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Final Report of CIOMS Working Group II. Springer Science & Business Media
Supersedes the 1993 revision (ISBN 9290360569).

A Casebook World Health Organization
This review considers ethical challenges to research design and informed consent in biomedical and behavioral studies conducted in resource-poor settings. A review of the literature explores relevant social, cultural, and ethical issues in the conduct of biomedical and social health research in developing countries. Ten case vignettes illustrate ethical challenges that arise in international research with culturally diverse populations. Recommendations for researchers and policy-makers concerned about ethical practices in multinational studies conducted in resource-poor settings are also listed.

Casebook on Ethical Issues in International Health Research Pharmaceutical Press
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.

Ethics and Epidemiology **Inst of Clinical Research**

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.

Science, Ethics, and Governance World Health Organization

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.

Ethical Criteria for Medicinal Drug Promotion Springer

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 .

Report of CIOMS Working Group III. Cioms

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.

Evidence Synthesis and Meta-Analysis for Drug Safety World Health Organization

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.

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

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

The Ways of Practical Reason in a Pluralist Society AFRICAN SUN MeDIA

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.

Practical Approaches to Risk Minimisation for Medicinal Products Saint Philip Street Press

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.

Human Genome Editing Routledge

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.

Biomedical Research Ethics Cambridge Law Handbooks

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.

Registries for Evaluating Patient Outcomes Cioms Publication

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.

Dictionary of Global Bioethics Council of Europe

L. Gostin ; L. Jordan

Research, Policy and Practice Routledge

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

Principles of Good Clinical Practice World Health Organization

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.

Drug-Induced Liver Injury International Ethical Guidelines for Health-Related Research Involving Humans

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.

A Resource for Research Ethics Committees Oxford University Press

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.

Report of Cioms Working Group IX Cioms Publication

Written by epidemiologists, ethicists and legal scholars, this bookprovides an in-depth account of the moral problems that often confrontepidemiologists, including both theoretical and practical issues. The topicscovered include informed consent, privacy and confidentiality protection, thebalancing of risks and benefits, ethical issues in the study of vulnerablepopulations, the institutional review board system, and professional

education.The solid, up-to-date analyses of these issues will be very helpful toepidemiologists in their practice, research and teaching. They encourage thelatest developments in the field and include detailed bibliographies.