

FOSTERING AN ETHICAL CULTURE IN RESEARCH AND PUBLICATION

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As Malaysia strives towards developed-nation status, we are increasingly aware of the importance of a strong scientific and research culture in our society. Our "K-economy" is closely linked to the ability to use scientific knowledge to improve our services and economic status. We recognise that, ultimately, what gives advanced countries the edge over others is the ability to harness science and technology to benefit every aspect of life, be it leisure, work, travel, dining or health. Advanced societies invest heavily in research, and research is all about understanding our world better, seeking for new knowledge, and devising new applications from this stock of knowledge to benefit society. It is no different in healthcare and medicine. In a progressive society, both patient and practitioner expect new advances to be made every year. Today, biomedical research is no longer the privilege of academics. It is an expected activity of all medical practitioners who want to understand disease better, subscribe to evidence-based practice and seek to be more effective in what they do. The *Malaysian Family Physician* has upheld this philosophy by running a series of educational articles on the research process.

Research misconduct and the need for research ethics

If one were true to the quest for knowledge, what can go wrong? Is not all pursuit of knowledge justified and good? Are not all researchers engaged in an altruistic activity that should be respected and upheld by society? That the series of research notes of this Journal should end with one on "ethical issues in research and publication" calls upon us to reflect on the chequered history of biomedical research and the checks and balances that are now an integral part of modern society. Unjustified experimentation on prisoners-of-war during the Second World War have so horrified the world and tarnished the image of biomedical scientists that the previously trusted position of medical researchers can be said to be lost forever. The need for ethical conduct of medical research led to the Declaration of Helsinki in June 1964 by the World Medical Association.¹ This is revised regularly² and remains the most widely accepted guideline for biomedical research. It forms the backbone of the ICH Harmonised Tripartite Guidelines for

Good Clinical Practice (ICH-GCP Guidelines), encompassing (1) respect for the dignity of research subjects (the right to information, informed consent and the right to refuse or withdraw from the study), (2) recognition that research should not override the health, well-being and care of research subjects (the benefits should outweigh the risk), and (3) principles of justice (the burden and benefits of research should be fairly distributed among subjects). The Malaysian Guidelines for Good Clinical Practice adopts the ICH-GCP Guidelines.³ Many young researchers fail to realise that signed consent does not automatically qualify as informed consent. The essence of informed consent requires explaining the research protocol (including possible adverse effects) to the potential research subject in understandable terms (i.e. simple layman language). There should be no coercion or financial reward for consenting to the study. No reasons need to be given by the subject who declines to participate or subsequently withdraws from the study.

Since publication is the endpoint of research, research ethics also apply here. The ethical issues in publication, however, are somewhat different. Fabrication and manipulation of research data, plagiarism and misrepresentation of credentials constitute the most grievous ethical breaches. When brought to light, the resulting scandal usually damages not only the researcher but also his associates and the Institution where he works. Other than loss of credibility, such breaches have resulted in resignation or dismissal of the delinquent researcher, legal suits, and even personal tragedies such as suicides. While many of us will readily frown at research fraud, it is important to recognise that plagiarism is no better. Plagiarism, the copying of another person's composition and presenting it as one's own is, in fact, theft of intellectual property. We know it is unacceptable when academics plagiarise articles sent to them for review, or a researcher plagiarises another person's grant application, or someone copies, more or less wholesale, a published article and submit it as his own. In the current "cut-and-paste" culture, young researchers and postgraduate students tend to plagiarise large portions of text and illustrations from books or other published works, believing that there can be no harm in merely copying something

that is already so well-written by someone else. In such a scenario, there is also copyright contravention to consider. The key lies in being transparent. Any "borrowing" of text should be indicated as quotations (with references). Reproductions of tables and figures should have permission from the publisher.

Ethical issues also arise from unjustified authorship, conflicts of interest, breaches of confidentiality, duplicate publications, simultaneous submissions of manuscripts, citation bias and misrepresentations. Editors are responsible for safeguarding the journal's ethical standards and will readily act against research misconduct. To reduce contentions, many journals have developed editorial policies which require authors to justify authorship, declare potential conflicts of interest, and state the journal's right of access to research data for verification, and the right to forward the manuscript to appropriate authority for investigation of misconduct.

The power of peer review

How can researchers be held accountable for what they do? Developing guidelines for ethical practice is one thing. Can it be ensured that researchers follow them? Modern society has fallen upon the power of peer review to define and enforce the standards expected in professional practice. In medical practice, peers have evolved a Code of Professional Conduct to ensure that doctors bear moral, ethical and professional responsibility for their patients. In biomedical research, studies involving human subjects are expected to undergo peer and public review by an independent Ethics Committee (Institutional Review Board) to ensure that they are conducted in accordance with ICH-GCP Guidelines, and the Declaration of Helsinki. The Ethics Committee should consist of a reasonable number and mix of medical/scientific professionals and non-medical/non-scientific members who collectively have the qualifications and experience to evaluate the scientific and ethical aspects of the research project. The main objectives of the Ethics Committee are to safeguard the rights, safety and well-being of human research volunteers, provide timely, comprehensive and independent review of the ethics of proposed studies and ensure that there is due regard to existing laws, regulations and community attitudes. The Ethics Committee has the authority to not only approve, require modification or disapprove a study (and its amendments), but also to monitor, suspend or terminate previously approved studies.

The International Committee for Medical Journal Editors have defined the common breaches of publication ethics.⁴ Most editors will not publish clinical trials that do not have Ethics Committee approval. Editors also depend heavily on peer review to not only judge the scientific worth of submitted manuscripts but also help detect author misconduct. Journal reviewers, being experts in their fields, can usually detect fraudulent and plagiarised articles quite readily. Such papers are rejected outright. Often the authors are also "blacklisted" by the Editorial Board. The authors may also be reported to the Head of the Institution in which they work.

Developing an ethical culture

The Committee on Publication Ethics, founded in 1997, provides a forum for scientific editors to deliberate on possible breaches of research and publication ethics. A summary of cases discussed over a 6.5 year period revealed that common causes of research misconduct were (in rank order) duplicate publication, authorship issues, lack of ethics approval, inadequate informed consent, falsification of data, plagiarism, unethical experimentation and conflicts of interest.⁵ It is clear that greater awareness needs to be propagated among researchers and reviewers of these common ethical breaches. Principal investigators of clinical studies should undergo training in ICH-GCP Guidelines. Along the same vein, training for reviewers and editors on how to detect and deal with breaches in publication ethics can help raise publication standards. Editors can also enforce ethical standards by firm editorial policies, including retraction of published work found later to be unethically composed. Finally, the standard of ethical practice in any community is dictated by the expectations of peers. We are what our peers think of us. Our reputation is our greatest asset, and a tarnished research reputation can mar a whole research career.

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