

# Ethical issues in clinical research in neurology

## Advancing knowledge and protecting human research subjects

The Ethics and Humanities Subcommittee of the American Academy of Neurology\*

Neurology is evolving rapidly as research brings to light new knowledge about diseases of the nervous system and novel diagnostic and treatment options. An important ingredient in improving our understanding of neurologic diseases is the conduct of well-designed clinical research studies, including epidemiologic, genetic, and natural history studies, and clinical drug trials. However, some research involving people with neurologic diseases presents serious ethical and regulatory challenges.

As the Decade of the Brain progresses, it is appropriate to give attention not only to the scientific but also the ethical dimensions of neurologic diseases. We give a brief overview of some ethical and regulatory considerations concerning the protection of human subjects in neurologic research.

**Ethical guidelines and federal regulations.** Biomedical and behavioral research funded or supported by the federal government, including the National Institutes of Health (NIH), is under the purview of regulations for the protection of human subjects (Title 45, Code of Federal Regulations, Part 46).<sup>1</sup> Also, in the United States, all clinical trials, regardless of the funding source, involving investigational drugs are under the regulatory purview of the Food and Drug Administration (FDA).<sup>2</sup> Both the FDA and the Department of Health and Human Services (DHHS) require that proposed clinical research undergo review by an Institutional Review Board (IRB) whose primary mandate is to protect the rights and safeguard the welfare of the subjects. In their deliberations, IRBs are expected to take into account the nature, content, and design of the research, ethical principles of the Belmont Report,<sup>3</sup> and, when appropriate, the regulatory requirements of DHHS and the FDA.

IRBs are important because research investigators have an inherent conflict of interest. As health care professionals, they are dedicated to promoting the welfare of individual patients; as researchers,

they seek generalizable knowledge applicable to persons other than their individual patients. Because the second goal may come in conflict with the first, our society has decided by law that an objective review of human subjects research by a group of diverse individuals is most likely to protect human subjects and promote ethically sound research. Although the IRB system is not perfect, conscientious IRBs reassure the American public that the rights and welfare of human subjects are seriously considered by people who do not have a vested interest in the outcome of the research. It is through this process of research review and approval that investigators, research institutions, IRB members, and others are held publicly accountable for their decisions and actions.

**Roles and responsibilities of research investigators.** An important, if not the most important, safeguard to the rights and welfare of human research subjects is knowledgeable, experienced clinical researchers. Particularly, the Principal Investigator's (PI) knowledge and skills are critical to the success of a particular research study. The PI has primary responsibility for the design of the study and for ensuring that it is conducted consistent with protocol and IRB requirements. He or she writes (or supervises the writing of) the protocol, submits it for review to the IRB, and ensures compliance with all IRB stipulations and decisions. Although institutions have varying requirements, protocols usually include a discussion of the human subjects protection issues that are relevant to the study and addresses, at a minimum, the risks to subjects; all procedures that are experimental; the anticipated benefits to subjects, if any; the anticipated number of subjects; the proposed consent document and consent process to be used; and appropriate safeguards if potentially vulnerable subjects are to be enrolled. Vulnerable subjects may include the elderly, prisoners, children, cognitively impaired individuals

\*See the Appendix on page 595 for a list of Subcommittee members.

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# Ethical Issues In Neurology

**Peter B. Kang**



## **Ethical Issues In Neurology:**

**Ethical Issues in Neurology** James L. Bernat, 2008 Written by an eminent authority from the American Academy of Neurology's Committee on Ethics Law and Humanities this book is an excellent text for all clinicians interested in ethical decision making The book features outstanding presentations on dying and palliative care physician assisted suicide and voluntary active euthanasia medical futility and the relationship between ethics and the law New chapters in this edition discuss how clinicians resolve ethical dilemmas in practice and explore ethical issues in neuroscience research Other highlights include updated material on palliative sedation advance directives ICU withdrawal of life sustaining therapy gene therapy the very low birth weight premature infant the developmentally disabled patient informed consent organizational ethics brain death controversies and fMRI and PET studies relating to persistent vegetative state

**Ethical and Legal Issues in Neurology** James L. Bernat, 2014-01-09 The definition and criterion of death have been rendered ambiguous by developments in organ support technology particularly the positive pressure ventilator and vasopressor medications that uncouple the unitary loss of vital functions in death and create cases in which the brain has been destroyed while circulation and ventilation can be supported Developing a biophilosophic analysis of the meaning of death before physicians can declare it requires four sequential steps 1 agreement on the paradigm conditions that frame the analysis and clarify the task 2 identifying the definition of death which makes explicit the meaning of death that is accepted in our consensual usage of the term but that has become obscured by technology 3 identifying the criterion of death that shows that the definition has been fulfilled and that can be incorporated into a death statute and 4 devising bedside tests of death for physicians to perform to satisfy the criterion Although there is a strong consensus on death determination medical standards in countries around the world that has been enshrined into laws and accepted by most societies and religions there remains an active dispute among scholars on the precise definition and criterion of death

**Ethical Dilemmas in Neurology** Adam Zeman, Linda L. Emanuel, 2000 An international team of recognized authorities offer a collection of thought provoking essays on ethical questions often faced by neurologists in clinical practice

**Practical Ethics in Clinical Neurology** Michael Williams, 2012-10-31 Almost every neurologist encounters ethical issues daily This exemplary ethics text meets the needs of students residents fellows and practicing neurologists who want an accessible case based text for learning and it meets the needs of directors of medical student clerkships and residency programs in neurology who want an accessible case based text for teaching The book's case based approach places key ethical principles into a practical real world context to aid in decision making Each chapter includes an outstanding array of learning features includes Learning Objectives Clinical Vignettes Questions to guide self study and group discussions Key Points Key Words Suggestions for Further Reading and more Clinical Pragmatism model helps readers analyze ethical issues in a clinical context Practical Ethics in Clinical Neurology is a companion to the most highly respected ethics text in neurology and neurosurgery Bernat's Ethical Issues in

Neurology 3rd edition      Ethical and Legal Issues in Neurology Eran Klein,Jason Karlawish,2014-01-09 Caring for persons with Alzheimer s disease presents neurologists with ethical challenges Some of these such as end of life care or research participation are well known and have significant overlap with challenges in other areas of medicine or other neurologic diseases such as cancer or traumatic brain injury while others such as the rise of biomarker based diagnostics are more novel and reflect the impact of developments in the science and clinical care of Alzheimer s disease A thoughtful and systematic approach to these challenges from the preclinical to the late symptomatic stage of this disease is required and will help clinicians be better advocates and stewards of their patients This chapter addresses a number of the most pressing ethical problems facing patients caregivers and clinicians during this disease including early and presymptomatic testing assessment of decision making capacity for treatment or research participation restriction of driving remote monitoring assisted suicide and treatment of disruptive behaviors      **Ethical and Legal Issues in Neurology** Lois Margaret Nora,2014-01-09 There is dynamic interplay between the disciplines of law and ethics and the result is often laws and regulation that impact the practice of clinical neurology This chapter explores how the disciplines of law and ethics inform and intersect with each other and how resulting law impacts the everyday work of the clinical neurologist Examples of how the core bioethical principles of nonmaleficence beneficence respect for autonomy and justice are manifest in legislative common and administrative laws are presented Examples of how these laws in turn impact the practice of neurology through protection of patient privacy the avoidance of conflict of interest and informed consent and other issues are offered      **Ethical and Legal Issues in Neurology** James L. Bernat,Richard Beresford,2014-01-09 Advances in our understanding of the brain and rapid advances in the medical practice of neurology are creating questions and concerns from an ethical and legal perspective Ethical and Legal Issues in Neurology provides a detailed review of various general aspects of neuroethics and contains chapters dealing with a vast array of specific issues such as the role of religion the ethics of invasive neuroscience research and the impact of potential misconduct in neurologic practice The book focuses particular attention on problems related to palliative care euthanasia dementia and neurogenetic disorders and concludes with examinations of consciousness personal identity and the definition of death This volume focuses on practices not only in North America but also in Europe and the developing world It is a useful resource for all neuroscience and neurology professionals researchers students scholars practicing clinical neurologists mental health professionals and psychiatrists A comprehensive introduction and reference on neuroethics Includes coverage of how best to understand the ethics and legal aspects of dementia palliative care euthanasia and neurogenetic disorders Brings clarity to issues regarding ethics and legal responsibilities in the age of rapidly evolving brain science and related clinical practice      **Practical Ethics in Clinical Neurology** Michael Williams,2015-04-24 Practical Ethics in Clinical Neurology A Case Based Learning Approach Practical Ethics in Clinical Neurology PECN is a case based ethics textbook designed for readers who want a concise accessible book to help them assess and resolve ethical challenges

in everyday practice With chapter topics and case content that reflect commonly encountered issues in adult and pediatric neurology PECN meets the needs of students residents fellows and practicing neurologists With easy web based access to key guidance documents from the American Academy of Neurology and references to important sections in Dr James L Bernat s *Ethical Issues in Neurology* 3rd ed the most highly respected ethics textbook in neurology PECN helps readers focus on the essential ethical and professional considerations in each case Directors of medical student clerkships and residency programs in neurology will find that PECN helps them meet the learning objectives of the AAMC ACGME and ABPN Look inside and explore Case based approach places key ethical principles into a practical real world context to aid in decision making An outstanding array of learning features includes the following sections Learning Objectives Clinical Vignettes Questions to guide self study and group discussions Key Points Key Words Suggestions for Further Reading and more Clinical pragmatism model helps readers analyze ethical issues in a clinical context *Ethical Issues in Neurology* ,1997

**Medicolegal Issues in Neurology, an Issue of Neurologic Clinics: Volume 41-3** Joseph S. Kass,Michael A. Rubin,2023-08-28 This issue of Neurologic Clinics guest edited by Dr Jos Biller is devoted to Therapy in Neurology This issue is one of four selected each year by the series Consulting Editor Dr Randolph W Evan Articles in this issue include Update on CGRP Antagonism in the Treatment of Migraine Advances in the Treatment of Multiple Sclerosis Advances in the Treatment of Neuromyelitis Optica Spectrum Disorder Advances and ongoing controversies in PFO closure and cryptogenic stroke Advances in neuromodulation neurostimulation in Neurology Advances in the treatment of muscular dystrophies and motor neuron disorders Advances in the management of small fiber neuropathies Update in the treatment of Idiopathic Intracranial Hypertension What is new in neuro oncology Advances in the surgical management of epilepsy Treatment of Viral Encephalitis An update on Botulinum toxin in neurology Cannabinoids in neurological illnesses and Pitfalls in Transitioning Neurological Care of the Developmentally Disabled from Pediatric to Adult Providers Contains 13 practice oriented topics including medical aid in dying legal and ethical issues in the neurology of reproductive health brain death ethical and legal challenges organ donation and controlled determination of death by circulatory criteria ethics and legal issues regarding global neurology and more Provides in depth clinical reviews of medicolegal issues in neurology offering actionable insights for clinical practice Presents the latest information on this timely focused topic under the leadership of experienced editors in the field Authors synthesize and distill the latest research and practice guidelines to create clinically significant topic based reviews **Ethical Issues in Behavioral Neuroscience** Grace Lee,Judy Illes,Frauke Ohl,2015-02-09 Behavioral neuroscience encompasses the disciplines of neurobiology and psychology to study mechanisms of behavior This volume provides a contemporary overview of the current state of how ethics informs behavioral neuroscience research There is dual emphasis on ethical challenges in experimental animal approaches and in clinical and nonclinical research involving human participants **Ethical and Legal Issues in Neurology** Peter B. Kang,2014-01-09 The field of neurogenetics is moving so

rapidly that new discoveries are announced almost weekly The tools available for the diagnosis of neurogenetic disorders have become powerful and complex and raise new ethical dilemmas that did not exist just a few years ago In addition to previous concerns about presymptomatic genetic testing and carrier testing the widening availability of next generation sequencing raises concerns about the reporting of incidental findings of unclear significance Genetically targeted therapies have now been proven to be efficacious for a few neurogenetic diseases and it is likely that gene therapies and cell based therapies will soon be applied to other neurologic disorders These therapies are generally quite expensive compared to other treatments Given the cost constraints that will be needed in the healthcare system in the United States and other countries and the likelihood that new genetically targeted therapies will be introduced society will face difficult questions regarding its obligations to fund expensive therapies both for large populations and for small numbers of patients with rare diseases Potential conflicts of interest involving both individuals and institutions will need ongoing vigilance Scientific advances will continue to raise consequential ethical questions in the field of neurogenetics Ethical and Legal Issues in Neurology

Marie-Aur lie Bruno, Steven Laureys, Athena Demertzi, 2014-01-09 Patients in coma vegetative state unresponsive wakefulness syndrome and in minimally conscious states pose medical scientific and ethical challenges As patients with disorders of consciousness are by definition unable to communicate the assessment of pain quality of life and end of life preferences in these conditions can only be approached by adopting a third person perspective Surveys of healthcare workers attitudes towards pain and end of life in disorders of consciousness shed light on the background of clinical reality where no standard medical legal framework is widely accepted On the other hand patients with locked in syndrome who are severely paralyzed but fully conscious can inform about subjective quality of life in serious disability and help us to understand better the underlying factors influencing happiness in disease In the medico legal arena such ethical issues may be resolved by previously drafted advance directives and when absent by surrogate representation Lately functional medical imaging and electrophysiology provide alternative means to communicate with these challenging patients and will potentially mediate to extract responses of medical ethical content Eventually the clinical translation of these advanced technologies in the medical routine is of paramount importance for the promotion of medical management of these challenging patients

Ethical and Legal Issues in Neurology Leo McCluskey, 2014-01-09 Acute and chronic peripheral and or central disorders of the voluntary motor system can produce profound paresis or paralysis at times with ophthalmoplegia while preserving consciousness and language function Although at times appearing to be unconscious these patients are awake and alert but unable to communicate manipulate their environment or participate in medical decision making Clinicians caring for these patients are ethically tasked with recognizing this clinical reality enacting measures to facilitate communication and abiding by ethical and legal principles that support autonomous patient centered decision making This chapter reviews the various disorders that may cause this state while using three exemplary disorders locked in syndrome caused by an anterior pontine

lesion high cervical spinal cord lesion and amyotrophic lateral sclerosis to discuss the management of these patients

**Ethical and Legal Issues in Neurology** Eric Racine, 2014-01-09 In this chapter evolution of ethics and bioethics is traced to show how an abstract and individualistic paradigm was at the core of mainstream ethics prior to the advent of bioethics and applied ethics Bioethics has transformed this individualistic paradigm because of its inherent interdisciplinarity and real world connection This evolution has raised questions regarding how nonabstract e g experiential and nonindividualistic e g social relational components of ethics could be married to normative theory and ethics reflection the latter usually not amenable to empiric research In the first part of this chapter pragmatism is introduced as an approach offering perspectives on the integration of social nonindividualistic aspects of ethics supporting the use of social science methods within ethics and neuroethics In the second part of this chapter using the example of disorders of consciousness a pragmatic perspective is explored to reframe questions and help foster nonreductionistic understandings of ethical questions and ethical dilemmas This chapter aims to generate reflections on a set of specific clinical contexts that will also stimulate a discussion on the nature of ethical approaches

**Ethical and Legal Issues in Neurology** Robert M. Taylor, 2014-01-09 Clinical ethics is the application of ethical theories principles rules and guidelines to clinical situations in medicine Therefore clinical ethics is analogous to clinical medicine in that general principles and concepts must be applied intelligently and thoughtfully to unique clinical circumstances The three major ethical theories are consequentialism whereby the consequences of an action determine whether it is ethical deontology whereby to be ethical is to do one's duty and virtue ethics whereby ethics is a matter of cultivating appropriate virtues In the real world of medicine most people find that all three perspectives offer useful insights and are complementary rather than contradictory The most common approach to clinical ethical analysis is principlism According to principlism the medical practitioner must attempt to uphold four important principles respect for patient autonomy beneficence nonmaleficence and justice When these principles conflict resolving them depends on the details of the case Alternative approaches to medical ethics including the primacy of beneficence care based ethics feminist ethics and narrative ethics help to define the limitations of principlism and provide a broader perspective on medical ethics

**Ethical and Legal Issues in Neurology** Tracy K. Koogler, 2014-01-09 The debate surrounding neurologically devastated newborns whether due to severe prematurity or genetic malformations has continued for over 40 years Duff and Campbell 1973 first discussed allowing these children to die in the 1970s In the 1980s others fought to make sure these children with disabilities were afforded all the rights of other children Recently some commentators have advocated for withdrawal of therapies and even euthanasia in the Netherlands Who is right What are the ethical principles that should be followed What decisions are appropriate for distraught parents to make This chapter reviews international views laws and guidelines surrounding the therapies and limitations of care for these imperiled newborns An ethical argument is presented for how to determine best interests for these special children utilizing the best interest standard Parents and physicians need to use

their individual expertise and values to work together to determine each individual child's best interests. Physicians may have to carry the burden for making final determinations to alleviate the guilt families may have in deciding to limit therapies.

**Medicolegal Issues in Neurology, An Issue of Neurologic Clinics, E-Book** Joseph S. Kass, Michael A.

Rubin, 2023-07-06 In this issue of Neurologic Clinics guest editors Drs Joseph S. Kass and Michael A. Rubin bring their considerable expertise to the topic of Medicolegal Issues in Neurology. Top experts in the field provide up-to-date focused guidance on how to identify and approach the major medicolegal and ethical issues that neurologists confront in today's clinical practice. Contains 13 practice-oriented topics including medical aid in dying, legal and ethical issues in the neurology of reproductive health, brain death, ethical and legal challenges, organ donation, and controlled determination of death by circulatory criteria, ethics and legal issues regarding global neurology, and more. Provides in-depth clinical reviews of medicolegal issues in neurology, offering actionable insights for clinical practice. Presents the latest information on this timely focused topic under the leadership of experienced editors in the field. Authors synthesize and distill the latest research and practice guidelines to create clinically significant, topic-based reviews.

**Ethical and Legal Issues in Neurology** C.

Christopher Hook, Keith M. Swetz, Paul S. Mueller, 2014-01-09 The increasing complexity of healthcare creates numerous ethical challenges in patient care and in institutional functions and policies. During the past several decades, clinical ethics consultation services and institutional ethics committees have been developed to assist patients, medical professionals, and institutions in addressing ethical challenges. This chapter discusses the nature of clinical ethics consultation and the training of ethics consultants and committees. The authors review the experience at their institution, Mayo Clinic. Finally, the value of ethics consultation as described in the medical literature is reviewed.

**An Integrative Guide to Consumer**

**Neuroscience** Sven Braeutigam, Peter Kenning, 2022 An Integrative Guide to Consumer Neuroscience provides a comprehensive guide to a complex interdisciplinary and emerging field that cuts across psychology, neuroscience, and consumer research.



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