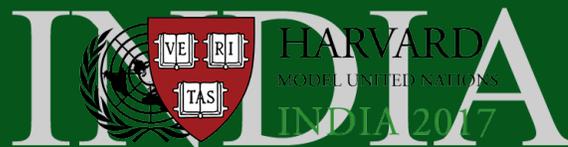


Update Paper for the United Nations Educational, Scientific, and Cultural Organization



BY ASSISTANT DIRECTOR KHUSHI MALIK

Recent Violations in Life Sciences Research

What is Clinical Misconduct?

Life sciences research is an integral and pivotal part of scientific and medical advancements. However, in academic history there have been several cases of malpractices and unethical conduct by scientists, sometimes even lauded scholars.

According to the Office of Research Integrity, misconduct is defined by the following terms:

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

Violation of the clinical code may be dealt with seriously depending on the intensity of the violation. The impact of such malicious research activities is far reaching. It has a great influence of institutions, journals and other science organizations that have based their research on the false papers published. In recent times there have been an “unparalleled number of retractions in high profile and reputable journals.” “Repercussions from research misconduct can take various forms: journal retractions, scientific ostracism, barred access to funding, and job loss. But rarely does it involve criminal charges, not to mention jail time.”

Case Study 1: Fake HIV vaccine research by

Biomedical Scientist

A former researcher at the Iowa State University, Dong-Pyou Han was charged of ethical misconduct (fabricating and falsifying data) in his research on the HIV vaccine.

Han's misconduct dates back to the year 2008, where he worked under Professor Michael Cho at the Case Western Reserve University in Cleveland. Professor Cho received grants from the National Institute of Health (NIH) and extensively researched on the HIV vaccine on mice. Cho and his team found that on injecting the mice with the GP41 vaccine, the immune system responded by producing antibodies, thereby revealing that mice had developed the ability to neutralize the HIV vaccine - proclaimed a major breakthrough among the scientific community. The Guardian reports that “Han said he initially accidentally mixed human blood with rabbit blood”, thus, resulting in human antibodies in the samples. However, it was not revealed by Han as he did not wish to disappoint his mentor and the team and continued to spike the samples in this manner.

This case of dishonest research shows the lack of integrity and dilemma faced by Han between confronting his professor and continuing research that was gaining international attention. Han was charged with four and a half years of imprisonment and an exorbitant fine of \$ 7.2 million to the NIH.

It is often said that Han's case brings forward the “uneven nature of penalties for scientific misconduct.”

The Nature reported that, “David Wright, a former ORI director, says that the benefit of criminal prosecution is unclear. Formally barring a researcher from receiving federal funds is usually a professional death sentence, even if the ban is short, he adds. ‘It's

questionable how much more is to be gained by jail time.”

Case Study 2 : Major setback to Quest Life Sciences

The Chennai-based Contract Research Organization (CRO) Quest Life Sciences was issued a Notice of Concern (NOC) by the World Health Organization (WHO) for “violation of procedures during clinical trials for HIV drugs” namely Lamivudine, Zidovudine and Nevirapines. During October 2014, the Investigators from WHO “observed lack of data integrity in clinical trial records, failures in protection of subject safety, inadequate quality assurance, among others.” “It said 67 per cent of the subject pre-study electrocardiograms (ECGs) were duplicates, with the details of the patients and dates having been changed to make the ECGs appear as if they were from different subjects who had participated in the study.” The Team from WHO said that, “This means that ECGs may not have been performed or were unreliable and therefore ineligible/unfit subjects could have been used in the study and protocol requirements have not been met.”

Such falsification in research could lead low quality manufacture and have detrimental effects. The response to the NOC was rejected by the WHO and the study was rejected.

In a similar revelation of misconduct in research, it was reported that nearly 700 drugs (that underwent bio-equivalence studies at Hyderabad-based GVK Bio Sciences’ facility) were banned from the European Union following the recommendation by the European Medicines Agency (EMA) due to reported false electrocardiograms.

Conclusion

In Conclusion, Dr. Freckelton rightly states, “For science, the challenge is to acknowledge the problem of fraud, understand the profiles and motives of the people who engage in it, take assertive steps to discourage it, and take active measures to reinstitute a culture of scholarly integrity.”

BIBLIOGRAPHIC ENDNOTES:

<https://ori.hhs.gov/definition-misconduct>

Freckelton, Ian QC; July 26, 2016 ‘When Scientists Lie’, Web <http://www.abc.net.au/radionational/programs/ockhamsrazor/when-scientists-lie-ian-freckleton-on-scholarly-miscon->

[duct-fraud/7660464](http://www.abc.net.au/radionational/programs/ockhamsrazor/when-scientists-lie-ian-freckleton-on-scholarly-misconduct-fraud/7660464)

Ibid.

Bernstein, Rachel; “HIV researcher found guilty of research misconduct sentenced to prison”, Web, July 6 2015. <http://www.sciencemag.org/careers/2015/07/hiv-researcher-found-guilty-research-misconduct-sentenced-prison>

Phillip, Abby, “Researcher who spiked rabbit blood to fake HIV vaccine results slapped with rare prison sentence” , July 1 2015, Web.

https://www.washingtonpost.com/news/to-your-health/wp/2015/07/01/researcher-who-spiked-rabbit-blood-to-fake-hiv-vaccine-results-slapped-with-rare-prison-sentence/?utm_term=.84610f7e8214

Ibid.

Ibid.

The Guardian, July 1, 2015, Web. “Scientist behind fake HIV breakthrough sentenced to prison after spiking results.”

<https://www.theguardian.com/society/2015/jul/01/iowa-scientist-hiv-breakthrough-dong-pyou-han>

Ibid.

Ibid.

Reardon, Sara. July 1, 2015, Web “US vaccine researcher sentenced to prison for fraud”

<http://www.nature.com/news/us-vaccine-researcher-sentenced-to-prison-for-fraud-1.17660>

Ibid.

July 7 2015, Financial Express, Web. “WHO puts Quest Life Sciences on notice for clinical code violation”

<http://www.financialexpress.com/industry/who-puts-quest-life-sciences-on-notice-for-clinical-code-violation/96615/>

“Quest Life Sciences gets WHO notice” July 8, 2015 Business Standard, Web.

http://www.business-standard.com/article/companies/quest-life-sciences-gets-who-notice-115070700687_1.html

Ibid.

Ibid.

Ibid.

The Business Standard, July 27, 2015, Web “EU ban on GVK-tested drugs from August 21” http://www.business-standard.com/article/companies/eu-ban-on-gvk-tested-drugs-from-august-21-115072600111_1.html

Ibid.