From the summit directors

Surgical innovation lives on the border between tradition and regulation in a vaguely defined frontier. Over the course of many centuries, a framework for clinical medical ethics has developed with broad consensus regarding fiduciary obligations between patient and doctor, the principles of beneficence and nonmaleficence, and, more recently, respect for persons and autonomy. During the past century, a parallel set of ethical and regulatory norms has developed surrounding the ethics of research involving human subjects. While both sets of frameworks—those governing clinical ethics and those governing research ethics—contribute to understanding the ethical challenges that arise in the course of surgical innovation, neither is alone sufficient to provide clear guidance.

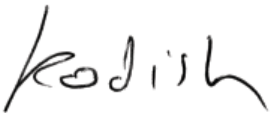
We decided that further discourse would help resolve some of the ambiguity that exists between the frameworks of clinical ethics and research ethics, and we set out to convene a summit meeting to provide a forum for this discourse. It was our hope that bringing together some of the nation's foremost surgical innovators with leading bioethicists would catalyze a series of presentations and discussions to create a meaningful ethical framework for thinking about surgical innovation. The summit took place May 8–9, 2008, at Cleveland Clinic, and we were not disappointed. We now have the pleasure of presenting the proceedings in text form.

The summit's five panel presentations and discussions and two keynote addresses shared the objective of educating participants about moral dilemmas that often arise in the conduct of device development and other innovations in surgery. Panelists suggested potential solutions to the challenges of protecting patients from risk without hindering creativity and progress.

The ethical challenges faced by surgical innovators will not go away. As we develop and refine technology, including new devices, procedures, and transplants, new problems will arise. Two examples of complicated issues on the horizon are robotic surgery and natural orifice transluminal endoscopic surgery (NOTES). While the specific developments will change, the ethical basis of our actions should remain constant. We need to always ask the same questions:

- Is this in the best interests of the patient?
- Have we been thoughtful and effective in the process of informed consent?
- Will our actions be consistent with our own professional integrity?

Our hope is that these proceedings will prompt the necessary next steps: further development of these ideas, writing of papers and convening of more meetings, and, most importantly, further innovation to continue helping patients.



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