Revised Cioms International Ethical Guidelines For Health

The definitive reference guide to designing scientifically sound and ethically robust medical research, considering legal, ethical and practical issues.

Since its first publication in 1996, Ethics and Epidemiology has been an invaluable resource for practicing public health professionals and MPH students around the world. This third edition presents an international perspective of prominent epidemiologists, ethicists, and legal scholars to address important ethical developments in epidemiology and related public health fields from the last decade, including the rise of public

health ethics and the complex inter-relations between professional ethics in epidemiology, public health ethics, and research ethics. Ethics and Epidemiology, Third Edition is organized topically and divided into four parts covering "Foundations," "Key Values and Principles," "Methods," and "Issues." New or updated chapters include ethical issues in public health practice, ethical issues in genetic epidemiology, and ethical issues in international health research and epidemiology. Now updated with timely global examples, Ethics and Epidemiology, Third Edition provides an in-depth account to the theoretical and practical moral problems confronting public health students and professionals and offers guidance for how justified moral conclusions can be reached.

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

and the Council of Europe's Convention on Human Rights and Biomedicine.

This Open Access book highlights the ethical issues and dilemmas that arise in the practice of public health. It is also a tool to support instruction, debate, and dialogue regarding public health ethics. Although the practice of public health has always included consideration of ethical issues, the field of public health ethics as a discipline is a relatively new and emerging area. There are few practical training resources for public health practitioners, especially resources which include discussion of realistic cases which are likely to arise in the practice of public health. This work discusses these issues on a case to case basis and helps create awareness and understanding of the

ethics of public health care. The main audience for the casebook is public health practitioners, including front-line workers, field epidemiology trainers and trainees, managers, planners, and decision makers who have an interest in learning about how to integrate ethical analysis into their day to day public health practice. The casebook is also useful to schools of public health and public health students as well as to academic ethicists who can use the book to teach public health ethics and distinguish it from clinical and research ethics.

Readings and Commentary

Protecting Human Subjects

Ethics Dumping

The Oxford Textbook of Clinical Research Ethics

Reviewing Clinical Trials

Evidence Synthesis and Meta-Analysis

for Drug Safety
Guidelines for Preparing Core Clinical-safety Information on Drugs
This textbook provides a brief history of human experimentation and reviews various theories of ethics from which the principles and rules that govern this research are derived. All relevant international documents and national regulations, policies and memoranda are referred to extensively to assist in addressing issues that regularly arise during the course of research involving human subjects. It includes

case examples and exercises and is of interest to students and experienced researchers.
Risk management of medicines is a wide and rapidly evolving concept and practice, following a medicine throughout its lifecycle, from first administration in humans through clinical studies and then marketing in the patient population at large. Previous reports from CIOMS I - VIII provided practical guidance in some essential components of risk management such as

terminology and reporting of adverse drug reactions, management of safety information from clinical trials, and safety signal detection. Beyond the detection, identification, and characterization of risk, "risk minimization" is used as an umbrella term for the prevention or mitigation of an undesirable outcome. Risk management always includes tools for "routine risk minimization" such as product information, the format depending on the jurisdiction, to inform the patient and the prescriber,

all of which serve to prevent or mitigate adverse effects. Until this current CIOMS IX document, limited guidance has been available on how to determine which risks need "additional risk minimization," select the appropriate tools, apply and implement such tools globally and locally, and measure if they are effective and valuable. Included in the report is a CIOMS framework for the evaluation of effectiveness of risk minimization, a discussion of future trends and developments, an annex

specifically addressing vaccines, and examples from real life.

The idea for this manual came from Pfizer in the US, which provided the Clinical Trials Centre at The University of Hong Kong, Hong Kong SAR, PR China with a nonbinding grant for its development. The general project layout protocol was accepted by Pfizer in July 2009. Pfizer has not in any way interfered with the project, except for providing nonbinding comments to the final product. The entire text of this manual was written

by Johan PE Karlberg. Marjorie A Speers provided considerable and essential comments on the contents and the first and subsequent drafts. A group of international human research protection experts mostly working in non-profit institutions or organisations - see Contributors for details - reviewed and provided important comments on the contents and final draft. It was solely created with the intention to promote human research protection of participants in clinical trials. This manual will be

translated into numerous languages and is provided free of charge as an electronic file over the Internet (http://www.ClinicalTrialMagnifier.com) and offered in print for a fee. The objective beyond this project is to establish educational activities, developed around the manual, and jointly organised with leading academic institutions worldwide.

Quality improvement in health care is now a stated objective of health services worldwide, yet effective delivery is not always

apparent. This book discusses research methods that should help to improve the delivery of quality.
Ethical Issues in International Biomedical Research
Understanding The Science of Change in Health Care
For the Common Good
International Bioethics and Human Rights
Current Challenges in Pharmacovigilance
A Toolbox
Ethical Principles for Medical Research Involving Human Subjects

The aim of this book is to provide research ethics committee

members with a resource that focuses on research ethics issues in Africa. The authors are currently active in various aspects of research ethics in Africa and the majority have been trained in the past by either the Fogarty International Center or Europe and Developing Countries Clinical Trial Partnership (EDCTP) sponsored bioethics training programmes . CIOMS, in association with the World Health Organization, started its work on ethics in health-related research in the late 1970s. Accordingly, CIOMS set out, in cooperation with WHO, to prepare guidelines to indicate how the ethical principles set forth in the Declaration of Helsinki of the World

Medical Association, could be effectively applied, particularly in low-resource settings, given their socio-economic circumstances, laws and regulations, and executive and administrative arrangements. Since then revised editions of the CIOMS ethical guidelines were published in 1993 and 2002. New developments in research have prompted CIOMS to again revise their ethical guidelines. The result is now available in this new publication. In the new 2016 version of the ethical guidelines, CIOMS provides answers to a number of pressing issues in research ethics. The Council does so by stressing the need for research having scientific and

social value, by providing special guidelines for health-related research in low-resource settings, by detailing the provisions for involving vulnerable groups in research and for describing under what conditions biological samples and health-related data can be used for research. Progress towards a world where all can enjoy optimal health and health care is crucially dependent on all kinds of research including research involving humans. Involving humans in medical research is necessary to improve the knowledge base on which medicine should be based. At the same time, individuals participating in health-related research have individual

human rights and have a right to be protected against the risks that research may bring to them. The tension between these two considerations has led the medical community to endorse ethical guidelines for health-related research. Research Ethics Committees can use these guidelines to evaluate whether a given research protocol is ethically acceptable or not.

In spite of recent progress in the harmonization of terminology and processes affecting work on the clinical safety of medicines consensus is needed on standards for many difficult aspects of day-to-day pharmacovigilance that continue to pose problems for both

the pharmaceutical industry and drug regulators. The CIOMS V Working Group has generated proposals for pragmatic approaches to dealing with such issues as: classification and handling of individual safety case reports from a variety of sources (spontaneous consumer reports solicited reports literature the Internet observational studies and secondary data bases disease and other registries regulatory ADR databases and licensor-licensee interactions); new approaches to case management and regulatory reporting practices (proper clinical evaluation of cases incidental vs other events patient and reporter identifiability seriousness criteria

expectedness criteria case follow-up criteria and the role and structure of case narratives); improvements and efficiencies in the format content and reporting of periodic safety update reports (PSURs) (including results of an industry survey on PSUR workloads and practices; proposals for high case volume and long time-period reports simplification of certain PSURs summary bridging reports addendum reports license renewal reports for EU and Japan dealing with old products and other technical details); determination and use of population exposure (denominator) data (sources of data and a guide to analytical approaches for a variety of

circumstances).The Group has also taken stock of the current state of expedited and periodic clinical safety reporting requirements around the world with summary data on regulations from more than 60 countries. Recommendations are made for enhancing the harmonization steps already taken as a result of previous CIOMS publications and the ICH process. In addition to dealing with unfinished and unresolved issues from previous CIOMS initiatives the report covers many emerging topics such as those involving new technologies. Its 20 Appendices provide a wealth of detailed explanations and reference information. It is the most

comprehensive and recent treatment of difficult pharmacovigilance issues affecting the working practices and systems of drug safety and other pharmaceutical professionals.
Records the papers and commentaries, with an edited discussion, presented at an international consultation convened by the Council for International Organizations of Medical Sciences (CIOMS) to guide revision of the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. The Guidelines, first issued in 1982 and then revised in 1993, are being updated and expanded to address a number of new and especially

challenging ethical issues. These include issues raised by international collaborative trials of drugs in developing countries, especially expensive drugs, and the use of placebo controls in randomized clinical trials. Others arise from the complexity of research in human genetics, including stem-cell research, and in reproductive biology. Throughout, particular attention is given to the difficult questions that arose during the heated debate over trials in developing countries, of short-duration zidovudine (AZT) therapy to reduce perinatal transmission of HIV. The International Ethical Guidelines for Biomedical Research Involving Human Subjects set out a

code of research ethics that is widely used by ethical review committees and other bodies responsible for reviewing and overseeing the ethical design of studies and conduct of research. The revision of the Guidelines is being coordinated by CIOMS, in collaboration with WHO. The consultation centered on seven specially commissioned papers, authored by international experts that explore some of the more difficult issues in depth. Each is followed by an invited commentary, often expressing opposing views, and a summary of the issues or conclusions that emerged during the subsequent debate. The first paper, on justice in international

research, deals with the question of whether proposals for research to be conducted in a developing country should make provision for future access of the population involved to the interventions under investigation. Also considered are questions that arise when research uses populations in developing countries to investigate interventions that will be of exclusive benefit to the industrialized world. Case studies of recent drug trials and their research protocols are discussed to illustrate circumstances in which use of populations in developing countries is justified or constitutes exploitation. Ethical challenges of the randomized controlled trial are

considered in the second paper, which includes a discussion on the equitable distribution of benefits and risks, the use of placebo for controls, and the obligation to ensure that the participation of controls does not compromise their medical care or endanger their health. A paper on informed consent in international health research considers how cultural factors influence communication and language in the informed-consent process and respect for privacy and confidentiality in the research. Subsequent papers address issues in genetics research and reproductive biology, including the moral status of fetuses and the use of embryos in research, and

examine the contribution which international human rights instruments can make in the application of the general principles of ethics to research involving human subjects. The final paper gives an overview of capacity building and the role of communities in international biomedical research.

Research Ethics in Africa

World Medical Association Declaration of Helsinki

Report of Cioms Working Group IX

Report of CIOMS Working Groups III and V : Including New Proposals for Investigator's Brochures

Pragmatic Approaches

Sharing Clinical Trial Data

Philosophical Foundations of

This volume examines the most important socio-cultural, political, economic, and policy issues related to emerging infectious diseases in Africa. The volume covers the work of the Global Emerging Pathogens Treatment Consortium (GET); it looks at the challenges of science education and communication in Africa, the global health and governance of pandemics and epidemics, and more. It looks beyond such threats as Ebola, SARS, and Zika to consider the ways communities have sought to contain these and other deadly pathogens. The chapters provide a better understanding of a global health

problem from an African perspective, which help clarify to readers why some responses have worked while others have not. Overall, the volume captures the state of the art, science, preparedness, and evolution of a topic important to the health of Africa and the world. It has a broad appeal across disciplines, from medical science and biomedical research, through research ethics, regulation and governance, science and health communication, social sciences, and is also of interest to general readers.

Ethical Issues in International Biomedical Research is the definitive book on the ethics of

research involving human subjects in developing countries. Using 21 actual case studies, it covers the most controversial topics, including the ethics of placebo research in Africa, what benefits should be provided to the community after completion of a research trial, how to address conflicts between IRBs in developed and developing countries, and undue inducement of poor people in developing countries. Each case is accompanied by two expert commentaries, written by many of the worlds leading experts in bioethics as well as new voices with research experience in developing countries. No other

volume has this scope. Students in bioethics, public and international health, and ethics will find this book particularly useful.
Sixth edition of the hugely successful, internationally recognised textbook on global public health and epidemiology comprehensively covering the scope, methods, and practice of the discipline.
This text aims to be a one-stop source for guidance and checking the rules for proper conduct of clinical trials, as well as providing a historical perspective of the clinical research landscape. Good Clinical Practice guidelines provide an international quality standard for the regulation of clinical trials.

They include standards on how clinical trials should be conducted, provide assurance of safety and efficacy of newly developed drugs and protect human rights. Principles of Good Clinical Practice describes the ethical principles and regulatory requirements that influence the current and future conduct of clinical research. As well as providing essential information on clinical trial design and pharmacovigilance, coverage also includes: informed consent; investigator and sponsor responsibilities; site monitoring; institutional review boards and dependent ethics committees; clinical trial registration and reporting; quality assurance; and

future implications for good clinical practices. Principles of Good Clinical Practice will be a definitive text for Clinical Development personnel at pharmaceutical companies, Contract Research Organizations (CROs), PharmD and postgraduate pharmacy students, and medical, pharmacy and drug company libraries

Principles of Good Clinical Practice

Report of CIOMS Working Group VIII.

Report of CIOMS Working Group X

The Cambridge Handbook of Health Research Regulation

Biomedical Research Ethics

Biomedical Research

A Casebook

Professionals in need of such training and bioethicists will be interested.
Supersedes the 1993 revision (ISBN 9290360569).
"Resolution WHA41.17 adopted by the Forty-first World Health Assembly, 13 May 1988" -- p.1.
This 2009 text supersedes the 1991 International Guidelines for Ethical Review of Epidemiological Studies. Its core consists of 24 guidelines with commentaries. A section outlines the historical background and the revision process, and includes an introduction, an account of earlier instruments and guidelines and a statement of general ethical principles. An Appendix lists the

items to be included in a research protocol to be submitted for epidemiological research involving human subjects. Also included in the appendices is the World Medical Association's 2008 Declaration of Helsinki. [Ed.].

Casebook on Ethical Issues in International Health Research

International Ethical Guidelines for Biomedical Research Involving Human Subjects

Socio-cultural Dimensions of Emerging Infectious Diseases in Africa

Encyclopedia of Malaria

Updating International Guidelines : a Consultation : Geneva, Switzerland, 15-17 March 2000

The Law and Ethics of Medical

Research

Ethical and Regulatory Aspects of Clinical Research

This open access book provides original, up-to-date case studies of "ethics dumping" that were largely facilitated by loopholes in the ethics governance of low and middle-income countries. It is instructive even to experienced researchers since it provides a voice to vulnerable populations from the fore mentioned countries. Ensuring the ethical conduct of North-South collaborations in research is a process

fraught with difficulties. The background conditions under which such collaborations take place include extreme differentials in available income and power, as well as a past history of colonialism, while differences in culture can add a new layer of complications. In this context, up-to-date case studies of unethical conduct are essential for research ethics training. At any point in the drug development process, systematic reviews and meta-analysis can provide

important information to guide the future path of the development program and any actions that might be needed in the post-marketing setting. This report gives the rationale for why and when a meta-analysis should be considered, all in the context of regulatory decision-making, and the tasks, data collection, and analyses that need to be carried out to inform those decisions. There is increasing demand by decision-makers in health care, the bio-pharmaceutical industry,

and society at large to have access to the best available evidence on benefits and risks of medicinal products. The best strategy will take an overview of all the evidence and where it is possible and sensible, combine the evidence and summarize the results. For efficacy, the outcomes generally use the same or very similar predefined events for each of the trials to be included. Most regulatory guidance and many Cochrane Collaboration reviews have usually given more

attention to assessment of benefits, while issues around combining evidence on harms have not been as well-covered. However, the (inevitably) unplanned nature of the data on safety makes the process more difficult. Combining evidence on adverse events (AEs), where these were not the focus of the original studies, is more challenging than combining evidence on pre-specified benefits. This focus on AEs represents the main contribution of the current CIOMS X report. The goal of the CIOMS X

report is to provide principles on appropriate application of meta-analysis in assessing safety of pharmaceutical products to inform regulatory decision-making. This report is about meta-analysis in this narrow area, but the present report should also provide conceptually helpful points to consider for a wider range of applications, such as vaccines, medical devices, veterinary medicines or even products that are combinations of medicinal products and medical

devices. Although some of the content of this report describes highly technical statistical concepts and methods (in particular Chapter 4), the ambition of the working group has been to make it comprehensible to non-statisticians for its use in clinical epidemiology and regulatory science. To that end, Chapters 3 and 4, which contain the main technical statistical aspects of the appropriate design, analysis and reporting of a meta-analysis of safety data are followed by Chapter 5

with a thought process for evaluating the findings of a meta-analysis and how to communicate these.
I. Defining "research"--II. Issues in study design . -- III. Harm and benefit -- IV. Voluntary informed consent -- V. Standard of care -- VI. Obligations to participants and communities -- VII. Privacy and confidentiality -- VIII. Professional ethics.
International Ethical Guidelines for Biomedical Research Involving Human SubjectsWorld Health

Organization
Quality Improvement Research
National Ethical Guidelines for Health and Health-related Research, 2017
Case Studies from North-South Research Collaborations
Ethics and Epidemiology
Theory and Practice
Ethics and Research on Human Subjects
Public Health Ethics: Cases Spanning the Globe
Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new

ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in

clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at

different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from

investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research--from funders, to researchers, to journals, to physicians, and ultimately, to patients. 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. This Dictionary presents a broad range of topics relevant in present-day global bioethics. With more than 500 entries, this dictionary covers organizations working in the field of global bioethics, international documents concerning bioethics, personalities

that have played a role in the development of global bioethics, as well as specific topics in the field.The book is not only useful for students and professionals in global health activities, but can also serve as a basic tool that explains relevant ethical notions and terms. The dictionary furthers the ideals of cosmopolitanism: solidarity, equality, respect for difference and concern with what human beings– and specifically patients – have in common, regardless of their

backgrounds, hometowns, religions, gender, etc. Global problems such as pandemic diseases, disasters, lack of care and medication, homelessness and displacement call for global responses.This book demonstrates that a moral vision of global health is necessary and it helps to quickly understand the basic ideas of global bioethics.

The use of human subjects in medical and scientific research has given rise to troubling ethical questions. How should

human subjects be selected for experiments? What should they be told about the research in which they are involved? How can their privacy be protected? When is it permissible to deceive them? How do we deal with subjects such as children, fetuses, and the mentally infirm, for whom informed consent is impossible? In this book, Dr. Robert J. Levine reviews federal regulations, ethical analysis, and case studies in an attempt to answer these questions. His book is an essential reference

for everyone--members of institutional review boards, scientists, philosophers, lawyers--addressing the ethical issues involved. "[Levine's] experience as a clinician, IRB chairman, writer and editor of a journal devoted exclusively to issues faced by IRBS makes him uniquely qualified to bring together the legal, ethical, and practical dimensions. . . [The book] is sophisticated but readable. . . [and] should be on every IRB administrator's desk and

in every medical ethics library."--Norman Fost, M.D., The New England Journal of Medicine "Levine. . . is one of the foremost historians of contemporary clinical science. . . . His book is at once a guide to primary sources for the history of clinical research in the late twentieth century and a pioneering secondary source about that history."--Daniel M. Fox, Bulletin of the History of Medicine "You will be charmed by the [book's] elegance and lucidity and. . . persuaded of its

relevance to doctors in any country."--Alex Paton, British Medical Journal "Should be of wide interest to those keen to see advances in medical research brought into general medical practice."--Gilbert Omenn, Issues in Science and Technology
Textbook of Research Ethics
A Guide for the Ethics Committee

A Resource for Research Ethics Committees
Maximizing Benefits, Minimizing Risk

An Indigenous Response to Deadly Epidemics

Clinical Trials in Developing Countries

L. Gostin ; L. Jordan

The growing globalization of medical research and the application of new biotechnologies in morally contested areas has forced a revision of international ethical guidelines. This book examines the controversies surrounding biomedical research in the twenty-first century from a human rights perspective, analyzing the evolution and changes in form and content of international instruments regulating the conduct of

biomedical research. The approach adopted is comparative and includes an evaluation of human rights and UK and US law on embryonic stem cell research, the HIV/AIDS trials in the developing world, the Alder Hey Inquiry and the human radiation and nerve gas experiments on human subjects in the US and the UK. This is the first book to analyze some of the major issues in biomedical research today from an international, comparative human rights perspective.

Infectious disease outbreaks are frequently characterized by scientific uncertainty, social and institutional disruption, and an overall climate of fear and distrust.

Invariably, the countries most affected by outbreaks have limited resources, under-developed legal and regulatory structures, and health systems that lack the resilience to deal with crisis situations. Policy-makers and public health professionals may be forced to weigh and prioritize potentially competing ethical values in the face of severe time and resource constraints . This document seeks to assist policy-makers, health care providers, researchers, and others prepare for outbreak situations by anticipating and preparing for the critical ethical issues likely to arise. In addition to setting forth ethical

principles applicable to infectious disease outbreaks generally, it shows how these principles can be adapted to different epidemiological and social circumstances.

In recent years public expectations for rapid identification and prompt management of emerging drug safety issues have grown swiftly. Over a similar timeframe, the move from paper-based adverse event reporting systems to electronic capture and rapid transmission of data has resulted in the accrual of substantial datasets capable of complex analysis and querying by industry, regulators and other public health organizations. These

two drivers have created a fertile environment for pharmacovigilance scientists, information technologists and statistical experts, working together, to deliver novel approaches to detect signals from these extensive and quickly growing datasets, and to manage them appropriately. In following this exciting story, this report looks at the practical consequences of these developments for pharmacovigilance practitioners. The report provides a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical

advice. But the report does not specify instant solutions. These will inevitably be situation specific and require careful consideration taking into account local needs. However, the CIOMS Working Group VIII is convinced that the combination of methods and a clear policy on the management of signals will strengthen current systems. Finally, in looking ahead, the report anticipates a number of ongoing developments, including techniques with wider applicability to other data forms than individual case reports. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit and it is this test which

signal detection methodologies need to meet if the expectations of all stakeholders are to be fulfilled.

Ethical Criteria for Medicinal Drug Promotion

Final Report of CIOMS Working Group II.

Dictionary of Global Bioethics

Practical Approaches to Risk Minimisation for Medicinal Products

Ethics and Regulation of Clinical Research

Guidance for Managing Ethical Issues in Infectious Disease Outbreaks

International Ethical Guidelines for Health-Related Research Involving Humans

Before new interventions can be used in disease control programmes, it is essential that they are carefully evaluated in "field trials", which may be complex and expensive undertakings. Descriptions of the detailed procedures and methods used in trials that have been conducted in the past have generally not been published. As a consequence, those planning such trials have few guidelines available and little access to previously accumulated knowledge. In this book the practical issues of trial design and conduct are discussed fully and in sufficient detail for the text to be used as a "toolbox" by field investigators. The toolbox has

now been extensively tested through use of the first two editions and this third edition is a comprehensive revision, incorporating the many developments that have taken place with respect to trials since 1996 and involving more than 30 contributors. Most of the chapters have been extensively revised and 7 new chapters have been added.

Alex John London defends a conception of the common good that grounds a moral imperative with two requirements. The first is to promote research that enables key social institutions to effectively, efficiently and equitably safeguard the basic interests of individuals. The second is to ensure that research

is organized as a voluntary scheme of social cooperation that respects its various contributors' moral claim to be treated as free and equal. Connecting research to the goals of a just social order grounds a framework for assessing and managing research risk that reconciles these requirements and justifies key oversight practices in non-paternalistic terms. The result is a new understanding of research ethics that resolves coordination problems that threaten these goals and provides credible assurance that the requirements of this imperative are being met.--

Ethical and Policy Issues in International Research

Practical Aspects of Signal Detection in Pharmacovigilance
International Reporting of Periodic Drug-safety Update Summaries
Field Trials of Health Interventions
International Ethical Guidelines on Epidemiological Studies
International Guidelines : Proceedings of the XXVIth CIOMS Conference, Geneva, Switzerland, 5-7 February 1992
Oxford Textbook of Global Public Health