Cioms Guidelines

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 present text is the revised/updated version of the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. It consists of 21 guidelines with commentaries. A prefatory section outlines the historical background and the revision process and includes an introduction an account of earlier instruments and guidelines a statement of ethical principles and a preamble. An Appendix lists the items to be included in the research protocol to be submitted for scientific and ethical review and clearance. The Guidelines relate mainly to ethical justification and scientific validity of research; ethical review; informed consent; vulnerability - of individuals groups communities and populations; women as research subjects; equity regarding burdens and benefits; choice of control in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for ethical review; and obligations of sponsors to provide health-care services. They are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects applying ethical standards in local circumstances and establishing or improving ethical review mechanisms. A

particular aim is to reflect the conditions and the needs of low-resource countries and the implications for multinational or transnational research in which they may be partners.

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.

Animals are widely used in neuroscience research to explore biological mechanisms of nervous system function, to identify the genetic basis of disease states, and to provide models of human disorders and diseases for the development of new treatments. To ensure the humane care and use of animals, numerous laws, policies, and regulations are in place governing the use of animals in research, and certain animal regulations have implications specific to neuroscience research. To consider animal research regulations from a global perspective, the IOM Forum on Neuroscience and Nervous System Disorders, in collaboration with the National Research Council and the Institute for Laboratory Animal Research, held a workshop in Buckinghamshire, UK, July 26-27, 2011. The workshop brought together neuroscientists, legal scholars, administrators, and other key stakeholders to discuss current and emerging trends in animal regulations as they apply to the neurosciences. This document summarizes the workshop.

Registries for Evaluating Patient Outcomes

A User's Guide

Report of CIOMS Working Group VIII.

Africa-Europe Research and Innovation Cooperation

Social Science Research Ethics in Africa

Practical Approaches to Risk Minimisation for Medicinal Products

Impact on Neuroscience Research: Workshop Summary

Research Ethics in Exercise, Health and Sports Sciences puts ethics at the centre of research in these rapidly expanding fields of knowledge. Placing the issues in historical context, and using informative case studies, the authors examine how moral theory can guide research design, education, and governance. As well as theoretical analysis, key practical concerns are critically discussed, including: informed consent anonymity, confidentiality and privacy plagiarism, misappropriation of authorship, research fraud

and 'whistleblowing' ethics in qualitative research vulnerable populations trans-cultural research. Providing an accessible and robust theoretical framework for ethical practice, this book challenges students, researchers and supervisors to adopt a more informed and proactive approach to ethics in exercise, health and sports research. This insightful text will be of great interest to those taking a kinesiology, human movement, sport science or sport studies degree course.

Not the issue: W.K. Mariner

This protocol covers the full range of research activities in the health field that involve interventions on human beings. It aims to protect the dignity and identity of everyone involved, without discrimination.

This book examines how an Ethics Review Committee using today's ethical standards as articulated in The Nuremburg Code, and the WHO/CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, might assess the scientific and ethical design of Edward Jenner's first experimental vaccine experiment. It explores the potential risks and benefits to young James, the adequacy of the preliminary evidence that Jenner used to justify performing his experiment, and how he might have complied with requirements for informed consent. In addition to its historical interest for 18th century England and for the origins of today's biomedical research ethics standards, the book is significant as a case study in the ethics of basic vaccine research. It thus raises relevant questions about today's vaccine research, particularly HIV vaccine research.

A Casebook

Practical Aspects of Signal Detection in Pharmacovigilance

Ethical Criteria for Medicinal Drug Promotion

Sharing Clinical Trial Data

Drug-Induced Liver Injury

Maximizing Benefits, Minimizing Risk

Ethical Issues in International Biomedical Research

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.

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

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 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.].

International Ethical Guidelines for Health-Related Research Involving Humans

Research Ethics for Social Scientists

Ethics and Regulation of Clinical Research

Ethics and Epidemiology

Principles of Good Clinical Practice

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

Guidelines for Preparing Core Clinical-safety Information on Drugs

This User ' s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified

according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User ' s Guide was created by researchers affiliated with AHRQ ' s Effective Health Care Program, particularly those who participated in AHRQ ' s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

These Good Participatory Practice guidelines aim to provide systematic guidance on the roles and responsibilities of entities funding and conducting biomedical HIV prevention trials towards participants and their communities. Such entities include investigators, research staff, pharmaceutical industry sponsors, foundations, government-supported research networks, non-governmental research sponsors, and all others involved in designing, financing, and executing clinical trials research.

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.

International Ethical Guidelines for Health-Related Research Involving HumansCioms Publication

Report of CIOMS Working Group III.

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

International Ethical Guidelines for Biomedical Research Involving Human Subjects

Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research

Design and Analysis of Vaccine Studies

Research Ethics in Exercise, Health and Sports Sciences

An Indigenous Response to Deadly Epidemics

"Resolution WHA41.17 adopted by the Forty-first World Health Assembly, 13 May 1988" -- p.1.

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.

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.

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.

Dictionary of Global Bioethics

Report of CIOMS Working Group X

International Ethical Guidelines on Epidemiological Studies

Ethics and Epidemiology : International Guidelines

A Resource for Research Ethics Committees

Ethics and Research on Human Subjects

Jenner on Trial

This book gives a voice to debates surrounding social science research ethics in Africa and brings them together in a coherent form to assist readers in being at the forefront of the discussions. The book gives an overview of the importance of research ethics in social sciences, as well as articulating the African influence on the subject matter. Subsequently it looks into specific frameworks and tools that researchers can apply in the process of doing research. Last but not least it also takes an in-depth look at traditional ethical issues pertaining to research in social sciences, through the lens of the African continent. This is the first book on social science research ethics in an African context and an indispensable resource for researchers, students, policy makers and research institutions in or interested in African research ethics.

This book is open access under a CC BY 4.0 license. This edited volume is concerned with the evolution and achievements of cooperation in research and innovation between Africa and Europe, and points to the need for more diversified funding and finance mechanisms, and for novel models of collaboration to attract new actors and innovative ideas. It reflects on the political, economic, diplomatic and scientific rationale for cooperation, while also examining practical developments, illustrated with examples, in the fields of food security, health, and climate change. The need to mobilise scientific knowledge and to ensure equality and fairness in the cooperation are recurrent themes. Africa-Europe Cooperation in Research and Innovation is essential reading for policy makers and researchers in international relations and science diplomacy.

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.

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.

Science, Ethics, and Governance

International Guidelines : Proceedings of the XXVth CIOMS Conference, Geneva, Switzerland, 7-9 November 1990

Biomedical Research Ethics

Human Genome Editing

Biomedical Research

Proceedings of the Xxvth CIOMS Conference, Geneva, Switzerland 7-9

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.
Genome editing is a powerful new tool for making precise alterations to an organism's genetic material. Recent scientific advances have made genome editing more efficient, precise, and flexible than ever before. These advances have spurred an explosion of interest from around the globe in the possible ways in which genome editing can improve human health. The speed at which these technologies are being developed and applied has led many policymakers and stakeholders to express concern about whether appropriate systems are in place to govern these technologies and how and when the public should be engaged in these decisions. Human Genome Editing considers important questions about the human application of genome editing including: balancing potential benefits with unintended risks, governing the use of genome editing, incorporating societal values into clinical applications and policy decisions, and respecting the inevitable differences across nations and cultures that will shape how and whether to use these new technologies. This report proposes criteria for heritable germline editing, provides conclusions on the crucial need for public education and engagement, and presents 7 general principles for the governance of human genome editing.
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
This book is a collection of fictionalised case studies of everyday ethical dilemmas and challenges, encountered in the process of conducting global health research in places where the effects of global, political and economic inequality are particularly evident. It is a training tool to fill the gap between research ethics guidelines, and their implementation 'on the ground'. The case studies, therefore, focus on 'relational' ethics: ethical actions and ideas that emerge through relations with others, rather than in regulations. This work was

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Global Challenges, Bi-regional Responses

International Animal Research Regulations

International Reporting of Periodic Drug-safety Update Summaries

Socio-cultural Dimensions of Emerging Infectious Diseases in Africa

Global Health Research in an Unequal World

Guidance for Managing Ethical Issues in Infectious Disease Outbreaks

Casebook on Ethical Issues in International Health Research

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.

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.

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.

Drug-Induced Liver Injury, Volume 85, the newest volume in the Advances in Pharmacology series, presents a variety of chapters from the best authors in the field. Chapters in this new release include Cell death mechanisms in DILI, Mitochondria in DILI, Primary hepatocytes and their cultures for the testing of drug-induced liver injury, MetaHeps an alternate approach to identify IDILI, Autophagy and DILI, Biomarkers and DILI, Regeneration and DILI, Drug-induced liver injury in obesity and nonalcoholic fatty liver disease, Mechanisms of Idiosyncratic Drug-Induced Liver Injury, the Evaluation and Treatment of Acetaminophen Toxicity, and much more. Includes the authority and expertise of leading contributors in pharmacology Presents the latest release in the Advances in Pharmacology series

Report of Cioms Working Group IX

Good Participatory Practice

International Guidelines : Proceedings of the XXVIth CIOMS Conference, Geneva, Switzerland, 5-7 February 1992

Guidelines for Biomedical HIV Prevention Trials

Pragmatic Approaches

Ethical Principles for Medical Research Involving Human Subjects

Research Ethics in Africa

As well as being a reference for the design, analysis, and interpretation of vaccine studies, the text covers all design and analysis stages, from vaccine development to post-licensure surveillance, presenting likelihood, frequentists, and Bayesian approaches.

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 .

Introduces students to ethical theory and philosophy. This work provides practical guidance on what ethical theory means for research practice; and, offers case studies to give real examples of ethics in research action.

Evidence Synthesis and Meta-Analysis for Drug Safety

World Medical Association Declaration of Helsinki

Final Report of CIOMS Working Group II.

An Ethical Examination of Vaccine Research in the Age of Smallpox and the Age of AIDS

Current Challenges in Pharmacovigilance