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Steven C. Stain, Aurora D. Pryor, Phillip P. Shadduck

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The SAGES Manual Ethics of Surgical Innovation Steven C. Stain, Aurora D. Pryor, Phillip P. Shadduck, 2016-05-04 This text provides a comprehensive review of the ethical issues involved with the development evaluation and introduction of new treatments of gastrointestinal diseases How several landmark surgical innovations were developed are described to show the challenges faced and the ethical dilemmas these innovators dealt with The challenges of dealing with regulatory issues and how to work with industry partners and investors when working on a new therapy is described Once a new technology has been brought to the market standards need to be developed regarding the training credentialing and adoption of the new technology There are insufficient standards of how to balance the desire to provide patients the latest therapy with the obligation that patients receive informed consent about the new technology and the relationship that the physician may have had with product development The book describes the national perspective of paying for new technology and provides one insurance company s approach to the introduction of innovative therapy The Sages Manual Ethics of Surgical Innovation will be a resource for surgeons researchers and health policy personnel to understand the ethical issues related to the development introduction and adoption of innovative therapies for gastrointestinal diseases Although the context for discussion is the application of innovation to gastrointestinal disease the ethical issues are applicable to any discussion of innovative medical or procedural therapies Institutional Review Boards, a System in Jeopardy United States. Congress. House. Committee on Government Reform and Oversight. Subcommittee on Human Resources, 1999

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circumcision and preexposure prophylaxis have shown positive results that warranted approval by the US Food and Drug Administration FDA and the World Health Organization WHO The major challenge experienced in new HIV prevention clinical trials that are underway and in approved interventions that are being scaled up apparently relates to HIV incidence that threatens the social value and scientific validity of the interventions Paradoxically the clinical trials and scale up interventions have become the new sources of HIV infection although the hypothesized benefit to be realized in the end is conceptualized as outweighing the current risks involved **Handbook of Bioequivalence Testing** Sarfaraz K. Niazi,2007-08-22 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct efficient and successful bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence and advances in the analytical technology used to detect drug and metabolite levels have made

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