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Raising the bar for the ethical integrity of clinical trials

The article by Dr. Mark Bernstein (on pages 329–332) identifies an essential framework to assess the bioethical integrity of clinical research. This sets new standards for investigators who aspire to develop effective clinical trials in surgery. Moreover, this excellent outline challenges us to introduce some novel strategies to prepare surgical investigators for rigorous ethical scrutiny of clinical trial proposals. These include

- changing the curricula in postgraduate and clinician–investigator training programs to identify issues relating to the ethical assessment of clinical studies
- internal peer-review of grant proposals, to include assessment(s) of bioethical concerns
- the participation of surgeons, surgeon–scientists and surgical trainees on research ethics boards

Addressing the needs of bioethical review in curricula is an essential part of the education program, and one consistent with the specialty training programs of the Royal College of Physicians and Surgeons of Canada (RCPSC), which address the preparation of capable surgeons and surgeon–scientists. The addition of didactic education in these curricula could be complemented by having postgraduate trainees, particularly those engaged in research-intensive training, to participate on the research ethics board of their host institutions on a quarterly basis throughout the year. This would ensure practical exposure to an important dimension of research practice and translation of new knowledge into practice. Participation in these committees will also enhance the collaborative experience, which is identified in the objectives of CanMEDS, the RCPSC's Canadian Medical Education Directions for Specialists project.

Internal peer review is a recognized form of improving the quality of grant proposals that succeed in winning competitive funding. The framework suggested by Dr. Bernstein should serve as an essential checklist to complete this dimension of internal review. Perhaps some of the symposia at our national surgical meetings of, for example, the Canadian Orthopedics Association or the Canadian Surgical Forum, should address peer-review assessment including bioethical integrity as a means of enhancing surgical investigation in Canada.

Participation of surgeons and surgical investigators on research ethics boards is always an issue, since the time commitment can be onerous. However, research ethics boards in most centres struggle with the same issue and are charged with the vagaries of adequately assessing the research and providing timely reviews to the investigators. Surgeons can inform this process. In my own department, we address these issues by designating shared responsibility for research ethics review to a group of surgical investigators so that the task arises every 3–4 months for any single individual.

In sum, Bernstein's framework provides for a thorough assessment of bioethical integrity in clinical trials in surgery. This challenges our greater surgical communities and the surgical academy alike to introduce innovations to meet the standards for the proper ethical conduct of research involving human subjects.

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