which participants and staff know which study arm (treatment or placebo) participants are in; there is no "blinding."

Orphan disease: See "Rare disease."

Orphan Drug Act: The *Orphan Drug Act* of 1983 provides incentives to researchers and pharmaceutical companies for developing drugs for rare disorders.

Patient advocacy group: Often founded by family members, these groups seek to connect people who have rare diseases and move research forward.

Penicillin: An antibiotic drug made from penicillium mold (or produced synthetically) used to treat infections and diseases.

Pharmacokinetics: The study of how the body absorbs, distributes, metabolizes, and eliminates a drug or vaccine.

Phenotype: Observable physical or biochemical characteristics resulting from both genetic makeup and environmental influences.

Pirfenidone: A drug developed by InterMune Inc. for the treatment of idiopathic pulmonary fibrosis.

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).

Pre-clinical: Describes stages of preliminary research involving basic discovery science, computer simulation, cell and tissue cultures, and animal trials. These stages precede clinical trials (with human participants).

Pulmonary fibrosis: Scarring or thickening of the lungs.

Ramifications: Consequences or results of actions, especially when not desired.

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.

- **Rare disease:** A disease that affects fewer than 1 in 1,500 people (in the U.S.). They are mostly genetic conditions passed on from parent to child.
- **Schizophrenia:** A mental illness resulting in greatly impaired thinking, emotional responses, and behaviors.
- Single-gene disorder: A disorder caused by a mutation in a single gene.
- **Social worker:** A professional who deals with the social, emotional, and environmental problems associated with a disease or disability.
- **Stakeholder:** A person with an interest or concern in something.
- **Stories of origin:** Stories that recount how something (or a people) came into being.

Syphilis: A sexually transmitted disease caused by bacteria, which can cause skin lesions. Left untreated, syphilis can cause inflammation, meningitis, and other central nervous system damage, as well as and cardiovascular damage. Syphilis can remain in the body undetected for many years (latency), and symptoms can appear more than 40 years later.

Tissue sample: Bodily fluids (e.g., blood or saliva) or tissue (e.g., cells, skin, bone, or muscle) for use in research.

Type II Diabetes: A chronic medical condition that affects how the body metabolizes sugar (glucose). Type II Diabetes typically begins in adulthood and patients are not usually dependent on the use of insulin to control their sugar levels.

Undue influence: Is exerted when a person of higher power or authority takes advantage of another person; undue influence can often include coercion.

Vulnerable (populations): Groups that may be exploited for use in research, e.g., children, people who are illiterate, and prisoners.

APPENDIX Creating Discussion Ground Rules

INTRODUCTION

The study of ethics involves consideration of conflicting moral choices and dilemmas about which reasonable people may disagree. Since a wide range of positions is likely to be found among students in most classrooms, it is especially important to foster a safe classroom atmosphere by creating some discussion ground rules. These ground rules are often referred to as "norms." An agreed-upon set of ground rules should be in place before beginning *The Science and Ethics of Humans in Research* curriculum.

OBJECTIVES

Students will be able to:

• Create and agree to classroom discussion norms.

PROCEDURE

Ask the students, "What can we do to make this a safe and comfortable group for discussing issues that might be controversial or difficult? What ground rules should we set up?" Allow students some quiet reflection time, and then gather ideas from the group in a brainstorming session. One method is to ask students to generate a list of ground rules in small groups and then ask each group to share one rule until all have been listed. Clarify and consolidate the ground rules as necessary.

Post norms where they can be seen by all, and revisit them often. If a discussion gets overly contentious at any time, it is helpful to stop and refer to the ground rules as a class to assess whether they have been upheld.

Some possible student ground rules/norms could include:

- A bioethics discussion is not a competition or a debate with a winner and a loser.
- Everyone will respect the different viewpoints expressed.
- If conflicts arise during discussion, they must be resolved in a manner that retains everyone's dignity.
- Everyone has an equal voice.
- Interruptions are not allowed, and no one person is allowed to dominate the discussion.
- Critique ideas, not people.
- Assume good intent.
- All are responsible for following and enforcing the rules.