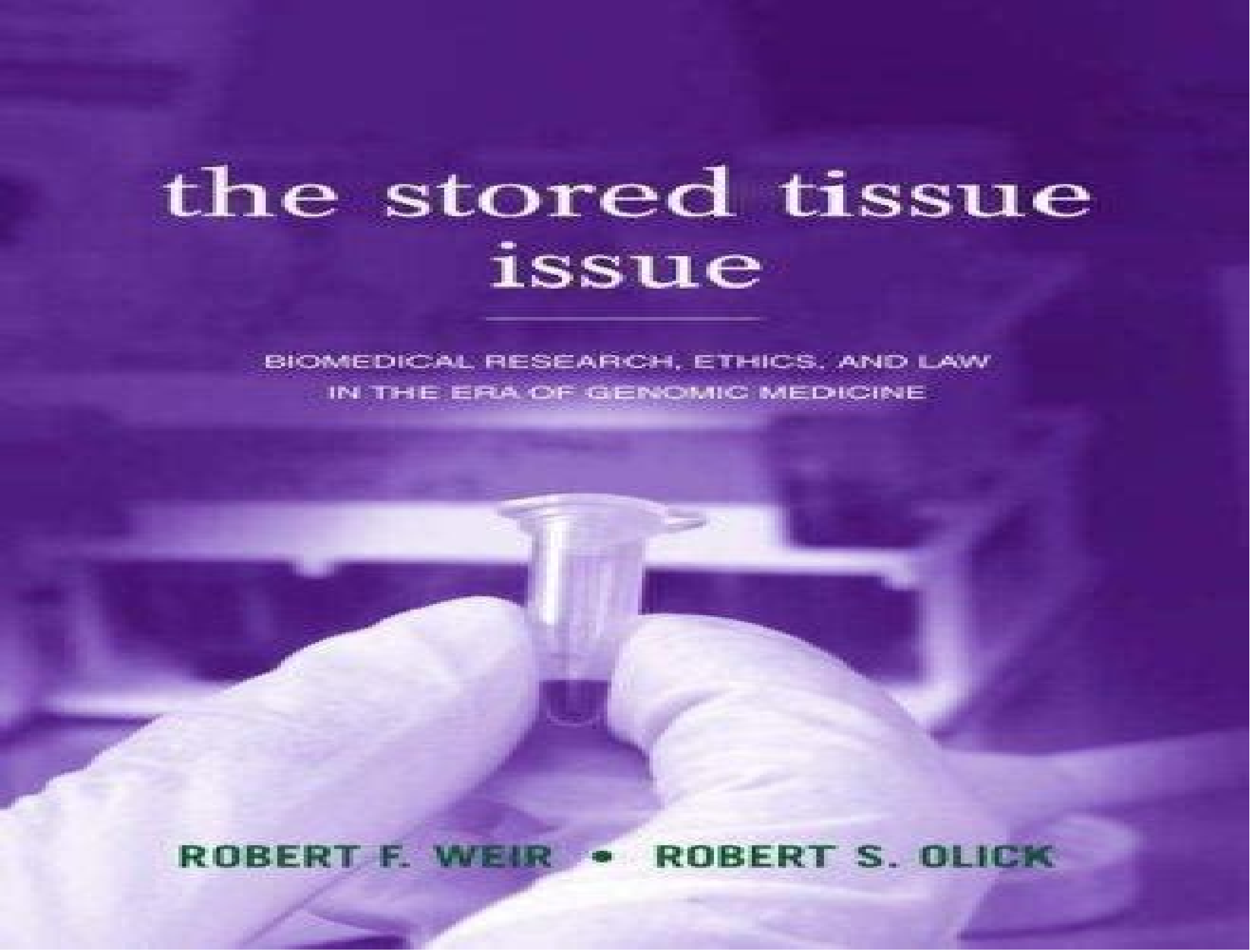

the stored tissue issue

BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA OF GENOMIC MEDICINE

ROBERT F. WEIR • ROBERT S. OLICK

Stored Tissue Issue Biomedical Research Ethics And Law In The Era Of Genomic Medicine

Gerard Quinn,Aisling de Paor,Peter Blanck

Stored Tissue Issue Biomedical Research Ethics And Law In The Era Of Genomic Medicine:

The Stored Tissue Issue Robert F. Weir,Robert S. Olick,Jeffrey C. Murray,2004-05-20 This book provides a thorough well balanced analysis of common research practices with banked tissues DNA and genetic data Describing many examples of beneficial tissue research the authors focus on problematic research practices controversial cases and federal and institutional policies that limit the informed choices of patients and research participants They offer a series of recommendations to help overcome these problems **The Stored Tissue Issue** Robert F. Weir,Robert S. Olick,2023

The Stored Tissue Issue Robert F. Weir,Robert S. Olick,2004-05-20 Genetics research with stored human tissues provides many benefits and holds much promise Yet how this critical research is conducted sometimes raises serious ethical legal and social concerns and it is difficult to balance the promise of biomedical research with our time honored commitments to individual choice in such fundamental matters as control over personal health information and the disposition of our bodily tissues Weir and Olick provide a thorough analysis of this critical phase in the era of genomic medicine While strongly supportive of the biomedical research enterprise they develop a critique of many common research practices with banked tissues DNA and genetic data Noting numerous examples of beneficial human tissue research they focus on problematic research practices controversial cases and federal and institutional policies that limit the informed choices of patients and research participants The authors offer a series of recommendations intended to limit the risks of inadequate informed consent to research for individuals families and groups and to strengthen the bonds of trust between the research enterprise and the public upon which biomedical progress depends This book offers a wealth of information plus well reasoned recommendations that will be of keen interest to geneticists other biomedical scientists research institutions policymakers students and others It will serve as a clarion call to move beyond traditional policies and practices toward a richer understanding of partnership between patients and research participants and the biomedical research enterprise a partnership for the benefit of all *Ethical Issues of Human Genetic Databases* Bernice Elger,2016-05-13 Following the boom in population databases in recent years there has been sustained and intense international debate about political processes and legal and ethical issues surrounding the protection and use of genetic data As a result several national and international organizations and committees have published widely differing guidelines and statements concerning genetic databases and biobanks Ethical Issues of Human Genetic Databases compares the new area of biobanking with the tradition of ethically accepted classical research and highlights the distinctive features of existing databases and guidelines The volume identifies areas of consensus and controversy while investigating the challenges posed to classical health research ethics by the existence of genetic databases analyzing the reasons for such varying guidelines The book will be essential to academics biobankers policy makers and researchers in the field of medical ethics *The Ethics of Research with Human Subjects* David B. Resnik,2025-02-27 In The Ethics of Research with Human Subjects David B Resnik PhD JD develops and defends an approach to thinking about ethical and policy dilemmas in research with human subjects based on the notion of trust The book explains why trust is important not only between investigators and research subjects but also between and among other stakeholders involved in the research enterprise including research staff sponsors institutions communities oversight committees government agencies and the public Dr Resnik argues that trust should be viewed as a distinct ethical principle for research with human subjects that complements other principles such as respect for human dignity beneficence non maleficence and justice The book applies the principle of trust to numerous issues including informed consent confidentiality privacy risk minimization risk benefit assessment payments for participation protection of vulnerable subjects experimental design research integrity and research oversight The book also includes discussions of the history of research involving human subjects moral theories and principles contemporary cases and proposed regulatory reforms This second edition of The Ethics of Research with Human Subjects expands upon and clarifies arguments and ideas discussed in the first edition and includes new material on emerging issues in human research ethics including community based research citizen science research challenge studies including COVID 19 experiments public health research genomics research social and behavioral research xenotransplantation experiments alternative study designs and research with people with compromised decisional capacity employees and students The book is of interest to undergraduate and graduate students who are studying ethical and policy issues related to research with human subjects as well as scientists and scholars who are interested learning more about the issues and thinking about what it means to promote integrity and trust in research with human subjects **Future Uses of the Department of Defense Joint Pathology Center Biorepository** Institute of Medicine,Board on the Health of Select Populations,Committee on the Review of the Appropriate Use of AFIP's Tissue Repository Following Its Transfer to the Joint Pathology Center,2013-01-13 Founded during the Civil War as the Army Medical Museum the Armed Forces Institute of Pathology AFIP amassed the world s largest collection of human pathologic specimens and was considered a premier consultation education and research facility by the end of the 20th century Samples from the AFIP were instrumental in helping to solve public health mysteries such as the sequence of the genome of the 1918 influenza virus that killed more than 40 million people worldwide In 2005 the federal Base Realignment and Closure Commission recommended that the AFIP be closed and its biorepository was transferred to the newly created Joint Pathology Center During the transition the Department of Defense asked the IOM to provide advice on operating the biorepository managing its collection and determining appropriate future use of specimens for consultation education and research Future Uses of the Department of Defense Joint Pathology Center Biorepository the IOM proposes a series of protocols standards safeguards and guidelines that could help to ensure that this national treasure continues to be available to researchers in the years to come while protecting the privacy of the people who provided the materials and maintaining the security of their personal information **Life on Ice** Joanna Radin,2017-03-27 After the atomic bombing at the end of World War II anxieties about survival in the nuclear age led scientists to begin stockpiling and freezing hundreds of thousands of blood samples from indigenous communities around the world These samples were believed to embody potentially invaluable biological information about genetic ancestry evolution microbes and much more Today they persist in freezers as part of a global tissue based infrastructure In Life on Ice Joanna Radin examines how and why these frozen blood samples shaped the practice known as biobanking The Cold War projects Radin tracks were meant to form an enduring total archive of indigenous blood before it was altered by the polluting forces of modernity Freezing allowed that blood to act as a time traveling resource Radin explores the unique cultural and technical circumstances that created and gave momentum to the phenomenon of life on ice and shows how these preserved blood samples served as the building blocks for biomedicine at the dawn of the genomic age In an era of vigorous ethical legal and cultural debates about genetic privacy and identity Life on Ice reveals the larger picture how we got here and the promises and problems involved with finding new uses for cold human blood samples **Genetic Research on Addiction** Audrey Chapman,2012-08-09 The manner in which genetic research associated with addiction is conducted interpreted and translated into clinical practice and policy initiatives raises important social ethical and legal issues Genetic Research on Addiction fulfils two key aims the first is to identify the ethical issues and requirements arising when carrying out genetically based addiction research and the second is to explore the ethical legal and public policy implications of interpreting translating and applying this research The book describes research guidelines on human protection issues such as improving the informed consent process protecting privacy responsibilities to minors and determining whether to accept industry funding The broader public health policy implications of the research are explored and guidelines offered for developing effective social interventions Highly relevant for clinicians researchers academics and policy makers in the fields of addiction mental health and public policy Human Tissue in Transplantation and Research David Price,2009-12-17 A proposal for resolving tensions between professionals and society regarding tissue for transplants and research while properly protecting donors interests Self-Ownership, Property Rights, and the Human Body Muireann Quigley,2018-04-19 How ought the law to deal with novel challenges regarding the use and control of human biomaterials As it stands the law is ill equipped to deal with these Quigley argues that advancing biotechnology means that the law must confront and move boundaries which it has constructed in particular those which delineate property from non property in relation to biomaterials Drawing together often disparate strands of property discourse she offers a philosophical and legal re analysis of the law in relation to property in the body and biomaterials She advances a new defence underpinned by self ownership of the position that persons ought to be seen as the prima facie holders of property rights in their separated biomaterials This book will appeal to those interested in medical and property law philosophy bioethics and health policy amongst others The Body in Bioethics Alastair V. Campbell,2009-05-07 Thorough and comprehensive this volume engages with recent debates about the uses and abuses of the human body both living and dead **Conducting Biosocial**

Surveys National Research Council,Division of Behavioral and Social Sciences and Education,Committee on Population,Committee on National Statistics,Panel on Collecting, Storing, Accessing, and Protecting Biological Specimens and Biodata in Social Surveys,2010-10-02 Recent years have seen a growing tendency for social scientists to collect biological specimens such as blood urine and saliva as part of large scale household surveys By combining biological and social data scientists are opening up new fields of inquiry and are able for the first time to address many new questions and connections But including biospecimens in social surveys also adds a great deal of complexity and cost to the investigator s task Along with the usual concerns about informed consent privacy issues and the best ways to collect store and share data researchers now face a variety of issues that are much less familiar or that appear in a new light In particular collecting and storing human biological materials for use in social science research raises additional legal ethical and social issues as well as practical issues related to the storage retrieval and sharing of data For example acquiring biological data and linking them to social science databases requires a more complex informed consent process the development of a biorepository the establishment of data sharing policies and the creation of a process for deciding how the data are going to be shared and used for secondary analysis all of which add cost to a survey and require additional time and attention from the investigators These issues also are likely to be unfamiliar to social scientists who have not worked with biological specimens in the past Adding to the attraction of collecting biospecimens but also to the complexity of sharing and protecting the data is the fact that this is an era of incredibly rapid gains in our understanding of complex biological and physiological phenomena Thus the tradeoffs between the risks and opportunities of expanding access to research data are constantly changing Conducting Biosocial Surveys offers findings and recommendations concerning the best approaches to the collection storage use and sharing of biospecimens gathered in social science surveys and the digital representations of biological data derived therefrom It is aimed at researchers interested in carrying out such surveys their institutions and their funding agencies

Taking Advance Directives Seriously Robert S. Olick,2001-07-18 In the quarter century since the landmark Karen Ann Quinlan case an ethical legal and societal consensus supporting patients rights to refuse life sustaining treatment has become a cornerstone of bioethics Patients now legally can write advance directives to govern their treatment decisions at a time of future incapacity yet in clinical practice their wishes often are ignored Examining the tension between incompetent patients prior wishes and their current best interests as well as other challenges to advance directives Robert S Olick offers a comprehensive argument for favoring advance instructions during the dying process He clarifies widespread confusion about the moral and legal weight of advance directives and he prescribes changes in law policy and practice that would not only ensure that directives count in the care of the dying but also would define narrow instances when directives should not be followed Olick also presents and develops an original theory of prospective autonomy that recasts and strengthens patient and family control While focusing largely on philosophical issues the book devotes substantial attention to legal and policy questions and includes case studies throughout An important resource for medical ethicists lawyers physicians nurses health care professionals and patients rights advocates it champions the practical ethical and humane duty of taking advance directives seriously where it matters most at the bedside of dying patients **Big Data, Databases and "Ownership" Rights in the Cloud** Marcelo Corrales Compagnucci,2019-11-02 Two of the most important developments of this new century are the emergence of cloud computing and big data However the uncertainties surrounding the failure of cloud service providers to clearly assert ownership rights over data and databases during cloud computing transactions and big data services have been perceived as imposing legal risks and transaction costs This lack of clear ownership rights is also seen as slowing down the capacity of the Internet market to thrive Click through agreements drafted on a take it or leave it basis govern the current state of the art and they do not allow much room for negotiation The novel contribution of this book proffers a new contractual model advocating the extension of the negotiation capabilities of cloud customers thus enabling an automated and machine readable framework orchestrated by a cloud broker Cloud computing and big data are constantly evolving and transforming into new paradigms where cloud brokers are predicted to play a vital role as innovation intermediaries adding extra value to the entire life cycle This evolution will alleviate the legal uncertainties in society by means of embedding legal requirements in the user interface and related computer systems or its code This book situates the theories of law and economics and behavioral law and economics in the context of cloud computing and takes database rights and ownership rights of data as prime examples to represent the problem of collecting outsourcing and sharing data and databases on a global scale It does this by highlighting the legal constraints concerning ownership rights of data and databases and proposes finding a solution outside the boundaries and limitations of the law By allowing cloud brokers to establish themselves in the market as entities coordinating and actively engaging in the negotiation of service level agreements SLAs individual customers as well as small and medium sized enterprises could efficiently and effortlessly choose a cloud provider that best suits their needs This approach which the author calls plan like architectures endeavors to create a more trustworthy cloud computing environment and to yield radical new results for the development of the cloud computing and big data markets *Institutional Review Board* Elizabeth A. Bankert,Robert J. Amdur,2006 This comprehensive reference covers three separate areas related to IRBs administration daily management and ethical issues This instructional manual provides IRB members and administrators with the information they need to run an efficient and effective system of protecting human research subjects while remaining in compliance with federal research regulations The text includes case studies sample forms and sample policy documents The updated Second Edition includes seven new chapters IRB Closure of Study Files Internet Research Research in Public Schools Phase I Clinical Trials in Healthy Volunteers Vulnerability in Research Balancing the Risks and Potential Benefits and HIPAA **The Cambridge Handbook of Human Dignity** Marcus Düwell,Jens Braarvig,Roger Brownsword,Dietmar Mieth,2014-04-10 This introduction to human dignity explores the history of the notion from antiquity to the nineteenth century and the way in which dignity is conceptualised in non Western contexts Building on this it addresses a range of systematic conceptualisations considers the theoretical and legal conditions for human dignity as a useful notion and analyses a number of philosophical and conceptual approaches to dignity Finally the book introduces current debates paying particular attention to the legal implementation human rights justice and conflicts medicine and bioethics and provides an explicit systematic framework for discussing human dignity Adopting a wide range of perspectives and taking into account numerous cultures and contexts this handbook is a valuable resource for students scholars and professionals working in philosophy law history and theology *Genetic Discrimination* Gerard Quinn,Aisling de Paor,Peter Blanck,2014-11-20 As genetic technologies advance genetic testing may well offer the prospect of detecting the onset of future disabilities Some research also forwards that certain behavioural profiles may have a strong genetic basis such as the determination to succeed or the propensity for risk taking As this technology becomes more prevalent there is a danger that genetic information may be misused by third parties and that particular genetic profiles may be discriminated against by employers by providers of social goods and services such as insurance companies and even by educational facilities This book explores the different forms and potential uses of genetic testing Drawing together leading experts in disability law bioethics health law and a range of related fields it highlights the ethical and legal challenges arising as a result of emerging and rapidly advancing genetic science On examining transatlantic perspectives on the matter chapters in the book ask whether the US Genetic Information Nondiscrimination Act GINA is proving to be an effective tool in addressing the issue of genetic discrimination and alleviating fears of discrimination The book also reviews what insights may be gained from GINA within employment and health insurance contexts and asks how the UN Convention on the Rights of Persons with Disabilities CRPD may impact similar debates within the European Union The book focuses particularly on the legislative and policy framework in the European Union with an emphasis on the gaps in protection and the scope for specific legislative action in this area This book will be of great interest to scholars and students of discrimination law bioethics and disability law and will be of considerable use to legal practitioners medical practitioners and policy makers in this area *Altruism Reconsidered* Peter Sýkora,Urban Wiesing,2016-04-01 As the use of human body parts has become increasingly commercialized a need has arisen for new approaches to regulation that moves beyond the paradigm of altruism During the course of this discussion the notion of property has become a key concept Focusing on practical and conceptual perspectives the multidisciplinary group of authors which includes specialists in philosophy law sociology biology and medicine have come together with practicing lawyers to consider both legal provisions and patterns of regulation in countries across Europe Identifying divergences between different legal traditions the authors explore various conceptual models which could be used to improve and to guide policy making With this twin focus on practical and conceptual perspectives this volume sets the standard for a detailed and innovative discussion of issues surrounding the regulation of research on human tissue

Medical Use of Human Beings Austen Garwood-Gowers,2019-07-19 Whilst activities like transplantation and medical research have typically been considered on a discrete basis they are also actually part of a broader phenomenon of medical means being employed to make use of human beings This book is the first ever systematic critique of such medical use of the human being as a whole It is divided into two parts The first part considers what constitutes an appropriate normative lens through which to view such medical use and its constraint It makes a reasoned ethical and human rights based case for preferring respect for human worth over any of the main alternative approaches that have been drawn on in specific contexts and outlines what this preference practically implies The second part uses this respect based lens to critique use discourse law and practice Drawing on three contrasting case study areas of warfare related medical use transplantation and human tissue research this book exposes both the context specific and thematic nature of shortfalls in respect Overall this book provides a compelling analysis of how medical use ought to be constrained and a compelling critique of the excesses of discourse practice and governance It is recommended to academics students policymakers and professionals whose work is focused on or intersects with the medical sector and anyone else with an interest in medicine and its limits *Principles of Pharmacogenetics and Pharmacogenomics* Russ B. Altman,Russ Altman,David Flockhart,David B. Goldstein,2012-01-23 This textbook presents the latest information on pharmacogenetics and pharmacogenomics for students professionals and researchers

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