Cioms Guidelines

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.

Until recently there has been no formal law covering many aspects of clinical research, making the ethical and scientific guidelines more important. Rapidly changing law gives researchers challenges when deciding research policies. There is relatively little teaching on the ethics of clinical research and this monograph intends to trigger thought and discussion as well as provide guidance in decision-making.

The 2014â€"2015 Ebola epidemic in western Africa was the longest and most deadly Ebola epidemic in history, resulting in 28,616 cases and 11,310 deaths in Guinea, Liberia, and Sierra Leone. The Ebola virus has been known since 1976, when two separate outbreaks were identified in the Democratic Republic of Congo (then Zaire) and South Sudan (then Sudan). However, because all Ebola outbreaks prior to that in West Africa in 2014â€"2015 were relatively isolated and of short duration, little was known about how to best manage patients to improve survival, and there were no approved therapeutics or vaccines. When the World Heath Organization declared the 2014-2015 epidemic a public health emergency of international concern in August 2014, several teams began conducting formal clinical trials in the Ebola affected countries during the outbreak. Integrating Clinical Research into Epidemic Response: The Ebola Experience assesses the value of the clinical trials held during the 2014â€"2015 epidemic and makes recommendations about how the conduct of trials could be improved in the context of a future international emerging or re-emerging infectious disease events.

This report from the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO covers the activities and outputs of the CIOMS/WHO Working Group on Vaccine Pharmacovigilance (2005-2010). This working group brought together experts from both industrialized and emerging countries representing regulatory agencies, vaccine industry, national and international public health bodies including WHO and CIOMS, academia and clinical care, contributing from their different perspectives. The report covers general terms and definitions for vaccine safety and discusses the application of such harmonized tools in vaccine safety surveillance and studies. As well, the report highlights case definitions for adverse events typically reported for vaccines. The report is addressed to those engaged in vaccine safety data collection and evaluation, and will also make a useful reading for others who want to familiarise themselves with vaccine safety terminology.

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.

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

ethical and practical issues.

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.

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

This is a collection of Ruth Macklin's previously published articles on ethics in global health and research. The articles range from a chapter in a book published in 1989 to a journal article currently in press. The essays fall into two broad categories: policy and practice, and multinational research.

Examining the theoretical and empirical status of applied ethics, this volume demonstrates how a pluralistic and democratic society can deal with ethical issues in the light of its moral conscience. The volume first sets the stage for a conception of applied ethics as applications of transnational civil ethics, based both on a discourse theory of knowledge (Apel, Habermas), and on an activities and capabilities approach (Aristotle, Sen). It then examines how applied ethics relates to important theoretical discussions in philosophy such as constructivism, virtue

ethics, hermeneutic and deliberative theory. The contributors discuss applied ethics in light of globalization and identify recurring dilemmas as well as the problem of universal norms. They close by considering two aspects of the institutional point of view - republicanism, and contractarianism and constitutional economics.

`This is an excellent book which can be recommended both to the professional ethicist seeking to situate research ethics for a social scientific audience and to social scientists seeking an overview of the current ethical landscape of their discipline' - Research Ethics Review Ethics is becoming an increasingly prominent issue for all researchers across the western world. This comprehensive and accessible guide introduces students to the field and encourages knowledge of research ethics in practice. Research Ethics for Social Scientists sets out to do four things: The first is to demonstrate the practical value of thinking seriously and systematically about what constitutes ethical conduct in social science research. Secondly, the text identifies how and why current regulatory regimes have emerged. Thirdly, it seeks to reveal those practices that have contributed to the adversarial relationships between researchers and regulators. Finally, the book hopes to encourage both parties to develop shared solutions to ethical and regulatory problems. Research Ethics for Social Scientists is an excellent introductory text for students as it: - introduces students to ethical theory and philosophy; - provides practical guidance on what ethical theory means for research practice; - provides case studies to give real examples of ethics in research action. The result is an informative, accessible and practical guide to research ethics for any student or researcher in the social sciences.

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. Supersedes the 1993 revision (ISBN 9290360569).

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.

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.

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.

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.

This book is the first major work that addresses a core question in biomedical research: the question of acceptable risk. The acceptable level of risks is regulated by the requirement of proportionality in biomedical research law, which state that the risk and burden to the participant must be in proportion to potential benefits to the participant, society or science. This investigation addresses research on healthy volunteers, children, vulnerable subjects, and includes placebo controlled clinical trials. It represents a major contribution towards clarifying the most central, but also the most controversial and complex issue in biomedical research law and bioethics. The EU Clinical Trial Directive, the Council of Europe’s Oviedo Convention (and its Additional Protocol), and national regulation in member states are covered. It is a relevant work for lawyers and ethicists, and the practical approach makes a valuable tool for researchers and members of research ethics committees supervising biomedical research.

This consensus report of the CIOMS DILI Working Group aims to provide a critical framework and essential set of tools to detect, diagnose, and manage DILI during drug development and in the post-marketing setting. The report is intended for clinical and basic pharmaceutical industry investigators who capture, analyze, and communicate liver safety data in drug development. It is also intended for regulatory scientists and expert consultants who comprehensively evaluate new products and emerging biomarkers for their association with DILI risk and for health care professionals who monitor and manage patients treated with potentially hepatotoxic drugs in clinical practice.

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.].

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.

L. Gostin ; L. Jordan

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.

This collection of essays addresses an important cross-section of issues in contemporary bioethics. It represents an essential contribution to global bioethics anchored and grounded on a continent most remarkable for its biological, cultural and linguistic diversity. It is a fitting beginning to addressing the observable absence of African voices in the rather lively global discourses of bioethics. The issues treated here include a discussion of the fundamental principles of bioethics; the place of African thought in medical research ethics, traditional medicine, and assisted conception; the

moral status of embryonic stem cells; research with vulnerable human beings; and sexual and reproductive health in Africa. It explores a paradigm of how the universal and the particular may be blended, how global bioethics can remain firmly anchored and committed locally, regionally, continentally.

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 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.

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.

International Ethical Guidelines for Health-Related Research Involving HumansCioms Publication

A comprehensive, best practices resource for public health and healthcare practitioners and students interested in humanitarian emergencies.

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.

"This chapter considers the history of the rise of ethical concerns in the public health movement and epidemiology, which is the study of the distribution and determinants of disease in human populations. Epidemiology is a basic science in public health. This chapter provides an overview of early developments in public health and ethics. More recent developments are also discussed, including the origins of bioethics, regulatory safeguards for human subjects research, public health ethics, and contemporary epidemiologic ethics"--

In using the example of informed consent guidelines for international research on human subjects, this book demonstrates one of the many useful ways that philosophy can be used to move from theory to praxis by providing a general picture of how a philosophical analysis of underlying concepts can affect the way that public policy is framed; the ways that such policies are exclusionary; and a general methodology for remedying injustices in public policy and practice once they have been identified. With diseases, such as AIDS, reaching epidemic proportions in less developed countries, medical research on human subjects in these areas is on the rise. Current international guidelines for research on human subjects stress the importance of informed consent, which is meant to ensure that people freely choose whether to participate in research trials. In an effort to be more globally applicable, many current international ethical guidelines for informed consent in research on human subjects attempt to incorporate community in the informed consent process. This book explains how these attempts encounter two primary problems: (1) they fail to adequately acknowledge the importance community has for many people in less developed countries; and (2) they fail to attend to the constraints to autonomy that oftentimes become magnified once community is involved in the informed consent process. The reason for these shortcomings can be traced to the current account of autonomy reflected in international informed consent guidelines, which is here referred to as the traditional account of autonomy. Although traditional autonomy can account for what this book defines as external constraints to autonomy, it is unequipped to recognize the internal constraints which arise in the medical context. In order to adequately recognize the importance of community in autonomy and to attend to internal constraints to autonomy, it is essential to adopt an account of relational autonomy. Using such a relational autonomy account, the book provides a set of minimally sufficient ethical conditions that can assist policy makers in revising international informed consent guidelines in research on human subjects, so that these guidelines better attend to community involvement in the informed consent process. To demonstrate how these conditions might

be used, the book also presents examples of possible revisions to the CIOMS Ethical Guidelines, one of the leading international ethical guidelines for research on human subjects.

In recent decades, advances in biomedical research have helped save or lengthen the lives of children around the world. With improved therapies, child and adolescent mortality rates have decreased significantly in the last half century. Despite these advances, pediatricians and others argue that children have not shared equally with adults in biomedical advances. Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research, we do not want to place children at risk of being harmed by participating in clinical studies. Ethical Conduct of Clinical Research Involving Children considers the necessities and challenges of this type of research and reviews the ethical and legal standards for conducting it. It also considers problems with the interpretation and application of these standards and conduct, concluding that while children should not be excluded from potentially beneficial clinical studies, some research that is ethically permissible for adults is not acceptable for children, who usually do not have the legal capacity or maturity to make informed decisions about research participation. The book looks at the need for appropriate pediatric expertise at all stages of the design, review, and conduct of a research project to effectively implement policies to protect children. It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular.

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.

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.