FELLOWSHIP TRAINING ACTIVITY GUIDE

ETHICS

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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ABOUT ETHICS

Ethics are principles or a set of values held by a person or group. These principles and rules include characteristics such as personal accountability, maintaining confidentiality and, in a public health context, ensuring the accuracy of testing results.

In this training activity guide, we will discuss how ethical, professional, and scientific behaviors help ensure scientific integrity and sustain effective relationships with stakeholders and the public.

LEARNING OBJECTIVES

Once you have completed all the activities in this guide and met with your mentor, you should be able to:

- Describe the principles of scientific conduct at it applies to your workplace
- Locate resources that provide details regarding professional and scientific codes of conduct

REFLECTION

Describe how the objectives above can help you in your position as a fellow:

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FELLOW PROFILE: SANJAY

Sanjay is a new fellow at a state public health laboratory. Sanjay has spent time working on undergraduate biological research in a university setting and understands the ethical considerations involved with his work there. He realizes that plagiarism, falsifying data and not giving proper credit are all unethical.

Now that he is in a public health laboratory with a much broader scope than his university laboratory, he realizes he has just scratched the surface of ethical concerns.

Let's look at some of the areas of ethical responsibility that Sanjay will have to deal with daily as he moves forward in his public health laboratory career.

PRINCIPLES OF ETHICAL PROFESSIONAL CONDUCT

Ethics is the method, perspective or procedure that can help an individual analyze complex issues and even decide how to act in certain situations. An ethical concern is concern with values and principles.

Ethical standards are particularly important for the conduct of scientific research. Government agencies that support scientific research have adopted specific rules and policies related to research ethics.

Examples include:

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Environmental Protection Agency (EPA)
- US Department of Agriculture (USDA)

See the Additional Resources section of this document to learn more about these principles.

ETHICAL CONSIDERATIONS

The functions of the public health laboratory serve to protect the public from disease through identification of pathogens and research on issues of public health concern. Ethical considerations must be at the forefront of any scientists' action in the laboratory.

For example, research must be published in a socially responsible manner. This social responsibility includes the concept of dual-use as scientific discovery can frequently be used for both good and evil.

For an overview of the considerations regarding dual-use, watch the short video Dual-Use Research - A Dialogue (https://youtu.be/0yS1ur24j40) presented by the National Institute of Health.

ETHICS DILEMMA IN PUBLIC HEALTH

In 2012 the scientific community faced a dual-use dilemma. Two researchers developed a genetically engineered strain of the H5N1 avian influenza virus, commonly known as the "bird flu." Results of the research potentially contributed to understanding of how the virus could be transmitted between humans. Controversy soon erupted surrounding the dual-use dilemma and publication of the results of the research.

The concern was that publication could lead to a pandemic as a potentially lethal pathogen was released into the human population either:

- by means of a laboratory accident as scientists attempted to duplicate the research, or
- through criminal activity that could lead to the unleashing of a terrorist weapon

Researchers, public health and government officials questioned whether the benefits gained by publication of the research outweighed the risks of the potential release of a pandemic. The results of the research were eventually published but the controversy continues.

If you would like to read more about this event, here is a link to the manuscript H5N1 Avian Flu RESEARCH and the Ethics of KNOWLEDGE (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3953619/), written by David Resnick.

In addition to dual-use research, ethical considerations also apply to:

- research and human subjects
- patient privacy
- animal welfare

HUMAN SUBJECTS PROTECTION

Research on human subjects brings up many ethical concerns and is tightly regulated by government and academic institutions.

Three basic ethical principles from the **Belmont Report**, created by the Office for Human Research Protections, form the basis for these policies and regulations:

- **Respect for Persons** – individuals should be treated as autonomous agents and persons with diminished autonomy should be protected. A basic example is protection of personal information. This means an individual's opinions and choices must not be restricted. It also means that researchers must protect children, as well as the ill and mentally disabled.
- **Beneficence** – researchers are obligated to maximize possible benefits and minimize possible harms to both research subjects and society at large. An example would be research on childhood illness that presents risks without immediate benefits to the children involved.
- **Justice** – injustice occurs when an individual is unfairly denied a benefit or when a burden is unfairly imposed. For example, historically the burdens of serving as research subjects fell largely on the poor while the benefits of improved medical care flowed to wealthier patients.

See the Additional Resources section of this document to read the **Belmont Report**

or find out more about the Office of Human Research Protections.

INFORMED CONSENT

Informed consent is one of the main tenets upon which human subjects research is based. Without it, the research cannot be considered to be ethical.

All participants in a research study must understand the purpose, the procedures, the potential risks and benefits of their involvement and their alternatives to participation.

See the Additional Resources section of this document for additional information about the requirements of informed consent.

PATIENT PRIVACY

HIPAA or Health Insurance Portability and Accountability Act of 1996 is United States legislation that provides data privacy and security provisions for safeguarding medical information.

The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and is applicable to institutions that conduct research.

Laboratories are permitted to use or disclose for research purpose health information which has been de-identified, in accordance with specific parameters.

The Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research.

ANIMAL WELFARE

The issue of using animals in scientific research is controversial. The position of the federal government on the issue is:

"The use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals."

The Animal Welfare Act is the only federal law in the US that regulates the treatment of animals in research. The law was later amended with the addition of the Improved Standards for Laboratory Animals Act. This

amendment created new minimum standards for the handling, housing, sanitation, feeding and other care practices of animals used in laboratory research. The psychological well-being of animals was also taken into consideration.

Each research facility is to establish an Institutional Animal Care committee to oversee research proposals and provide oversight for animal experimentation.

The Public Health Service Policy on Humane Care and Use of Laboratory Animals is applicable to all public health service conducted or supported activities involving animals.

The policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals.

See the Additional Resources section of this document for guidance on the use of laboratory animals consult the "*Guide for the Care and Use of Laboratory Animals*" and the Animal Research Advisory Committee Guidelines.

ACTIVITY: KNOWLEDGE CHECK

Earlier in this seminar we discussed the principles of ethical professional conduct and four agencies were mentioned:

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Environmental Protection Agency (EPA)
- US Department of Agriculture (USDA)

Select one of these agencies and locate their ethics policies on their website. Write down the agency that you have selected and 3 facts that you have learned from their policies.

CASE STUDY: HENRIETTA LACKS

Let's consider a real-life ethics case, described in the book The Immortal Life of Henrietta Lacks, by author Rebecca Skloot.

In 1950, Henrietta Lacks, a poor African- American woman in her early 30s, was admitted to Johns Hopkins Hospital for treatment of cervical cancer. During surgery, Henrietta's cells were harvested without her consent or knowledge and were cultured and grown for further research, becoming the HeLa cell line, the first immortal cell line.

Because of the unique nature of her cells, they ended up being used by research facilities for countless studies around the world, generating a multimillion-dollar industry around the production and use of the HeLa line, continuing on to this day.

Research involving HeLa has led to medical and scientific breakthroughs. It has also led to new and evolving policies concerning patient and research subject rights.

Based on what you know of Henrietta Lacks' story, what considerations were ignored during her care and what negative effects might this bring about?

CASE STUDY RESOLVED

1. No informed consent was given - Mrs. Lacks did not give permission for her cells to be harvested and in fact, was not even asked.
2. Lack of beneficence and justice – there was no benefit for Mrs. Lacks to provide her cells and her family also received nothing, despite the untold number of medical and scientific breakthroughs and the money made from the discoveries. A year later, Mrs. Lacks died due to her illness and her family continued to struggle living in poverty.
3. Loss of privacy – Mrs. Lacks name was used during the research and due to the publication of the article, her family lost all anonymity.
4. Ethical dilemma – Did the merits of scientific and medical discovery outweigh the lack of benefit and privacy to Mrs. Lacks' family?

NEXT STEPS: MENTOR MEETING

Meet with your mentor to discuss:

- Principles of scientific conduct as it applies to your laboratory
- Your answers to the Henrietta Lacks case study

ADDITIONAL RESOURCES

Resource Name/Title	Institution	Website/Periodical Information
Guidelines for Ethical Conduct in the Care and Use of Nonhuman Animals in Research	American Psychological Association	This **brochure** outlines the guidelines that were developed by the American Psychological Association (APA) for use by psychologists working with nonhuman animals.
Public Health Ethics Training Materials	CDC	Free **training materials** and opportunities provided by the CDC.
Ethical Considerations	Center for Innovation in Research and Training (CIRT)	The purpose of this **module** is to introduce and discuss ethical issues that should be considered when designing and conducting a research project.
Health Information Privacy (HIPAA)	DHHS	This **brochure** discusses the HIPAA Privacy Rule, which establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.
Comparison of FDA and HHS Human Subject Protection Regulations	FDA	This **webpage** compares human subjects protection regulations between agencies.
Summary of Principles of Ethical Research	Leeds University	Knowledge check regarding the general principles of ethics. (**online quiz**)

Resource Name/Title	Institution	Website/Periodical Information
On Being a Scientist: A Guide to Responsible Conduct in Research	National Academy of Sciences	A full-text online **book** discussing the guiding principles to conducting ethical scientific research.
Dual-Use Research - A Dialogue	National Institutes of Health	This educational **video** was produced by the National Institutes of Health (U.S. Department of Health and Human Services) to raise awareness and understanding about the issue of dual use life sciences research.
Guide for the Care and Use of Laboratory Animals	National Research Council	This **brochure** provides guidance on the care and use of animals during research.
Animal Research Advisory Committee Guidelines	NIH - Office of Animal Care & Use	This **webpage** provides links to additional resources with animal care and use guidelines.
The Belmont Report	Office for Human Research Protections	On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This **report** outlines the guidelines to be followed.
Introduction to the Responsible Conduct of Research	Office of Research Integrity/DHHS	The ORI Introduction to RCR **brochure** seeks to supplement existing resources by making a comprehensive overview of basic rules of the road for responsible research available to all PHS-funded researchers. It has been prepared with the needs of small and mid-size research institutions and beginning researchers in mind, since ORI has often been asked to provide resources for this community, but it may find use in other settings.

Resource Name/Title	Institution	Website/Periodical Information
Office for Human Research Protections (OHRP)	OHRP/DHHS	This **website** provides an overview of the Office for Human Research Protections (OHRP), which provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services.
Informed Consent Information	OHRP/DHHS	This **webpage** provides links to additional resources regarding informed consent.
H5N1 Avian Flu Research and the Ethics of Knowledge	National Library of Medicine	This example is used in the Ethics module. Author **manuscript** available through abstract on NCBI site