AUTHORS AND CONTRIBUTORS

Renee Agatsuma, MSEd
Former Faculty, Garfield High School, Seattle, WA

Myra Arnone, MAT
Faculty, Redmond High School, Redmond, WA

Dawn Brown, MEd
Science Teacher, Truman Career Academy,
Federal Way, WA

Jeanne Ting Chowning, MS
Northwest Association for Biomedical Research,
Seattle, WA

Elise Cooksley, MS
Faculty, Two Rivers High School, North Bend, WA

Paula Fraser, MLS
Bellevue, WA

Joan Griswold, MIT
Northwest Association for Biomedical Research,
Seattle, WA

Lindsey Own
Faculty, The Evergreen School, Shoreline, WA

Rosetta Eun Ryong Lee
Faculty, Seattle Girls School, Seattle, WA

Jodie Spitze
Faculty, Kent-Meridian High School, Kent, WA

Dianne Thompson
Faculty, Kent-Meridian High School, Kent, WA

EXPERT REVIEWERS

Gail B. Broder, MHS
HIV Vaccine Trials Network
Fred Hutchinson Cancer Research Center
Seattle, WA

Kelly Edwards, PhD
Faculty, Department of Bioethics and Humanities
University of Washington School of Medicine
Seattle, WA

Barbara Waxman, PhD
Paragon Education Network
Seattle, WA

Chris Witwer, CIP
Compliance Manager
Institute for Systems Biology
Seattle, WA

PROJECT MANAGEMENT, EDITING, AND CURRICULUM PRODUCTION

Kristen Clapper Bergsman, MEd, and Kathryn True
Laughing Crow Curriculum LLC

COVER DESIGN

Cover produced by Laughing Crow Curriculum LLC
Designed by Clayton DeFrate Design

GRAPHIC DESIGN

Clayton DeFrate Design

COPYEDITING

Polly Freeman, MA

PROOFING

Joanna Prasertong,
Laughing Crow Curriculum LLC
FUNDING SOURCE

This curriculum was made possible by “Collaborations to Understand Research and Ethics” (CURE), supported by the National Center for Research Resources and the Division of Program Coordination, Planning, and Strategic Initiatives of the National Institutes of Health through Grant #R25OD011138. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH, or NWABR’s consultants or advisory board members.

COLLABORATIONS TO UNDERSTAND RESEARCH ETHIC (CURE) LEADERSHIP TEAM

Jeanne Chowning, MS
Principal Investigator, CURE
Director of Education
Northwest Association for Biomedical Research

Susan Adler
Co-Principal Investigator, CURE
Executive Director
Northwest Association for Biomedical Research

Joan Griswold, MIT
Curriculum Design Lead
Northwest Association for Biomedical Research

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CURE ADVISORY BOARD

Bill Cameron, PhD
Associate Professor, Dept. of Behavioral Neuroscience
Oregon Health and Science University

Carolyn Cohen, MEd
Cohen Research & Evaluation

Susanna Cunningham, PhD
Professor
Dept. of Biobehavioral Nursing & Health Systems
University of Washington

Nora Disis, PhD
Director, Center for Translational Medicine in Women’s Health
Institute for Translational Health Sciences
University of Washington

Kelly Edwards, PhD
Associate Professor, Dept. of Medical History & Ethics
Director, ELSI/Outreach Core, Center for Ecogenetics and Environmental Health
University of Washington

Judy Fenyk-Melody, DVM, DACLAM
Director, Preclinical
Amgen

José Lopez, MD
Executive Vice President for Research
Puget Sound Blood Center

Dana Riley Black, PhD
Center for Inquiry Science
Institute for Systems Biology

Louisa Stark, PhD
Director, Genetic Science Learning Center
Eccles Institute of Human Genetics
University of Utah

Beverly Torok-Storb, PhD
Senior Scientist
Fred Hutchinson Cancer Research

Reitha Weeks, PhD
Resident Scientist
Northwest Association for Biomedical Research

Elaine Woo
Science Program Manager
Seattle Public Schools
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CURRICULUM OVERVIEW

Why do scientists involve human participants in biomedical research? Who participates in research and why? Furthermore, how does the complex—and sometimes difficult—history of humans in research influence current attitudes, policies, and practices?

This curriculum introduces students to the way research is conducted with human participants, the related rules and regulations, and the bioethical principles that guide scientists when working with humans in research. Lesson strategies and bioethical discussions engage students in science content and promote an understanding of the role of science in society.

RESEARCH ETHICS SERIES ENDURING UNDERSTANDINGS

• The biomedical research process is interconnected, complex and dynamic, requiring information and tools of reasoning.

• The biomedical research process is driven by the future benefit to people and animals.

• The biomedical research process has evolved due to analytical reflection by society and scientists regarding accepted practices and continues to do so as our knowledge expands.

• The biomedical research process requires active participation by scientists, consumers, clinicians, citizens, and research participants.

The Science and Ethics of Humans in Research curriculum is part of NWABR’s Research Ethics Series, which also includes The Nature of Scientific Research, and The Science and Ethics of Animal Research (see page 8).

INSTRUCTIONAL COMPONENTS

Elements: The curriculum consists of a formative assessment, five sequential lessons, a film guide for the movie RARE, and a summative assessment.

Time:

<table>
<thead>
<tr>
<th>Element</th>
<th>Approximate Time Required</th>
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<tbody>
<tr>
<td>Formative Assessment</td>
<td>20 minutes</td>
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<tr>
<td>Lessons One through Five</td>
<td>1 class period of 55 minutes each</td>
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<tr>
<td>RARE Film Guide</td>
<td>1–2 class periods of 55 minutes each</td>
</tr>
<tr>
<td>Summative Assessment</td>
<td>1 class period to begin; additional time depends on how much in-class time is given for writing the paper</td>
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Targeted Audiences: Grades 7–12

Systems Thinking

Science is a human enterprise conducted in a social context; science and its technological applications clearly have interconnected ethical implications. This curriculum seeks to integrate elements of the research endeavor and impact student learning in the following ways:

• Students learn to look at the interconnections between parts in a system rather than looking at qualities of separate objects.

• Students see a “web” of interconnection between a set of events, rather than thinking linearly about the events.

• Students understand that a whole system may have different properties than the parts of the system.

Fostering a Safe Classroom Environment

It is especially important to foster a safe classroom atmosphere when students must consider and discuss possibly controversial issues. The ethical issues addressed throughout this curriculum may involve conflicting moral choices. Please review or create classroom discussion ground rules (“norms”) before beginning the unit (see Appendix, Creating Discussion Ground Rules).
THE SCIENCE AND ETHICS OF HUMANS IN RESEARCH

Essential Questions

1. How does the history of research with humans influence attitudes, policies, and current practices?

2. Why do scientists involve humans in research? How do scientists recruit, engage, and partner with study participants?

3. What is the process used to make decisions regarding humans in research, and how are costs and benefits evaluated?

4. How does the process of carrying out ethical trials involving humans influence the amount of time needed to develop new cures and treatments?

5. How can my actions reflect my position on research involving humans?

LESSON OVERVIEW

The 5 E Learning Cycle Model, as publicized through its use in the BSCS (Biological Sciences Curriculum Study) science program, incorporates five phases of learning: engagement, exploration, explanation, elaboration, and evaluation. The lessons in this curriculum follow the 5 E Model to guide students through this powerful cycle of learning. In the lesson plan descriptions provided below, notes indicate which stage of the 5 E Learning Cycle Model aligns with each lesson plan.

Formative Assessment: Identifying Misconceptions

“Engage”
Students begin the unit with an activity in which they sort their prior knowledge and any misconceptions about research involving human participants. In the Human Research Background Sort, students decide whether research statements are accurate or not by sorting them into two categories and explaining their reasoning. This helps teachers elicit student ideas about research involving human participants and take into consideration the students’ prior knowledge for the remainder of the unit. Students will revisit these statements throughout the unit to confirm or refute their positions.

Lesson One: Historical Context of Humans in Research

“Explore & Explain”
In this lesson, students gain insight into the historical context of human participants in research. Students participate in an activity in which they analyze four historically notable case studies where ethics remain unclear. Students develop their own list of ethical guidelines by creating a concept map and then comparing their guidelines to the principles outlined in the Belmont Report: Respect for Persons (including autonomy), Beneficence, and Justice. This lesson provides a preliminary understanding of the difficulties and considerations that need to be taken into account when involving humans in research.

Lesson Two: Applying the Belmont Principles

“Elaborate”
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.
Lesson Three: Institutional Review Boards—The Nitty Gritty

“Explore”
Students are introduced to the concept of an Institutional Review Board (IRB), also known as an Ethics Committee (EC), 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.

Lesson Four: Participating In Research

“Explore & Elaborate”
Students begin by gathering their own behavioral, medical, and genetic information, and prepare a cheek swab DNA sample. Next, students consider using their information to participate in a number of simulated research projects. This leads to a discussion about how the amount of time, degree of involvement, level of risk, and reasons for participation can vary for different types of research studies. Finally, students think about the ramifications of the fast-growing technology of biobanking in the context of clinical research and discuss their personal views.

Lesson Five: Clinical Trials

“Explore & Explain”
In this lesson, students learn about the purpose and structure of clinical trials by simulating three phases of a clinical trial. Using colored beads to represent a local population that could be involved in research, students recruit participants for a study researching the effects of a medication on high blood pressure, a fairly common condition. After students complete three clinical trial phases for this drug, they consider the challenges of running a clinical trial testing medication for a rare disease. Students will also be introduced to elements of clinical trial study design including the use of placebos, randomization, and blinded studies.

RARE Film Guide: Curriculum Supplement—Exploring Rare Disease Research

“Elaborate”
This activity is designed to be used with the film RARE, a documentary that explores the major issues affecting people living with a rare genetic disorder, Hermansky-Pudlak Syndrome (HPS). Before the film, students explore and share their ideas about general themes in the film by responding to statements in a Silent Chalk Talk. Students are then asked to view the film from the perspective of a stakeholder in regard to a clinical trial testing a new drug for HPS. Stakeholders include Donna Appell, a mother working to find a cure for her 21-year-old daughter who has HPS; Heather Kirkwood, a woman with HPS who is involved in a clinical trial for a drug to treat people with HPS; and Dr. William Gahl, a researcher from the National Institutes of Health (NIH) who works with people with HPS and runs the clinical trial in which Heather is enrolled. After watching the film, students gather for another Silent Chalk Talk, and meet in small groups to discuss the film’s ethical issues from different perspectives.

Summative Assessment: Position Paper

“Evaluate”
Students demonstrate what they have learned over the course of the unit by identifying and justifying their personal position regarding their own participation in a real clinical trial. Students evaluate a trial using a decision-making model to consider ethical protections, the scientific and social value of the trial, and the potential risks and benefits of their possible participation in the trial. Students then write a paper detailing how their decision to participate or not reflects their position on research involving humans.
RESEARCH ETHICS SERIES

The Science and Ethics of Humans in Research is part of the following curricular set:

The Social Nature of Scientific Research

- How is scientific research different from other ways of discovery and learning about the world?
- How does the ethical conduct of scientific research lead to a process that promotes accountability, integrity, and intellectual honesty?
- How are scientific research and society shaped and influenced by each other?
- How does scientific research develop and change in response to new evidence, knowledge, and the application of new tools?
- What is my role and responsibility in being a scientifically literate citizen?

The Science and Ethics of Animal Research

- Why do scientists use animals in research?
- How does the history of animal research influence current views and policies?
- How do ethical considerations influence the use of animals in research?
- How can my actions reflect my position on the use of animals in research?

The Science and Ethics of Humans in Research

- How does the history of research with human participants influence attitudes, policies, and current practice?
- Why do scientists involve humans in research? How do scientists recruit, engage, and partner with study participants?
- What is the process used to make decisions regarding humans in research, and how are costs and benefits evaluated?
- How does the process of carrying out ethical trials involving humans influence the time needed to develop new cures and treatments?
- How can my actions reflect my position on research involving humans?

Each unit is designed to be used independently or as part of a larger curricular set. All three units are available from http://www.nwabr.org.
CORRELATION TO NATIONAL LEARNING STANDARDS

National Standards Alignment: Science (Grades 5–12)

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## Comprehension and Collaboration, Grades 9–10

1. Initiate and participate effectively in a range of collaborative discussions (one-on-one, in groups, and teacher-led) with diverse partners on topics, texts, and issues, building on others’ ideas and expressing their own clearly and persuasively.

   - a. Come to discussions prepared, having read and researched material under study; explicitly draw on that preparation by referring to evidence from texts and other research on the topic or issue to stimulate a thoughtful, well-reasoned exchange of ideas.

   - b. Work with peers to set rules for collegial discussions and decision-making (e.g., informal consensus, taking votes on key issues, presentation of alternate views), clear goals and deadlines, and individual roles as needed.

   - c. Propel conversations by posing and responding to questions that relate the current discussion to broader themes or larger ideas; actively incorporate others into the discussion; and clarify, verify, or challenge ideas and conclusions.

   - d. Respond thoughtfully to diverse perspectives, summarize points of agreement and disagreement, and, when warranted, qualify or justify their own views and understanding and make new connections in light of the evidence and reasoning presented.

## Framework for K–12 Science Education

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### Crosscutting Concepts

| Patterns | • | • |
| Systems and System Models | • | • |
| Energy and Matter: Flows, Cycles, and Conservation | • | • |

### Core Ideas: Life Sciences

| LS 1: From Molecules to Organisms: Structures and Processes | • |
| LS 2: Ecosystems: Interactions, Energy, and Dynamics D: Social Interactions and Group Behaviors | • |
| LS 3: Heredity: Inheritance and Variation of Traits | • |
