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Ethical Issues in International Biomedical Research International Ethical Guidelines for Health-Related Research Involving Humans

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.

Field Trials of Health Interventions World Health Organization

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

Registries for Evaluating Patient Outcomes Inst of Clinical Research

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.

The Law and Ethics of Medical Research Cioms Publication

L. Gostin ; L. Jordan

Ethics and Epidemiology World Health Organization

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 published by Saint Philip Street Press pursuant to a Creative Commons license permitting commercial use. All rights not granted by the work's license are retained by the author or authors.

Human Genome Editing Oxford University Press

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.

The Ways of Practical Reason in a Pluralist Society Academic Press

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.

Evidence Synthesis and Meta-Analysis for Drug Safety Council of Europe

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.

International Guidelines : Proceedings of the XXVIth CIOMS Conference, Geneva, Switzerland, 5-7 February 1992 World Health Organization
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.
International Bioethics and Human Rights Government Printing Office
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.
Ethical Criteria for Medicinal Drug Promotion 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.
Report of CIOMS Working Groups III and V : Including New Proposals for Investigator's Brochures World Health Organization
Supersedes the 1993 revision (ISBN 9290360569).
Oxford University Press, USA
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.
Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research World Health Organization
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.
Principles of Good Clinical Practice Pharmaceutical 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.
Research Ethics in Africa Cioms Publication
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.

Drug-Induced Liver Injury Routledge

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.

Ethical Principles for Medical Research Involving Human Subjects National Academies Press

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.

Clinical Research Involving Pregnant Women Saint Philip Street Press

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.

Report of CIOMS Working Group VIII. SAGE

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.].