

Preface

Surgeons have been leaders in the development of new therapies and technologies for generations. Surgeon innovators are critical partners in surgical device development—to discover unmet needs, to shepherd the new product development process, to design and conduct clinical trials, to establish evidence-based and financially responsible clinical guidelines, and to define training and credentialing processes. Yet, participating in innovation creates a number of ethical issues that must be recognized and managed wisely by the physicians—relationships with industry partners, necessary for device development, regulatory approval, manufacturing, and marketing; relationships with investors and corporations who provide the millions of dollars required to bring a product to market; and relationships with patients, especially those who “go first,” who deserve to know the role that the surgeon had in the development of the product and what financial gain he/she may receive from the product. Additionally, many new technologies or therapies are more expensive than their predecessors. Insurance companies, federal healthcare programs, and the public will ultimately bear the cost of newer therapies, and these payors need to have a mechanism for the evaluating and adopting innovative treatments.

The purpose of this manual is to review the many ethical issues involved in the development, evaluation, and introduction of new treatments for gastrointestinal diseases. We have asked recognized surgical innovators to describe how several landmark procedures were developed in order to illustrate the challenges and ethical dilemmas that they struggled with. Selected chapters will explain how to work with industry

partners and investors, and the challenges of dealing with increasing and uncertain regulatory issues. Once a new technology has been brought to the market, guidelines and standards need to be developed regarding the training, credentialing and adoption of the technology. There are often insufficient standards for balancing the desire to provide patients the latest therapy with the obligation to provide an appropriate and transparent informed consent process. These issues will also be addressed.

This manual was borne of two symposia at the Society of Gastrointestinal and Endoscopic Surgeons (SAGES) Annual Meeting, sessions that the editors were honored to host--Innovations in the Era of Conflict of Interest and Transparency, and The Ethics of Innovation. We appreciate the encouragement of then SAGES President, Dr Gerald Fried, to proceed with this project. We are also indebted to the SAGES Board and staff for their tremendous support. We hope that these chapters will serve a resource for surgeons and other physician innovators, researchers and health policy personnel, the medical device industry, and university biodesign departments to better understand the ethical issues related to the development, introduction and adoption of innovative therapies.

Albany, NY, USA
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October 2015

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The SAGES Manual Ethics of Surgical Innovation

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2016, XVII, 280 p. 19 illus., 15 illus. in color., Softcover

ISBN: 978-3-319-27661-8