Research Ethics and Scientific Misconduct in Biomedical Research

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Summary

Scientists have the responsibility of judging what is best for the patient and the optimal conditions for the conduct of the study. All physicians should ensure that research they participate in is ethically conducted. Every clinician should learn and receive training in the responsible conduct of research and publication, and each project must be reviewed by an institutional review committee.

Scientific misconduct is defined as any practice that deviates from those accepted by the scientific community and ultimately damages the integrity of the research process. “Sloppy Research” and “Scientific Fraud” include activities which can violate science, records and publication. Sloppy research is due to absence of appropriate training in research discipline and methodologies. In contrast, scientific fraud is defined as deliberate action during application, performance of research, and publication. It includes piracy, plagiarism and fraud.

Research institutions should adopt rules and regulations to respond to allegations, start investigational operations and perform appropriate sanctions.

Keywords: Research Ethics; Scientific Misconduct; Scientific Fraud.

Scientific research is based upon values such as integrity, honesty, trust as well as respect for academic, scientific and intellectual achievements. Integrity of the research study reflects the adherence of scientists to honest and reproducible methods in proposing, performing, evaluating and reporting research. Ethics are the branch of philosophy dealing with the concepts of honor, truthfulness, moral values, objectivity, honesty and integrity [2, 10, 11].

Scientists for centuries have been depending on each other and the rules of their community to protect the honest and objective measures during the research process. The concept of integrity and ethics is at the heart of research practice, clinical practice and publication issues that concern young investigators, chairmen, academic staff, and editors. Each individual’s personal integrity in an academic institution as a researcher or a staff-member leads to the integrity and ethics of their institutions [2, 11, 15].

All the senior staff and lecturers have the responsibility for teaching ethical principles to new trainees in the institutions. There is an important need to teach junior scientists and students about research and publication ethics at a very early stage of their education [16, 20].

There are six essential components that have an effect on the results of biomedical research [15]:

a) Investigator: Person who is responsible for conducting the study and if successful research study leads to career advancement, promotion and possibly financial gains.

b) Employer/Institution: The place where investigator performs his/her research studies. The institution may gain credibility and profitability by the success of the researcher.

c) Sponsor of the research

d) Patient (in clinical research studies)

e) Scientific Community: Group which needs reliable scientific information

f) Public: Community who pays for biomedical research through taxes and donations.

Scientists who do clinical research involving their patients must have the responsibility of judging between what is best for the patient and what is optimal for the conduct of the study [15, 20]. In any case, physicians as researchers must consider their primary role as care-supplier “first” and as investigators “second”. All physicians should ensure that research they participate in is ethically conducted [19, 20, 23].

Each investigator must be aware of the following issues before, during and after the research process [16, 20, 23]:
a. Validity

- A study is scientifically valid if it answers the questions that it asks.
- It should have a large enough number of subjects to provide statistically valid results.
- The techniques employed should be reliable, reproducible and sufficient to test the hypothesis.
- The study should not risk human subjects during the process.

b. Value

Valuable research has to designed to produce knowledge that ultimately proves to be important, reproducible, productive and contributory. The scientific community and the peers have to benefit from the results [11, 20].

c. Ethical Issues

Each research study must be reviewed by an interdisciplinary review committee or has to meet strictly outlined criteria for review [20].

Ethical committees should review several aspects of a proposed study including its risks, benefits, consent forms, the importance and impact of the new information to be gained and the confidentiality issues [19, 20, 23, 25].

Each human study dealing with patients and volunteer control subjects should be submitted to an ethical review committee. Investigators without access to an ethical committee may wish to contact to nearest academic medical center willing to review the protocol [16, 25].

d. Compensation

Payments should commensurate with the time and effort spent and the expenses incurred in recruitment [16].

e. Authorship

Authorized authorship requires involvement in developing a study’s conception and design, analyzing, performing and interpreting results, drafting or revising the manuscript’s intellectual content and approving the final text [3, 22, 24, 25].

Clinicians who are interested in contributing to research should spend some time learning about the responsible conduct of research and should receive training and advice from experienced senior investigators, because ethical conduct and scientific research demands careful consideration, planning and attention to detail [16, 20].

Scientific Misconduct

Scientific misconduct is defined by the U.S. Public Health Service as “any practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research and ultimately damage the integrity of the research process” [20, 23]. However “questionable research practices or sloppy research” should include research practices or actions that violate the values of research process due to inadequate training and supervision [6, 20, 22, 24].

“Sloppy research” or questionable research practices include activities which can violate traditions of science, waste time and resources. These activities include failing to retain significant research data, keeping inadequate research records, utilizing inappropriate statistical methods or publishing preliminary research data without peer-review or validation. Most common cause of “Sloppy Research” is the absence of appropriate training in research and research methodologies [6, 20, 22].

Although some scientists have suggested that incidents of misconduct in research and publications are underreported, estimates given in U.S. government studies have been low. The Office of Scientific Integrity (OSI) in the Public Health Service in Washington, D.C. found evidence of misconduct in fewer than 20 cases from March 1989 through March 1991 [3, 20, 22]. Infrequent case disclosures of scientific misconduct still raise important concerns and questions among grant financiers, scientists, institutions, public and media. Scientific misconduct has to be taken into account as a serious matter. The Royal College of Physicians classifies “scientific misconduct” as Piracy, Plagiarism and Fraud [3, 6, 22].

a. Piracy

Deliberate exploitation of ideas, work, text or other materials from another person(s) without acknowledgement [3, 20].