Cioms Guidelines

Research Ethics in AfricaPrinciples of international biolawAssessing Tuberculosis Prevalence Through Population-based SurveysClinical Research Involving Pregnant WomenEvidence Synthesis and Meta-Analysis for Drug SafetyVulnerabilityEthics in Clinical ResearchSocial Science Research Ethics in AfricaTextbook of Research EthicsACCCN's Critical Care Nursing - E-BookInternational Ethical Guidelines for Biomedical Research Involving Human SubjectsGlobal Mental Health TrialsDouble Standards in Medical Research in Developing CountriesEthical Issues in International Biomedical ResearchCommunity, Autonomy and Informed ConsentHandbook for Good Clinical Research Practice (GCP)Legal and Ethical Regulation of Biomedical Research in Developing CountriesEthics in Epidemiology and Clinical ResearchSMQsGuidelines for Preparing Core Clinical-safety Information on DrugsEthical Challenges in Study Design and Informed Consent for Health Research in Resource-poor SettingsIntegrating Clinical Research into Epidemic ResponseEthics in Global HealthReinventing Patient RecruitmentCurrent Challenges in PharmacovigilanceReligious Perspectives on Human Vulnerability in BioethicsEthics and EpidemiologyInternational Ethical Guidelines for Health-Related Research Involving HumansDrug SurveillanceThe Nuremberg Trials: International Criminal Law Since 1945The Ethics of Biomedical ResearchTemple international and comparative law journalfMRIResearch Ethics for Social ScientistsBeyond AutonomyInternational Ethical Guidelines on Epidemiological StudiesRegistries for

Evaluating Patient OutcomesLaw and Global HealthHuman Population Genetic Research in Developing CountriesHuman Genome Editing

Research Ethics in Africa

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.

Principles of international biolaw

A revised new edition of this comprehensive critical care nursing text, developed with the Australian College of Critical Care Nurses (ACCCN). This second edition of

ACCCN's Critical Care Nursing has been fully revised and updated for critical care nurses and students in Australia and New Zealand. As well as featuring the most recent critical care research data, current clinical practice, policies, procedures and guidelines specific to Australia and New Zealand, this new edition offers new and expanded chapters and case studies. The ultimate guide for critical care nurses and nursing students alike, ACCCN's Critical Care Nursing 2e has been developed in conjunction with the Australian College of Critical Care Nurses (ACCCN). As with the first edition, the text in ACCCN's Critical Care Nursing 2e reflects the expertise of ACCCN's highly-qualified team of local and international critical care nursing academics and clinicians. This authoritative nursing resource takes a patient-centred approach, encouraging practising critical care nurses and students to develop effective, high-quality critical care nursing practice. ACCCN's Critical Care Nursing 2e outlines the scope of critical care nursing, before detailing the core components and specialty aspects of critical care nursing, such as intensive care, emergency nursing, cardiac nursing, neuroscience nursing and acute care. Specific clinical conditions such as emergency presentations, trauma, resuscitation, and organ donation are featured to explore some of the more complex or unique aspects of specialty critical care nursing practice. expanded chapters for cardiovascular, respiratory and neurological content new chapters on Quality and Safety; Recovery and Rehabilitation; Psychological care; and Obstetric emergencies new case studies elaborate on relevant care issues critiques of recent research publications explore related topics practice tips highlight areas of care

particularly relevant to daily clinical practice learning activities support knowledge, reflective learning and understanding

Assessing Tuberculosis Prevalence Through Population-based Surveys

The aim of this publication is to brief drug regulatory authorities, scientific institutions and pharmaceutical companies worldwide about the development, purpose and appropriate use of Standardized MedDRA Queries (SMQs) in drug surveillance. Two papers in this publication are to assist in the rational use of search queries in the identification and retrieval of potentially relevant individual case safety reports from a database and to harmonize presentation of search results. It also includes examples to illustrate the structure and content of end product.

Clinical Research Involving Pregnant Women

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.

Evidence Synthesis and Meta-Analysis for Drug Safety

Rapid advances in genetics and medicine present both opportunities and threats to the advancement of human rights and public health in this era of globalization. While such advances contribute significantly to progress against disease, they may also pose profound global public policy concerns in that the ethical and policy considerations that follow from scientific advances lag far behind. In this context, the aim of this book is to present the current global efforts to develop common principles relating to biomedicine. Section I sets forth the pivotal role that the principle of human dignity plays in this domain, and identifies a number of other principles that can be drawn from the recent international policy documents on bioethics. Section II provides detailed commentaries on recent international instruments relating to biomedicine adopted by UNESCO and the Council of Europe. Section III elaborates upon specific biomedical human rights issues that are the subject of contemporary international standard-setting efforts, including

biomedical research, population biobanks, genetic testing, and advance directives. Essays in each of these sections examine the extent to which promoting and protecting human rights has created a common framework for contemporary international lawmaking in the field of biomedicine and the strengths and limitations of international law as a tool for advancing biomedical human rights.

Vulnerability

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.

Ethics in Clinical 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.

Social Science Research Ethics in Africa

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.

Textbook of Research Ethics

Current Legal Issues, like its sister volume Current Legal Problems (now available in journal format), is based upon an annual colloquium held at University College London. Each year leading scholars from around the world gather to discuss the relationship between law and another discipline of thought. Each colloquium examines how the external discipline is conceived in legal thought and argument, how the law is pictured in that discipline, and analyses points of controversy in the use, and abuse, of extra-legal arguments within legal theory and practice. Law and Global Health, the sixteenth volume in the Current Legal Issues series, offers an insight into the scholarship examining the relationship between global health and the law. Covering a wide range of areas from all over the world, articles in the volume look at areas of human rights, vulnerable populations, ethical issues, legal responses and governance.

ACCCN's Critical Care Nursing - E-Book

Global mental health is a dynamic field of global health; a core aspect of the story which has led to its emergence has been the conduct of randomised controlled trials (RCTs) evaluating innovative delivery systems of packages of care for mental disorders in low-resource settings. Global Mental Health Trials brings together many of the world's leading researchers active in the fields of RCTs in low- and medium-resource countries and settings related to improving mental health care. It

presents clear and practical information about how to conduct such trials in these settings, along with critical methodological and ethical issues related to such trials, learning from the positive and negative experiences of expert scientists in many countries worldwide who have completed such trials. This book serves as a valuable resource for practitioners in mental health - psychiatrists, psychiatric nurses nursing, psychologists, social workers, and occupational therapists - as well as researchers in the areas of psycho-social treatments in mental health, mental health services research, and programme and systems evaluation.

International Ethical Guidelines for Biomedical Research Involving Human Subjects

Analyses the limitations of respect for autonomy and consent in human research ethics and explores alternative ethical approaches.

Global Mental Health Trials

With the advance of biomedicine, certain individuals and groups are vulnerable because of their incapacities to defend themselves. The International Bioethics Committee as a UNESCO working group has for the last several years dedicated to deepen this principle of human vulnerability and personal integrity. This book

serves to supplement this effort with a religious perspective given a great number of the world's population is affiliated with some religious traditions. While there is diversity within each of these traditions, all of them carry in them the mission to protect the weak, the underprivileged, and the poor. Thus, here presented is a collection of papers written by bioethics experts from six major world religions—Buddhism, Christianity, Confucianism, Hinduism, Islam and Judaism—who were gathered to discuss the meaning and implications of the principle of vulnerability in their respective traditions.

Double Standards in Medical Research in Developing Countries

Ethical Issues in International Biomedical Research

Community, Autonomy and Informed Consent

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.

Handbook for Good Clinical Research Practice (GCP)

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.

Legal and Ethical Regulation of Biomedical Research in Developing Countries

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.].

Ethics in Epidemiology and Clinical Research

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.

SMQs

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.

Guidelines for Preparing Core Clinical-safety Information on Drugs

Examines the many ethical issues related to biomedical research, including the use of animals in research, research on human subjects, clinical trials, international research ethics policies, and other related topics.

Ethical Challenges in Study Design and Informed Consent for Health Research in Resource-poor Settings

Integrating Clinical Research into Epidemic Response

Ethics in Global Health

60 years after the trials of the main German war criminals, the articles in this book attempt to assess the Nuremberg Trials from a historical and legal point of view,

and to illustrate connections, contradictions and consequences. In view of constantly reoccurring reports of mass crimes from all over the world, we have only reached the halfway point in the quest for an effective system of international criminal justice. With the legacy of Nuremberg in mind, this volume is a contribution to the search for answers to questions of how the law can be applied effectively and those committing crimes against humanity be brought to justice for their actions.

Reinventing Patient Recruitment

Human population genetic research (HPGR) seeks to identify the diversity and variation of the human genome and how human group and individual genetic diversity has developed. This book asks whether developing countries are well prepared for the ethical and legal conduct of human population genetic research, with specific regard to vulnerable target group protection. The book highlights particular issues raised by genetic research on populations as a whole, such as the potential harm specific groups may suffer in genetic research, and the capacity for current frameworks of Western developed countries to provide adequate protections for these target populations. Using The People's Republic of China as a key example, Yue Wang argues that since the target groups of HPGR are almost always from isolated and rural areas of developing countries, the ethical and legal frameworks for human subject protection need to be reconsidered in order to

eliminate, or at least reduce, the vulnerability of those groups. While most discussion in this field focuses on the impact of genetic research on individuals, this book breaks new ground in exploring how the interests of target groups are also seriously implicated in genetic work. In evaluating current regulations concerning prevention of harm to vulnerable groups, the book also puts forward an alternative model for group protection in the context of human population genetic research in developing countries. The book will be of great interest to students and academics of medical law, ethics, and the implications of genetic research.

Current Challenges in Pharmacovigilance

Records the proceedings of an international conference convened to consider mechanisms for improving international cooperation in the surveillance of drug safety and the reporting of adverse reactions. Attended by close to 200 representatives of regulatory authorities and the pharmaceutical industry as well as clinical pharmacologists, the conference aimed to identify the strengths and weaknesses of existing mechanisms for international cooperation and to propose improvements for the future.

Religious Perspectives on Human Vulnerability in Bioethics

Ethics and Epidemiology

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.

International Ethical Guidelines for Health-Related Research Involving Humans

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 Surveillance

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 .

The Nuremberg Trials: International Criminal Law Since 1945

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. Second, the text identifies how and why

current regulatory regimes have emerged. Third, 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.

The Ethics of Biomedical Research

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.

Temple international and comparative law journal

Alongside globalization, the sense of vulnerability among people and populations has increased. We feel vulnerable to disease as new infections spread rapidly across the globe, while disasters and climate change make health increasingly precarious. Moreover, clinical trials of new drugs often exploit vulnerable populations in developing countries that otherwise have no access to healthcare and new genetic technologies make people with disabilities vulnerable to discrimination. Therefore the concept of 'vulnerability' has contributed new ideas to the debates about the ethical dimensions of medicine and healthcare. This book explains and elaborates the new concept of vulnerability in today's bioethics. Firstly, Henk ten Have argues that vulnerability cannot be fully understood within the framework of individual autonomy that dominates mainstream bioethics today: it is often not the individual person who is vulnerable, rather that his or her vulnerability is created through the social and economic conditions in which he or she lives. Contending that the language of vulnerability offers perspectives beyond the traditional autonomy model, this book offers a new approach which will enable bioethics to evolve into a global enterprise. This groundbreaking book critically

analyses the concept of vulnerability as a global phenomenon. It will appeal to scholars and students of ethics, bioethics, globalization, healthcare, medical science, medical research, culture, law, and politics.

fMRI

There has been a rapid increase in the pace and scope of international collaborative research in developing countries in recent years. This study argues that whilst ethical regulation of biomedical research in Africa and other developing countries has attracted global attention, legal liability issues, such as the application of common law rules and the development of legally enforceable regulations, have been neglected. It examines some of the major research scandals in Africa and suggests a new ethical framework against which clinical trials could be conducted. The development of research guidelines in Uganda, Tanzania, Malawi and Nigeria are also examined as well as the role of ethics committees. Providing a detailed analysis of the law of negligence and its application to research ethics committees and their members, common law and constitutional forms of action and potential negligence claims, the book concludes by suggesting new protocols and frameworks, improved regulation and litigation. This book will be a valuable guide for students, researchers, and policy-makers with an interest in medical law and ethics, bioethics, customary law in Africa and regulation in developing countries.

Research Ethics for Social Scientists

Recent international developments show that essential medications can be made affordable and accessible to developing countries, and that double standards need not prevail. This is the first book to examine these issues, drawing the bold conclusion that double standards in medical research are ethically unacceptable."--BOOK JACKET.

Beyond Autonomy

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.

International Ethical Guidelines on Epidemiological Studies

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.

Registries for Evaluating Patient Outcomes

Over the past two decades, fMRI has evolved into an invaluable clinical tool for routine brain imaging. This book provides a state of the art overview of fMRI and its use in clinical practice. Experts in the field share their knowledge and explain how to overcome diverse potential technical barriers and problems. Starting from the very basics on the origin of the BOLD signal, the book covers technical issues, anatomical landmarks, the full range of clinical applications, methods of statistical analysis, and special issues in various clinical fields. Comparisons are made with other brain mapping techniques, such as DTI, PET, TMS, EEG, and MEG, and their combined use with fMRI is also discussed. Since the first edition, original chapters have been updated and new chapters added, covering both novel aspects of analysis and further important clinical applications.

Law and Global Health

This book discusses ‘how’ to respectfully and responsibly include pregnant women in clinical research. In sharp contrast, the existing literature predominantly focuses on the reasons ‘why’ the inclusion of pregnant women in clinical research is necessary – viz., to develop effective treatments for women during pregnancy, to promote fetal safety, to reduce harm to women and fetuses from suboptimal care, and to allow access to the benefits of research participation. This book supports the shift to a new default position, whereby pregnant women are included in clinical research unless researchers argue convincingly for their exclusion. This shift raises many as yet unexplored ethical and policy questions about existing barriers to the equitable inclusion of pregnant women in research. This book is original in three key ways. First, it presents an unparalleled depth of analysis of the ethics of research with pregnant women, bringing together many of the key authors in this field as well as experts in research ethics and in vulnerability who have not previously applied their work to pregnant women. Second, it includes innovative theoretical work in ethics and disease specific case studies that highlight the current complexity and future challenges of research involving pregnant women. Third, the book brings together authors who argue both for and against including more pregnant women in formal clinical trials.

Human Population Genetic Research in Developing Countries

This publication provides countries with practical guidelines for planning population-based surveys to estimate the prevalence of tuberculosis (TB) at a national level. TB prevalence surveys yield useful information in areas where notification data obtained through routine surveillance are incomplete, or of unproven accuracy, and in areas with an estimated TB prevalence of more than 100 per 100 000. These surveys are used to evaluate the performance of the TB program, and to assess trends over time. To achieve this objective, data are collected through standards methods in a well-defined study population. This document is meant to provide information on the core survey methods, including diagnostic tests for TB, screening strategies, and case definitions. The target audience includes TB experts and advisers at national and international levels, and investigators involved in prevalence surveys.

Human Genome Editing

During the last five years, clinical research and development costs have risen exponentially without a proportionate increase in the number of new medications. While patient recruitment for clinical studies is only one component in the development of a new medicine or treatment, it is one of the most significant

bottlenecks in the overall drug development process. Now it is imperative that industry leaders see beyond reactive measures and recognize that advancing their approach to patient recruitment is absolutely essential to advancing medicine and continuing the stability of their corporate brand across the globe. Reinventing Patient Recruitment: Revolutionary Ideas for Clinical Trial Success is a definitive guide to planning, implementing and evaluating recruitment strategies and campaigns globally. The combined experience of the authors provides a depth of perspective and boldness of innovative leadership to set the standards for future patient recruitment programs and practices. This book is a must-have for pharmaceutical, biotechnology and medical device industry professionals concerned with enrolling for domestic and multinational clinical studies and remaining on time and on budget.

ROMANCE ACTION & ADVENTURE MYSTERY & THRILLER BIOGRAPHIES & HISTORY CHILDREN'S YOUNG ADULT FANTASY HISTORICAL FICTION HORROR LITERARY FICTION NON-FICTION SCIENCE FICTION