

# The JMA Guidelines for Physician's Professional Ethics 2008

First version in 1951, and revised in 2000, 2004, and 2008

JMAJ 52(2): 75–91, 2009

Japan Medical Association\*<sup>1</sup>

## Chapter 1: The Duty and Responsibility of the Physician

### 1. The basic duty and responsibility of the physician

#### (1) Acquisition of medical knowledge and skill and continuing education

Physicians must possess professional competencies substantiated by valid medical knowledge and skill. For this sake, physicians are obliged to continue to acquire medical skills based on ever-progressing modern medical sciences throughout their professional careers, and must discharge their responsibility to practice medicine based on exact evidence. They should continue learning through various media including printed materials and taking various opportunities to attend lectures and training sessions by academic societies and medical associations. They should collect a wide range of information and exert what they have learned on their daily practice of medicine.

#### (2) The spirit of study and the involvement in medical research

Physicians working in any medical field should always contribute to the progress and development of medicine. For the improvement of medicine, it is important not only to provide better medical care to individual patients but also to try to advance research as the basis for medical care.

In addition to direct involvement in medical research, physicians may participate in research by cooperating in the research conducted by others and making an appropriate evaluation of the research conducted by others.

In conducting the research and development

of novel medical techniques, one should respect the spirit of the World Medical Association (WMA) Declaration of Helsinki, be honest and modest, and always think much of both scientific attitude and ethical perspective. For any research programs which might raise ethical problems, one should also request appropriate organizations such as the Institutional Review Board (IRB) to make an assessment.

#### (3) Cultivating of character and retaining of dignity

It is important for physicians to associate with many people and cultivate wide discernment supported by the full utilization of knowledge and experience. They should also respect the dignity of the medical profession and the social mission of being a physician, be responsible for their speech and behavior, and respond to the trust of patients and society. This trust is supported and fostered not only by medical knowledge and skill, but also by several virtues such as integrity, courtesy, cleanliness, modesty, and good manners. The endeavor to cultivate one's character and retain dignity is their duty to society in general and to the medical circle. Furthermore, they must behave and speak in a manner respecting the rights of patients and exhibiting love for humanity, based on the spirit of the WMA Declaration of Lisbon and complying with current laws and regulations.

### 2. The duty and responsibility of the physician to the patient

#### (1) Explanation of the disease name/condition to the patient

Except in emergency cases requiring immediate life-saving treatment, it is fundamental to the

\*1 Contact address: [jmaintl@po.med.or.jp](mailto:jmaintl@po.med.or.jp)

physician-patient relationship that the physician sufficiently explains to the patient about his/her medical condition, and the patient, with sufficient understanding of the disease, works with the physician to overcome the illness. Therefore, generally speaking, a physician who has diagnosed a patient should provide him/her with a detailed account of the diagnosis including the name of the disease, and explain the course of the disease, the types and methods of tests and treatments, and other relevant facts in plain terms that the patient can comprehend easily.

However, as an exception to this general principle, the physician is allowed to withhold information when the disclosure of the disease name and condition would cause excessive emotional distress for the patient and obstruct treatment, or otherwise there is a justifiable reason. In such situation, the attending physician should make a decision after careful deliberation, heeding the opinions of other physicians. If the physician withholds information from the patient, it is important that an appropriate family member of the patient is informed of the disease name and condition.

### **(2) Explanation of the disease name and condition to the patient's family**

So long as the patient has the normal ability to make decisions, the explanation and disclosure of the disease name and condition are normally given directly to the patient. Many families in Japan have strong ties among members, and the patient and his/her family support each other. In such cases, it is necessary to give detailed explanation of the disease name and condition to family members as well.

However, if the patient does not want the disease name and condition to be known by family members, the physician should comply with this preference. If the family objects to the disease name and condition being disclosed to the patient, the physician should try to persuade the family to understand the need for explanation to the patient, unless the physician considers such disclosure is detrimental to the patient.

It is also important to keep records of these processes and situations for future reference.

### **(3) Patient consent**

When the physician provides medical care, it is essential to obtain the consent of the patient

based on his/her free will. In obtaining patient consent, the physician needs to give an explanation relevant to the proposed medical care. It is important that the physician should obtain "informed consent," which means that the physician gives sufficient explanation to the patient about the purpose, details, and nature of tests, of treatment, and of procedures, as well as what risks and relative advantages are involved in the choice to receive or decline the proposed care and what alternative procedures are available, and the patient gives consent with sufficient understanding of the explanation. When a highly invasive test or treatment is proposed, it is desirable that the written consent is made including the description of the explanation to the patient. The physician should see to it that obtaining of the written consent is not a mere formality. If the patient wants a second opinion, the physician should positively respond to the request. [See (12) Consultation or second opinion.]

If the patient lacks or is suspected of lacking the normal ability to make decisions, it is important to explain the disease condition and treatment to an appropriate member of the patient's family, a proxy of the patient, or a person acting for the interests of the patient and obtain consent.

### **(4) Patient consent and blood transfusion refusal**

In relation to the physician's responsibility to provide medical care and obtain patient consent, there is an emerging problem that some patients refuse blood transfusion for religious reasons, conflicting with the belief of physicians that blood transfusion should be used when needed for lifesaving. Whether to prefer lifesaving or faith is a controversial problem. However, the Supreme Court of Japan has ruled that, when there is a possibility of blood transfusion for lifesaving during a surgical operation, the physician should explain this fact to the patient and let the patient decide whether or not to undergo the operation, and a physician failing to give this explanation may be charged with illegal infringement of the patient's personal rights. Physicians need to pay attention to this Supreme Court judgment.

### **(5) Preparation and retention of medical records**

The physician, after examining or treating a patient, should fill in the medical records kept for each patient, describing the diagnosis at that time, chief symptoms, and the details of the tests

and treatment conducted for the disease and symptoms in concrete terms. The medical records should be retained with various test data and other materials in an organized manner so that they can be retrieved when needed. This allows the physician to prepare for seeing the patient next time or sometime in the future, as well as to review and evaluate past medical practice. In addition, the practice of physician's preparation and retention of medical records as routine is important for the purpose of ensuring the scientific and transparent services as the physician. For this sake, the physician must keep the records of medical services to describe appropriately the required information based on fact.

In Japan, the Medical Practitioners Law, the Medical Care Law, and the Rules for Medical Care Services of Medical Institutions and Physicians in the National Health Insurance System (Health Insurance Medical Care Rules), and other regulations demand relevant persons to prepare and retain medical records and other documents as a legal obligation.

#### **(6) Confidentiality**

The physician acquires highly confidential information about the patient during the process of medical practice. A leakage of such information from the physician to others may cause a real loss to the patient or injure his/her reputation. It also disrupts the physician-patient relationship, causing difficulty in the smooth continuation of medical care. Physicians have therefore long attached importance to confidentiality as professional ethics. The legislation, including the Criminal Code, also takes lines to advocate patient confidentiality and the duty of physicians to protect it.

The physician is exempted from confidentiality regarding patient information only when the patient has remitted confidentiality by giving consent or permission, or when social and public interest overrides the protection of the patient's interest. According to a recent ruling of the Supreme Court, the act of reporting the detection of a positive stimulant reaction in the patient's urine to the police is legally acceptable. In addition, there are cases in which the Court clearly stated that the legal violation of confidentiality is not applicable such cases as the notice of child abuse, the reporting of domestic violence conducted by the patient's spouse, and the reporting of elderly abuse conducted by the "care-taker."

A physician who has leaked patient information to an outsider (a third party) without a justifiable reason is not only denounced ethically but also accused of the violation of legal requirements such as Article 134 of the Criminal Code. The physician may also face a civil lawsuit for damages on the basis of the invasion of privacy and defamation.

The demand of the news media for information disclosure is escalating, and the media coverage of such issues as announcing the disease condition of celebrities and organ transplantation from brain-dead donors is overheated. This situation calls for consideration regarding the protection of patient confidentiality and privacy. Physicians should also give sufficient consideration to the protection of patient confidentiality and privacy in the context of the growing trend towards information disclosure.

#### **(7) Protection and disclosure of patient's personal information and medical information**

The Act on the Protection of Personal Information (Personal Information Protection Act) was fully enforced in April 2005 under the principle of respect for personality. Under this Act, every medical institution is treated as a business handling personal information, and is placed under the management obligation to ensure the appropriate acquisition, retention, and use of personal information including the medical information concerning patients.

Although a business handling personal information of 5,000 or less individuals annually is exempted from legal obligation, the guidelines of the Ministry of Health, Labour and Welfare (MHLW) require that all medical institutions should adhere to the law, irrespective of the limit of 5,000 individuals.

Medical institutions must take measures to ensure that the acquired personal information concerning patients is retained securely and safely, and that the information should not be leaked to outsiders not only by physicians but also by all employees and contractors. In particular, the protection of the information stored in computers requires sufficient precautions.

When the patient or his/her proxy requests the disclosure of relevant medical information, it should be disclosed as a rule.

The disclosure of information concerning

details of medical care may be needed for the sake of study presentation and for improving the transparency of medical services. In such cases, patient consent should be obtained before disclosure and care should be taken so that individual patients may not be identified.

Disclosure of medical information may require full attention to the patients such as providing consultation services for them. Physicians should thoroughly understand what is required of them, referring to the Japan Medical Association “Guidelines on the Handling of Personal Information Related to Medical Practice.”

#### **(8) The obligation to comply with request for treatment**

The current Medical Practitioners Law (Article 19) provides for “the obligation to comply with request for treatment,” stating that a physician who is engaged in medical practice shall not refuse a patient’s request for examination or treatment without justifiable reason.

Here, “a physician who is engaged in medical practice” is defined as “a self-employed physician, a physician employed at a hospital, or the like, who declares to provide medical services to the public or a large number of specified persons.” Although “the obligation to comply with request for treatment” is closely associated with the place of medical practice, it is not an obligation accompanying the status of being a physician.

The physician must comply with a patient’s wishes to the extent possible when it is possible to provide medical care at the place of his or her practice, and in particular when there is an urgent need for treatment. However, the physician may refuse, if there is “justifiable reason.” This may include several cases, such as working outside a specialty, working outside business hours, and the past nonpayment of medical fees. Because situations may differ in different cases, the physician should make an appropriate judgment based on good sense.

#### **(9) Voluntary medical care (aid) in an emergency**

A physician may be asked to provide emergency aid on a train or an airplane. A physician may also encounter a person lying on the street in need of aid. In such cases, the physician should voluntarily provide care to the extent possible.

#### **(10) Prohibition of treatment without examination**

From the standpoint of patient safety, performing treatment and procedures without directly examining the patient involves the risk of unexpected harm to the body and life of the patient. The physician must not make clinical diagnosis, perform treatment, medication (issuance of a prescription), or other procedures, or prepare a medical certificate without directly examining the patient. This rule is stipulated in Article 20 of the Medical Practitioners Law (prohibition of treatment without examination).

The physician should not make specific diagnosis or recommend a treatment method to a patient seeking advice via telephone, radio, television, the Internet, mail, newspaper, magazine, etc. Judging from information on the patient, if necessary, the physician should advise the patient to see a physician.

#### **(11) Obligation to issue prescriptions**

The Medical Practitioners Law provides that a physician who recognizes the need for preparing and administering a medicine for therapeutic purpose must issue a prescription to the patient or the person who is actually taking care of the patient. This rule concerning the physician’s obligation to issue prescriptions admits many exceptions.

#### **(12) Consultation or second opinion**

With the advancement of medicine and the diversification of medical specialties, physicians often encounter cases involving problems that may not be solved by themselves. In such cases, the physician should seek the opinion of other physicians either by asking them to see the patient (consultation) or by providing information to them. The physician should encourage the patient to have a consultation or a second opinion when such actions are considered necessary, as well as when asked by the patient. It is desirable that the physician informs the patient about the availability of hospital-clinic collaboration, hospital-hospital collaboration, and clinic-clinic collaboration, and also tries to provide an environment encouraging patients to seek the opinion of other physicians. On the other hand, the physician who participates in a consultation should sincerely state objective opinions to the patient based on the given information, and promptly communicate

the result to the attending physician. When conducted according to necessity, consultation and second opinion are usually beneficial to both the patient and the physician, and should be promoted for the purpose of reaching better decision making. However, the clinical responsibility resides in the attending physician even in the case of consultation with another physician. Recognizing this fact, the attending physician should develop a treatment plan incorporating the opinions of others and endeavor to provide the medical care that is considered the most appropriate, by virtue of seeking the opinion of specialists in other departments and practicing team medicine with other medical professionals.

### **(13) Advertisements and publicity activities**

The Medical Care Law imposes strict regulations on the advertisements and publicity activities conducted by physicians and medical institutions for the purpose of protecting patients from false or misleading advertisements, and only advertisements stating a predetermined set of information are allowed. However, from the standpoint of respect for the patient's right of self-determination and the need for information disclosure, it has become important to promote the provision of information so that patients can select appropriate medical institutions in accordance with their conditions, and restrictions on advertisements have been relaxed. Websites are not treated as advertisements under the Medical Care Law, because they are accessed by patients on their own will to obtain information. However, some of the websites that are intended to attract patients in the general public are regarded as advertisements, and are subject to the restrictions on advertisements. In any case, it is important that physicians should avoid exaggerated advertisements and select appropriate information media in conducting advertisements and publicity activities.

### **(14) Medical care without scientific evidence**

A physician is a provider of medical services and also a scientist keeping an eye on both experience and substantiation. However, the progress of medicine depends on the exploration of unknown areas, and the distinction between leading-edge experimental treatment and fraudulent "fake medicine" is often obscure. In addition, it seems impossible to refute the practical value of traditional and alternative medicine, which cannot be

explained completely within the framework of modern science. The physician, however, should provide medical care based on scientific evidence, and should be cautious in the use of therapeutic interventions lacking sufficient scientific evidence. When such interventions are used, the physician should explain to the patient about the lack of sufficient evidence and obtain consent in advance, and the physician should never use the interventions for the sake of profit.

### **(15) Sale of goods and provision services that are not included in medical care**

It is a social role of physicians as healthcare professions to recommend goods and services that are useful for the promotion of health and facilitation of daily living of people, such as foods and household utensils other than medicines and medical devices, and such acts should be widely accepted. It is acceptable that items needed for patients under medical care are sold within a medical institution, but this should be limited to items that are useful for the convenience of patients. Items that may harm the health of patients or bring the medical institution into disrepute should not be sold. In addition, physicians and operators of medical institutions should refrain from pursuing profit from the sale of such goods and services. Physicians, even outside of medical institutions, should not use their positions in support of the marketing of health-related goods lacking scientific evidence.

### **(16) Actions to help patients fulfill their responsibilities**

While medical care is a cooperative effort between the physician and the patient and naturally the physician must respect the will of the patient, the patients must also fulfill their responsibilities. For example, patients are responsible for giving correct description of their disease condition and wishes, and also conforming to the therapeutic instructions they agree to follow. Although information concerning diseases and treatments has become widely available and the knowledge of people has improved, it is difficult for lay people to gain sufficient understanding of diseases, and some people have incorrect knowledge. Therefore, it is important that physicians help patients so that they can gain correct knowledge about diseases and healthcare.

**(17) Reward and gratuity for the provision of medical services**

Physicians must not demand reward for the provision of medical services other than the prescribed fee. Physicians must refrain from receiving gratuity from patients, because such an act rouses the suspicion of consciously or unconsciously giving preferential treatment in medical care in return and, if conducted customarily, undermines the people's trust in medical care as a whole.

**(18) The responsibilities of the primary care physician**

A physician who has been selected as the primary care physician by a patient needs to keep track of comprehensive health information concerning the patient on a routine basis, including the life history and drug use history of the patient. The primary care physician is the physician who retains the most information about the patient's healthcare as a result of continued medical care, and the one that the patient would choose first at the time of illness. Therefore, the primary care physician should routinely give counsel to the patient, refer the patient to specialists as needed, and proactively engage in continuing medical education to be able to serve the patient's needs in medical care, healthcare, and welfare. The primary care physician should also participate in the development of systematic cooperation in community healthcare to ensure the continuity of medical services during emergencies as well as at normal times, and assure the patients by informing them about such cooperation.

**3. The mutual responsibilities among physicians****(1) Mutual respect and collaboration among physicians**

With the advancement of medicine and various medical technologies, the community of physicians has come to comprise an increasing number of specialists in various areas. On the other hand, the need for physicians providing comprehensive healthcare is also emphasized. In this situation with increasing specialization and diversification of physicians, it has become all the more important to promote mutual collaboration among physicians, such as the exchange of opinions among physicians and hospital-clinic collaboration. Every physician should respect other physicians with different academic backgrounds and different

experiences, and this mutual respect among physicians forms the basis for the trust of patients. In addition, physicians should also recognize the scope of their specialties and capabilities. If they consider the conditions of patients are outside their own specialty or the limits of their capabilities, they should without hesitation ask for cooperation or consultation, or make a referral to other physicians. For this sake, physicians should maintain good relationships among them and collaborate through such mutual relationships.

**(2) Respect for the attending physician**

The attending physician holds all the responsibility for the medical care concerning the disease or injury in question, and other physicians must respect the judgment and position of the attending physician. However, if it is objectively evident that another option is better than the judgment of the attending physician, other physicians should communicate their opinions and give necessary guidance to the attending physician, either directly or by way of colleagues, considering the interest of the patient.

In the case that a patient consults a physician other than his/her attending physician without a referral, the physician should listen to the patient and endeavor to obtain the treatment plan and other information concerning the patient's care from the attending physician. Depending on the situation, it is desirable that the patient after receiving care is instructed to see the attending physician again.

**(3) Patient brokering and solicitation**

Physicians must not engage in the act of receiving a fee or other consideration for referring a patient, and must not cooperate with an agency that conducts such acts. In addition, physicians must not engage in the act of patient solicitation for the sake of profit. If referral is considered necessary for the sake of the patient, the physician should naturally explain the need to the patient and refer the patient to an appropriate physician. In such cases, the physician must not demand any compensation for making the referral, except for appropriate administration fees.

**(4) Advice and criticism to other physicians**

It is important that physicians teach the knowledge and skills of their own acquisitions to other physicians, and try to correct inappropriate medi-

cal practice of other physicians by directly or indirectly giving advice, suggestions, or guidance.

At the same time, careless criticism of other physicians should be avoided, as it is an act that not only brings the targeted physicians into disrepute and damages the people's trust in them but also incites unnecessary anxiety in patients and causes other unexpected impacts. In particular, imprudent criticism against a physician who has seen the same patient before has long been considered futile as stated from the past "Do not criticize the previous doctor" and "The second doctor is always better." In addition to the reasons mentioned above, the previous physician and the second physician to see a patient are often presented with different disease conditions and receive different information, and it is often easier for the second physician to make a correct diagnosis. Therefore, it is pointless to criticize the previous physician. It should also be noted that thoughtless criticism of the previous physician may trigger an unproductive medical dispute. This point needs attention also in the process of consultation. In particular, it is impermissible to slander other physicians in an attempt to raise one's own reputation.

#### **(5) Disagreements and disputes among physicians**

Disagreements regarding clinical matters frequently occur among physicians, but this usually is a reflection of a healthy process of decision making. In such cases, the opinion of the attending physician is respected as a rule unless it is necessary to prefer a second opinion. So long as the cause of dispute lies with the physicians, any dispute among physicians should be solved among physicians without involving the patients.

#### **(6) Supply and sharing of medical information among physicians**

When more than one physician provides medical care for a patient, it is necessary to ensure that the medical information regarding the patient is transferred and shared appropriately. When considered necessary, a physician may directly request the physician who previously attended the patient to supply test records and other medical information regarding the patient after obtaining patient consent. The physician receiving the request from another physician should provide the medical information needed by the requesting physician, including various test records and

radiographs, after obtaining the patient's consent. Physicians in a medical institution, however, may share medical information among them unless the patient has stated an objection. In this case, care must be taken to prevent the leakage of patient information to outsiders.

### **4. Relationship with other healthcare professionals and providers**

#### **(1) Collaboration with other healthcare professionals**

With the specialization and diversification of healthcare, various academic fields related to healthcare have developed, and a variety of healthcare professionals have evolved, including pharmacists and nurses. These professionals are supporting modern healthcare practice, offering their professional knowledge and skill while working in a healthcare team. In addition, there is an increasing need for collaboration between healthcare professionals and welfare professionals for the purpose of supporting elderly people requiring care and people with diseases and disabilities living in institutions and at home, as well as enhancing health maintenance and promotion among community inhabitants.

To provide high-quality healthcare in collaboration with workers in various vocations, physicians should first understand their occupational roles and legal responsibility correctly, and develop mutual cooperation respecting the positions of these workers. In team medicine, physicians should take leadership and responsibility in the decision making regarding healthcare services, based on an exchange of opinions with team members and according to their professional knowledge, values, and legal requirements.

In addition, physicians must pay heed to protect patient information and to prevent the conduct of medical procedures by unqualified persons.

#### **(2) Relationship with healthcare providers**

Physicians have plenty of opportunities to interact with healthcare providers, such as medical representatives from pharmaceutical companies and sales persons from medical device manufacturers. The relationship with these persons may be a source of new scientific knowledge related to their products and useful information supporting medical practice, and therefore it is desirable to develop a good cooperative relationship with them. However, decisions on the purchase and

use of drugs and other medical supplies should not be made giving priority to personal interest in the relationship with providers. The transactions with providers must be fair and appropriate. In particular, inappropriate actions in the payment of prices for drugs and medical supplies damage the credibility of physicians, and must be avoided.

### **(3) Sharing of medical information**

In providing medical care to patients, it is often necessary to share information among a wide range of persons, including the attending physician, pharmacists, nurses, and other healthcare workers, as well as social workers, clinical psychologists, and office clerks. In this case, healthcare workers and office clerks within the same medical institution are allowed to access the medical information concerning the patient only when there is an occupational necessity. Because the patient's medical information is in itself extremely confidential personal information, the physician managing such information must give sufficient instructions to healthcare workers and office clerks, and prevent the leakage of patient information to unauthorized persons. Except for cases stipulated in the law, such as disclosure based on a court order, any disclosure of medical information to a party outside the medical institution requires the consent of the patient as a rule. [See (7) Protection and disclosure of patient's personal information and medical information.]

## **5. The duty and responsibility to society**

### **(1) Reporting of unnatural deaths**

Article 21 of the Medical Practitioners Law states, "If a physician finds an unnatural feature in the examination of a corpse or the examination of a stillborn infant at the gestational age of 4 months or more, the physician must submit a report to the police station having jurisdiction within 24 hours." Article 33-2 of the Law provides for a fine of up to 500,000 yen (5,000 USD, 1 USD = 100 yen) for violation of this rule.

The opinions of physicians concerning unnatural deaths vary widely. Regarding the presence of an "unnatural feature," the Supreme Court decision in 1918 ruled that "an unnatural feature in a corpse refers to all cases where the corpse has a feature that may be considered to disprove unquestionable death from disease, and does not exclude the cases where the physician dismisses the suspicion of a crime in the causation of

death." The Supreme Court decision on April 13, 2004 indicated that "a physician who finds an unnatural feature in the examination of a corpse bears the obligation of reporting even when the physician may be charged with professional negligence resulting in death during medical practice in relation to the causation of death. Hence, Article 21 of the Medical Practitioners Law also applies to a fatal accident resulting from medical practice, and the physician who caused the accident is not exempted from the obligation to report under this Article.

### **(2) Reporting on medical accidents and investigation of causes within medical institutions**

It is the fundamental responsibility of physicians and medical institutions to ensure and protect the safety of the lives and bodies of patients and citizens. To fulfill this responsibility, physicians and medical institutions must establish a system for reporting of medical accidents in each organization. Any medical accident taking place in the organization must be investigated to determine the cause, recognizing the principle of "To Err is Human," and systematic measures to prevent accidents must be developed in each medical institution.

The manager of a medical institution is required to ensure (i) the development of management guidelines, (ii) the establishment of a management system (e.g., establishment of a commission), (iii) the utilization of the institutional accident report system, and (iv) safety management activities and personnel education.

### **(3) Reporting of medical accidents to public review organizations**

The amendment to the Medical Care Law in 2004 started two reporting programs intended to strengthen and ensure the implementation of medical safety measures. One is the program in which large-scale medical institutions are obliged to report accidents resulting in death and serious impairment, the causes of accidents are investigated, and measures for improvement are explored and proposed. In the other program, medical institutions of all sizes across Japan are asked to cooperate in the reporting of incidents and minor accidents that did not cause serious results. Both of these programs had been implemented in substance since about 2001 by the



MHLW, and were enforced in full under the amended Law. Japan Council for Quality Healthcare (JCQHC) has been operating the former program since October 1, 2004 and the latter since April 2004.

It is extremely important to continue the process of accumulating information about many medical accidents of various kinds, investigating the causes of accidents through expert review, exploring the measures for improvement, and feeding timely proposals back to medical practice, and every medical institution should participate and cooperate in these programs.

In addition, Item 2 of Article 77-4-2 of the Pharmaceutical Affairs Law demands of the operators of hospitals and clinics, physicians, and some other professionals that "if they come to know a fact about the occurrence of a disorder, impairment, or death suspected to have been caused by the side effect of a pharmaceutical or a medical device or other causes associated thereof, or about the occurrence of an infection suspected to have been caused by the use of the said item, and they recognize the necessity for the sake of preventing the occurrence or expansion of health hazard, they must report the fact to the MHLW." Relevant persons need to pay attention to this provision.

#### **(4) Response to medical accidents**

When an accident that may cause impairment in the patient occurs during medical practice, it is important that the physician in charge makes the best effort to treat the patient. At the same time, it is also important to explain the situation to the patient and his/her family.

Nobody should ever try to evade responsibility by falsifying medical records after the occurrence of an accident or dispute. When it is necessary to correct medical records, corrections must be made in such a way that one can tell who corrected what; deletions and additions should both be legible, the date and time of correction should be indicated, and a signature should be placed.

In the case of a serious medical accident, the physician in charge and the manager of the medical institution must provide sufficient explanation to the patient and his/her family. In an accident caused by apparent negligence, they must apologize to the patient and his/her family and act in good faith.

Every medical institution and every physician

engaging in clinical practice must be covered by professional medical insurance or hospital liability insurance.

#### **(5) Dissemination of information to society**

It is important that the practice of healthcare as a cooperative effort between healthcare workers and patients take root and be recognized in society at large, and this requires that the various fields of knowledge related to medical care and the awareness of present issues in healthcare be shared widely as common knowledge in society. For this sake, physicians need to educate and raise the awareness of people through various activities, not only to impart expert knowledge regarding medicine and diseases but also to raise the awareness of healthcare systems and the present issues surrounding healthcare. In the society of highly advanced information services, the role of news media is becoming increasingly important. Physicians should cooperate with various media channels in disseminating correct medical information to patients and the general public.

The appearance of physicians in the mass media as experts in medicine and healthcare to give professional information and appropriate opinions via various media including television, newspapers, magazines, and the Internet is an important way of fulfilling their social responsibility. When physicians communicate and explain medical knowledge to the general public, they should endeavor to provide representative opinions with sufficient scientific basis. They should speak with dignity and modesty and should refrain from self-advertisement.

#### **(6) Response to the mass media**

When physicians respond to requests from the mass media, it is important that they act faithfully and fairly to the recipients of information. Commenting on medical accidents and malpractices requires prudence. They should recognize that it is irresponsible to make careless comments that may be transmitted to the public via the mass media while information is insufficient.

When asked to attend media interviews, physicians should first request an explanation of the purpose of coverage and their positioning, and should accept only after sufficient understanding. Whenever possible, they should preview the content of coverage and make sure that their

comments are not distorted in editing and other processes. Physicians must not disclose the symptoms and other information concerning patients to the media without patient consent. This principle should be observed and the protection of the human rights and privacy of patients should be given the highest priority even in the case of particularly newsworthy patients and public figures.

#### **(7) Public health activities**

Physicians bear heavy responsibilities to society; they should esteem the public nature of medical practice and support the development of society through the medical services; they should not only treat individual patients but also cooperate, as professions with special knowledge, to improve and promote health of the whole community inhabitants and public health in communities, thereby ensuring the healthy living of people throughout the country. From this standpoint, physicians are required to cooperate in public health activities such as health examinations, vaccination, and stop-smoking guidance in public places, and to cooperate in community healthcare systems. In particular, providing education and guidance to ordinary people is an important means of preventing several serious infections and lifestyle-related diseases (adult diseases) that have been emerging in recent years. In addition, physicians should endeavor to disseminate and educate correct medical knowledge for the sake of ensuring the well-being of people, and to improve and promote public health through cooperation in health promotion and other activities in communities.

#### **(8) Healthcare under public health insurance**

The practice of healthcare is in itself a social action, and physicians as professions with special knowledge must share responsibilities regarding the health of people and the promotion of welfare in communities. Considering the public nature of medical practice and the fact that it is intended to maintain or restore the lives and health of people, it is important to establish and improve sound social security systems, in particular the health insurance system and the long-term care insurance system, so that sufficient healthcare services may be provided appropriately. Healthcare under public health insurance is conducted according to the contracts between insurers and

insurance medical institutions in the public systems based on the Health Insurance Act and other relevant laws. Physicians providing medical care under public health insurance must practice appropriately in compliance with specified rules, and must realize that any fraud that may undermine the system is impermissible.

Physicians are also responsible for the maintenance and improvement of the system for healthcare under public health insurance. To maintain a social security system, it is necessary to ensure appropriate allocation of limited healthcare resources. Physicians are responsible for supporting the appropriate operation of the system from the standpoint of conserving public healthcare resources, and need to help the smooth operation of the health insurance system. It is also an important duty of physicians to endeavor to rationalize and improve any rules and systems that may disadvantage patients.

#### **(9) Participation in international activities**

The expert competencies of physicians can be utilized for good purposes across national borders. In response to local conflicts occurring in many parts of the world and major natural disasters such as earthquakes and floods, countries outside the affected area may extend important humanitarian aid in the form of dispatching physicians and supplying medicines. However, many developing countries are suffering from a multitude of problems that must be solved in the field of healthcare, and the assistance from developed countries is important in this area. It is desirable that physicians contribute to international healthcare assistance and cooperation activities in various ways, such as the positive cooperation in the activities of the World Health Organization (WHO).

It is also important to promote the international exchange of medical information and the global cooperation in healthcare, including the collaboration with the WMA. Every physician should contribute to international activities following their own conscience.

## **Chapter 2: Terminal Care**

### **1. Terminal care (the care for the patients in the terminal stage)**

Physicians have long believed as their ethics that it is their job to try every means to sustain patient

survival for as long as possible. However, a new way of thinking has emerged, asserting that patients who are approaching death and have no prospect of recovery should receive care to value the patient's quality of life (QOL) and human dignity, rather than the aimless continuation of life-sustaining treatment. The QOL of patients, however, is judged depending on the selection made by the patients themselves. Life-sustaining treatment in the terminal stage should be based on the patient's own will. If the patient is considered to want life-sustaining treatment, care should be selected based on his/her will.

Needless to say, patients in the terminal stage have the right to receive appropriate medical care based on informed consent. It is the duty of physicians to try to prevent the infringement of this right. Issues related to the healthcare costs for the elderly, in particular the healthcare costs during the terminal stage, have recently been brought into question from the standpoint of healthcare economy in relation to the financial predicament of the health insurance system. In this situation, physicians must provide the best medical care possible and offer the possibility of spending the last moments of life in various forms including home care, ensuring that the patients' right of survival should not be compromised.

The importance of the role of family members who watch and care for the patient must be recognized in terminal care. The physician must provide appropriate medical care while maintaining adequate communication with the family. In particular, recent public demands for the enrichment of home care have made the role of the family all the more important. Under such conditions that the patient has impaired decision-making ability due to old age or other reasons, the treatment policy in terminal care should be determined considering the opinion of family members regarding what would be the best for the patient.

A problem attracting much attention in recent years is the care for the patients in the terminal stage of cancer, who tend to have clear consciousness until death and have much pain. In treating these patients, it is important to remove pain and distress and support these patients so that they can spend the remainder of their lives comfortably. Patients experience various forms of pain, including physical pain, mental pain, social pain, and spiritual pain. The care to palliate and remove these pains should be given through team care

involving not only the physician in charge but also nurses, social workers, religious practitioners, and family members.

Pain reduction is one of the most important treatments for the patients in the terminal stage of cancer. It is important to prescribe appropriate and sufficient analgesics and sedatives. Narcotics and other potent drugs may be needed in many cases, and this may result in the hastening of death. Although there are some objections to such treatment, this is a result of pain reduction, and many consider it acceptable so long as it is performed based on the patient's will.

The number of facilities providing terminal care in this line, called palliative care wards (hospices), is increasing in Japan, as well as in other countries. Home care for terminally ill patients is also being promoted recently. In terminal care, the patient must be given appropriate care to the end and be seen off warmly. The physician must interact with the patient to the end, and should never forsake the patient.

At present, physicians are required to address the diversification of patients in the terminal stage. In addition to the patients in the terminal stage of cancer, physicians need to provide care for the patients in the terminal stage of chronic disease, where gradual progression of chronic symptoms causes eventual death, and the terminal care for elderly patients developing gradual debilitation. Medical care should be given considering various factors such as the individual patient's condition in the terminal stage, the patient's QOL, and the decision-making ability. While the diversification of the patients in the terminal stage emphasizes the importance of terminal care, it is also causes difficulties in the decision regarding what is the best treatment for the patient. Physicians must provide medical care for the good of patients in this situation, and must recognize the gravity of their responsibility.

## 2. Withholding and withdrawal of life-sustaining treatment in terminally ill patients

Recent advances in medicine and healthcare have enabled us to save the lives of many patients. Nevertheless, there are increasing cases where terminally ill patients with no possibility of recovery are aimlessly given life-sustaining treatment. Increasing opinion is raised that excessive treatment should be discontinued, because it is not

only meaningless but also a potential infringement of the dignity of patients.

The WMA Declaration of Lisbon on the Rights of the Patient, adopted by the WMA in September/October 1981, pronounces that the patient is entitled to humane terminal care and to be provided with all available assistance in making dying as dignified and comfortable as possible. Placing greater emphasis on the patient's QOL rather than the pointless attempt to sustain life, end-of-life care should be practiced considering the options of withholding and withdrawing life-sustaining treatment depending on individual cases. In particular, we are faced with problems involving procedures such as the administration of drugs, chemotherapy, hemodialysis, artificial respiration, blood transfusion, and nutrition and hydration. The withdrawal of such treatments leads to the death of the patient, and therefore the decision to take such actions must be made with prudence. Judgment regarding the withholding and withdrawal of life-sustaining efforts should not be made by the attending physician only, but be made in team medicine, where the attending physician makes the final decision supported the opinions of the medical care team comprising other physicians and various health-care professionals.

Two important prerequisites for withholding and withdrawing therapeutic actions are: (1) the fact that the patient is affected by an incurable disease, and is in terminal stage, where there is no hope of recovery and death is expected in the near future; and (2) the presence of currently valid indication of the patient's wishes requesting the withholding or withdrawal of therapeutic actions.

The decision regarding the impossibility of recovery and the inevitability of death, mentioned in (1) above, is not always a simple matter. The indication of the patient's wishes, mentioned in (2), must be confirmed by the oral statement of the patient, but in the case that the patient has lost the ability to make sound judgment, by an advice written indication provided by the patient (an advance directive or a living will). Some professions consider that even if the advance indication of patient's wishes is not obtained directly from the patient, a decision may be made based on the wishes expressed by the patient's family and/or other appropriate persons, provided that they are sufficient for the inference of the patient's

wishes. In this case, it is important that the physician obtains sufficient information from family and/or other appropriate persons as the basis for the inference of the patient's wishes. In essence, the physician should have full discussion with the patient's family and/or other appropriate persons and consider what would be the best for the patient.

The decision regarding these requirements involves considerable difficulty, and should not be made solely on the discretion of the attending physician. The decision should be made carefully following the above-mentioned procedures of team medicine.

The presence of ambiguities, both in terms of medical ethics and legal matters, regarding the withholding or withdrawal of medical treatment in terminal care and the procedures for such action is not desirable from the standpoints of the rights of patients and the responsibility of physicians. Physicians should comply with the ethics guidelines provided here and the MHLW Guidelines Regarding the Decision-Making Process in End-of-Life Care. In addition, it is desirable that medical institutions develop concrete rules regarding this problem.

### 3. Euthanasia

The word euthanasia originally refers to the act of ending the life of a patient who suffers from unrecoverable disease and is distressed by severe pain, for the sake of providing relief from pain. However, this word is nowadays used with various meanings, frequently causing terminological confusion. The act of euthanasia is very akin to homicide and involves many controversial issues.

The principal issue regarding euthanasia is whether one should admit the act of shortening life to remove the pain of a terminally ill patient who has no prospect of recovery and is suffering from severe pain (active euthanasia) and, if such an act is permissible, what should be the requirements for the conduct of this act. The involvement of a physician in (active) euthanasia may take two forms: the physician may directly administer a fatal drug and end the life of the patient, or the physician may prescribe a fatal drug and give it to the patient, who voluntarily takes the drug. The latter is generally regarded as the act of aiding suicide (assisting suicide). In some Western countries, there are movements toward legalizing voluntary active euthanasia as physician-assisted

suicide (PAS).

The 1995 court decision (Yokohama District Court) on the case of euthanasia at Tokai University, which was the first euthanasia case involving a physician in Japan, ruled that positive euthanasia is permissible if the following requirements are met:

- (1) The patient is suffering from unbearable physical pain;
- (2) The death of the patient is inevitable and imminent;
- (3) Every means to remove and palliate the physical pain of the patient has been exhausted and there are no alternative measures; and
- (4) There is an explicit indication of the patient's will to accept shortening of life.

However, in view of the recent development of palliative medicine, it is hardly conceivable that there may be situations where one must resort to (active) euthanasia for the purpose of removing physical pain. Only a minority of lawyers are supporting the legality of (positive) euthanasia. As an ethical duty, physicians should not take part in (active) euthanasia.

The WMA Declaration on Euthanasia, adopted by the 39th WMA General Assembly, Madrid, Spain, October 1987 stated: "Euthanasia, that is the act of deliberately ending the life of a patient, even at the patient's own request or at the request of close relatives, is unethical." The WMA General Assembly in Washington, October 2002, reaffirmed that euthanasia is against the fundamental ethical principles of medicine.

## Chapter 3: Reproductive Medicine

### 1. Assisted reproductive technology

#### **(1) As a rule, assisted reproductive technology should be practiced using sperm and eggs from the married couple who want to have a child and receive treatment.**

At present, there are no legal regulations on the procedures involving assisted reproductive technology (ART) in Japan, and these are practiced under physicians' voluntary regulation conforming to the pronouncement of the Japan Society of Obstetrics and Gynecology (JSOG). According to the JSOG report in 2005, there were 18,168 children born through in vitro fertilization in 2004, representing 1.6% of the children born in that year.

The issue concerning ART attracting the most

attention from society is the debate about the ethical appropriateness of "ART using donor gametes (sperm and eggs)." Artificial insemination with donor semen (AID) has been conducted in Japan using spermatozoa from anonymous donors, and over 50 years of clinical experience has been accumulated since the birth of the first child in 1949. More than 10,000 children have been born through AID. However, there still are various problems affecting the welfare of children, such as the establishment of the parent-child relationship under the Civil Code and the children's right to know their origins. Considering this situation, the physician in charge should not positively recommend AID using donor gametes. As a rule, it should be recognized that ART may be offered only to an infertile couple who are both alive and want to have a child using their own gametes.

However, AID using donor gametes is not always unethical, if the couple is diagnosed as having no possibility of pregnancy through any other medical procedure, fully understands the necessary medical information, and receives treatment after sufficient counseling. In this case, AID should be practiced only at medical institutions with sufficient provisions to advocate the children's right to know their origins and protect personal information concerning gamete donors. The act of mediating the procurement of gametes or assisting in such mediation for profit is absolutely impermissible.

#### **(2) Facilities conducting in vitro fertilization and embryo transfer must operate in a registration system and report the number of cases, outcomes, and other data.**

Facilities conducting in vitro fertilization must be registered with JSOG. To be registered, each facility is examined and directed carefully in terms of facility standards, personnel standards, through the practice of written informed consent, the provision of counseling opportunities, and the propriety of the constitution of the IRB.

Registered facilities must report not only the number of ART cases but also the clinical outcomes of individual cases.

#### **(3) Gestational surrogacy is not allowed.**

Possible forms of gestational surrogacy include the transferring of the fertilized eggs from an infertile couple wanting a child into the uterus of a woman other than the wife (so-called host

mother) and the artificial insemination of the sperm from the husband into the uterus of a woman other than the wife (so-called surrogate mother). The former is the prevailing form of gestational surrogacy among the cases in the world.

Gestational surrogacy in both forms involves various problems affecting the welfare of the child. Article 35 of the Convention on the Rights of the Child (adopted by the United Nations General Assembly in 1989) prohibits “the abduction of, the sale of or traffic in children for any purpose or in any form,” and some consider that a gestational surrogacy contract infringes this provision.

The report of the Health Sciences Council Assisted Reproductive Technology Committee (April 2003) states that gestational surrogacy is prohibited and the practice of gestational surrogacy and mediation thereof should be regulated using penalties. The pronouncement of JSOG and the proposal of Japan Federation of Bar Associations also disapprove of gestational surrogacy. The act of mediating the practice of gestational surrogacy for profit or assisting in such mediation, as well as taking part in the practice of reproductive medicine anticipating gestational surrogacy, is unethical, and should not be conducted.

## 2. Preimplantation genetic diagnosis

Preimplantation genetic diagnosis (PGD) is a medical procedure requiring exceedingly sophisticated technology. It is practiced as clinical studies only after ethical review of individual cases.

PGD is the procedure in which a blastomere is placed under the microscope from the early embryo produced by in vitro fertilization, and specific genes in the cell are analyzed to make a diagnosis. It is used for the purpose of avoiding serious genetic diseases in the child and habitual abortion.

More than 4,000 cases have been performed in the world. In Japan, 31 cases at 6 facilities have been approved by the individual case review of JSOG since 2004. On the other hand, strong objection to this technology exists in society, considering it leads to the selection of lives.

The practice of PGD involves the use of techniques imposing burden on the mother’s body, such as the induction of ovulation, ovum collection, and embryo transfer. In addition, there are many problems such as the risk of complications

and adverse effects, the effect of blastomere removal on the embryo, the accuracy of diagnosis, and bioethical issues. For this reason, PGD should be practiced only after individual cases are examined by the IRB of each facility and also by JSOG, and the practice should be limited to the physicians and medical institutions having advanced knowledge and skill in reproductive medicine.

Couples desiring PGD should undergo the process of sufficient explanation and informed consent, and receive genetic counseling from professions having expert knowledge in clinical genetics. This technology must not be used for non-medical purposes (e.g., choosing the gender of the child to satisfy the wishes of the couple).

## Chapter 4: Research Involving Human Subjects and Advanced Medicine

### 1. Advanced technology and medical ethics

Physicians should constantly and independently consider what the way should be to develop and practice advanced medical technologies. When they opt to use such technologies, they should perform medical procedures on their own responsibility after carefully listening to what the patients want, discussing with patients, and obtaining the written consent. It is only when the physician respects the wishes of the patient and the patient has trust in the medical knowledge and humanistic qualities of the physician that advanced medical technologies can develop soundly in society without lack of direction.

Physicians, as researchers in the medical profession, must observe the following principles in conducting research involving human subjects.

- (1) Consideration for the safety, welfare, and rights of the persons involved in research (hereinafter referred to as “subjects”) must take precedence over consideration for the benefit of research and the benefit to society.
- (2) Physicians must not conduct research unless the benefit to the patient that can justify expected risk is confirmed by an independent IRB consisting of appropriate members.
- (3) Physicians must submit a report to the IRB concerning the sources of research fund, sponsors, institutional affiliations, and other potential conflicts of interest.
- (4) To ensure the voluntariness of the subjects’

participation in research, the subject should not be paid compensation for the participation in research. Parts of the human body used in research or the information concerning them should not be treated as an object of non-gratuitous transaction. However, payment of the costs required for participation, as well as the costs of storage, processing, transport, etc., is allowed within fair limits.

- (5) Physicians must obtain informed consent from subjects in advance, sufficiently considering the Declaration of Helsinki. Persons with impaired decision-making ability should be given special consideration according to the Council for International Organizations of Medical Sciences (CIOMS) Guidelines and the Declaration of Helsinki.
- (6) In the event of health injury in subjects resulting from the participation in research, physicians must do their best to treat the patients.
- (7) In disclosing research information and presenting research results, physicians should pay sufficient attention to protect personal information concerning subjects based on the Personal Information Protection Act enforced in 2005.
- (8) In publishing research results, authors and publishers must clearly declare the sources of research funds, institutional affiliations, and potential conflicts of interest.

## 2. The WMA Declaration of Helsinki— Ethical principles for medical research involving human subjects

The Declaration of Helsinki is an international declaration defining the ethical principles that all persons taking part in research, including physicians, must observe in conducting medical research involving human subjects (hereinafter referred to as “medical research”). The core of the Declaration is the protection of the human rights of subjects in medical research. It is so named because it was adopted by the 1964 WMA General Assembly in Helsinki. The 2004 Declaration was developed through major revisions by the 1975 WMA General Assembly in Tokyo and the 2000 WMA General Assembly in Edinburgh.

The five important basic principles of the Declaration are: “the precedence of the welfare of patients and subjects,” “voluntary participation in research based on the free will of subjects,” “the need to obtain informed consent,” “advance

examination and continued monitoring by a research ethics committee,” and “the need for medical research to conform to scientific principles and be based on laboratory experimentation.” The 2000 revision in Edinburgh expanded the coverage of the Declaration from physicians to all researchers, and the object of protection from human beings to the materials, genes, and medical information derived from human beings. As a result, the range of research covered by the Declaration was expanded considerably.

The Declaration of Helsinki has become established as international ethical principles that must be observed by all persons related to medical research, and the adherence to and respect for the Declaration is proclaimed in various aspects of medical research around the world. In Japan, its spirit is embodied through the ICH-GCP agreement in the Ministry Order regarding new drug development under the Pharmaceutical Affairs Act. In addition, adherence to the Declaration of Helsinki is proclaimed in the Ethical Guidelines Concerning Clinical Research defined by the MHLW, the rules of the research ethics committees of medical universities and national and public research institutions, and various medical research guidelines made by the government.

## 3. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects

The CIOMS, in collaboration with the WHO, published International Ethical Guidelines for Biomedical Research Involving Human Subjects in 1982 for the purpose of promoting and establishing the Declaration of Helsinki, which is the international guidelines for research involving human subjects, in developing countries. This publication has been revised twice in accordance with the major amendments to the Declaration of Helsinki. The current version published in 2002 is based on the major revision of the Declaration of Helsinki by the 2000 WMA General Assembly in Edinburgh. It contains 21 specific guidelines with a commentary on each guideline. In addition to covering the important paragraphs in the Declaration of Helsinki, the CIOMS Guidelines stipulate the obligation to provide compensation for injury in subjects, and the need for ethical considerations to protect vulnerable groups, including women, children, and people in developing countries. This publication must be read by all persons

engaging in clinical research and those working in collaboration with researchers in developing countries.

#### 4. New drug development and GCP

Because a drug is a substance that acts in the human body, the process of new drug development necessarily involves study to evaluate the safety and efficacy through actual use on human subjects. Such study is a form of human experimentation, and is an inevitable step in the process of research. Many countries have therefore adopted a system where basic research and animal experimentation are followed by safety study on healthy persons and then by the study on safety and efficacy in patients, and where the drug is approved only when it is proved to have an appropriate level of efficacy. This system has been adopted as the standards to be observed in the process of new drug development called “Good Clinical Practice for Trial of Drugs (GCP)” in Western countries since the latter half of the 1970s, following the adoption of the Declaration of Helsinki.

In Japan, the Ministry of Health and Welfare established the Standards for the Implementation of Clinical Trials on Pharmaceutical Products (the GCP Standards) in October 1989 and enforced them in October 1990. After the international agreement on ICH-GCP Standards realizing international harmonization of standards for new drug development was reached in May 1996, the Ministry amended the Pharmaceutical Affairs Act and issued the Ordinance Regarding the Good Clinical Practice (the New GCP) in 1996, which came into effect on April 1, 1997. The New GCP standards are playing extremely important roles in the protection of the human rights of research subjects.

#### 5. Conflicts of interest in clinical research

Clinical research institutions and related academic organizations, as well as individual researchers (physicians), are making great contributions to the advancement of prevention, diagnosis, and treatment of diseases through educational activities and clinical research. However, because clinical research involves human subjects, it should be conducted with the assurance of ethical and scientific qualities from the standpoint of protecting the human rights, lives, and safety of research subjects, who are in a vulnerable position.

The practice of clinical research frequently involves monetary relationship with sponsors and affiliated research institutions within industry-academia collaboration, and it is often the case that the outcomes of research are directly connected to the interest of sponsors and other parties. However, the presence of conflicts of interest in individual researchers is not a problem in itself. The presence of serious conflicts of interest may lead to situations in which research subjects may suffer undue disadvantages, researchers may conduct inappropriate clinical study, or distorted research results may be presented because of the intents of funding sources. Therefore, researchers are required to observe the organizational guidelines regarding conflicts of interest, to disclose the information about the monetary benefit and other related benefits (positions, interests, etc.) appropriately on a self-reporting basis within the organization, and to act appropriately in the execution of clinical research and the publication and provision of results. While this is basically a matter of conscience of individual researchers, all researchers must conform to the guidelines and generally comply with the standards indicated in the guidelines.



**The Committee on Medical Ethics and Quality Improvement  
of the Japan Medical Association  
(As of March 2008)**

**Chair**

Yasuhiko MORIOKA      Honorary Director, Japanese Red Cross Medical Center  
Advisor, Japan Medical Association

**Members** (*Alphabetical order*)

Yoshinori BANDO      Board Member, Kagawa Medical Association  
Hideto EMOTO      Board Member, Tokyo Medical Association  
Norio HIGUCHI      Professor of Law, University of Tokyo  
Akisato IWATA      Chairman, Medical Forum  
Toshihiko KATO      Advisor, Nagoya Medical Association  
Hirohisa KAWAHARA      Board Member, Aichi Medical Association  
Kiyokazu KOKUBU      Board Member, Nara Medical Association  
Toyokazu KUMAGAI      Vice-President, Gifu Medical Association  
Tadayoshi KUSANO      President, Research Institute for Advancement of Living Standards  
Mariko KUSUMOTO      Executive Officer, Japanese Nursing Association  
Saku MACHINO      Professor, Graduate School of Law, Sophia University  
Nobumitsu OKITA      President, Saga Medical Association  
Yutaro ONISHI      President, Nagano Medical Association  
Fumimaro TAKAKU      President, Japanese Association of Medical Sciences  
President, Jichi Medical University  
Yuzo TAKAYA      Vice-President, Fukushima Medical Association  
Hiroyuki TSUCHIYA      Vice-President, Tochigi Medical Association  
Mitsunori UENO      Board Member, Hokkaido Medical Association  
Kazuki YAMADA      Board Member, Wakayama Medical Association

**Expert Members**

Saburo SONE      Research Director, Institute of Health Biosciences,  
University of Tokushima Graduate School  
Tatsuo KUROYANAGI      Lawyer and Legal Advisor, Japan Medical Association  
Akihiko OKUDAIRA      Lawyer and Legal Advisor, Japan Medical Association

**Observers**

Rintaro SAWA      Research Director, Japan Medical Association Research Institute  
Koji BANNO      Visiting Researcher, Japan Medical Association Research Institute  
Wataru MIZUTANI      Senior Researcher, Japan Medical Association Research Institute