

Research Ethics Committees: Preserving Research Integrity and the Public Trust

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The research ethics committee (REC) is critical to the preservation of research integrity and public trust in research without which the research enterprise will fail.

In a recent published review of data on national regulations and RECs worldwide, the Caribbean region was identified as one of the areas with only a few published guidelines (1) despite previous effort at encouraging the establishment of RECs (2). The lack of published guidelines suggests that there is much work yet to be done in strengthening the research ethics framework in the Caribbean. At the same time a new or renewed focus on improving research ethics compliance will require that resources be made available for achieving the goals. Establishing a proper framework for research includes strengthening the capacity for research ethics oversight and providing training opportunities in research ethics for researchers and potential researchers. This should be the goal of relevant government agencies, academic and research institutions and professional bodies.

Research, apart from satisfying the desire to know, is critical to the development of a society (3–6) and therefore the society has a moral duty to encourage research. However, since critical decisions affecting individuals, groups, communities, cities and nations are made based on research findings, there is an equal moral duty to ensure research integrity. Findings of research may be disseminated through various means but regardless of the means of communication, research findings can have a very significant influence on decisions with impact on individuals and societies (7, 8). The integrity of the research enterprise is therefore of importance to the individual and society and as such researchers and research institutions must make every attempt to preserve the public trust (3, 7, 8). Although it is a generally held belief that the majority of research is conducted ethically and with integrity, over the years there have been several unfortunate incidents of research misconduct (3, 7–10). These occurrences have served to raise concern about the conduct of research not only within the academic/research/publishing establishment but also amongst the public. Whilst a lot of attention has been focused on misconduct in biomedical re-

search, the risk is that with misconduct in research, not only could biomedical research be brought into disrepute, but that the general research enterprise could suffer significant damage. Should this happen, it is possible that researchers and research institutions could find it increasingly difficult to be able to pursue meaningful research and for findings from research to be taken seriously especially in the biomedical field (3, 7, 8). At the same time, in the absence of meaningful research, development and hence the public will be the greatest loser. It is therefore critical to preserve integrity and public trust in research.

How might we then attempt to preserve integrity and the public trust in research? Integrity and public trust can only be achieved through transparency in research. Transparency in the process of research will help to reassure all, including the public, and contribute to the continuation of their trust in research and researchers. This is only possible if researchers join together to consistently demonstrate adherence to the agreed upon standards of ethical research and research integrity (11). For Biomedical research, the current standards have been documented in several codes and declarations beginning with the Nuremberg Code in 1949 (12). The Nuremberg Code was developed out of the recommendations of the judges who presided over the trial of 23 German Doctors accused of conducting improper research for the then Nazi government of Germany. The Nuremberg Code set forth the basic requirements for satisfaction before research using human subjects should be permitted and has formed the basis for all other declarations, codes and regulations produced since then. These codes, declarations and regulations are intended as guides to proper conduct of research and provide a reference point for the evaluation of research and research conduct as it relates to research ethics compliance, thereby minimizing the occurrence of research misconduct (12–18).

Research ethics essentially seeks to achieve the goals of the protection of human/animal subjects in its broadest definition (individually, as a community, as a race, as a nation), from harm in or as a result of research and ensuring integrity in research by requiring that researchers observe certain ethical standards (13). Research ethics compliance on the other hand is a means of assuring that the objectives of research ethics have been satisfied. Because a researcher is so intimately involved in the research it is often not possible for him/herself to certify the true extent of risk and harm involved in their research and thus the ethical nature of the research. It is therefore recommended that a system of inde-

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pendent review, with representation of the non-scientific community, be employed to adjudicate on such matters. This review system, REC or Institutional Review Board (IRB) is vested with the authority to approve or withhold approval for proposed research based on the level of ethical concerns and how they are addressed. This independent committee is given the responsibility to ensure that research proposals satisfy the institutionally agreed ethical standards as well as internationally agreed standards. In the absence of a scientific review committee the REC is also given the responsibility of assuring that the research is scientifically sound and of benefit (19).

In fulfilling their mandate, RECs have an important duty to perform and in so doing may seem to researchers to be overbearing and burdensome, even unnecessary. If we accept however, that preservation of integrity and the public's trust in research is of paramount importance and that the best mechanism is to have transparency through an independent mechanism to give that assurance, then we must agree that the REC is absolutely necessary. To underscore the belief that this independent review system is necessary for protecting the public's interest, many funding and publishing institutions have a mandatory requirement for the process to be utilized if funding is to be provided or publication allowed (20–22). Researchers therefore ignore research ethics to their own, their institution and possibly their country's peril. There is an additional and equally important argument for the REC in that it provides some protection for the subjects of research, the researchers themselves and the institutions involved in research. This protection is achieved by careful documentation of deliberations and decisions, and the consequent follow-up and review of approved protocols, including adverse event reporting. It is my view that the benefits to the researcher of a review system is such that the researcher needs the review system more than the review system needs the researcher, for without the "guarantee" of the review system, research may well become a discredited activity thus adversely affecting the livelihood of researchers and research institutions.

In order to better understand research ethics and optimally utilize the review system, researchers and potential researchers should be encouraged to review material relevant to ethical concerns in research. The prior review and understanding of the tenets of research ethics should assist the researcher in understanding the requirements of the REC. If there is a prior understanding of the requirements and the reason for the requirements of the REC, the researcher should then be more able to satisfy those requirements with minimum delay thus eliminating one of the complaints. This self-serving approach should serve to make it appealing for researchers to seek out and complete an educational programme in research ethics. However, the matter of certification of researchers in matters of research ethics should be a concern for our local and national institutions and not only to satisfy international requirements. This is because the

matter of research ethics is of such great importance and relevance as personal, institutional and even national reputation could be at stake. Therefore, in order to reinforce the importance of research ethics for the researcher they should be required to show evidence of having completed an approved educational programme before being allowed to conduct research. The protection of the research process demands that a system of monitoring be in place as a deterrent to misuse and abuse with risk of serious harm to the process. This misuse or abuse has the potential to occur not only in the context of internationally funded research but also in local research, especially in the context of academic recognition and advancement, the "publish or perish" environment (7–8).

After all, if research subjects have reason to fear research and research institutions cannot be seen to act ethically in research, then trust and confidence in research will be eroded. Although compliance with international standards will help, we must not be comfortable with that fact and ignore or procrastinate in attending to the need to establish our own system of protecting our people, our potential research subjects from unacceptable risk, harm and violation of self and this is true for all facets of research affecting humans, animals and the environment which they occupy, whether it is biomedical or social or behavioural. It therefore behooves us to develop and implement local standards for compliance, incorporate them into the educational requirements, and to ensure that the opportunities for education in research ethics exist. Those who have already attended to these concerns should be congratulated and be encouraged to let it be known by publishing it. The publication of such information will help to inform others of the current status and can serve as a guide to others who would wish to do likewise. Our development depends on research, as do our researchers and research institutions. It is therefore imperative that the resources be found and that researchers and potential researchers agitate for an efficiently functioning research ethics review system.

ACKNOWLEDGEMENTS

The author wishes to acknowledge the valuable contribution of the following persons: Ms Cheryl Brown of the Office of Sponsored Research Mona, Dr Kenneth Goodman, Director of the Bioethics Programme at The University of Miami, Dr Ray Moseley from University of Florida and Professor Ewart Thomas of Stanford University.

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