Emerging Policies For Biomedical Research

Enhancing the Vitality of the National Institutes of Health National Research Council 2003-08-29 The report says that important organizational changes are needed at the National Institutes of Health to ensure the agency meets future challenges effectively. In particular, the report advises NIH to devote additional resources to innovative interdisciplinary research that reflects its strategic objectives and cuts across all agency's institutes and centers. The report recommends that Congress should establish a formal process for determining how specific proposals for changes in the number of NIH agencies and centers should be addressed.

The Ethics of Biomedical Research Baruch A. Brody 1998 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.

An Examination of Emerging Bioethical Issues in Biomedical Research National Academies of Sciences, Engineering, and Medicine 2020-08-10 On February 26, 2020, the Board on Health Sciences Policy of the National Academies of Sciences, Engineering, and Medicine hosted a 1-day public workshop in Washington, DC, to examine current and emerging bioethical issues that might arise in the context of biomedical research and to consider research topics in bioethics that could benefit from further attention. The scope of bioethical issues in research is broad, but this workshop focused on issues related to the development and use of digital technologies, artificial intelligence, and machine learning in research and clinical practice; issues emerging as nontraditional approaches to health research become more widespread; the role of bioethics in addressing racial and structural inequalities in health; and enhancing the capacity and diversity of the bioethics workforce. This publication summarizes the presentations and discussions from the workshop.

Large-Scale Biomedical Science National Research Council 2003-07-19 The nature of biomedical research has been evolving in recent years. Technological advances that make it easier to study the vast complexity of biological systems have led to the initiation of projects with a larger scale and scope. In many cases, these large-scale analyses may be the most efficient and effective way to extract functional information from complex biological systems. Large-Scale Biomedical Science: Exploring Strategies for Research looks at the role of these new large-scale projects in the biomedical sciences. Though written by the National Academies' Cancer Policy Board, this book addresses implications of large-scale science extending far beyond cancer research. It also identifies obstacles to the implementation of these projects, and makes recommendations to improve the process. The ultimate goal of biomedical research is to advance knowledge and provide useful innovations to society. Determining the best and most efficient method for accomplishing that goal, however, is a continuing and evolving challenge. The recommendations presented in Large-Scale Biomedical Science are intended to facilitate a more open, inclusive, and accountable approach to large-scale biomedical research, which in turn will maximize progress in understanding and controlling human disease.

Ethical Conduct of Clinical Research Involving Children Institute of Medicine 2004-07-09 In recent decades, advances in biomedical research have helped save or lengthen the lives of children around the world. With improved therapies, child and adolescent mortality rates have decreased significantly in the last half century. Despite these advances, pediatricians and others argue that children have not shared equally with adults in biomedical advances. Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research, we do not want to place children at risk of being harmed by participating in clinical studies. Ethical Conduct of Clinical Research Involving Children considers the necessities and

challenges of this type of research and reviews the ethical and legal standards for conducting it. It also considers problems with the interpretation and application of these standards and conduct, concluding that while children should not be excluded from potentially beneficial clinical studies, some research that is ethically permissible for adults is not acceptable for children, who usually do not have the legal capacity or maturity to make informed decisions about research participation. The book looks at the need for appropriate pediatric expertise at all stages of the design, review, and conduct of a research project to effectively implement policies to protect children. It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular.

Enhancing Scientific Reproducibility in Biomedical Research Through Transparent Reporting National Academies of Sciences, Engineering, and Medicine 2020-05-28 Sharing knowledge is what drives scientific progress - each new advance or innovation in biomedical research builds on previous observations. However, for experimental findings to be broadly accepted as credible by the scientific community, they must be verified by other researchers. An essential step is for researchers to report their findings in a manner that is understandable to others in the scientific community and provide sufficient information for others to validate the original results and build on them. In recent years, concern has been growing over a number of studies that have failed to replicate previous results and evidence from larger meta-analyses, which have pointed to the lack of reproducibility in biomedical research. On September 25 and 26, 2019, the National Academies of Science, Engineering, and Medicine hosted a public workshop in Washington, DC, to discuss the current state of transparency in the reporting of preclinical biomedical research and to explore opportunities for harmonizing reporting guidelines across journals and funding agencies. Convened jointly by the Forum on Drug Discovery, Development, and Translation; the Forum on Neuroscience and Nervous System Disorders; the National Cancer Policy Forum; and the Roundtable on Genomics and Precision Health, the workshop primarily focused on transparent reporting in preclinical research, but also considered lessons learned and best practices from clinical research reporting. This publication summarizes the presentation and discussion of the workshop.

Law and Ethics in Biomedical Research Duff William Ramus Waring 2006-01-01 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.

Bridges to Independence National Research Council 2005-07-26 A rising median age at which PhD's receive their first research grant from the National Institutes of Health (NIH) is among the factors forcing academic biomedical researchers to spend longer periods of time before they can set their own research directions and establish there independence. The fear that promising prospective scientists

will choose other career paths has raised concerns about the future of biomedical research in the United States. At the request of NIH, the National Academies conducted a study on ways to address these issues. The report recommends that NIH make fostering independence of biomedical researchers an agencywide goal, and that it take steps to provide postdocs and early-career investigators with more financial support for their own research, improve postdoc mentoring and establish programs for new investigators and staff scientists among other mechanisms. Funding Health Sciences Research Institute of Medicine 1990-02-01 Biomedical scientists' concern about the future of funding of health science research prompted this volume's exploration of the financing of the entire health research enterprise and the complex reasons underlying these increasing concerns. The committee presents clear-cut recommendations for improving allocation policies to ensure a balanced distribution of resources that will allow the biomedical research community to build on exciting recent discoveries in many areas. Funding Health Sciences Research also provides the first-ever comprehensive reports on the 1980s policies that have affected the research landscape, including stabilization, downward negotiation, and extended grant duration. *The Next Generation of Biomedical and Behavioral Sciences Researchers* National Academies of Sciences, Engineering, and Medicine 2018-06-18 Since the end of the Second World War, the United States has developed the world's preeminent system for biomedical research, one that has given rise to revolutionary medical advances as well as a dynamic and innovative business sector generating high-quality jobs and powering economic output and exports for the U.S. economy. However, there is a growing concern that the biomedical research enterprise is beset by several core challenges that undercut its vitality, promise, and productivity and that could diminish its critical role in the nation's health and innovation in the biomedical industry. Among the most salient of these challenges is the gulf between the burgeoning number of scientists qualified to participate in this system as academic researchers and the elusive opportunities to establish long-term research careers in academia. The patchwork of measures to address the challenges facing young scientists that has emerged over the years has allowed the U.S. biomedical enterprise to continue to make significant scientific and medical advances. These measures, however, have not resolved the structural vulnerabilities in the system, and in some cases come at a great opportunity cost for young scientists. These unresolved issues could diminish the nation's ability to recruit the best minds from all sectors of the U.S. population to careers in biomedical research and raise concerns about a system that may favor increasingly conservative research proposals over high-risk, innovative ideas. The Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through evaluates the factors that influence transitions into independent research careers in the biomedical and behavioral sciences and offers recommendations to improve those transitions. These recommendations chart a path to a biomedical research enterprise that is competitive, rigorous, fair, dynamic, and can attract the best minds from across the country. **Contemporary Issues for Protecting Patients in Cancer Research** Institute of Medicine 2014-09-19 In the nearly 40 years since implementation of federal regulations governing the protection of human participants in research, the number of clinical studies has grown exponentially. These studies have become more complex, with multisite trials now common, and there is increasing use of archived biospecimens and related data, including genomics data. In addition, growing emphasis on targeted cancer therapies requires greater collaboration and sharing of research data to ensure that rare patient subsets are adequately represented. Electronic records enable more extensive data collection and mining, but also raise concerns about the potential for inappropriate or unauthorized use of data, bringing patient protections into a new landscape. There are also long-standing concerns about the processes and forms used to obtain informed consent from patients participating in clinical studies. These changes and challenges raise new ethical and practical questions for the oversight of clinical studies,

and for protecting patients and their health information in an efficient manner that does not compromise the progress of biomedical research. Contemporary Issues for Protecting Patients in Cancer Research is the summary of a workshop convened by the National Cancer Policy Forum of the Institute of Medicine in February 2014 to explore contemporary issues in human subjects protections as they pertain to cancer research, with the goal of identifying potential relevant policy actions. Clinical researchers, government officials, members of Institutional Review Boards, and patient advocates met to discuss clinical cancer research and oversight. This report examines current regulatory provisions that may not adequately protect patients or may be hindering research, and discusses potential strategies and actions to address those challenges.

Biomedicine in the Twentieth Century: Practices, Policies, and Politics C. Hannaway 2008-02-11 Biomedicine in the Twentieth Century: Practices, Policies, and Politics is a testimony to the growing interest of scholars in the development of the biomedical sciences in the twentieth century and to the number of historians, social scientists and health policy analysts now working on the subject. The book is comprised of essays by noted historians and social scientists that offer insights on a range of subjects that should be a significant stimulus for further historical investigation. It details the NIH's practices, policies and politics on a variety of fronts, including the development of the intramural program, the National Institute of Mental Health and mental health policy, the politics and funding of heart transplantation and the initial focus of the National Cancer Institute. Comparisons can be made with the development of other American and British institutions involved in medical research, such as the Rockefeller Institute and the Medical Research Council. Discussions of the larger scientific and social context of United States' federal support for research, the role of lay institutions in federal funding of virus research, the consequences of technology transfer and patenting, the effects of vaccine and drug development and the environment of research discoveries all offer new insights and suggest questions for further exploration.

Clinical Research and the Law Patricia M. Tereskerz 2012-05-07 This book provides a comprehensive resource for medical professionals on the various legal aspects involved in conducting clinical research. It encompasses legal and ethical issues such as duty of care, research malpractice and negligence, standards of care, informed consent, liability issues for Institutional Review Boards (IRB), conflicts of interest, insider trading and the disclosure and withholding of clinical trial results. It will also provide legal guidance on research contracts, setting up clinical trials and common legal pitfalls encountered in medical research.

Report of the President's Biomedical Research Panel: Appendix B: Approaches to policy development for biomedical research United States. President's Biomedical Research Panel 1976

Conflict of Interest in Medical Research, Education, and Practice Institute of Medicine 2009-09-16 Collaborations of physicians and researchers with industry can provide valuable benefits to society, particularly in the translation of basic scientific discoveries to new therapies and products. Recent reports and news stories have, however, documented disturbing examples of relationships and practices that put at risk the integrity of medical research, the objectivity of professional education, the quality of patient care, the soundness of clinical practice guidelines, and the public's trust in medicine. Conflict of Interest in Medical Research, Education, and Practice provides a comprehensive look at conflict of interest in medicine. It offers principles to inform the design of policies to identify, limit, and manage conflicts of interest without damaging constructive collaboration with industry. It calls for both short-term actions and long-term commitments by institutions and individuals, including leaders of academic medical centers, professional societies, patient advocacy groups, government agencies, and drug, device, and pharmaceutical companies. Failure of the medical community to take convincing action on conflicts of interest invites additional legislative or regulatory measures that may be overly broad or unduly burdensome. Conflict of Interest in Medical Research, Education, and Practice

makes several recommendations for strengthening conflict of interest policies and curbing relationships that create risks with little benefit. The book will serve as an invaluable resource for individuals and organizations committed to high ethical standards in all realms of medicine.

Health Care Policy in an Age of New Technologies Kant Patel 2015-05-20 Revolutionary advances in biomedical research and information systems technology pose new and difficult issues for American health care policy, especially in the context of managed care. Health Care Policy in a New Millennium takes on this challenging array of issues where the dignity of individual life meets the imperatives of national-level health-care systems - patients' rights, rationing of care, organ transplants, genetic research, confidentiality of medical records, the right to die, and other ethical dilemmas. The book places these critical questions about the quality of life in our society in their political, legal, social, economic, and ethical contexts.

Toward Precision Medicine National Research Council 2012-01-16 Motivated by the explosion of molecular data on humans-particularly data associated with individual patients-and the sense that there are large, as-yet-untapped opportunities to use this data to improve health outcomes, Toward Precision Medicine explores the feasibility and need for "a new taxonomy of human disease based on molecular biology" and develops a potential framework for creating one. The book says that a new data network that integrates emerging research on the molecular makeup of diseases with clinical data on individual patients could drive the development of a more accurate classification of diseases and ultimately enhance diagnosis and treatment. The "new taxonomy" that emerges would define diseases by their underlying molecular causes and other factors in addition to their traditional physical signs and symptoms. The book adds that the new data network could also improve biomedical research by enabling scientists to access patients' information during treatment while still protecting their rights. This would allow the marriage of molecular research and clinical data at the point of care, as opposed to research information continuing to reside primarily in academia. Toward Precision Medicine notes that moving toward individualized medicine requires that researchers and health care providers have access to very large sets of health- and disease-related data linked to individual patients. These data are also critical for developing the information commons, the knowledge network of disease, and ultimately the new taxonomy.

Legal and Ethical Regulation of Biomedical Research in Developing Countries Remigius N. Nwabueze 2016-04-22 There has been a rapid increase in the pace and scope of international collaborative research in developing countries in recent years. This study argues that whilst ethical regulation of biomedical research in Africa and other developing countries has attracted global attention, legal liability issues, such as the application of common law rules and the development of legally enforceable regulations, have been neglected. It examines some of the major research scandals in Africa and suggests a new ethical framework against which clinical trials could be conducted. The development of research guidelines in Uganda, Tanzania, Malawi and Nigeria are also examined as well as the role of ethics committees. Providing a detailed analysis of the law of negligence and its application to research ethics committees and their members, common law and constitutional forms of action and potential negligence claims, the book concludes by suggesting new protocols and frameworks, improved regulation and litigation. This book will be a valuable guide for students, researchers, and policy-makers with an interest in medical law and ethics, bioethics, customary law in Africa and regulation in developing countries.

Strategies to Leverage Research Funding Institute of Medicine 2004-10-27 Since 1992 the Department of Defense (DOD), through the U.S. Army Medical Research and Material Command, has received congressionally earmarked appropriations for programs of biomedical research on prostate, breast, and ovarian cancer; neurofibromatosis; tuberous sclerosis; and other health problems. Appropriations for these Congressionally Directed Medical Research Programs are used to support peer reviewed extramural research project, training,

and infrastructure grants. Congress has become concerned about funding increases for these programs given current demands on the military budget. At the request of Congress, the Institute of Medicine (IOM) examined possibilities of augmenting program funding from alternative sources. The resulting IOM book, Strategies to Leverage Research Funding: Guiding DOD's Peer Reviewed Medical Research Programs, focuses on nonfederal and private sector contributions that could extend the appropriated funds without biasing the peer review project selection process.

Sources of Medical Technology Institute of Medicine 1995-01-01 Evidence suggests that medical innovation is becoming increasingly dependent on interdisciplinary research and on the crossing of institutional boundaries. This volume focuses on the conditions governing the supply of new medical technologies and suggest that the boundaries between disciplines, institutions, and the private and public sectors have been redrawn and reshaped. Individual essays explore the nature, organization, and management of interdisciplinary R&D in medicine; the introduction into clinical practice of the laser, endoscopic innovations, cochlear implantation, cardiovascular imaging technologies, and synthetic insulin; the division of innovating labor in biotechnology; the government- industry-university interface; perspectives on industrial R&D management; and the growing intertwining of the public and proprietary in medical technology.

Capitalizing on New Needs and New Opportunities National Research Council 2001-02-11 This report addresses a topic of recognized policy concern. To capture the benefits of substantial U.S. investments in biomedical R&D, parallel investments in a wide range of seemingly unrelated disciplines are also required. This report summarizes a major conference that reviewed our nation's R&D support for biotechnology and information technologies. The volume includes newly commissioned research and makes recommendations and findings concerning the important relationship between information technologies and biotechnology. It emphasizes the fall off in R&D investments needed to sustain the growth of the U.S. economy and to capitalize on the growing investment in biomedicine. It also encourages greater support for inter-disciplinary training to support new areas such as bioinformatics and urges more emphasis on and support for multi-disciplinary research centers.

Beyond the HIPAA Privacy Rule Institute of Medicine 2009-03-24 In the realm of health care, privacy protections are needed to preserve patients' dignity and prevent possible harms. Ten years ago, to address these concerns as well as set guidelines for ethical health research, Congress called for a set of federal standards now known as the HIPAA Privacy Rule. In its 2009 report, Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research, the Institute of Medicine's Committee on Health Research and the Privacy of Health Information concludes that the HIPAA Privacy Rule does not protect privacy as well as it should, and that it impedes important health research.

The Role of NIH in Drug Development Innovation and Its Impact on Patient Access National Academies of Sciences, Engineering, and Medicine 2020-02-27 To explore the role of the National Institutes of Health (NIH) in innovative drug development and its impact on patient access, the Board on Health Care Services and the Board on Health Sciences Policy of the National Academies jointly hosted a public workshop on July 24â€"25, 2019, in Washington, DC. Workshop speakers and participants discussed the ways in which federal investments in biomedical research are translated into innovative therapies and considered approaches to ensure that the public has affordable access to the resulting new drugs. This publication summarizes the presentations and discussions from the workshop.

Biomedical Informatics Edward H. Shortliffe 2013-12-02 The practice of modern medicine and biomedical research requires sophisticated information technologies with which to manage patient information, plan diagnostic procedures, interpret laboratory results, and carry out investigations. Biomedical Informatics provides both a conceptual framework and a practical inspiration for this swiftly emerging scientific discipline at the intersection of computer science, decision science, information science,

cognitive science, and biomedicine. Now revised and in its third edition, this text meets the growing demand by practitioners, researchers, and students for a comprehensive introduction to key topics in the field. Authored by leaders in medical informatics and extensively tested in their courses, the chapters in this volume constitute an effective textbook for students of medical informatics and its areas of application. The book is also a useful reference work for individual readers needing to understand the role that computers can play in the provision of clinical services and the pursuit of biological questions. The volume is organized so as first to explain basic concepts and then to illustrate them with specific systems and technologies.

Private and Public Investments in Biomedical Research Maya M. Durvasula 2021 Recent policy attention has focused on proposals to reduce prices for drugs that have received public funding. From an implementation perspective, such policies rely on public disclosure of government support for research. In this paper, we highlight two conceptual problems with past attempts to measure these public disclosures, and construct a new data set which corrects for these problems. Our corrected measures suggest that under-reporting of public research support is less of an issue than previously thought.

Setting Allocation Priorities Robert H. Blank 1993-11-24 Volume 1 discusses the problems inherent in allocating limited biomedical technologies: whose needs take precedence, what individual rights and responsibilities are involved, and when societal good justifies restricting individual good. Volume Two focuses on whether and when life-extending technologies should be used or withdrawn.

Redesigning the Clinical Effectiveness Research Paradigm Institute of Medicine 2010-09-20 Recent scientific and technological advances have accelerated our understanding of the causes of disease development and progression, and resulted in innovative treatments and therapies. Ongoing work to elucidate the effects of individual genetic variation on patient outcomes suggests the rapid pace of discovery in the biomedical sciences will only accelerate. However, these advances belie an important and increasing shortfall between the expansion in therapy and treatment options and knowledge about how these interventions might be applied appropriately to individual patients. The impressive gains made in Americans' health over the past decades provide only a preview of what might be possible when data on treatment effects and patient outcomes are systematically captured and used to evaluate their effectiveness. Needed for progress are advances as dramatic as those experienced in biomedicine in our approach to assessing clinical effectiveness. In the emerging era of tailored treatments and rapidly evolving practice, ensuring the translation of scientific discovery into improved health outcomes requires a new approach to clinical evaluation. A paradigm that supports a continual learning process about what works best for individual patients will not only take advantage of the rigor of trials, but also incorporate other methods that might bring insights relevant to clinical care and endeavor to match the right method to the question at hand. The Institute of Medicine Roundtable on Value & Science-Driven Health Care's vision for a learning healthcare system, in which evidence is applied and generated as a natural course of care, is premised on the development of a research capacity that is structured to provide timely and accurate evidence relevant to the clinical decisions faced by patients and providers. As part of the Roundtable's Learning Healthcare System series of workshops, clinical researchers, academics, and policy makers gathered for the workshop Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Practice-Based Approaches. Participants explored cutting-edge research designs and methods and discussed strategies for development of a research paradigm to better accommodate the diverse array of emerging data resources, study designs, tools, and techniques. Presentations and discussions are summarized in this volume.

Biomedical Scientists and Public Policy H. H. Fudenberg 1978-11 This book brings together the views of authors involved in many aspects of biomedicine-from research on basic biology to clinical investU˙igation of the causes and treatment of human disease to hospital adminisU˙tration ·to health care planning on the state and Federal levels to ConU˙gressionallegislation

covering biomedical research, medical education, the development of medical technology, and the delivery of health care. The purpose is not to present a "party line" representing a consensus of these often divergent viewpoints, and we do not suggest that we have found solutions to the many problems encountered in the interaction of scientists, administrators, legislators, and the recipients of health care. These articles are intended primarily to communicate to both biomedical scientists and intelligent laymen the processes, social and political as well as scientific, whereby biomedical science advances, and the need for biomedical scientists to take an interest and initiative not only in scientific research but also in research on health care delivery and in related public issues before the legislative and administrative branches of government

Advancing the Nation's Health Needs National Research Council 2005-08-13 This report is the twelfth assessment of the National Institutes of Health National Research Service Awards program. The research training needs of the country in basic biomedical, clinical, and behavioral and social sciences are considered. Also included are the training needs of oral health, nursing, and health services research. The report has been broadly constructed to take into account the rapidly evolving national and international health care needs. The past and present are analyzed, and predictions with regard to future needs are presented.

Conflict of Interest and Medical Innovation Institute of Medicine 2014-06-16 Scientific advances such as the sequencing of the human genome have created great promise for improving human health by providing a greater understanding of disease biology and enabling the development of new drugs, diagnostics, and preventive services. However, the translation of research advances into clinical applications has so far been slower than anticipated. This is due in part to the complexity of the underlying biology as well as the cost and time it takes to develop a product. Pharmaceutical companies are adapting their business models to this new reality for product development by placing increasing emphasis on leveraging alliances, joint development efforts, early-phase research partnerships, and public-private partnerships. These collaborative efforts make it possible to identify new drug targets, enhance the understanding of the underlying basis of disease, discover novel indications for the use of already approved products, and develop biomarkers for disease outcomes or directed drug use. While the potential benefits of collaboration are significant, the fact that the relationships among development partners are often financial means that it is vital to ensure trust by identifying, disclosing, and managing any potential sources of conflict that could create bias in the research being performed together. Conflict of Interest and Medical Innovation is the summary of a workshop convened by the Institute of Medicine Roundtable on Translating Genomic-Based Research for Health in June 2013 to explore the appropriate balance between identifying and managing conflicts of interest and advancing medical innovation. A wide range of stakeholders, including government officials, pharmaceutical company representatives, academic administrators and researchers, health care providers, medical ethicists, patient advocates, and consumers, were invited to present their perspectives and participate in discussions during the workshop. This report focuses on current conflict of interest policies and their effect on medical innovation in an effort to identify best practices and potential solutions for facilitating innovation while still ensuring scientific integrity and public trust.

Trust and Integrity in Biomedical Research Thomas H. Murray 2010-09 Highly Commended in the Basis of Medicine, 2011 BMA Medical Book Awards. British Medical Association News of financial entanglements among biomedical companies and researchers has increasingly called into question the worth and integrity of medical studies, nearly three-fifths of which are funded by industry. This volume assesses the ethical, quantitative, and qualitative questions posed by the current financing of biomedical research. The ten essays collected here reflect the wide range of opinions about perceived financial conflicts of interest in medical studies. The opening section provides an overview of the issue, describing the origins of, and concerns raised by, dubious financial arrangements; explaining how certain common situations

intensify problematic funding structures; weighing the risks and benefits of commercialized research funding; and detailing the nature, extent, and consequences of the present relationship among academe, government, and industry in the health sciences. The second section compares how the idea of conflicts of interest differs in biomedical research, legal work, and journalism. It includes a challenging look at the term itself and an argument for managed financial incentives. The final section describes and analyzes the existing regulatory regime, poses questions and directions for future self and external regulation, and provides perspectives from a third-party research company. This considered, balanced discussion will interest scholars of bioethics, public health, and health policy.

Children in Medical Research Lainie Friedman Ross 2006-02-09 Lainie Ross presents a rigorous critical investigation of the development of policy governing the involvement of children in medical research. She examines the shift in focus from protection of medical research subjects, enshrined in post-World War II legislation, to the current era in which access is assuming greater precedence. Infamous studies such as Willowbrook (where mentally retarded children were infected with hepatitis) are evidence that before the policy shift protection was not always adequate, even for the most vulnerable groups. Additional safeguards for children were first implemented in many countries in the 1970s and 1980s; more recent policies and guidelines are trying to promote greater participation. Ross considers whether the safeguards work, whether they are fair, and how they apply in actual research practice. She goes on to offer specific recommendations to modify current policies and guidelines. Ross examines the regulatory structures (e.g. federal regulations and institutional review boards), the ad hoc policies (e.g. payment in pediatric research and the role of schools as research venues), the actual practices of researchers (e.g. the race/ethnicity of enrolled research subjects or the decision to enroll newborns) as well as the decision-making process (both parental permission and the child's assent), in order to provide a broad critique. Some of her recommendations will break down current barriers to the enrolment of children (e.g. permitting the payment of child research subjects; allowing healthy children to be exposed to research that entails more than minimal risk without requiring recourse to 407 panels); whereas other recommendations may create new restrictions (e.g., the need for greater protection for research performed in schools; restrictions on what research should be done in the newborn nursery). The goal is to ensure that medical research is done in a way that promotes the health of current and future children without threatening, to use the words of Hans Jonas, 'the erosion of those moral values whose loss . . . would make its most dazzling triumphs not worth having'.

Beyond Consent Jeffrey P. Kahn 2018-04-13 Since the publication of the first edition of Beyond Consent, issues of justice remain critical in discussions, debates, and policy making in biomedical research in involving human subjects. The second edition adds new content in two different ways, first by asking authors to examine the issues identified in the first edition by asking what has changed and what new issues arise in the contemporary environment, and second by adding chapters to take on issues that are salient today and looking forward. The result is a new treatment of the issues of justice in research through fresh perspectives and by examining the latest issues. The editors have assembled a group of leading scholars and researchers as contributors, and author the final chapter themselves. This collection is a vital resource for students and scholars of bioethics, medicine, and public health policy; as well as for members of institutional review boards (IRBs), research administrators, and policy makers.

Research Misconduct Policy in Biomedicine Barbara K. Redman 2013-10-11 An analysis of current biomedical research misconduct policy that proposes a new approach emphasizing the context of misconduct and improved oversight. Federal regulations that govern research misconduct in biomedicine have not been able to prevent an ongoing series of high-profile cases of fabricating, falsifying, or plagiarizing scientific research. In this book, Barbara Redman looks critically at current research misconduct policy and proposes a new approach that emphasizes institutional context and

improved oversight. Current policy attempts to control risk at the individual level. But Redman argues that a fair and effective policy must reflect the context in which the behavior in question is embedded. As journalists who covered many research misconduct cases observed, the roots of fraud “lie in the barrel, not in the bad apples that occasionally roll into view.” Drawing on literature in related fields—including moral psychology, the policy sciences, the organizational sciences, and law—as well as analyses of misconduct cases, Redman considers research misconduct from various perspectives. She also examines in detail a series of clinical research cases in which repeated misconduct went undetected and finds laxity of oversight, little attention to harm done, and inadequate correction of the scientific record. Study questions enhance the book's value for graduate and professional courses in research ethics. Redman argues that the goals of any research misconduct policy should be to protect scientific capital (knowledge, scientists, institutions, norms of science), support fair competition, contain harms to end users and to the public trust, and enable science to meet its societal obligations.

Debates Over Authority in Medical Decision Making Robert H. Blank 1993-01-01 This series of annual volumes on biomedical policy identifies cutting-edge issues that arise from a rapidly growing array of new technologies. Volume II focuses on two substantive areas beset by novel power conflicts: decisions involving end-of-life technologies - physicians, patients, and public officials locked in new battles over whether and when life-extending technologies should be begun or ended, and rules governing medical experimentation - researchers, government officials, and patients vying to determine who will receive experimental medical treatment and what procedures should be instituted to protect the recipients.

Emerging Policies for Biomedical Research William N. Kelley 1993-01-01 The book abstracts & excerpts significant articles about science issues that influence the development of national policy. Commentaries by CEOs of academic health centers explore a myriad of topics including societal goals, priority setting, allocation of the funds for biomedical research, biotech, & global competition, integrity in scientific research, public perceptions, & ethical challenges in the use of genetic information. The book provides a unique reference for policy makers, analysts, & those interested in health care policy.

The Public Shaping of Medical Research Peter Wehling 2014-11-27 Patient organizations and social health movements offer one of the most important and illuminating examples of civil society engagement and participation in scientific research and research politics. Influencing the research agenda, and initiating, funding and accelerating the development of diagnostic tools, effective therapies and appropriate health-care for their area of interest, they may champion alternative, sometimes controversial, programs or critique dominant medical paradigms. Some movements and organizations advocate for medical recognition of contested illnesses, as with fibromyalgia orADHD, while some attempt to "de-medicalize" others, such as obesity or autism. Bringing together an international selection of leading scholars and representatives from patients' organizations, this comprehensive collection explores the interaction between civil society groups and biomedical science, technology development, and research politics. It takes stock of the key findings of the research conducted in the field over the past two decades and addresses emerging problems and future challenges concerning the interrelations between health movements and patient organisations on the one hand, and biomedical research and research policies on the other hand. Combining empirical case studies with conceptual discussion, the book discusses how public participation can contribute to, as well as restrict, the democratization of scientific knowledge production. This volume is an important reference for academics and researchers with an interest in the sociology of health and illness, science and technology studies, the sociology of knowledge, medical ethics or healthcare management and research, as well as medical researchers and those involved with health-related civil society organizations.

Policies for Biomedical Research United States. Congress. House. Committee on Science and

Technology. Task Force on Science Policy 1987 Biomedical Institutions, Biomedical Funding, and Public Policy H. Hugh Fudenberg 2012-12-06 The world is on the threshold of a great new industrial revolution, a 1 scientific-industrial revolution. Recombinant DNA technology and hybridoma technology ("monoclonal antibodies") have already pro vided unique investment opportunities for venture capitalists. Hence published reports of biomedical research are no longer restricted to scientific journals, but now appear regularly not only in weekly news 2 magazines like Time and U. S. News & World Report,3 but also in the financial sections of The New York Times,4 The Wall Street Journal,S 6 8 Business Week, Fortune,7 and The Economist, as well as in such stock 9 market advisory publications as New Issues and Inc. (The Magazine for Growing Companies). 10 These publications now appear to be as impor tant to biomedical scientists in keeping abreast of new scientific devel opments in biotechnology as is Current Contents. (The costs of health cost provision and of fundamental biomedical research are now also being followed by such media.) Conversely, Wall Street financial bro kers increasingly no longer confine their reading to economic journals but are also perusing Nature,ll Science,12 and Science N 13 for infor ews mation on both fiscal and scientific advances in these areas. It is obvious that the information explosion in biotechnology is crossing traditional boundaries (e. g. , ref. 14). This volume is the second of several that are intended to inform both the biomedical community and interested intelligent laymen of the political and economic implications of biomedical research.

Human Medical Research Jan Schildmann 2012-03-14 Medical research involving human subjects has contributed to considerable advancements in our knowledge, and to medical benefits. At the same time the development of new technologies as well as further globalisation of medical research raises questions that require the attention of researchers from a range of disciplines. This book gathers the contributions of researchers from nine different countries, who analyse recent developments in medical research from ethical, historical, legal and socio-cultural perspectives. In addition to reflections on innovations in science such as genetic databases and the concept of “targeted therapy” the book also includes analyses regarding the ethico-legal regulation of new technologies such as human tissue banking or the handling of genetic information potentially relevant for participants in medical research. Country and culture-specific aspects that are relevant to human medical research from a global perspective also play a part. The value of multi- and interdisciplinary analysis that includes the perspectives of scholars from normative and empirical disciplines is a shared premise of each contribution.

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