LA IMMACULADA CONCEPCION SCHOOL

SENIOR HIGH SCHOOL
GRADE 12–APPLIED SUBJECT: PRACTICAL RESEARCH III

TOPIC: RESEARCH NORMS AND MISCONDUCTS -LESSON #8
APRIL 27-30,2020

ETHICS IN RESEARCH

Ethics- pertains to the moral principles that govern one's behavior in relation to any activity.

Ethical Standards-require a researcher to voluntarily present the outcome of the inquiry before the stakeholders, regardless of results.

- A scholarly work should be subjected to close scrutiny.
- It requires competence and expertise.
- Intellectual property rights should be respected and other people's contributions should be acknowledged.

Moral and social responsibility should be seriously considered in any research undertaking or inquiry.
Human life should always be protected and prioritized during the conduct of the study.
It is unethical to discriminate against people on account of their gender, race, or religion.

Research must promote critical thinking and improve problem solving abilities and skills-it should not be used for black propaganda or pursue unfounded allegations against an individual, group of people or an organization.

Research Ethics dictates good relations between research collaborators. Trust, respect, and cooperation are fundamental values that should be adhered to by people involved in the field of research.
Researchers should be open to constructive criticism, learn from biased and prejudicial comments.

Non-compliance with ethical standards of research can be classified into two:
1. Research misbehavior
2. Research misconduct

Deviations from generally accepted research practices are considered unethical. They may constitute acts that violate institutional or professional policies or a code of ethics but may not be viewed as research misconduct according to the United States' Federal Policy. These may include, but are not limited to the following:

- Conflict of Interest
- Poorly maintained research records and laboratory notebooks
- Violation of animal welfare in handling laboratory test animals
- Submitting for publication one paper to two different journals and concealing such act from both publishers
- Sabotaging your colleagues' or someone else's work
- Guest or ghost authorship even if a colleague has no significant contribution to the paper
- Non-inclusion of outliers from a data set without explaining your reason for doing so
- Proceeding with the presentation of your results to the public even without going through a peer-review process
- Enhancing the significance of your research using inappropriate statistical techniques or analytical methods.
- A discrepancy between a procedural description and what was actually carried out
- Improper waste disposal

Reference: Inquiries, Investigations, and Immersions
by: Dahlia del Castillo Apodaca pp.23-25

ACTIVITY

Directions: Answer the following questions in 2-3 meaningful sentences. Do this in a whole sheet of paper.
1. What are the various manifestations of ethics in the conduct of research?
2. How do you classify ethical standards in research?
3. Cite some examples of real-life situations requiring adherence to ethical standards.

ACTIVITY
Directions: Read the article below and answer the given questions based on your understanding.

James M. Wilson is a medical geneticist who once headed the University of Pennsylvania's (Penn) Institute for Human Gene Therapy. He spearheaded research work in the field of gene therapy as a potential cure for hereditary defects. In August 1999, he, together with other Penn scientists, conducted a clinical trial to examine "the safety of a therapy for ornithine transcarbamylase (OTC) deficiency, a rare disorder in which the liver lacks a functional copy of the OTC gene. The defect prevents the body from eliminating ammonia, a toxic breakdown product of protein metabolism. They had engineered a weekend adenovirus, or cold virus, to deliver a normal copy of the OTC gene into the liver" Seventeen patients underwent this kind of treatment and showed severe liver reactions. But even though the results were not good, Dr.Wilson decided to proceed with the testing and included Jesse Gelsinger, an 18-year old from Tucson, Arizona, in this trial. The clinical trial was not successful as Jesse succumbed to multiple organ failures while undergoing gene therapy at the University of Pennysylvania . "Gelsinger's family became enraged as they learned details of the trial that hadn't disclosed to them: The fact that Wilson held equity in Genovo and that some of the animals in his trials had suffered toxic, even fatal, side effects from their injections. (The researchers didn't think the animal deaths were relevant to the safety of the human trials because the animals had received far higher doses of the viruses.

Source: http://www.wired.com/2013/08/the-fall-andd-rise-of-gene-theraphy-2/(last accessed on 29 June 2015)

A settlement was arranged by the university, paying off a sum of money for the wrongful death lawsuit filed by Jesse's family. Dr.Wilson, who was responsible for the protocol and its compliance, admitted that" the protocol was not written in a way in which there was enough clarity to know when the ammonia had to be what [level], and that was a significant shortcoming." Dr. Wilson further mentioned that scientists who develop therapies should not initiate testing in humans. As of 2009.with a grant from GlaxoSmithKline, he has distributed 120 new adenovirus-associated viruses to 700 investigators around the world for further study, in the hope that there will be no more repeat of cases similar to Jesse Gelsinger's.

Source: http://www.scientificamerican.com/article/gene-therapy-an-interview/(last accessed on 19 January 2016)

Questions:
1. Was Dr. Wilson's decision entirely ethical? Why or why not?
2. Has he been diligent in discussing the limitations of the clinical trials performed in the past prior to Jess Gelsinger's trial treatment?
3. What were the responsibilities of Dr. Wilson to the participants in the clinical tests?

TOPIC: Research Misconduct: Fabrication and Falsification -Lesson 9
April 27-30, 2020

The United States Federal Policy defines "research misconduct as fabrication, falsification or plagiarism in proposing, performing or reviewing research, or reporting research results."

Criteria set by the US Federal Policy regarding research misconduct
1. Misconduct constitutes the inability to present all pieces of evidence in relation to certain allegations.
2. There should be an element of deliberate and irresponsible performance of the said act.
3. Misconduct pertains to deviations from normally acceptable practices.

The US Federal Policy defines" **fabrication** "as an act of composing data results and recording or reporting them. On the other hand, "**falsification**" is an act of manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately presented in the research record."

Consequences of Research Misconduct
Research misconduct is a grave offense in the scientific community.

- It affects the integrity of the whole process of scientific inquiry, allowing highly significant research findings to go down the drain.
- It would also mean retraction of journal articles from the reputable publication circulation, if it has already been published.
- It damages the reputation of the researchers involved
- The very essence of a scientific inquiry (being scholarly work) is tarnish.

ACTIVITY
Directions: Read the article below and give your reaction regarding the situation.

In January 2014, a breakthrough research project on stem cell technology was reported in the British journal *Nature.* Two papers were authored by Haruko Obokata ,a promising scientist from RIKEN, a quasi-government research institution based in Kobe, Japan. The said article aught the interest and attention of other prolific researchers .Other scientists tried to adapt her methods using the reported methodologies but they couldn't get the same results. This triggered a lot of questions including an accusation of research misconduct. As a result, the two papers were retracted and became subject of an investigation by RIKEN.
Access the following Web sites:
http://www.bbc.com/news/health-26836930 (last accessed on 9 June 2015)
http://www3.riken.jp/stap/e/fl documentl.pdf(last accessed on 29 June 2015)

Read carefully the information indicated in those sources and answer the following questions:
1. Based on your knowledge of research misconduct, did Dr. Obokata's act represent research misconduct? Explain your answer.

2. If indeed she had been involved in research misconduct, were the indicators of a deliberate attempt to commit such misconduct? Identify each of those deliberate actions initiated by Dr.Obokata?
3. List specific acts involving research misconduct committed by Obokata and categorize them as falsification, fabrication, or plagiarism.

ACTIVITY
Consider both Dr. Wilson's and Dr. Obokata's case.
1. Which case constitutes an act of research misbehavior? Why do you think so?
2. Who committed grave research misconducts? Justify your answer.
3. What could have been done in both cases to prevent these unethical behaviors from happening?