

The Censor's Hand

THE MISREGULATION OF HUMAN-SUBJECT RESEARCH

Carl E. Schneider

7. Regulatory Authority

Check as Applicable:

- ☐ Data from this study are subject to FDA regulation and oversight, either through submission or inspection.
- ☐ This study is federally funded. (If checked, a copy of the entire grant must be submitted)
- ☐ This study is not subject to FDA regulation, nor is it federally funded.

8. Check as applicable:

☐ Drug or Biologic Study:

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☐ 2 Phase

☐ 3 Phase

☐ 4 Other: _____

IND #: if applicable: _____

Device Study (check all that apply): Investigational

☐ Class I Significant Risk: submit IDE #, letter from FDA and device specifications

☐ Class II Non-Significant Risk: submit justification, including regulatory citations and 510k# if applicable)

☐ Class III HUD – submit HUD# and FDA letter

☐ Marketed: being in accordance with approved labeling (submit approved labeling)

☐ IDE exemption: provide category as per 21 CFR 812.2

This study does not involve a drug, biologic or device

9. Approximate number of investigative sites to be submitted: _____

10. Is the language in the submitted ICF that addresses compensation for research-related injury language consistent with the language in the investigate sites' contracts? N/A Yes No (Attach explanation)

11. Have any other IRBs (local or central) reviewed this study?

☐ Yes

☐ No

☐ N/A

If yes, describe the outcome of the review, including any issues that required resolution prior to final approval:

The Censors Hand The Misregulation Of Human Subject Research Basic Bioethics

**Holly Fernandez Lynch, Barbara E.
Bierer, I. Glenn Cohen, Suzanne M.
Rivera**

The Censors Hand The Misregulation Of Human Subject Research Basic Bioethics:

The Censor's Hand Carl E. Schneider, 2015-04-10 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

The Myth of the Moral Brain Harris Wiseman, 2016-02-19 An argument that moral functioning is immeasurably complex mediated by biology but not determined by it Throughout history humanity has been seen as being in need of improvement most pressingly in need of moral improvement Today in what has been called the beginnings of the golden age of neuroscience laboratory findings claim to offer insights into how the brain does morality even suggesting that it is possible to make people more moral by manipulating their biology Can moral bioenhancement using technological or pharmaceutical means to boost the morally desirable and remove the morally problematic bring about a morally improved humanity In *The Myth of the Moral Brain* Harris Wiseman argues that moral functioning is immeasurably complex mediated by biology but not determined by it Morality cannot be engineered there is no such thing as a moral brain Wiseman takes a distinctively interdisciplinary approach drawing on insights from philosophy biology theology and clinical psychology He considers philosophical rationales for moral enhancement and the practical realities they come up against recent empirical work including studies of the cognitive and behavioral effects of oxytocin serotonin and dopamine and traditional moral education in particular the influence of religious thought belief and practice Arguing that morality involves many interacting elements Wiseman proposes an integrated bio psycho social approach to the consideration of moral enhancement Such an approach would show that by virtue of their sheer numbers social and environmental factors are more important in shaping moral functioning than the neurobiological factors with which they are interwoven

Thinking Ecologically, Thinking Responsibly Nancy Arden McHugh, Andrea Doucet, 2021-12-01 *Thinking Ecologically Thinking Responsibly* brings together a transdisciplinary cohort of feminist critical

race Indigenous and decolonial scholars who build upon and seek to widen and deepen the legacy and potential of feminist philosopher Lorraine Code's work. Since the publication of her 1987 book *Epistemic Responsibility*, Code has been at the forefront of linking epistemologies, ontologies, ethics, and epistemic injustice to guide critical frameworks for responsible situated knowing and practices. This volume both enacts and expands Code's theories, epistemologies, and practices. It points to how concepts such as epistemic responsibility and approaches like ecological thinking are not only theoretical frameworks for knowing the world well; they are also practices and approaches that more and more feminists and critical thinkers are embodying in their work in order to think, write, and live critically and responsibly.

The Ethics of Research with Human Subjects David B. Resnik, 2025-02-27. In *The Ethics of Research with Human Subjects*, David B. Resnik, PhD, JD, develops and defends an approach to thinking about ethical and policy dilemmas in research with human subjects based on the notion of trust. The book explains why trust is important not only between investigators and research subjects but also between and among other stakeholders involved in the research enterprise, including research staff, sponsors, institutions, communities, oversight committees, government agencies, and the public. Dr. Resnik argues that trust should be viewed as a distinct ethical principle for research with human subjects that complements other principles such as respect for human dignity, beneficence, non-maleficence, and justice. The book applies the principle of trust to numerous issues, including informed consent, confidentiality, privacy, risk minimization, risk-benefit assessment, payments for participation, protection of vulnerable subjects, experimental design, research integrity, and research oversight. The book also includes discussions of the history of research involving human subjects, moral theories and principles, contemporary cases, and proposed regulatory reforms. This second edition of *The Ethics of Research with Human Subjects* expands upon and clarifies arguments and ideas discussed in the first edition and includes new material on emerging issues in human research ethics, including community-based research, citizen science, research challenge studies, including COVID-19 experiments, public health research, genomics research, social and behavioral research, xenotransplantation experiments, alternative study designs, and research with people with compromised decisional capacity, employees, and students. The book is of interest to undergraduate and graduate students who are studying ethical and policy issues related to research with human subjects, as well as scientists and scholars who are interested in learning more about the issues and thinking about what it means to promote integrity and trust in research with human subjects.

Absolutely Essential Jonathan D. Moreno, 2025-09-16. What the end of the post-World War II global political system means for bioethics and beyond. In *Absolutely Essential*, Jonathan Moreno explores the field of bioethics as both a creature and a key element of the post-World War II rules-based order. According to this order, international relations are to be organized according to principles of open markets, liberal democracy, and multilateral organizations. Drawing on the author's four decades of experience in the field, the book raises key questions about the future of bioethics in a changed world order while also theorizing new ways to think about bioethics after the COVID-19 pandemic and the reordering of global alliances.

For bioethicists this book will contextualize the field in an entirely new light while readers unfamiliar with bioethics will appreciate that this seemingly esoteric field is in fact a paradigmatic creation of the global system now undergoing sweeping change

Making Modern Medical Ethics Robert Baker, 2024-02-20 The little known stories of the people responsible for what we know today as modern medical ethics In Making Modern Medical Ethics Robert Baker tells the counter history of the birth of bioethics bringing to the fore the stories of the dissenters and whistleblowers who challenged the establishment Drawing on his earlier work on moral revolutions and the history of medical ethics Robert Baker traces the history of modern medical ethics and its bioethical turn to the moral insurrections incited by the many unsung dissenters and whistleblowers African American civil rights leaders Jewish Americans harboring Holocaust memories feminists women and Anglo American physicians and healthcare professionals who were veterans of the World Wars the Cold War and the Vietnam War The standard narrative for bioethics typically emphasizes the morally disruptive medical technologies of the latter part of the twentieth century such as the dialysis machine the electroencephalograph and the ventilator as they created the need to reconsider traditional notions of medical ethics Baker however tells a fresh narrative one that has historically been neglected e g the story of the medical veterans who founded an international medical organization to rescue medicine and biomedical research from the scandal of Nazi medicine and also reveals the penalties that moral change agents paid e g the stubborn bureaucrat who was demoted for her insistence on requiring and enforcing research subjects informed consent Analyzing major statements of modern medical ethics from the 1946 1947 Nuremberg Doctors Trials and Nuremberg Code to A Patient's Bill of Rights Making Modern Medical Ethics is a winning history of just how respect and autonomy for patients and research subjects came to be codified

Enlightenment Now Steven Pinker, 2018-02-13 THE TOP TEN SUNDAY TIMES BESTSELLER Bristles with pure crystalline intelligence deep knowledge and human sympathy Richard Dawkins Is modernity really failing Or have we failed to appreciate progress and the ideals that make it possible If you follow the headlines the world in the 21st century appears to be sinking into chaos hatred and irrationality Yet Steven Pinker shows that this is an illusion a symptom of historical amnesia and statistical fallacies If you follow the trendlines rather than the headlines you discover that our lives have become longer healthier safer happier more peaceful more stimulating and more prosperous not just in the West but worldwide Such progress is no accident it's the gift of a coherent and inspiring value system that many of us embrace without even realizing it These are the values of the Enlightenment of reason science humanism and progress The challenges we face today are formidable including inequality climate change Artificial Intelligence and nuclear weapons But the way to deal with them is not to sink into despair or try to lurch back to a mythical idyllic past it's to treat them as problems we can solve as we have solved other problems in the past In making the case for an Enlightenment newly recharged for the 21st century Pinker shows how we can use our faculties of reason and sympathy to solve the problems that inevitably come with being products of evolution in an indifferent universe We will never have a perfect world but defying the

chorus of fatalism and reaction we can continue to make it a better one *Ethics in Everyday Places* Tom Koch, 2022-11-01

An exploration of moral stress distress and injuries inherent in modern society through the maps that pervade academic and public communications worlds In *Ethics in Everyday Places* ethicist and geographer Tom Koch considers what happens when as he puts it you do everything right but know you've done something wrong The resulting moral stress and injury he argues are pervasive in modern Western society Koch makes his argument from the ground up from the perspective of average persons and through a revealing series of maps in which issues of ethics and morality are embedded The book begins with a general grounding in both moral stress and mapping as a means of investigation The author then examines the ethical dilemmas of mapmakers and others in the popular media and the sciences including graphic artists journalists researchers and social scientists Koch expands from the particular to the general from mapmaker and journalist to the readers of maps and news He explores the moral stress and injury in educational funding poverty and income inequality Why aren't we angry that one in eight fellow citizens lives in federally certified poverty transportation modeling seen in the iconic map of the London transit system and the hidden realities of exclusion and U S graft organ transplantation This uniquely interdisciplinary work rewrites our understanding of the nature of moral stress distress and injury and ethics in modern life Written accessibly and engagingly it transforms how we think of ethics personal and professional amid the often conflicting moral injunctions across modern society Copublished with Esri Press *Specimen Science* Holly Fernandez Lynch, Barbara E. Bierer, I. Glenn Cohen, Suzanne M. Rivera, 2017-10-13

Legal regulatory and ethical perspectives on balancing social benefit and human autonomy in research using human biospecimens Advances in medicine often depend on the effective collection storage research use and sharing of human biological specimens and associated data But what about the sources of such specimens When a blood specimen is drawn from a vein in your arm is that specimen still you Is it your property intellectual or otherwise Should you be allowed not only to consent to its use in research but also to specify under what circumstances it may be used These and other questions are at the center of a vigorous debate over the use of human biospecimens in research In this book experts offer legal regulatory and ethical perspectives on balancing social benefit and human autonomy in biospecimen research After discussing the background to current debates as well as several influential cases including that of Henrietta Lacks the contributors consider the rights obligations risks and privacy of the specimen source different types of informed consent under consideration broad blanket and specific implications for special patient and researcher communities and the governance of biospecimen repositories and the responsibilities of investigators Contributors Rebecca A Anderson Heide Aung Avery Avrakotos Mark Barnes Jill Barnholtz Sloan Benjamin Berkman Barbara E Bierer Mark A Borreliz Jeffrey R Botkin Dan Brock Ellen Wright Clayton I Glenn Cohen Lisa Eckstein Barbara J Evans Emily Chi Fogler Nanibaa A Garrison Pamela Gavin Aaron J Goldenberg Christine Grady Kate Gallin Heffernan Marylana Saadeh Helou Sara Chandros Hull Elisa A Hurley Steven Joffe Erin P Johnson Julie Kaneshiro Aaron S Kesselheim Isaac Kohane David Korn

Russell Korobkin Bernard Lo Geoffrey Lomax Kimberly Hensle Lowrance Holly Fernandez Lynch Bradley A Malin Karen J Maschke Eric M Meslin P Pearl O Rourke Quinn T Ostrom David Peloquin Rebecca Pentz Jane Perlmutter Ivor Pritchard Suzanne M Rivera Erin Rothwell Andrew P Rusczyk Rachel E Sachs Carol Weil David Wendler Benjamin Wilfond Susan M Wolf Engaging with Ethics in International Criminological Research Michael Adorjan, Rose Ricciardelli, 2016-06-10

Despite a voluminous literature detailing the procedures of research ethics boards and institutional ethical review processes there are few texts that explore the realpolitik of conducting criminal research in practice This book explores the unique lived experiences of scholars engaging with ethics during their criminological research and focuses on the ethical dilemmas that researchers encounter both in the field and while writing up results for publication Who benefits from criminological research What are the roles and impacts of ethics review boards How do methodological and theoretical decisions factor in to questions of ethical conduct and research ethics governance This book is divided into four parts Part I Institutional arrangements and positionality explores the ongoing and expanding process of ethics protocol and procedures principles of confidentiality and the positionality of the researcher Part II Trust and research with vulnerable populations examines the complexity of work involving prisoners indigenous peoples and victims of extreme violence power dynamics between researchers and participants and the challenges of informed consent Part III Research on and with police reflects on the importance of transparent relations with police best practices and the consequences of undertaking research in authoritarian contexts Part IV Emerging areas scrutinizes the ethics of carceral tours and suggests possible alternatives and offers one of the first sociological and criminological examinations of dark net cryptomarkets Drawing upon the experiences of international experts this book aims to provoke further reflection on and discussion of ethics in practice This book is ideal for students undertaking courses on research methods in criminology as well as a key resource for criminology researchers around the world

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