Acceptable Risk In Biomedical Research European Perspectives International Library Of Ethics Law And The New Medicine

Environmental Systems Science: Theory and Practical Applications looks at pollution and environmental quality from a systems perspective. Credible human and ecological risk estimation and prediction methods are described, including life cycle assessment, feasibility studies, pollution control decision tools, and approaches to determine adverse outcome pathways, fate and transport, sampling and analysis, and cost-effectiveness. The book brings translational science to environmental quality, applying groundbreaking methodologies like informatics, data mining, and applications of secondary data systems. Multiple human and ecological variables are introduced and integrated to support calculations that aid environmental and public health decision making. The book bridges the perspectives of scientists, engineers, and other professionals working in numerous environmental and public health fields addressing problems like toxic substances, deforestation, climate change, and loss of biological diversity, recommending sustainable solutions to these and other seemingly intractable environmental problems. The causal agents discussed include physical, chemical, and biological agents, such as per- and polyfluoroalkyl substances (PFAS), SARS-CoV-2 (the COVID-19 virus), and other emerging contaminants. Provides an optimistic and interdisciplinary approach, underpinned by scientific first principles and theory to evaluate pollutant sources and sinks, applying biochemodynamic methods, measurements and models Deconstructs prior initiatives in environmental assessment and management using an interdisciplinary approach to evaluate what has worked and why Lays out a holistic understanding of the real impact of human activities on the current state of pollution, linking the physical sciences and engineering with socioeconomic, cultural perspectives, and environmental justice Takes a life cycle view of human and ecological systems, from the molecular to the planetary scale, integrating theories and tools from various disciplines to assess the current and projected states of environmental quality Explains the elements of risk, reliability and resilience of built and natural systems, including discussions of toxicology, sustainability, and human-pollutant interactions based on spatial, biological, and human activity information, i.e. the exposome

The second edition of the gold standard text in the field, Nonhuman Primates in Biomedical Research provides a comprehensive, up-to-date review of the use of nonhuman primates in biomedical research. The Biology and Management volume provides basic information on the natural biology of nonhuman primates and the current state of knowledge regarding captive management.Each chapter contains an extensive list of bibliographic references, photographs, and graphic illustrations to provide the reader with a thorough review of the subject. * Fully revised and updated, providing researchers with the most comprehensive review of the use of nonhuman primates in biomedical research * Addresses commonly used nonhuman primate biomedical models, providing researchers with species-specific information * Includes four color images throughout

The development of new drugs is very complex, costly and risky. Its success is highly

dependent on an intense collaboration and interaction between many departments within the drug development organization, external investigators and service providers, in constant dialogue with regulatory authorities, payers, academic experts, clinicians and patient organizations. Within the different phases of the drug life cycle, drug development is by far the most crucial part for the initial and continued success of a drug on the market. This book offers an introduction to the field of drug development with a clear overview of the different processes that lead to a successful new medicine and of the regulatory pathways that are used to launch a new drug that are both safe and efficacious. "This is the most comprehensive and detailed book on drug development I have ever read and I feel that it is likely to become a staple of drug development courses, such as those taught at Masters Level in my own University.... I think in the light of increasing integration of company and academic approaches to drug development both sides can read this book... (and, therefore)... this book could not be more timely." —Professor Mike Coleman, University of Aston, UK (from his review of the final manuscript)

Bone is a complex biological material that consists of both an inorganic and organic phase, which undergoes continuous dynamic biological processes within the body. This complex structure and the need to acquire accurate data have resulted in a wide variety of methods applied in the physical analysis of bone in vivo and in vitro. Each method has it

This anthology aims to provide Nordic perspectives on the young and evolving field of health law – or biomedical law – by reflecting on issues that have been explored within the activities of the Nordic Network for Research in Biomedical Law. In the emergence of this fairly new legal discipline, it has become very clear that the Nordic region forms a part of Europe that has been strongly influenced by both hard and soft law initiatives from the European Union and the Council of Europe, but also that Nordic identity, culture, and collaboration clearly remain an important factor in the legal development of this particular region.

This book is the first major work that addresses a core question in biomedical research: the question of acceptable risk. The acceptable level of risks is regulated by the requirement of proportionality in biomedical research law, which state that the risk and burden to the participant must be in proportion to potential benefits to the participant, society or science. This investigation addresses research on healthy volunteers, children, vulnerable subjects, and includes placebo controlled clinical trials. It represents a major contribution towards clarifying the most central, but also the most controversial and complex issue in biomedical research law and bioethics. The EU Clinical Trial Directive, the Council of Europe’s Oviedo Convention (and its Additional Protocol), and national regulation in member states are covered. It is a relevant work for lawyers and ethicists, and the practical approach makes a valuable tool for researchers and members of research ethics committees supervising biomedical research.
First published in 2008.

Imagine yourself without a face—the task seems impossible. The face is a core feature of our physical identity. Our face is how others identify us and how we think of our ‘self’. Yet, human faces are also functionally essential as mechanisms for communication and as a means of eating, breathing, and seeing. For these reasons, facial disfigurement can endanger our fundamental notions of self and identity or even be life threatening, at worse. Precisely because it is so difficult to conceal our faces, the disfigured face compromises appearance,

status, and, perhaps, our very way of being in the world. In Saving Face, sociologist Heather Laine Talley examines the cultural meaning and social significance of interventions aimed at repairing faces defined as disfigured. Using ethnography, participant-observation, content analysis, interviews, and autoethnography, Talley explores four sites in which a range of faces are “repaired:” face transplantation, facial feminization surgery, the reality show Extreme Makeover, and the international charitable organization Operation Smile. Throughout, she considers how efforts focused on repair sometimes intensify the stigma associated with disfigurement. Drawing upon experiences volunteering at a camp for children with severe burns, Talley also considers alternative interventions and everyday practices that both challenge stigma and help those seen as disfigured negotiate outsider status. Talley delves into the promise and limits of facial surgery, continually examining how we might understand appearance as a facet of privilege and a dimension of inequality. Ultimately, she argues that facial work is not simply a conglomeration of reconstructive techniques aimed at the human face, but rather, that appearance interventions are increasingly treated as lifesaving work. Especially at a time when aesthetic technologies carrying greater risk are emerging and when discrimination based on appearance is rampant, this important book challenges us to think critically about how we see the human face.

The essays selected for this volume focus on issues that arise when attempting to design, review and undertake research involving human participants who are experiencing a private or public emergency. The main themes discussed by the essays are: the distinctive and significant ethical questions as to how research participants can be treated during emergency settings; the ethical challenges raised by emergencies for researchers undertaking research and its effects on the nature of research pursued; and procedural obstacles raised by emergencies which can affect the quality of good research ethics review. The volume is unique in that it is the first collection to exclusively deal with all of the central ethical aspects of conducting human subject research in the context of emergency.

Based on the National Academy of Sciences approach to quantitative risk assessment. Emphasizes how an accurate assessment of cancer risk must draw on a wide range of disciplines, such as biology, chemistry, physics, engineering, and the social sciences. Provides tables of Poisson confidence limit fa

Biomedical Ethics for Engineers provides biomedical engineers with a new set of tools and an understanding that the application of ethical measures will seldom reach consensus even among fellow engineers and scientists. The solutions are never completely technical, so the engineer must continue to improve the means of incorporating a wide array of societal perspectives, without sacrificing sound science and good design principles. Dan Vallero understands that engineering is a profession that profoundly affects the quality of life from the subcellular and nano to the planetary scale. Protecting and enhancing life is the essence of ethics; thus every engineer and design professional needs a foundation in bioethics. In high-profile emerging fields such as nanotechnology, biotechnology and green engineering, public concerns and attitudes become especially crucial factors given the inherent uncertainties and high stakes involved. Ethics thus means more than a commitment to abide by professional norms of conduct. This book discusses the full suite of emerging biomedical and environmental issues that must be addressed by engineers and scientists within a global and societal context. In addition it gives technical professionals tools to recognize and address bioethical questions and illustrates that an understanding of the application of these measures will seldom reach consensus even among fellow engineers and scientists. · Working tool for biomedical engineers in the new age of technology · Numerous case studies to illustrate the direct application of ethical techniques and standards · Ancillary materials available online for easy integration into any academic program

Fulfilling the Presidentâ€™s Vision for Space Exploration (VSE) will require overcoming many

challenges. Among these are the hazards of space radiation to crews traveling to the Moon and Mars. To explore these challenges in some depth and to examine ways to marshal research efforts to address them, NASA, NSF, and the NRC sponsored a workshop bringing together members of the space and planetary science, radiation physics, operations, and exploration engineering communities. The goals of the workshop were to increase understanding of the solar and space physics in the environment of Earth, the Moon, and Mars; to identify compelling relevant research goals; and discuss directions this research should take over the coming decade. This workshop report presents a discussion of radiation risks for the VSE, an assessment of specifying and predicting the space radiation environment, an analysis of operational strategies for space weather support, and a summary and conclusions of the workshop.

Human microbiome research has revealed that legions of bacteria, viruses, and fungi live on our skin and within the cavities of our bodies. New knowledge from these recent studies shows that humans are superorganisms and that the microbiome is indispensible to our lives and our health. This volume explores some of the science on the human microbiome and considers the ethical, legal, and social concerns that are raised by this research.

Celebrating the 20th anniversary of the Baltic Yearbook of International Law, this volume contains a selection of articles chosen by the editors to showcase the Yearbook's important contribution to international legal scholarship and practice. It thus offers ground-breaking articles on diverse legal areas, including international humanitarian law, international human rights law, peaceful settlement of disputes, European Union law, and the history of international law. Naturally, issues relevant to the international legal status of the Baltic States and the consequences of their occupation by the Soviet Union are also explored, as well as to transitional justice and the collapse of communism. Finally, articles on new areas, such as bioethics and cyperspace, are also included, showing where the development of science prompts the need for legal regulation. This wide-ranging selection reflects the Yearbook's aim to offer a unique forum among international legal periodicals - where the past meets the future.

In 1997, the Council of Europe established the Convention on Human Rights and Biomedicine. It is generally regarded as an important addition to the general human rights laid down in the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950), in particular with a view to the developments in modern biology and medicine. The Biomedicine Convention, which entered into force in 2000, is a framework treaty, meaning that a number of issues have to be dealt with or will be elaborated in additional Protocols; at this moment, three such Protocols have already been opened for signature. This volume of essays, written in honour of Henriette Roscam Abbing upon her retirement as Professor of Health Law at the University of Utrecht, gives an overview of some of the most important issues raised by the Convention. In six parts, this volume discusses the basic concepts and leading principles; the provision of services; the rights of patients; research; human tissue and genetics; and the implementation of the Convention.

Written by a highly respected academic and experienced textbook author, Medical Law: Core Text provides a lively and engaging overview of the key topics of the medical law syllabus.

To address the growing complexities of childhood cancer, Nathan and Oski's Hematology and Oncology of Infancy and Childhood has now been separated into two distinct volumes. With this volume devoted strictly to pediatric oncology, and another to pediatric hematology, you will be on the cutting edge of these two fields. This exciting new, full-color reference provides you with the most comprehensive, authoritative, up-to-date information for diagnosing and treating children with cancer. It brings together the pathophysiology of disease with detailed clinical guidance on diagnosis and management for the full range of childhood cancers, including aspects important in optimal supportive care. Written by the leading names in pediatric oncology, this resource is an essential tool for all who care for pediatric cancer patients. Offers

comprehensive coverage of all pediatric cancers, including less common tumors, making this the most complete guide to pediatric cancer. Covers emerging research developments in cancer biology and therapeutics, both globally and in specific pediatric tumors. Includes a section on supportive care in pediatric oncology, written by authors who represent the critical subdisciplines involved in this important aspect of pediatric oncology. Uses many boxes, graphs, and tables to highlight complex clinical diagnostic and management guidelines. Presents a full-color design that includes clear illustrative examples of the relevant pathology and clinical issues, for quick access to the answers you need. Incorporates the codified WHO classification for all lymphomas and leukemias.

Medical Law and Ethics covers the core legal principles, key cases, and statutes that govern medical law alongside the key ethical debates and dilemmas that exist in the field to ensure that the law is firmly placed in context.Carefully constructed features highlight these debates, drawing out the European angles, religious beliefs, and feminist perspectives which influence legal regulations. Other features such as 'a shock to the system', 'public opinion' and 'reality check' introduce further socio-legal aspects andcontribute to the lively and engaging manner in which the subject is approached.Online Resource CentreThis book is accompanied by an Online Resource Centre which includes:Bibliography and further readingLinks to key casesAuthor video podcastWeb linksLinks to key sites with information on medical law and ethics

This publication, the fifth in the Ethical Eye series, contains contributions from a multidisciplinary group of authors from different countries in Europe which examine a range of ethical issues arising from the use of biomedical research. Topics discussed include: the problems of obtaining consent, standards for the selection and recruitment of participants for research, the use of placebos, clinical trials of new medicines or experimental treatments for cancer sufferers, industry-sponsored clinical trials, the internationalisation of medical research, and gender aspects. The publication looks at various international and European standards governing this field including the Helsinki Declaration of the World Medical Association, EU DIrective 2001/20 on pharmaceutical research, and the Council of Europe's Convention on Human Rights and Biomedicine.

This book begins the discourse on post-trial access to drugs in developing countries. Underlying ethical issues in global health inequalities and global health research serve as the context of the debate. Due to rampant allegations of violations of rights of research participants, especially in developing countries, it discusses the regulatory infrastructure and ethical oversight of international clinical research, thus emphasizing the priority of safeguarding the rights of research participants and host populations as desiderata in conducting clinical trials in developing countries. This is the first book that analyzes the major obstacles of affordable access to drugs in developing countries – patent and non-patent factors and how they can be overcome through a middle ground approach and a new paradigm to establish global health justice which includes national and global health responsibilities. The book also deals extensively with all complex aspects of the discourse on affordable access to drugs in developing countries, including intellectual property law, international regulations, political and cultural systems, international trade agreements. Furthermore it contains a robust ethical debate and in-depth analysis. The book crafts a paradigm of global health justice involving a sliding scale of national and global responsibilities for the realization of the right to health in general and access to drugs in particular.

"This chapter considers the history of the rise of ethical concerns in the public health movement and epidemiology, which is the study of the distribution and determinants of disease in human populations. Epidemiology is a basic science in public health. This chapter provides an overview of early developments in public health and ethics. More recent developments are also discussed, including the origins of bioethics, regulatory safeguards for human subjects

research, public health ethics, and contemporary epidemiologic ethics"--

When a young man named Jesse Gelsinger died in 1999 as a result of his participation in a gene transfer research study, regulatory agencies in the United States began to take a closer look at what was happening in medical research. The resulting temporary shutdown of some of the most prestigious academic research centres confirmed what various recent reports in the United States as well as Canada had claimed; that the current system of regulatory oversight was in need of improvement. Law and Ethics in Biomedical Research uses the Gelinger case as a touchstone, illustrating how three major aspects of that case - the flaws in the regulatory system, conflicts of interest, and legal liability - embody the major challenges in the current medical research environment. Editors Trudo Lemmens and Duff R. Waring, along with a host of top scholars in the field, demonstrate why existing models of research review and human subject protection are in need of improvement, and how more stringent regulatory and legal means can be used to strengthen the protection of research subjects and the integrity of research. The contributors also address conflicts of interest, paying particular attention to the growing commercialization of medical research, as well as the legal liability of scientific investigators, research institutions, and governmental agencies. Legal liability is a growing concern in medical research and this fascinating study is, in the international context, one of the first to explore the liability of various parties involved in the research enterprise.

Ethics in Psychiatry: (1) presents a comprehensive review of ethical issues arising in psychiatric care and research; (2) relates ethical issues to changes and challenges of society; (3) examines the application of general ethics to specific psychiatric problems and relates these to moral implications of psychiatry practice; (4) deals with recently arising ethical problems; (5) contains contributions of leading European ethicists, philosophers, lawyers, historians and psychiatrists; (6) provides a basis for the exploration of culture-bound influences on morals, manners and customs in the light of ethical principles of global validity.

Research with human subjects has long been controversial because of the conflicts that often arise between promoting scientific knowledge and protecting the rights and welfare of subjects. Twenty-five years ago the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research addressed these conflicts. The result was the Belmont Report: Ethical Principles and Guidance for Research Involving Human Subjects, a report that identified foundational principles for ethical research with human subjects: respect for persons, beneficence, and justice. Since the publication of Belmont, these three principles have greatly influenced discussions of research with human subjects. While they are often regarded as the single-most influential set of guidelines for biomedical research and practice in the United States (and other parts of the world), not everyone agrees that they provide adequate guidance. Belmont Revisited brings together a stellar group of scholars in bioethics to revisit

the findings of that original report. Their responses constitute a broad overview of the development of the Belmont Report and the extent of its influence, especially on governmental commissions, as well as an assessment of its virtues and shortcomings. Belmont Revisited looks back to reexamine the creation and influence of the Belmont Report, and also looks forward to the future of research—with a strong call to rethink how institutions and investigators can conduct research more ethically.

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In the past 30 years, the population of prisoners in the United States has expanded almost 5-fold, correctional facilities are increasingly overcrowded, and more of the country's disadvantaged populations—racial minorities, women, people with mental illness, and people with communicable diseases such as HIV/AIDS, hepatitis C, and tuberculosis—are under correctional supervision. Because prisoners face restrictions on liberty and autonomy, have limited privacy, and often receive inadequate health care, they require specific protections when involved in research, particularly in today's correctional settings. Given these issues, the Department of Health and Human Services' Office for Human Research Protections commissioned the Institute of Medicine to review the ethical considerations regarding research involving prisoners. The resulting analysis contained in this book, Ethical Considerations for Research Involving Prisoners, emphasizes five broad actions to provide prisoners involved in research with critically important protections: • expand the definition of "prisoner"; • ensure universally and consistently applied standards of protection; • shift from a category-based to a risk-benefit approach to research review; • update the ethical framework to include collaborative responsibility; and • enhance systematic oversight of research involving prisoners.

The 2e of the gold standard text in the field, Nonhuman Primates in Biomedical Research provides a comprehensive, up-to-date review of the use of nonhuman primates in biomedical research. The publication emphasizes the biology and management, diseases, and biomedical models for nonhuman primate species most commonly used in research. Each chapter contains an extensive list of bibliographic references, photographs, and graphic illustrations to provide the reader with a thorough review of the subject. The Biology and Management volume provides basic information on the natural biology of nonhuman primates and the current state of knowledge regarding captive management. The Diseases volume provides thorough reviews of naturally occurring diseases of nonhuman primates, with a section on biomedical models reviewing contemporary nonhuman primate models of human diseases. Now in four color throughout, making the book more visually stimulating to enhance learning and ease of use Fully revised and updated, providing researchers with the most comprehensive review of the use of nonhuman primates in biomedical research Addresses commonly used nonhuman primate biomedical models, providing

researchers with species-specific information

Information technology is transforming the practices of medicine, nursing, and biomedical research. Computers can now render diagnoses and prognoses more accurately than humans. The concepts of privacy and confidentiality are evolving as data moves from paper to silicon to clouds. Big data promises financial wealth, as well as riches of information and benefits to science and public health. Online access and mobile apps provide patients with an unprecedented connection to their health and health records. This transformation is as unsettling as it is exhilarating. This unique new book is essential for anyone who uses computers in health care, biomedical research or public health, and cares about the ethical issues that arise in their work. With chapters spanning issues from professionalism and quality to mobile health and bioinformatics, it establishes what will become the 'core curriculum' in ethics and health informatics, a growing field which encourages truly inter- and multidisciplinary inquiry.

Human rights are essential to global health, yet rising threats in an increasingly divided world are challenging the progressive evolution of health-related human rights. It is necessary to empower a new generation of scholars, advocates, and practitioners to sustain the global commitment to universal rights in public health. Looking to the next generation to face the struggles ahead, this book provides a detailed understanding of the evolving relationship between global health and human rights, laying a human rights foundation for the advancement of transformative health policies, programs, and practices. International human rights law has been repeatedly shown to advance health and wellbeing - empowering communities and fostering accountability for realizing the highest attainable standard of health. This book provides a compelling examination of international human rights as essential for advancing public health. It demonstrates how human rights strengthens human autonomy and dignity, while placing clear responsibilities on government to safeguard the public's health and safety. Bringing together leading academics in the field of health and human rights, this volume: (1) explains the norms and principles that define the field, (2) examines the methods and tools for implementing human rights to promote health, (3) applies essential human rights to leading public health threats, and (4) analyzes rising human rights challenges in a rapidly globalizing world. This foundational text shows why interdisciplinary scholarship and action are essential for health-related human rights, placing human rights at the center of public health and securing a future of global health with justice.

Examines the many ethical issues related to biomedical research, including the use of animals in research, research on human subjects, clinical trials, international research ethics policies, and other related topics.

Blackstone's Statutes have a 25-year tradition of trust and quality, and a rock-solid reputation for accuracy, reliability, and authority. Content is extensively reviewed to ensure a close map to courses. Blackstone's Statutes lead the market: consistently recommended by lecturers and relied on by students for

exam and course use. Each title is: DT Trusted: ideal for exam use DT Practical: find what you need instantly DT Reliable: current, comprehensive coverage DT Relevant: content based on detailed market feedback Visit www.oxfordtextbooks.co.uk/orc/statutes/ for accompanying online resources, including web links, video guides to reading and interpreting statutes, exam tips, and an interactive sample Act of Parliament.

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This is an in-depth study of the contentious issues in Irish healthcare and deals with issues such as assisted suicide, abortion, adolescent treatment refusal, end of life care, retention of biological samples, involuntary admission to care and the regulation of stem cell research.