January 2016

Responsible Conduct of Research: How Research Misconduct Impacts the Principal Investigator, the Research Team and the Study

Case Scenario

Dr ABC is the Principal Investigator (PI) of an industry-sponsored randomised, double-blind, placebo controlled trial. According to the study protocol, after informed consent has been obtained, enrolled subjects will be issued with a unique subject code and the investigational product (IP) will be dispensed. The total number of target recruitment subjects is 10, and there were 6 subjects recruited till date.

During a scheduled site monitoring visit, the senior monitor noticed that 4 out of the 6 informed consent forms had similar handwriting/style for the names of subjects and signatures. When the medical records of these 4 subjects were requested for source documentation verification, the clinical research coordinator verbalised that the medical records of these subjects could not be found by the medical records office. In addition, the senior monitor could not find other evidence to support the existence of these 4 subjects.

Based on the lack of evidence for these 4 subjects, the senior monitor suspected that a research misconduct, fabrication has occurred. She immediately notified the sponsor of the situation. The sponsor advised her to escalated the situation to the institution's clinical research office for further investigation of the alleged research misconduct. Within the week, the institution temporarily suspended the study's recruitment of trial subjects and conducted a thorough investigation of the alleged research misconduct.

At the end of the investigation, there were no evidence to substantiate the existence of these 4 subjects (there were no medical records with the names of these subjects) and it was uncovered that the recruited subjects does not exist. From the outcome of the investigation, the institution concluded that this was a valid research misconduct, and proceeded to informed the approving Institutional Review Board, as well as the regulatory authority of the research misconduct and provided a report of the investigation.

How research misconduct could impact the PI, the research team and the study? Here are some impacts of research misconduct, but not limited to:

1. Possible loss of reputation and reliability of the PI, research team and institution.
2. Debarment from eligibility to receive future funds for grants and contracts.
3. Submission of retraction of published articles by the ^respondent.
4. Suspension or termination of an award, if any.
5. Professional licenses may be revoked.
6. Possible termination of the study site.
7. Loss of employment.

^respondent: refers to the defendant, in this case, it refers to the individual who have committed the valid research misconduct.

Note: The research community is strongly recommended to confer with their institution's policies and guidelines for any components of research misconduct reporting that they are unsure of.

References:

1. NHG Responsible Conduct of Research (https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/responsibleconductofresearch/responsibleconductofresearch+)

2. NHG Responsible Conduct of Research, Core Components https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/responsibleconductofresearch/corecomponentsofrcr+

3. NHG Responsible Conduct of Research Manual https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/resourcesforrcr

4. National Institute of Health Office of Extramural Research: Research Integrity https://grants.nih.gov/grants/research_integrity/research_misconduct.htm

Article Contributed By: **Ms. Grace Xie, Senior CRC, Investigational Medicine Unit, NUH**
Edited By: NHG-RDO