Human gene transfer is widely regarded as a promising approach for treating a variety of disorders, but its development has been beset by major ethical challenges. *Gene Transfer and the Ethics of First-in-Human Research* uses the example of gene transfer to examine the ethical and policy issues that arise when testing novel and complex medical interventions in human beings for the first time. Issues examined include analysis and management of risk, assessment of scientific value, when to initiate human testing, informed consent in early phase studies, the recruitment of economically disadvantaged study volunteers, and how researchers might better engage members of the public. This book is relevant to ethicists, legal practitioners, policy makers, geneticists, and researchers involved in clinical trials of novel medical interventions.

This is the first book on the ethics of gene transfer since 1997, and the very first comprehensive account of the ethics of translational clinical research.

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“This fine book delivers an in-depth analysis of gene transfer research, and much more. Kimmelman’s informed and careful examination is relevant to many areas of cutting-edge science... [and] offers incisive criticism, but admirable balance as well.... In an era that emphasizes translational work in biomedical research, Kimmelman supplies much-needed guidance to ethicists, scientists, and policymakers.”

Rebecca Dresser, JD  
Daniel Noyes Kirby Professor of Law  
Professor of Ethics in Medicine  
Washington University in St. Louis

“Sets a new standard for bioethical scholarship that is at once scientifically well-grounded, politically astute, philosophically original, and a pleasure to read. In addition to providing an exceptionally clear guide to the history and challenges of human gene transfer research, Kimmelman uses that story to introduce the next chapter in our ethical thinking about the first human trials of all kinds.”

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