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Clinical Research The Censor's Hand *Conducting Biosocial Surveys* **Handbook on Using Administrative Data for Research and Evidence-based Policy** *IRBs and Security Research: Myths, Facts and Mission Creep Reconstructing Research Integrity Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences*

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Professionals in need of such training and bioethicists will be interested. This book is designed as an instructional manual that gives Institutional Review Board (IRB) members and administrators the information they need to run an efficient and effective system of protecting human research subjects, in compliance with federal research regulations. This reference provides a step-by-step approach to practical details of IRB administration and includes case studies, sample forms, and sample policy documents, as well as decision-making algorithms and lists of approval criteria for their resolution. ""Two important aspects covered in this text are the ethical considerations in qualitative research methodologies, and the attention that is needed in University Research Ethics Committees to understanding and addressing these methodologies."" The second edition of this innovative work again provides a unique perspective on the clinical discovery process by providing input from experts within the NIH on the principles and practice of clinical research. Molecular medicine, genomics, and proteomics have opened vast opportunities for translation of basic science observations to the bedside through clinical research. As an introductory reference it gives clinical investigators in all fields

an awareness of the tools required to ensure research protocols are well designed and comply with the rigorous regulatory requirements necessary to maximize the safety of research subjects. Complete with sections on the history of clinical research and ethics, copious figures and charts, and sample documents it serves as an excellent companion text for any course on clinical research and as a must-have reference for seasoned researchers. *Incorporates new chapters on Managing Conflicts of Interest in Human Subjects Research, Clinical Research from the Patient's Perspective, The Clinical Researcher and the Media, Data Management in Clinical Research, Evaluation of a Protocol Budget, Clinical Research from the Industry Perspective, and Genetics in Clinical Research *Addresses the vast opportunities for translation of basic science observations to the bedside through clinical research *Delves into data management and addresses how to collect data and use it for discovery *Contains valuable, up-to-date information on how to obtain funding from the federal government Drwaing on extensive archival sources, Laura Stark reconstructs the daily lives of scientists, lawyers, administrators, and research subjects working - and 'warring' - on the campus of the National Institutes of Health, where they first wrote the rules for the treatment of human subjects. This book traces the historic transformation of institutional review boards (IRBs) from academic committees to compliance bureaucracies. Sarah Babb opens the black box of contemporary IRB decision-making, which is increasingly outsourced to specialized private firms. This book delineates effective roles for librarians on Institutional Review Boards (IRB) and the Institutional Animal Care and Use Committees (IACUC) and provides guidance for librarians on how to serve on them. Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences examines how to update human subjects protections regulations so that they effectively respond to current research contexts and methods. With a specific focus

on social and behavioral sciences, this consensus report aims to address the dramatic alterations in the research landscapes that institutional review boards (IRBs) have come to inhabit during the past 40 years. The report aims to balance respect for the individual persons whose consent to participate makes research possible and respect for the social benefits that productive research communities make possible. The ethics of human subjects research has captured scientific and regulatory attention for half a century. To keep abreast of the universe of changes that factor into the ethical conduct of research today, the Department of Health and Human Services published an Advance Notice of Proposed Rulemaking (ANPRM) in July 2011. Recognizing that widespread technological and societal transformations have occurred in the contexts for and conduct of human research since the passage of the National Research Act of 1974, the ANPRM revisits the regulations mandated by the Act in a correspondingly comprehensive manner. Its proposals aim to modernize the Common Rule and to improve the efficiency of the work conducted under its auspices. Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences identifies issues raised in the ANPRM that are critical and feasible for the federal government to address for the protection of participants and for the advancement of the social and behavioral sciences. For each identified issue, this report provides guidance for IRBs on techniques to address it, with specific examples and best practice models to illustrate how the techniques would be applied to different behavioral and social sciences research procedures. For an increasing number of hospitals and universities the institutional review board (lRB) has become a way of life. Spurred into existence by public outcries about the unethical nature of certain modern scientific experiments, the IRB represents the most visible evidence of institutional commitment to ethical review of clinical research. However, this exponential growth of IRB activities has not

occurred without growing pains. Like the Environmental Protection Agency, IRBs have had to develop procedures and standards without a clear consensus as to what would be optimal for science and society. Each IRB has perforce devised its own modus operandi, subject to general principles and guidelines laid down by others but still relatively free to stipulate the details of its functioning. Thus one can applaud the general idea as well as the overall performance of IRBs without asserting that the millenium has arrived. The composition, philosophy, efficiency, responsibilities, and powers of IRBs remain topics suit able for debate. It is still possible (and appropriate) for IRB members to worry both about the propriety of their decisions and the personal costs of their service. An argument that the system of boards that license human-subject research is so fundamentally misconceived that it inevitably does more harm than good. Medical and social progress depend on research with human subjects. When that research is done in institutions getting federal money, it is regulated (often minutely) by federally required and supervised bureaucracies called “institutional review boards” (IRBs). Do—can—these IRBs do more harm than good? In The Censor's Hand, Schneider addresses this crucial but long-unasked question. Schneider answers the question by consulting a critical but ignored experience—the law's learning about regulation—and by amassing empirical evidence that is scattered around many literatures. He concludes that IRBs were fundamentally misconceived. Their usefulness to human subjects is doubtful, but they clearly delay, distort, and deter research that can save people's lives, soothe their suffering, and enhance their welfare. IRBs demonstrably make decisions poorly. They cannot be expected to make decisions well, for they lack the expertise, ethical principles, legal rules, effective procedures, and accountability essential to good regulation. And IRBs are censors in the place censorship is most damaging—universities. In sum, Schneider argues that IRBs are bad regulation that inescapably

do more harm than good. They were an irreparable mistake that should be abandoned so that research can be conducted properly and regulated sensibly. This manual will help Institutional Review Boards (IRBs) conduct ethics review that balances the major moral considerations in research with human subjects. Current challenges in the IRB environment are addressed with arguments and insights from dozens of scholars. Useful to the IRB member at any level of experience, Balanced Ethics Review provides the necessary tools needed to create a systemic blueprint for promoting the research and dissemination of scientists and scholars within the standard norms of regulation. Having decided to focus attention on the "weak link" of human fallibility, a growing number of security researchers are discovering the US Government's regulations that govern human subject research. This paper discusses those regulations, their application to research on security and usability, and presents strategies for negotiating the Institutional Review Board (IRB) approval process. It argues that a strict interpretation of regulations has the potential to stymie security research. This short, smart analysis will engage scholars across academia. The author finds that these committees are predominantly influenced by members of research institutions and by the researchers themselves. Yet researchers, and their institutions, stand to gain considerable benefits from the experiments they conduct. Dr McNeill argues that committees of review, as they are presently constituted, cannot be relied on to ensure an equitable balance between the interests of researchers and the interests of the human subjects experimented on. He proposes a radically different rationale and model for committee review. An argument that the system of boards that license human-subject research is so fundamentally misconceived that it inevitably does more harm than good. Medical and social progress depend on research with human subjects. When that research is done in institutions getting federal money, it is regulated (often minutely) by federally

required and supervised bureaucracies called “institutional review boards” (IRBs). Do—can—these IRBs do more harm than good? In The Censor's Hand, Schneider addresses this crucial but long-unasked question. Schneider answers the question by consulting a critical but ignored experience—the law's learning about regulation—and by amassing empirical evidence that is scattered around many literatures. He concludes that IRBs were fundamentally misconceived. Their usefulness to human subjects is doubtful, but they clearly delay, distort, and deter research that can save people's lives, soothe their suffering, and enhance their welfare. IRBs demonstrably make decisions poorly. They cannot be expected to make decisions well, for they lack the expertise, ethical principles, legal rules, effective procedures, and accountability essential to good regulation. And IRBs are censors in the place censorship is most damaging—universities. In sum, Schneider argues that IRBs are bad regulation that inescapably do more harm than good. They were an irreparable mistake that should be abandoned so that research can be conducted properly and regulated sensibly. Brings together international scholars across the social and behavioural sciences and education to address those ethical issues that arise in the theory and practice of research within the technologically advancing and culturally complex world in which we live. The Essential Resource for All IRB Members! Designed to give Institutional Review Board (IRB) members the information they need to protect the rights and welfare of research subjects in a way that is both effective and efficient, the chapters of the Institutional Review Board Member Handbook are short and to the point. Topic-specific chapters list the criteria IRB members should use to determine how to vote on specific kinds of studies and offer practical advice on what IRB members should do before and during full-committee meetings. NEW CHAPTERS in this Edition Include: * Definition of Human Subject Research, Exempt & Expedited Review Categories * IRB Member Conflict of Interest All chapters are completely updated

for 2010 practice! This handbook is an excellent accompaniment to Institutional Review Board: Management and Function, Second Edition and the Study Guide that IRB members can access and refer to quickly and easily. v. 1. Research findings -- v. 2. Concepts and methodology -- v. 3. Implementation issues -- v. 4. Programs, tools and products. Institutional Review Boards (IRBs) are federally-mandated, locally-administered groups charged with evaluating risks and benefits of human participant research at their institution. To a greater or lesser extent, risks and potential benefits exist in virtually any research with human participants, including research in the behavioral/social sciences. Federal law and APA standards require IRB review of all human participant research projects. IRB review and approval will likely bring an investigator into contact with two inter-related groups: the IRB and the professional staff that administers IRB activities. Due to a variety of factors, including increased IRB and faculty workload and enhanced federal oversight, the potential for conflict among IRB members, IRB administrators, and investigators may be great. Indeed, anecdotal evidence suggests that this potential for conflict may be particularly high for behavioral scientists, and that dissatisfaction with IRB review may jeopardize compliance with federal regulations, research participant protection, and research itself. The purpose of this paper is to suggest specific strategies that IRB members, IRB administrators, and investigators can use to avoid potential conflict and facilitate human research participant protection. We contend that when these groups understand and face these responsibilities collaboratively, conflict will be minimized and safe, ethical, high quality research will flourish. Much of the literature on human subject regulation asserts that Institutional Review Boards (IRBs) have failed at the task of regulating human subjects research. These critiques of IRB law can be grouped into three loose categories: critiques of IRB law as law, critiques of IRBs as regulation, and critiques of IRBs as a system of norm creation.

Moving beyond critique, we rethink the literature on IRBs drawing on the tools and scholarship of the social sciences. In particular, we examine human subjects regulation as an insufficient remedy to inequalities between weak and powerful actors, as a site of professional claims- and career-making, and as an occasion for institutionalization. Finally, distinguishing between the regulation of science and the regulation of ethics, we observe that the latter is far more difficult because ethics are contextual and subject to social construction. For these reasons, IRBs often substitute bureaucratic ethics for professional ethics. Institutional Review Board (IRB) members and oversight personnel face challenges with research involving new technology, management of big data, globalization of research, and more complex federal regulations. Institutional Review Board: Management and Function, Third Edition provides everything IRBs and administrators need to know about efficiently managing and effectively operating a modern and compliant system of protecting human research subjects. This trusted reference manual has been extensively updated to reflect the 2018 revisions to the Federal Policy for the Protection of Human Subjects (Common Rule). An essential resource for both seasoned and novice IRB administrators and members, Institutional Review Board: Management and Function provides comprehensive and understandable interpretations of the regulations, clear descriptions of the ethical principles on which the regulations are based, and practical step-by-step guidance for effectively implementing regulatory oversight. 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. Conducting Research with Human Participants: An IRB Guide for Students and Faculty by Nathan Durdella is the only guidebook students and faculty will need to navigate the IRB process and secure swift approval of research protocols. This book serves as an advisor to walk researchers through all the details of drafting, submission, and revision of materials for Institutional Review Boards so they can complete their research

projects or dissertations faster. This text walks readers through the history of Institutional Review Boards, the contemporary context of ethical research, strategies to effectively draft, submit, and revise an IRB protocol, and guidance on working with an approved protocol in the field. The latest updates to the Common Rule and other regulatory frameworks, including special protections for working with vulnerable groups, are covered throughout the text. Not every research project goes according to plan, so adverse events and reporting receive special coverage. A final chapter on ethical research practices beyond IRB compliance encourages researchers to think through how to exit the field of research and ensure their research benefits the individuals, families, and communities in which they work. Take the guesswork out of the IRB process from start to finish with this handy guide. Biomedical research on humans is an important part of medical progress. But, when health and lives are at risk, safety and ethical practices need to be the top priority. The need for the committees that regulate and oversee such research—institutional review boards, or IRBs—is growing. Evaluating the Science and Ethics of Research on Humans is a guide for new and veteran members of IRBs that will help them better understand the issues involved and the tasks they will be required to perform. The most important purpose of an IRB is to protect the human participants in research. For three major research areas—drugs, medical devices, and genetic information—Dennis J. Mazur shares the methods he has found useful in protecting human participants through the systematic review of scientific protocols and informed consent forms and through adherence to the federal regulations that apply. New members will gain understanding of how proposed research projects are to be reviewed from both scientific and ethical dimensions, how and when to ask key questions of principal investigators, how to work with principal investigators and research teams to ensure the best protection of human

participants, and why to schedule regularly spaced reviews of a project that may have adverse outcomes. Containing helpful summaries and checklists throughout and based on Mazur's thirty years of research experience, this accessible and informative guide will give all IRB members the tools they need to protect human lives and facilitate the research process. The Notice of Proposed Rule Making (NPRM) proposes the largest change to the Code of Federal Regulations pertaining to research in twenty years. With the advent of multisite clinical trials many regulatory issues have arisen--in particular the benefit of Local Institutional Review Boards (IRBs) versus central IRB review. Staff members of IRBs at academic medical centers in Georgia were interviewed to assess their experiences working with both types of IRB review and the impact it has had at their institutions. Data from the study revealed that employees of local IRBs are open to the use of central IRB review. Ethics in Social Science Research: Becoming Culturally Responsive provides a thorough grounding in research ethics, along with examples of real-world ethical dilemmas in working with vulnerable populations. Author Maria K. E. Lahman aims to help qualitative research students design ethically and culturally responsive research with communities that may be very different from their own. Throughout, compelling first person accounts of ethics in human research—both historical and contemporary—are highlighted and each chapter includes vignettes written by the author and her collaborators about real qualitative research projects. This book exposes significant threats to research integrity and identifies policies and practices that can reverse these trends. It is focused on human research and US policy. Recent assessments have shown inadequacies in institutions, policies, and practices that seriously compromise ethics. The presumed self-regulatory nature of the scientific endeavor has been exposed to have allowed unabated areas of poor-quality science, an incomplete and inaccessible scientific record, conflicts of interest, differing notions of accountability,

virtually no evidence base to direct research integrity policy, and a growing sense of alienation, moral injury and even revolt among scientists. Reconstructing Research Integrity aims to capture ways of vigorously moving toward scientific and ethical rigor, including self-correction and emerging or already-successful initiatives. The book begins with analysis of the full system of institutions, policies, and practices involved in production, dissemination, and application of research, including an examination of the blind spots in research ethics ideology, policy, and practice. The book then identifies policies and practices that can reverse harmful ethical trends, such as strengthening Responsible Conduct of Research (RCR) training and improving self-regulation in the scientific community. Finally, the book discusses the constant evolution of research ethics and integrity, which is illustrated by emerging research fields like gene editing and data science. This book will be of interest to all research administrators in academic, commercial and government positions; to policy advisors at the National Science Foundation and at the National Academies of Science, Engineering, and Medicine; to graduate students in research ethics; to advanced bioethics education programs across the globe; and to researchers and consultants in ELSI (ethical, legal, and social implications) programs. Across a broad range of disciplines--in medicine, social science, and the humanities--researchers, scholars, teachers, and administrators increasingly are looking for new ways to approach ethical issues in research with human subjects. Questions about how relationships between funders and researchers should affect research design, for example, or whether the potential benefits of research can outweigh the importance of its subjects' interests are inadequately addressed by the prevailing, regulation-based research ethics paradigm. This book constitutes a reexamination of research ethics. It combines case studies and commentaries by a multidisciplinary group of scholars and researchers to explore such topics as

informed consent, conflict of interest, confidentiality, and research on illegal behavior. All human subjects research takes place within complex social, cultural, and political contexts, the contributors argue. Increased consideration of the relationships between researchers and their subjects, funders, and institutions within these contexts will facilitate research that is sensitive and responsible as well as scientifically fruitful. Beyond Regulations features a keynote essay by Ruth Macklin. Other contributors are Marcela Aracena Alvarez, Jorge Balan, B. Susan Bauer, Alan F. Benjamin, Lynn Blanchard, Allan M. Brandt, J. Pat Browder, Barbara Entwisle, Sue E. Estroff, Renee C. Fox, Lara Freidenfelds, Gail E. Henderson, Nancy M. P. King, Loretta M. Kopelman, Ernest N. Kraybill, Barry M. Popkin, Silvina Ramos, Desmond K. Runyan, Jane Stein, Ronald P. Strauss, Keith A. Wailoo, and Cynthia Waszak. Across a broad range of disciplines--in biomedicine, the social sciences, and the humanities--researchers, scholars, administrators, and teachers increasingly struggle with questions of ethics in research with human subjects. All research takes place in complex social, cultural, political, and economic contexts; yet the prevailing principle-based research ethics paradigm does not adequately account for them. This book reexamines research ethics using a new relationships paradigm. Through in-depth cases, commentaries, and essays, a multidisciplinary group of scholars and researchers addresses informed consent, conflict of interest, confidentiality, and other issues, considering questions like: What relationships should researchers have with their subjects' communities? When researchers and subjects have different views about research, who should have control? How should relationships between funders and researchers affect research design? Can research be so potentially beneficial that its importance outweighs the interests of subjects? Examining the relationships between researchers and subjects, communities, funders, and institutions--including considerations of authority and voice--can facilitate

human subjects research that is morally sensitive and responsible as well as scientifically fruitful. All studies on people involving diseases, from cancer to autism, and behavior. Yet ethical violations persist. At the same time, critics have increasingly attacked these committees for delaying or blocking important studies. Partly, science is changing, and the current system has not kept up. Since the regulations were first conceived 40 years ago, research has burgeoned 30-fold. Studies often now include not a single university, but multiple institutions, and 40 separate IRBs thus need to approve a single project. One committee might approve a study quickly, while others require major changes, altering the scientific design, and making the comparison of data between sites difficult. Crucial dilemmas thus emerge of whether the current system should be changed, and if so, how. Yet we must first understand the status quo to know how to improve it. Unfortunately, these committees operate behind closed doors, and have received relatively little in-depth investigation. In this multi-method dissertation project I conduct policy analysis and utilize results from a discipline-wide survey (n=258) to examine the intersection of Writing Studies researchers disciplinary affiliation, research context, and personal disposition in relation to the local implementation of federal policy regarding human subjects research. I elaborate on the context of this project, discussing the September 2015 release of the Notice of Proposed Rulemaking (NPRM) to revise and update the Common Rule, 45.CFR Part 46, and the Conference on College Composition and Communications formal comment in response to the proposed rules provisions. I discuss the process of designing and implementing the survey used to establish a disciplinary representation of Writing Studies researchers perceptions of, and experiences with, IRBs. The results of this survey (Chapter 4) indicate how Writing Studies researchers presently interface with the process of local policy implementation. In Chapter 5, data from the survey are set against the Final Rule (released January

19, 2017) to provide a new taxonomy for Writing Studies researchers regarding how to interface with IRBs. Finally, the major theoretical contribution is articulated in Chapter Six: a call for human subjects researchers in Writing Studies to consider IRBs as justice-oriented, rather than positivist, in design and purpose. I argue increasingly reciprocal relationships between IRBs and Writing Studies researchers will help ensure Writing Studies research is not overly influenced by IRB review, nor that Writing Studies researchers are unwilling or unable to interface with IRBs to build more ethical and robust research agendas. Experts from different disciplines offer novel ideas for improving research oversight and protection of human subjects. The current framework for the regulation of human subjects research emerged largely in reaction to the horrors of Nazi human experimentation, revealed at the Nuremburg trials, and the Tuskegee syphilis study, conducted by U.S. government researchers from 1932 to 1972. This framework, combining elements of paternalism with efforts to preserve individual autonomy, has remained fundamentally unchanged for decades. Yet, as this book documents, it has significant flaws—including its potential to burden important research, overprotect some subjects and inadequately protect others, generate inconsistent results, and lag behind developments in how research is conducted. Invigorated by the U.S. government's first steps toward change in over twenty years, Human Subjects Research Regulation brings together the leading thinkers in this field from ethics, law, medicine, and public policy to discuss how to make the system better. The result is a collection of novel ideas—some incremental, some radical—for the future of research oversight and human subject protection. After reviewing the history of U.S. research regulations, the contributors consider such topics as risk-based regulation; research involving vulnerable populations (including military personnel, children, and prisoners); the relationships among subjects, investigators, sponsors, and

institutional review boards; privacy, especially regarding biospecimens and tissue banking; and the possibility of fundamental paradigm shifts. Contributors Adam Braddock, Alexander Morgan Capron, Ellen Wright Clayton, I. Glenn Cohen, Susan Cox, Amy L. Davis, Hilary Eckert, Barbara J. Evans, Nir Eyal, Heidi Li Feldman, Benjamin Fombonne, Elisa A. Hurley, Ana S. Iltis, Gail H. Javitt, Greg Koski, Nicole Lockhart, Holly Fernandez Lynch, Michael McDonald, Michelle N. Meyer, Osagie K. Obasogie, Efthimios Parasidis, Govind Persad, Rosamond Rhodes, Suzanne M. Rivera, Zachary M. Schrag, Seema K. Shah, Jeffrey Skopek, Laura Stark, Patrick Taylor, Anne Townsend, Carol Weil, Brett A. Williams, Leslie E. Wolf Institutional Review Boards (IRBs) are committees that review research studies involving human subjects to assure that they will be conducted in compliance with federal regulations designed to protect those subjects. Recently, claims have been made that this system of IRB review-particularly insofar as it is applied to social and behavioral research-constitutes censorship that violates the First Amendment. Taking a look at the actual regulations that govern IRBs provides a useful way to evaluate these claims. Doing so demonstrates that in fact many social and behavioral research studies are not even subject to IRB review. Another very large group of such studies falls into an exempt category, and receives very cursory review. Admittedly, the current system is imperfect and a variety of improvements can and should be made to eliminate those review requirements that do little to protect subjects. But even with these problems, getting IRB approval of social and behavioral research studies should in the great majority of cases be a relatively non-burdensome task that is a minimal hindrance to the conduct of the research. That burden should rarely if ever rise to the level of triggering constitutional protections against censorship. Critics of the system would be better served by trying to improve the functioning of the IRB at their own institutions, and by working to enact appropriate

changes to the regulations, than by throwing up the red flag of censorship. The Oxford Textbook of Clinical Research Ethics is the first comprehensive and systematic reference on clinical research ethics. Under the editorship of experts from the U.S. National Institutes of Health of the United States, the book's 73 chapters offer a wide-ranging and systematic examination of all aspects of research with human beings. Considering the historical triumphs of research as well as its tragedies, the textbook provides a framework for analyzing the ethical aspects of research studies with human beings. Through both conceptual analysis and systematic reviews of empirical data, the contributors examine issues ranging from scientific validity, fair subject selection, risk benefit ratio, independent review, and informed consent to focused consideration of international research ethics, conflicts of interests, and other aspects of responsible conduct of research. The editors of The Oxford Textbook of Clinical Research Ethics offer a work that critically assesses and advances scholarship in the field of human subjects research. Comprehensive in scope and depth, this book will be a crucial resource for researchers in the medical sciences, as well as teachers and students. 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. Designed to give Institutional Review Board (IRB) members the information they need to protect the rights and welfare of research subjects in a way that is both effective and efficient, the chapters of the Institutional Review Board Member Handbook are short and to the point. Topic-specific chapters list the criteria IRB members should use to determine how to vote on specific kinds of studies and offer practical advice on what IRB members should do before and during full-committee meetings. This handbook is an excellent accompaniment to Institutional Review Board: Management and Function, Third Edition (ISBN: 978-1-284-18115-9) and the Study Guide that IRB members can access and refer to quickly and easily. The book has three sections: -Part 1: Background Information, containing background information on human subject research -Part 2: The Full Committee IRB Meeting, comprised of eight chapters focused on the research proposal review process. This Handbook intends to inform Data Providers and researchers on how to provide privacy-protected access to, handle, and analyze administrative data, and to link them with existing resources, such as a database of data use agreements (DUA) and templates. Available publicly, the Handbook will provide guidance on data access requirements and procedures, data privacy, data security, property rights, regulations for public data use, data architecture, data use and

storage, cost structure and recovery, ethics and privacy-protection, making data accessible for research, and dissemination for restricted access use. The knowledge base will serve as a resource for all researchers looking to work with administrative data and for Data Providers looking to make such data available. 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 Essential Resource for All IRB Members! Designed to give Institutional Review Board (IRB) members the information they need to protect the rights and welfare of research subjects in a way that is both effective and efficient, the chapters of the Institutional Review Board Member Handbook are short and to the point. Topic-specific chapters list the criteria IRB members should use to determine how to vote on specific kinds of studies and offer practical advice on what IRB members should do before and during full-committee meetings. NEW CHAPTERS in this Edition Include: * Definition of Human Subject Research, Exempt & Expedited Review Categories * IRB Member Conflict of Interest All chapters are completely updated for 2010 practice! This handbook is an excellent accompaniment to Institutional Review Board: Management and Function, Second Edition and the Study Guide that IRB members can access and refer to quickly and easily. Identifies Institutional Review Board (IRB) and professional med. assoc. (MA) human-subject recruitment guidelines that exceed guidelines set forth by the Dept. of Health and Human Services (HHS). HHS guidelines do not address the

recruitment practices that IRBs and others involved in clinical research find troubling. Here, HHS presents other sources of guidance for IRBs and investigators, from MA and IRBs. Includes Canadian guidelines on recruitment practices to illustrate how these practices have been addressed by another nation¿s research community. This report focuses on guidance on how 3 main issues -- recruitment incentives, the dual investigator-physician role, and the confidentiality of medical records -- should be handled. Tables.

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