

Buena práctica clínica

Estándares de calidad de cuidados

1. Los neurocirujanos deben cultivar un alto nivel de dedicación profesional para brindar al paciente un cuidado con compasión y respeto por el valor de la vida humana.
2. Debemos mantener un alto nivel de competencia profesional en las técnicas neuroquirúrgicas y el avance del conocimiento. Debemos seguir estudiando, mejorar nuestras habilidades, y aplicar nuevos conocimientos, siempre y cuando seguimos operando y estamos al cuidado de los pacientes.
3. We must also recognize the limits of our professional competence. i. We should perform only those procedures for which we have adequate training and experience. Only in exceptional circumstances, when a more experienced surgeon is not available, to save life, or to prevent serious disability, should we perform operations outside our competency. ii. We should avoid performing complex procedures infrequently, and encourage subspecialization. iii. We should refer patients to colleagues whose expertise is more suited to a specific need 4. Neurosurgeons must make a careful and competent assessment of patients, taking a full history of the patient's condition, performing a careful physical examination, and arranging appropriate investigations. 5. We should perform surgery when we believe the patient will substantially benefit, and when the level of risk for complications is acceptable to the patient and family members. 6. We must avoid serving as the surgeon of last resort for a desperate patient seeking surgical intervention that has been rejected by many of our peers, and that may not help the patient or stop the advance of disease. 3 7. We should be willing to consult with colleagues about options for care, and explain this process to our patients. 8. We should respect and cooperate fully with other specialists when working with a team approach to care, and give recognition of the teamwork involved in caring for patients. 9. We should work to ensure good continuity of care. 10. Experienced neurosurgeons must provide adequate oversight and supervision for younger physicians and support staff as they care for patients. We must remain personally involved in the care of patients for whom we have primary responsibility, avoiding, when possible, travel during the early postoperative period and in times of high medical risk. We should ensure that adequate supervision and capacity for emergency intervention are always available. 11. When transferring care of a patient to another physician, whether by personal choice or at the request of a patient or outside party, we should cooperate fully with the physician who receives the transferred patient. 12. When visiting and treating patients in other centers, neurosurgeons should enter into formal agreements before providing patient care. We should satisfy ourselves that the staff and facilities are adequate for continuity and a good standard of care for the surgery we perform, and remain personally involved in caring for the patient during the early postoperative period, usually defined as 24-48 hours or until the patient is stable. 13. We should keep clear, up to date, detailed, and accurate clinical records, with full descriptions of operative procedures, significant medical events, medical management, the names of other caregivers, and summaries of important discussions with patients and family members. 14. A prompt and thorough discharge summary and appropriate followup should be arranged. 15. We should work in cooperation with the administrative staff of our medical centers, health care policy makers, and community leaders to increase and improve resources for neurosurgical care. 16. When patient care may be compromised by inadequate facilities or equipment, lack of reimbursement for important medical services, or shortages of medical and support staff, neurosurgeons should address the issues to the best of their ability. 17. We should keep clear, up to date, detailed, and accurate clinical records, with full descriptions of operative procedures, significant medical events, medical management, the names of other caregivers, and summaries of important discussions with patients and families. 18. A prompt and thorough discharge summary and appropriate followup should be arranged. Relationships with Patients and Family

Members The Duty of Care 19. All patients are entitled to receive care at the standards of best practice. 20. Neurosurgeons should always treat patients and their families, fellow health care professionals, and all others, with dignity and respect. 21. We should encourage patients in their right to request a second opinion, as it is important for the patient to have full confidence in the choice of a surgeon. 4 22. Neurosurgeons should make all clinical records and investigations easily accessible to the patient and other caregivers. 23. Neurosurgeons should provide guidance as to the optimal course of action, while enabling patients to participate in decisions regarding their own care. 24. We should not promote treatments that are recognized as failing to meet the recognized standard of care. 25. We should obtain a fully informed consent prior to any operation. 26. Patients should not be deprived of necessary care because of an inability to pay. Neurosurgeons should continue their traditional assumption of a part of the responsibility for the medical care of those who cannot afford to pay for services and who lack adequate medical coverage. 27. We should advocate for patients in dealing with third parties when appropriate. 28. Personal beliefs should never prejudice decisions regarding patient care. 29. We should treat patients even at the cost of personal sacrifice and legitimate self interest. There is thus no justification to refuse to treat patients because their diagnosis could pose a risk to the health of the neurosurgeon. 30. When a personal moral judgment or religious belief prevents the neurosurgeon from recommending a particular therapy or operation, the patient and family should be told, and given the opportunity to seek alternative care. 31. We should not diminish our professional services to patients who have acted in such a way as to harm their own health. 32. In time of war, we should provide care impartially, on the basis of need, to all participants, and to civilians. 33. Prisoners should be treated without discrimination, and we should not be a party to torture, or to any form of physical or psychological punishment. Patient Communication 34. We should listen to patients, respect their views, and respond to their questions. 35. We should be sensitive to the patient's feeling of vulnerability. 36. We should bring comfort to patients, and act to relieve pain and suffering, especially for those who are dying. 37. Neurosurgeons should be willing to provide patients with clear information, and discuss fully the benefits, risks, and costs of appropriate treatment alternatives using language that allows them to understand the issues at hand. 38. We must weigh our decisions on what information to disclose and how to present that information, with consideration for cultural mores and values, as well as the makeup of individual patients. This becomes particularly important when we are treating patients with malignant diseases, and they wish to discuss their prognosis. 39. We should be careful about discussing outcomes that our proposed treatment or surgery may be unlikely to provide, and should never guarantee that a particular treatment will be effective. 40. We must ensure that the information we provide is accurate and up to date, and can be verified if challenged. 41. We must not compare our services directly with the services provided in another institution. 42. We should be honest with patients and their families about the reasons for complications, and express our sincere regret when the situation does not go according to plan. 5 Patient Privacy and Confidentiality 43. Respect the patient's right of privacy. Ensure the patient is at ease and accompanied when necessary during examinations. 44. Patients have a right to expect that information about them will be held in confidence by their doctors. When the patient is a competent adult, information about the patient's medical situation can generally be shared with family members only with the patient's approval. However there are cultures where it is customary to readily share information with the nextof- kin or close relatives. 45. In situations where there is clear risk of major disability or death, it may be good practice to disclose this possibility to relatives as it may help them to accept a poor outcome if this does occur. 46. Information that is essential for delivery of health care should be shared with other members of the health care team, however the physician should not reveal confidential communications or information without the consent of the patient when speaking with colleagues and associates not directly involved in the patient's care. 47. Patient confidentiality must be protected when conducting and presenting clinical and scientific research, and in interfaces with medical equipment companies. Patient confidentiality must also be strictly protected when using medical images, films, and photographs, and when conveying data stored in computers. 48. In some circumstances the duty to society may override the

patient's right to confidentiality: i. When patients may be entering an activity or employment for which they are unfit, and where they may pose a danger to others. In this case we should attempt to dissuade the patient, and attempt to obtain permission for disclosure when feasible. ii. When disclosure is a legal requirement, such as notification of specific disease. iii. When disclosure is required by a court of law. 49. When disclosure is required, the amount and nature of information that is shared should never be more than the minimum to meet the specific needs of the moment. 50. When information concerning a specific patient is requested by the media, the physician must obtain the consent of the patient or an authorized representative before disclosure, and then may release only authorized information, or that which is public knowledge. 51. Questions from the media regarding circumstances surrounding news events such as violence, trauma, or natural disasters should be referred to the appropriate police, public health, government, or other authorities. Ending Patient Relationships 52. On rare occasion, for example where a patient has been violent, has stolen from the premises, or has persistently acted unreasonably, it may be necessary to end a professional relationship with a patient. However, we should never end a patient relationship due to our personal beliefs regarding a patient's private life, due to the patient's inability to pay for surgical or medical care, or due to a complaint from the patient about the medical team. 53. If a relationship must be ended, the patient should be informed orally and in writing. We must take care to ensure continuity of care via a prompt and smooth referral process to a competent physician, with a full transfer of patient records and communications. 6 Standards of Personal and Professional Life 54. Always act fairly and honestly in all private and professional matters. 55. Never make false or misleading claims regarding qualifications, training, appointments, surgical experience or skill, or health. 56. Neurosurgeons should avoid overwork to the level that it leads to excessive tiredness or stress, and thus diminished competence. 57. We should avoid lifestyles and personal habits that may impair competence. 58. We should report personal health issues that could affect patient care to the appropriate administrative leader. 59. All surgeons reach an age when the technical competence and personal stamina necessary to perform surgical procedures may decline. We are responsible to adjust our activity as appropriate when that time occurs. 60. The neurosurgeon's self-interest is subordinate to patient care. Patient referrals, the choice of procedure, and the use devices or surgical aids must never be affected by personal financial benefit. 61. Respect the professionalism of others involved in health care, and do not compete with colleagues for professional or financial gain, to the detriment of those colleagues or patients. 62. Communicate personally or via clear patient records with referring and family physicians. For patients with conditions requiring urgent treatment it may be necessary to provide treatment first, and inform primary care physicians once treatment has been complete. 63. Avoid unnecessary criticism of colleagues. 64. If there is reason to believe the actions of a colleague are endangering patients, we have a duty to make every effort to persuade that colleague to change his or her practice. If this approach fails, we must act to protect patients from risk when there is good reason to believe the ability of a colleague to provide a high standard of care is compromised. 65. Sexual harassment is unethical. A physician should not enter into a sexual relationship with a current patient, or into any other abusive or exploitative relationship. 66. Sexual relationships between medical supervisors and trainees, and between physicians and other co-workers, raise concerns because of the inherent inequalities in status and power. Even a consensual relationship may have a negative effect on patient care. Financial Concerns and Business Relationships 67. As neurosurgeons we should ideally limit the source of our professional income to services actually rendered to the patients under our supervision, for services we are personally and identifiably responsible to provide or oversee. 68. Fees should be commensurate with services rendered. 69. Fees and terms for payment should be clearly communicated to patients, and they should be allowed a reasonable amount of time for payment without harassment. To the greatest extent possible, we should consider the financial resources of our patients, and we should treat patients as we would wish our families to be treated. 70. The division of income among members of an organized group may be based on the value of services performed by each member as determined by group members. 71. In cases where the physician has a financial interest in an enterprise related to a patient's care, the patient should be

informed of this fact. 72. When a portion of a fee is to be paid to another clinician or institution, the patient should be clearly apprised of this fact. 73. Material incentives to use any institution, service, medication, or equipment should never be accepted. Payments to encourage patient referrals should never be made. Medico-Legal Responsibilities Legal systems and national customs differ, and thus neurosurgeons from around the world face diverse medico-legal environments. It is the responsibility of a neurosurgeon to understand and function within the legal boundaries where he or she resides and practices. Clearly, this statement cannot serve as a legal guide for every situation. It is a basic human right for competent adults to make informed decisions about their own medical care. Similarly, in many nations it is the right of the patient, and often of a legally recognized guardian or representative, to make decisions about care at the end of life. The process of obtaining informed consent for surgical treatments, and the option of creating a "living will," are intended to protect the rights of patients, rather than physicians. Clear records documenting the dates and substance of conversations with patients and their families, as well as our own decision processes, should be kept. Agreements on Treatment 74. We should determine whether patients are competent – whether they are able to understand and evaluate the information we provide about options for care, and make reasonable decisions. When there is reasonable doubt as to a patient's competence to make informed decisions, we should consult other experts, including a psychiatrist or experienced layperson when appropriate. We should consider the opinions of relatives. 75. Once competence is established, we should give understandable information to patients: i. Explain the purposed, expected benefits, and risks of the proposed treatment. ii. Discuss treatment alternatives. iii. Provide unbiased information on the advantages and disadvantages of recommended and alternative treatments, and offer advice. iv. Explain the likely consequences of refusing the treatment being offered. v. When asked, we should freely describe our personal experience and our results with this treatment in other patients. 76. We may describe risks and benefits as cited in the world literature, but we must also describe our own experience and results with the patients we treat when requested. 77. When another member of the staff presents this information to a patient, we should ensure that this individual is sufficiently knowledgeable to provide a full description of treatment alternatives, and to answer questions that arise during the discussion. 78. We must remember that the patient has the right to choose between treatments, or to refuse treatment altogether. We must respect this right. 79. If there is a disagreement between the patient and family members, and the patient is competent, we must respect the patient's decision. 80. In cases where the patient refused treatment or chooses an alternative that we believe is less than optimal, it may be appropriate to seek the patient's permission to discuss the choice with family members. This process can help to maintain trust and confidence at a later stage if the patient's condition deteriorates. 81. Psychiatric patients may be competent to participate in decisions regarding their care. Medical competence should be determined in consultation with those responsible for the patient's psychiatric care. 82. When patients are temporarily incompetent, treatments that are lifesaving or prevent serious disability should be given, but other treatments should be delayed until the patient can render an informed decision. 83. When patients are incompetent due to psychiatric disability, treatment to preserve life and prevent disability may be given. When feasible, legal authorization for such treatment should be sought. 84. When patients are unconscious or medically incompetent, and in the absence of any advance directives from the patient declining such intervention, we are responsible to perform procedures that are lifesaving and prevent severe or permanent disability. Depending on circumstances, and on national law and custom, treatment decisions may be made after discussions with relatives, consideration by a hospital ethics committee, or legal advisement. Treatment Agreements When Children Are Patients 85. When minor children are patients, agreement on the course of treatment should be reached with the patient's parents, or with the person legally responsible when there are no parents. 86. Children who are under the age of consent, but able to understand what is proposed, should be informed and consulted regarding their treatment. 87. In some circumstances, children may have the right to accept treatment even if their parents do not agree. Parents should not have the right to withhold agreement to procedures that may be lifesaving or may prevent serious disability.

When faced with a situation where parents refuse such treatment, we are advised to seek legal authority before operating when time allows. Planning for End-of-Life Care and Advance Directives 88. We should provide a good opportunity for our patients to discuss and plan for end-of-life care. This should include the ability to discuss scenarios and treatment preferences, and to make a formal "living will" or "advance directive" and proxy designation. 89. We should help patients who wish to establish advance directives to submit the appropriate documentation and comply with legal requirements in a timely manner. 90. We should provide trustworthy assurances that we will continue to care for the patient, even in a state of unconsciousness: i. We must be skilled in detection and management of the physical and mental suffering that are characteristic of end-stage disease, including pain, fatigue, and depression. We must use our skill and resources to alleviate suffering at this stage. ii. We must honor patient directives for withholding or withdrawing life-sustaining intervention, within the limits of local law. This includes patient preferences for less complex intervention (e.g. antibiotics, artificial nutrition), as well as more complex and invasive (e.g. dialysis, mechanical respiration), and in situations involving imminent or more distant death. iii. In situations where a dying patient must be transferred to another facility, we should make efforts to ensure that the care will be adequate, and that the facility will honor the patient's advance directives. When feasible, a physician who has provided personal care for a patient should attempt to visit that patient, even after transfer. 9 iv. We should support a patient's desire to die at home when there is appropriate support and agreement from loved ones. v. When care of a patient becomes difficult for loved ones, we should provide or refer patients for medical resources such as long-term, or hospice care, when they are available. 91. We should support and facilitate a patient's wish to meet personal goals at the end of life, such as communication with loved ones, attending to spiritual needs, taking a final trip, or finishing an important task. Decisions on Not Starting or Withholding Treatment 92. The decision to offer a neurosurgical operation can be complex. Often the chances of stopping or slowing disease progression, or relieving symptoms, must be carefully weighed against the risks of injury and sustained disability. In some circumstances a recommendation against surgical intervention should be considered good practice. 93. In some instances it may be appropriate to avoid or withdraw active treatment: i. When, because of the patient's condition, treatment is unlikely to produce benefit. ii. When the patient has stipulated in advance that he or she does not wish to undergo advanced procedures for the sake of briefly prolonging life. iii. In cases where family resources are extremely limited, and when there is no insurance, it is acceptable to avoid costly treatment when there is no prospect for prolonged survival, in order to preserve minimal financial resources for the sake of the surviving spouse and dependents. In these situations, withholding treatment should be a consensus decision by the medical team, and a hospital ethics committee should ideally be consulted. 94. In all circumstances, treatment to relieve pain and suffering, and provide emotional support, should be continued. Participation as an Expert Witness in Legal Proceedings 95. Neurosurgeons should protect patient confidentiality during involvement in legal proceedings. 96. We should cooperate with lawyers to provide justice to those who may have suffered through medical accidents. 97. When serving as expert witnesses, neurosurgeons should maintain a fair and unbiased position based on the facts of the case at hand. We should always consider and present the diversity of medical opinions, as supported by acceptable practice, within the standards of current scientific knowledge, rather than championing a single or universal approach to care. 98. It is appropriate for a neurosurgeon who serves as an expert witness to accept reasonable fees for his or her time in preparing a deposition and testifying. However, a neurosurgeon should not accept any payment that is contingent on the outcome of a legal proceeding, since this may create a conflict of interest or lead to bias during testimony. Teaching & Training 99. Neurosurgeons in teaching institutions have a duty to teach medical students and train young postgraduate physicians. We should freely pass along our particular skills to others in order to raise the standard of neurosurgical practice. 10 100. We should always respect patient dignity and confidentiality during the teaching process. 101. We should ask patients if they agree to take part in clinical teaching. While we should endeavor to explain the importance of training for society, patients' refusal must be accepted, and must not adversely affect medical care.

102. Neurosurgeons should directly and honestly answer patient requests for information about the training and experience of the physicians involved in their care. 103. We should ensure that fully trained and experienced neurosurgeons are fully responsible for patient care at all times, and that young physicians and trainees have easy access to help and advice. 104. Experienced neurosurgeons are responsible to decide when trainees have achieved sufficient competence and clinical maturity to assist in operations, to operate with supervision, and to operate independently. 105. The aim should be to enable all trainees to reach the same level of competence. We should clearly inform trainees of the standards they are expected to achieve, and provide them with sufficient time and oversight to reasonably achieve these goals in training programs. 106. We should provide trainees with periodic assessment of progress and counseling as needed, in a fair and conscientious manner. In cases where performance is not up to standard, trainees should be informed at an early point. 107. Experienced neurosurgeons should be honest and objective in appraising or assessing the performance of physicians that we examine, supervise, and train. Patients are put at risk when someone who has not reached or maintained a satisfactory standard of practice is unfairly protected or promoted to higher levels of clinical responsibility. 108. We should encourage leaders in medical education, neurosurgical training, and in professional meetings to include discussions and presentations of ethical issues into the syllabi and agendas for their programs. 109. Neurosurgeons should be leaders in their larger medical communities, providing seminars and information to facilitate early diagnosis and prompt treatment of neurological problems by primary care and specialty physicians who may be the first contact point for patients with tumors, neurovascular disease, and other conditions. Integrating the Principles of Evidence-Based Medicine (EBM) No study, or combination of studies, can anticipate each factor affecting an individual patient, or lead to development of algorithms that will provide simple answers for every therapeutic question. On the other hand, no individual surgeon can reliably sift through the myriad of accumulated reports and individual variations affecting patient care decisions to define clear and consistent principles for treatment. The discipline of evidence-based medicine (EBM) emphasizes use of a defined set of principles to critically analyze and synthesize research findings, and disseminate evidence into practice. When applied with skill and judgment, these analytic principles have the potential to capture and integrate the wealth of information in our fast-evolving subspecialty into better patient care decisions, improved outcomes, and better information for patients and their families. EBM can also help us to define high quality clinical research as a means to elucidate general principles that are relevant for the care of many neurosurgical patients. 110. We should seek to define the role and appropriate use of EBM in our daily clinical routines. 111. It is appropriate to include the principles and processes of EBM in the curricula of residency and fellowship training programs, as well as continuing medical education programs for senior neurosurgeons. i. Develop capability and allocate time for formal instruction in EBM techniques: question formulation, literature search, critical assessment (type and quality) and synthesis of evidence, and proper application of evidence to an individual patient situation. ii. Provide reliable, in-department, high-speed internet access to online databases, studies, and EBM Web resources. iii. Evaluate the success of initial programs in order to improve and expand future training efforts. 112. When feasible and appropriate, the EBM process should be brought to bear on the care of individual patients. 113. We should seek cooperation between neurosurgeons and between medical centers to initiate carefully designed research programs with the goal of accumulating a growing base of high quality evidence, and thus widening the breadth of patient care decisions that are informed by the best principles of EBM. Clinical Research & Clinical Trials 114. The ultimate goal of research should be the betterment of mankind, alleviation of suffering, and the ultimate improvement of neurosurgical practice. The potential benefits of any neurosurgical research should always be greater than any potential risk to the subject. Research that knowingly jeopardizes the health, safety, or longevity of human subjects is unethical. 115. Neurosurgeons should refrain from participating in research for which they and their collaborators are not qualified, or in which they cannot remain fully objective throughout the research process. We should commence a research project only when we have reasonable confidence that the resources necessary to follow it through to completion will be available. 116. We should use invasive

procedures solely for research only in the most exceptional circumstances, and with the greatest safeguards to subjects. 117. Research must always be conducted in full compliance with national laws and professional regulations, including the Declaration of Helsinki and local Institutional Review Boards (IRBs). Committees reviewing research protocols must be fully independent, and should include nonmedical members, as well as individuals who are knowledgeable in the ethics of research. Such committees should monitor ongoing investigations through regular reports. 118. Neurosurgeons may participate in industry-sponsored clinical trials to establish the efficacy and safety of drugs, biologicals, or devices for the purpose of registration with government regulatory authorities such as the Europeans Medicines Agency (EMA), the US Food and Drug Administration (FDA), or their equivalent. Such research may be managed by an outside Contract Research Organization (CRO), or a Site Management Organization (SMO), however an External Review Board (ERB) that is fully independent of the investigators and funding entities must be engaged for the active monitoring of data collection and participant safety. 12 119. It is appropriate for a neurosurgeon who is conducting research on behalf of an outside entity to accept reasonable fees, including research and academic support, for his or her time in performing the study. However, a neurosurgeon should not accept any payment or honoraria that is contingent on the outcome of a study, or on providing specific findings to an organization, since this may create a conflict of interest or lead to bias during the research process. 120. Similarly, investigators should not participate in sponsored clinical trials of drugs or devices when they, a relative, or a colleague have an employment, an ownership interest, or another conflict that precludes objective and nonbiased evaluation during the study process. 121. Purposes and endpoints of research vary widely. The purposes, applications, consequences, and sponsorship of research projects should be clearly disclosed to all those who are materially affected, including patients participating in the research project, subjects, collaborators, and funders. 122. If there is reason to believe that a colleague is conducting scientific or medical research in an unethical manner, for example by misrepresenting data, using the work of colleagues in an unfair manner, or recruiting subjects with inappropriate techniques, it is appropriate to alert the relevant authorities. At a minimum, neurosurgeons should refuse to participate in research practices they consider clearly unethical. Protection of Patients & Research Subjects 123. It is incumbent on collaborators in neurosurgical research programs to protect the safety, dignity, and privacy of patients participating in research, in full compliance with standards promulgated by governmental authorities such as the U.S. National Institutes of Health, the General Medical Council of the UK, and the International Association for Cancer Research (IARC) for the protection of human research subjects. 124. A conflict between roles may emerge during research, since the physician-patient relationship is different from the researcher-research participant relationship. In such situations, the physician-patient relationship must take precedence. For example, a physician must be prepared to recommend that a patient not participate in a research project if current treatment is providing good management of a chronic condition and the project requires randomization. 125. Unless they are unable to read, competent patients participating in research must be fully informed, in writing, about the purpose and methods of the research, and must give their voluntary, fully informed, and explicit consent to participate. 126. In broad terms, investigators must inform their subjects regarding: i. The study's rationale and methods, including randomization, when relevant ii. Alternatives to the proposed treatment, including alternative treatments available within the center, as well as study or treatment protocols that may be offered in other centers iii. Their right to receive full treatment, should they decline to participate in the study under discussion iv. Their right to "opt out" of the study at any point without prejudicing future treatment v. The risks of participation, including possible complications inherent to the proposed treatment vi. Contingency plans for treating complications vii. All existing and potential conflicts of interest 13 127. The patient's consent should be sought if tissue removed in an operation is to be used for research at any time. If the tissue is to be removed solely for research, the patient's consent for removal is required. 128. The involvement and consent of families to participate in research is not sufficient in situations where the patient is competent. As is the case in all research, studies involving patients who are not competent must have potential benefits that are greater than

the potential risks for the patient. The informed consent of relatives or legal representatives is required for incompetent patients. If such consent is withheld, then the patient should be excluded from the research protocol. 129. Investigators must confirm that the consent form fully complies with requirements of the Institutional Review Board (IRB) and the External Review Board (ERB), as well as with relevant laws pertaining to patient confidentiality. The process of obtaining adequate informed consent is both complex and sensitive. It is advisable to work with an expert consultant or counsel to develop the consent protocol. Confidentiality of Data, Protection of Intellectual Property & Publication of Research Findings 130. All collaborators in research and scientific investigations are responsible for the ethical integrity, as well as the scientific and academic integrity of all aspects of the research process, and of the publications, communications, presentations, and proposals relating to all studies. 131. Research participants may have obligations to co-investigators and to trial sponsors to hold the nature and findings of a study in confidence. Because information obtained in the course of commercially sponsored trials may have significant intellectual property and economic value, trial participants must refrain from improper disclosure of any data to any outside party without the express permission of the sponsor and of co-investigators. The need to protect intellectual property may be a major factor influencing the timing of disclosure. 132. The results of research should not be published through any nonmedical media prior to publication in refereed scientific journals, or presentation at a medical or scientific meeting. 133. There have been numerous recent reports of distortion and dishonesty in the reporting of research results. Authors of publications must observe the highest standards of honesty, disclosing a fair and balanced report of research data and findings. Failure to make proper disclosure may damage not only the authors and their institutions, but also the larger scientific and medical community, as well as patients, by setting false standards of care. 134. At the time of publication, data should be fully and accurately disclosed, with appropriate recognition of sources. Investigators are responsible to ensure that data analysis, manuscript preparation, and presentation are objective and free of commercial input, influence, or bias. Concerns over confidentiality and the need to protect intellectual property, should never be motivation to hide or obscure any research findings. 135. Plagiarism is unethical. Neurosurgeons should not claim as their own, any intellectual property, results, or findings that are reported by others, and should not use language or direct quotations from other publications without appropriate attribution. 136. Ethical dilemmas and conflicts of interest will inevitably be encountered – in study design, research collaboration arrangements, funding arrangements, and other areas. Investigators should be trained to anticipate these dilemmas and to disclose potential conflicts, whether real or apparent, promptly and openly. 14 137. Direct and indirect industry sponsorship often leads to the appearance of material conflict of interest, even where no conflict exists. Thus, it is appropriate to fully disclose all sources of funding or sponsorship, including nonmonetary resources that contributed to the analysis, preparation, or dissemination of research findings. 138. Data from original research should be retained for a reasonable period of time, and should be available for external review when appropriate. This is particularly important for data that is used to substantiate a claim, or to prove/disprove a hypothesis. 139. No research on human subjects should be published or presented in a scientific forum unless the authors show such research has been approved by a Research Ethics Committee, and the privacy of the subjects is protected according to their wishes. 140. The International Committee of Medical Journal Editors (ICMJE) has recommended the following criteria for authorship of submitted manuscripts: i. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data, ii. Drafting the article or revising it critically for important intellectual content, iii. Final approval of the version to be published All authors should meet requirements i-iii, and all those who qualify for authorship should be shown. When there are many contributors to a publication, one author should accept overall responsibility for the whole work. Limited exceptions to the full requirements for authorship are appropriate when authors are participants in a multicenter trial, where publication of findings from participating centers rests with the principle investigators. Conflicts of Interest in Research & Clinical Practice 141. A conflict of interest exists when an investigator, author, reviewer, or editor has a financial or personal

relationship that inappropriately influences or biases his/her actions. Financial relationships, such as employment, consultancies, stock ownership, honoraria, and paid expert testimony are the most easily identifiable conflicts, and have the greatest potential to undermine the credibility of academic institutions, investigators, authors, and journals, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion. 142. We must work to ensure the independence of our scientific conferences and publications. Neurosurgeons who are asked to review publications or to referee grant applications, abstracts, and scientific papers should do so fairly and objectively. When there is a conflict of interest, it should be disclosed, and the individual should disqualify himself/herself as a reviewer. 143. Editors, reviewers, and referees are responsible to ensure that commercial bias does not influence the findings or the presentation of results in publications and scientific forums, in order to ensure that standards of patient care are defined in a safe and honest manner. Members of editorial boards should encourage editors to undertake reasonable audits of research data when appropriate. 144. Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care. However if company representatives provide such gifts directly to neurosurgeons, they could create a relationship that could influence use of the company's products and create conflicts of interest. Hence gifts and support for educational programs and conference attendance should ideally be accepted by only individuals who do not select products for purchase, and who do not directly influence those decisions. 15 145. When companies underwrite medical conferences or lectures other than their own, or contribute to the publication of medical or scientific literature, responsibility for and control over the selection of content, faculty, educational methods, and materials should remain with the organizers of the conferences or lectures and publishers. 146. Scholarships or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible, as long as academic or training institutions determine who will receive the funds. 147. Subsidies from industry that are directly paid to neurosurgeons for the costs related to travel, lodging, or other personal expenses of attending conferences or meetings, or to compensate for the neurosurgeon's time, should ideally not be accepted. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. 148. It is appropriate for a neurosurgeon who serves as faculty at conferences or meetings to accept reasonable honoraria, and to accept reimbursement for reasonable travel, lodging, and meal expenses. 149. Individual gifts by representatives of businesses that produce or sell medical products or services that may be procured by neurosurgeons should primarily entail a benefit to patients and should be of minimal value. Cash payments should not be accepted. 150. No gifts should be accepted if there are strings attached. For example, neurosurgeons should not accept gifts if they are given in relation to the individual prescribing practices. New Procedures, Materials, and Devices 151. A new or innovative procedure, material, or device is one for which the safety and effectiveness has not yet been established. The development of these new technologies and techniques must be accompanied by scientific assessment of their safety, efficacy, and value for patients. The rigor and scope of the assessment may range from carefully monitored observational studies to controlled clinical trials, depending on the novelty and complexity of the technology. 152. New techniques and technologies should not be publicized before such scientific assessment, the results of which should be published in peer-reviewed medical journals. Neurosurgeons on editorial review boards should encourage editors to publish negative as well as positive results from such trials. 153. Introduction of new practices into clinical practice requires appropriate education and training of surgeons, as well as evaluation of their use of the new technology. The qualifications of those who propose to use the new technology must be carefully assessed. These individuals must have had comprehensive education and experience in the management of the disease process for which the technology is applied, and must acquire the necessary technical skills and competence to recognize and manage any complications resulting from the new technology. 154. Acquisition of new technical skills and development of appropriate support facilities and expertise within the supporting medical team is similarly required. 155. Outcomes from

the new practices should be monitored, especially during the early period following introduction. 16 Tissue and Organ Transplantation 156. Although tissue transplantation has only a limited place in neurosurgical practice, this may change with time. Transplantation should only be undertaken in specialized centers with the facilities to provide the treatment and evaluate results. All national laws and professional regulations must be respected. 157. Tissue for transplantation, including fetal tissue, should only be obtained and used within national laws and professional regulations. Any prior views of potential donors, and the wishes of bereaved families should be taken into account. No financial or other inducement should be used to obtain such tissue. 158. We should work within national laws, religious beliefs, and social customs to maximize the supply of cadaver organs to other surgical disciplines. The relatives of potential donors and the public should be made aware of the potential benefits to patients and society. 159. The formal process of determining brain death should be undertaken by doctors independent of the transplant team, following accepted legal and clinical protocols. Advertising and Publicity 160. Neurosurgeons have the right to inform medical colleagues and the public about their services by way of notices and advertisements in print, audio, and electronic forums, and with nameplates on buildings. Publicity should primarily serve the interests of patients, rather than physicians. 161. Communications may include accurate representation of the educational background of the physician, the basis by which fees are determined, available credit or other means of payment, the nature of neurosurgical care provided, and any other information that is not deceptive. 162. Communications to the public must be accurate, and they must not omit material information without which the communication would be deceptive. Objective claims as to the experience, competence, and quality of physicians and the services they provide may be made only when they are factually supportable. Generalized claims regarding satisfaction with a physician's treatment may be made if they are representative of the experience of similar patients treated by this physician. 163. We should not, directly or through other parties, make claims of superiority over the work of other neurosurgeons, or other comparable surgical procedures. 164. We must be responsible for information relating to our own practices that is produced and disseminated by other institutions. 165. Communications must not convey false, deceptive, or misleading information through statements, testimonials, photographs, graphs, or other means, and must not omit material information without which the communication may be deceptive. 166. Discussions of specific treatments and procedures should only discuss benefits that reflect efficacy established by clinical trials or broad discussion in refereed scientific forums. If communications refer to benefits or other attributes of neurosurgical procedures that involve significant risks, a realistic assessment of the safety and efficacy must also be included, as well as the availability of alternatives, with descriptions and/or assessments of the benefits and attributes of those alternatives where necessary to avoid deception. Readers should be directed to seek further information from qualified health care professionals. 17 167. We should not promote the use of procedures that are new or experimental. We should take an active role in protecting the public from direct-to-consumer advertising that promotes false expectations, and we should deny requests for inappropriate treatment or procedures that result from such promotional efforts. 168. Aggressive, high-pressure advertising and publicity should be avoided, especially when it could create unjustified medical expectations. Advertisements should not be created with the intent of appealing to an individual's anxiety. They should not exploit the vulnerability of patients or their families, or take advantage of any lack of knowledge. 169. Advertisements should not put pressure on people to use a service, or arouse unnecessary fear regarding future health. Neurosurgeons should not advertise their services by telephoning or by visiting prospective patients, either in person or through a third party. 170. The Internet has enabled health care professionals, patients, and other consumers to gain unparalleled access to health information, and has transformed our relationships with patients. This ease of access, combined with the lack of peer review for most material with broad public access, mandates a higher level of vigilance on the part of neurosurgeons who contribute material to this forum. We must exercise great care to participate only in professionally responsible websites, and to protect the accuracy and appropriateness of medical information and perspectives on care that we provide for online access.

Readers should be directed to seek further information from qualified health care professionals. 171. On pages/websites where we provide material content, we should only allow links to other information sources that we know to be accurate and reliable. 172. Medical websites should clearly disclose sources of outside funding, including cooperative relationships with commercial firms, and the distinction between a purely medical assessment and an advertisement should be clearly made. Narrowing the Gap – Neurosurgery in the Developed & Developing World 173. Neurosurgeons in the developed world have a moral and social obligation to help their peers in the developing world to gain theoretical and practical knowledge that will enable them to improve the standard of care in all nations of the world. 174. Thus, we should seek to provide young physicians from these nations with residency and fellowship opportunities, enable them to become members in our professional societies, and support their participation in international congresses and scientific forums. 175. In addition, we should support efforts by the of the WFNS Foundation, and by national and regional neurosurgical societies, to provide training and equipment for neurosurgeons in the developing world, through financial contributions and/or by sharing our time and skills as volunteer trainers and mentors.

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