

*Revised January, 2020*

## **Article I. Name and Purpose**

**Sect. 1.** The name of this organization shall be the International Society for Developmental Psychobiology, Inc.

**Sect. 2.** The purposes of this Society shall be:

(a) To promote and encourage research on the development of behavior in all organisms including man, with special attention to the effects of biological factors operating at any level of organization. Such research may involve both descriptive and experimental methods and be undertaken under either natural or controlled conditions.

(b) To facilitate communication of research results and theory in the area of Developmental Psychobiology through the use of both professional and popular printed media and through the presentation of papers at meetings of the Society.

(c) To foster application of the valid findings of research to human affairs in a way beneficial to mankind.

## **Article II. Membership**

**Sect. 1.** There shall be four categories of membership in the Society: Member, Student Member, Early Career Member and Retired/Spouse Member.

**Sect. 2.** Members shall be persons who (a) hold a doctoral degree and (b) present satisfactory evidence of having made a substantial contribution to the academic literature in the field of human or animal behavior or biology. Established independent researchers in the field not meeting requirement (a & b) listed above, and desiring full member status must be accepted by unanimous vote of the Executive Committee.

**Sect. 3.** Student Member shall be persons who hold a baccalaureate degree and who are full-time workers in a research setting or who are registered as full-time candidates for a baccalaureate or higher degree who wish to participate in the activities of the Society. An application for Student membership shall be sponsored by a Member of the Society, or a faculty or professional member of the institution in which the applicant is situated. Student Member shall be voting members of the Society but may not stand for office in the Society, except for the office of Student Member Representative.

**Sect. 4.** Early career members shall be persons who have received their doctoral degree within the past seven years (i.e. postgraduate students). This includes those in their first seven years after receiving their Ph.D. including those teaching as an adjunct, instructor, or assistant professor. Early career members also include any postgraduate student engaged at least half-time with a formal postdoctoral fellowship or traineeship, or who is in an intern or resident position in any discipline. Early career members may not have previously been a regular member in the

Society. Early career membership is limited to seven years (regardless of career position), but may be extended by 1 year due to parental leave.

**Sect. 5.** Retired/Spouse Member shall be former, Full or Student Members who have retired but who wish to maintain contact with the Society. Upon retirement, members may request Retired/Spouse Member status. They will be required to pay dues to the Society but will not be required to subscribe to the Journal.

**Sect. 6.** Membership shall become effective following submission of all required materials and upon the receipt of dues for current fiscal year and notification of acceptance by the Secretary who will review the submitted materials.

### **Article III. Officers**

**Sect. 1.** The officers of this Society shall consist of a President, a President-elect, a Past-President, a Secretary, a Treasurer, a Program Officer, a Conference Coordinator, three board Members, a Representative to the Federation of Associations in Behavioral & Brain Sciences (FABBS) one or two student Member Representatives, a Historian, a representative of the International Perinatal Brain and Behavior Network and, in the years when they have been elected, a Secretary-elect, a Treasurer-elect, a Program Officer-elect, and a Conference Coordinator-elect. The voting members shall include all non-student officers.

**Sect. 2.** The term of the office of the President shall be two years, preceded by two years as President-elect; the term of the President-elect shall be two years; the term of the Past-President shall be two years preceded by two years as President; the term of the Secretary shall be three years preceded by one year as Secretary-elect; the term of the Secretary-elect shall be one year; the term of the Treasurer shall be three years preceded by one year as Treasurer-elect; the term of the Treasurer-elect shall be one year; the term of the Program Officer shall be three years preceded by one year as Program Officer-elect; the term of the Program Officer-elect shall be one year; the term of the Conference Coordinator shall be three years preceded by one year as Conference Coordinator-elect; the term of the Conference Coordinator-elect shall be one year; the term of Representative to the Federation of Associations in Behavioral & Brain Sciences (FABBS) shall be three years; the terms of the board members not serving ex officio shall be three years each; except on the first election board member shall be assigned by lot to 1, 2, or 3 year terms, so that thereafter only one such board member be elected each year, and the term of the Student Member Representative(s) shall be two years. The terms of the historian and Representative of the International Perinatal Brain and Behavioral Network shall be three years. No officer of the Society may succeed himself/herself in the same office without one year intervening between terms, unless there are no other nominees or candidates for that position.

**Sect. 3.** It shall be the duty of the President to preside at all official meeting of the Society, to act ex officio as Chairperson of the Board of Directors, to exercise Supervision of the affairs of the Society with the Approval of the Board of Directors and to perform such other duties as are incident to the office or as may properly be required of him/her by vote of the Board of Directors.

**Sect. 4.** It shall be the duty of the President-elect in the absence or incapacity of the President to assume the duties of the President.

**Sect. 5.** It shall be the duty of the Past-President in the absence or incapacity of the President-elect to assume the duties of the President-elect.

**Sect. 6.** It shall be the duty of the Secretary to keep all records of all meetings of the Society, to issue calls and notices for meetings and nominations, to publish a newsletter, to issue application forms for membership in the Society, to gather all required forms for membership in the Society, and to gather all required information pertaining thereto, and to act as Secretary of the Board of Directors and Executive Committee.

**Sect. 7.** It shall be the duty of the Secretary-elect to assist the Secretary, to become familiar with the duties and responsibilities of the office of Secretary, and, in the absence or incapacity of the Secretary, to assume the duties of the Secretary.

**Sect. 8.** It shall be the duty of the Treasurer to have custody of all funds and properties of the Society, to collect dues, to make disbursements as authorized by the Board of Directors, to present in a written report to the Board of Directors at its annual meeting a summary of the assets and expenditures of the preceding fiscal year, and to file such income tax returns as is necessary for the Society. The fiscal year of the Society shall terminate on December 31 of each year.

**Sect. 9.** It shall be the duty of the Treasure-elect to assist the Treasure, to become familiar with the duties and responsibilities of the office of Treasure, and, in the absence or incapacity of the Treasure, to assume the duties of the Treasure.

**Sect.10.** It shall be the duty of the Program Officer to preside over a Program Committee consisting of the Executive Committee of the Society in order to plan and arrange programs for the scientific meetings of the Society.

**Sect. 11.** It shall be the duty of the Program Officer-elect to assist the Program Officer, to become familiar with the duties and responsibilities of the office of Program Officer, and, in the absence or incapacity of the Program Officer, to assume the duties of the Program Officer.

**Sect. 12.** It shall be the duty of the Conference Organizer to make arrangements regarding the time, place and organization of the scientific meetings of the Society.

**Sect. 13.** It shall be the duty of the Conference Organizer-elect to assist the Conference Organizer, to become familiar with the duties and responsibilities of the office of Conference Organizer, and, in the absence or incapacity of the Conference Organizer, to assume the duties of the Conference Organizer.

**Sect. 14.** It shall be the duty of the Representative of the Federation of Associations in Behavioral & Brain Sciences (FABBS), to attend the annual meeting of that Federation, respond to the requests for information from the Federation and report to the Board of Directors(at the annual Board Meeting) and the membership (at the annual business meeting) on the activities of

the Federation. The Society shall, if necessary, provide travel funds not exceeding the amount of \$500.00 per year to the Representative to cover his/her expenses in attending the annual meeting of the Federation. It shall be understood that the Representative undertakes the office with full knowledge that any expenses over \$500.00 must be assumed by him/her personally.

If the Representative cannot attend the annual meeting of the Federation, an alternative may be designated with the approval of the President.

**Sect. 15.** It shall be the duty of the Student Member Representative to represent the Student members to Board of Directors.

**Sect. 16.** In the case of the death, incapacity or resignation of any officer, the Board of Directors shall by majority vote, except as provided in Art. III, Sects. 4 5, 7, 9, 11 and 13, elect a successor to serve pro tempore until the end of the next annual meeting of the Society.

**Sec 17.** The three board members should each be the chair of one of the standing committees: sponsorship committee (1st year), science communications committee (2nd year) and awards committee (3rd year). Further, the historian will be the chair of the history committee and the program-director will be chair of the program committee and they will report to the board about the activities of those committees.

#### **Article IV. Board of Directors**

**Sect. 1.** The officers of the Society, as provided in Art. III, Sect. 1, and 3 Directors not serving ex officio, shall compromise the Board of Directors, which is empowered to conduct the business of the Society between meetings.

**Sect. 2.** The President shall be ex officio Chairperson of the Board of Directors, and the Secretary shall be Secretary of the Board of Directors.

#### **Article V. Nominations and Elections**

**Sect. 1.** When an office is scheduled to fall vacant, the Nominations Committee shall through the Secretary present to the membership by mail ballot, the names of qualified individuals, willing to serve, who are members in good standing. The Secretary shall tabulate and record the vote, and notify the candidates and the Board of Directors of the results of the election. The general membership shall also be apprised of the results within 30 days.

**Sect. 2.** Incoming Officers shall assume office on the first day after the close of the annual meeting of the Society. All officers shall hold office until their successors are elected and accept office.

**Sect. 3.** If any Officer fails to accept election or to assume office, the Board of Directors may, by majority vote, elect a successor to serve pro tempore until the end of the next annual meeting of the Society.

**Sect. 4.** The President of the Society shall be so considered elected to the Office of Past-President upon expiration of his/her term as President.

**Sect. 5.** The President-elect of the Society shall be considered elected to the Office of President upon expiration of his/her term as President-elect.

**Sect. 6.** The Secretary-elect of the Society shall be considered elected to the Office of Secretary upon expiration of his/her term as Secretary-elect.

**Sect. 7.** The Treasurer-elect of the Society shall be considered elected to the Office of Treasurer upon expiration of his/her term as Secretary-elect.

**Sect. 8.** The Program Officer-elect of the Society shall be considered elected to the Office of Program Officer upon expiration of his/her term as Program Officer-elect.

**Sect. 9.** The Conference Organizer-elect of the Society shall be considered elected to the Office of Conference Organizer upon expiration of his/her term as Conference Organizer-elect.

## **Article VI. Meetings**

**Sect. 1.** The Society shall hold at least one regular scientific and one regular business meeting per year, the time and place of meetings to be determined by the Board of Directors. In addition, the Board of Directors may by majority vote call a meeting of the membership when it considers such a meeting to be necessary or beneficial to all members of the Society.

**Sect. 2.** Whenever possible, scientific meetings shall be arranged in cooperation with other scientific organizations whose meetings Society members frequently attend. Such meetings held in conjunction with other organizations shall be designed to foster understanding and scientific interchange between Society members and specialists in other disciplines according to the purposes set forth in Art. 1, Sect. 2., of this constitution.

**Sect. 3.** Notice of scientific meetings of the Society shall be mailed to the membership at least 4 months before the date set for the meeting; in the case of business meeting of the membership, at least one month.

**Sect. 4.** The purposes of Society meetings shall be the presentation of scientific research papers, the transaction of business, and the discussion of such other matters as may come before the Society.

**Sect. 5.** All members and Students Members of the Society shall be eligible to present papers at scientific meetings. The Program Committee may invite persons, whether members or not, to present papers in the general area of interest to members.

**Sect. 6.** A quorum of meetings of the Board of Directors shall be a majority of the elected officers present and voting. A quorum at business meetings of the Society shall be 10% or 20

members, whichever is smaller. All actions of the officers and the Board of Directors shall be reported to the membership at the annual business meeting.

**Sect. 7.** The Board of Directors shall decide the times and place of all meetings, with the exception the meetings of the Board of Directors may also be called at any time by the President.

**Sect. 8.** The rules contained in 0. Garfield Jones, Parliamentary Procedure at a Glance, 1949, Meredith Press, 1716 Locust Street, Des Moines, Iowa 50303, shall, except when abrogated by special rules of order adopted by the Society, govern the conduct of all meetings.

## **Article VII. Committees**

**Sect. 1.** The committees of the Society shall consist of such standing committees provided in the Constitution and Bylaws and such special committees as created by the President.

**Sect. 2.** The President, Past-President and President-elect will serve as an Executive Committee, to handle such matters as deemed necessary by the President between yearly meetings of the Board of Directors. One of the functions of the Executive Committee shall be to vote on petitions from individuals requesting full membership in the Society who do not meet normal membership requirements.

**Sect. 3.** The Executive Committee shall serve as a Nominations Committee for all elected Officers of the Society. The Nominations Committee shall obtain input from the Student Members for nominations for the Office of Student Member Representative. The President of the Society shall serve as the Chairperson of the Nominations Committee.

**Sect.4.** Any member in good standing may initiate the formation of committees and committee activities by request for authorization and approval by the Board of Directors at any time, or by the membership at the annual business meeting. The Chairperson for any committee so formed shall be appointed by the President (See Art. VII, Sect. 1).

## **Article VIII. Dues and Assessments**

**Sect. 1.** The Society shall be empowered to collect annual dues and other assessments of special dues as recommended to the membership by the Board of Directors.

**Sect. 2.** Members and Student members shall be dropped automatically from membership for nonpayment of dues over two consecutive years following notification by the Secretary through regular dues notices. Former members and Student members shall be reconsidered for reinstatement upon reapplication to the Society.

## **Article IX. Amendments to the Constitution**

**Sect. 1.** Amendments to the constitution may be proposed by a majority vote of the Board of Directors, or by a written petition submitted to the Secretary. Such petition shall bear the signature of 15 or more members of the Society. Proposed amendments to the constitution must

be submitted to all members by mail or electronically. To be carried, such amendments must be confirmed by 67 percent of the total number of members voting, as indicated in returned, marked mail or electronic ballots received by a stated deadline.

## **Article X. General Considerations**

**Sect. 1.** Notwithstanding any other provision of these **articles, the association is organized** exclusively for one or more of the following purposes: religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children animals, as specified in Section 501(c)(3) of the Internal Revenue Code of 1954.

**Sect. 2.** No part of the net earnings of the association shall inure to the benefit of any member, trustee, director, officer of the association or any private individual (except the reasonable compensation may be paid for services rendered to or for the association, and no member, trustee, officer of the association or any private individual shall be entitled to share in the distribution of statements), any political campaign on behalf of any candidate for public office.

**Sect. 3.** No substantial part of the activities of the association shall be carrying on propaganda, or otherwise attempting to influence legislation (except as provided by Internal Revenue Code Section 501 (h)), or participating in, or intervening in (including the publication or distribution of statements), any political campaign on behalf of any candidate for public office.

**Sect. 4.** In the event of dissolution, all of the remaining assets and property of the association shall after necessary expenses thereof be distributed to such organizations as shall qualify under Section 501 (c)(3) of the Internal Revenue Code of 1986, as amended, or, to another organization to be used in such a manner as in the judgment of a justice of the Supreme Court of the State of New York will best accomplish the general purposes for which this association was formed.

## **Article XI. Founding of the Society**

**Sect. 1.** The Society shall be deemed to have been founded as of the date of the first annual meeting, 1967.

**Sect. 2.** The Founding Members of the Society are: Joseph Altman, James E. Birren, Wagner H. Bridger, Victor H. Denenberg, Samuel Eiduson, R.J. Ellingson, John L. Fuller, Herman Harvey, B. J. Key, John A. King, William A. Mason, Gilbert W. Meier, Howard Moltz, Grant Newton (Chairman), Hanus Papousek, Mark Rosenzweig, F. J. Schulte, J. P. Scott.

## **Article XII. Distribution of Assets Upon Winding Up**

Upon the dissolution of the corporation, assets shall be distributed for one or more exempt purposes within the meaning of section 501 (c) (3) of the Internal Revenue Code, or the corresponding section of any future federal tax code, or shall be distributed to the federal government, or to a state or local government, for a public purpose. Any such assets not so

disposed of shall be disposed of by a Court of Competent Jurisdiction of the county in which the principal office of the corporation is located, exclusively for such purposes or to such organization or organizations, as said Court shall determine, which are organized and operated exclusively for such purposes.

### **Article XIII. Developmental Psychobiology**

**Sect. 1.** The official journal of the Society is Developmental Psychobiology under contractual arrangement with its Publisher, Wiley & sons, Inc., 605 Third Avenue, New York, NY 10158. The Society will adhere to the terms of said contract terms, including the right to cancel the contract under the termination provisions set from within.

**Sect. 2.** During the year preceding the termination of the Journal Editor's term, the Executive Committee (President, Past-President, President-elect) shall act on behalf of the Society to nominate an Editor-in -chief for the Journal. To initially appoint the Editor for a mutually agreed upon term, normally 5-years, the contract between the Journal and the Editor must include signatures from all three members of the Executive Committee. To renew such appointment, if agreed upon by the Editor, all three members of the Executive Committee must again sign the contract. Typically, the Editor appoints the Associate Editors. The Editor also appoints the Editorial Board, although under the contractual arrangement with the Publisher the Society retains the right to nominate individuals for the Editorial Board to the Publisher for approval.

**Sect. 3.** The Society agrees that a subscription to the Journal is an integral part of membership in the Society. Accordingly, subscription fees are incorporated in the dues structure of the Society for all members other than spouses, Retired/Spouse Member and hardship cases who may be exempted from the subscription requirement up to a maximum of five percent of the membership. To request an exemption on the basis of financial hardship, members must apply formally in writing to the Board of Directors.

## **Subject Protection in Research**

[International Society for Developmental Psychobiology's Principles for the Use of Animals in Research](#) (ISDP's Principals)

[The Helsinki Declaration](#)

[Association for the Accreditation of Human Research Protection Programs](#) (AAHRPP)

### **ISDP Principles for the Use of Animals in Research:**

The purpose of the Society is to promote research and communicate research results on the development of behavior in order to advance knowledge and alleviate suffering for the benefit of mankind. We pledge to acquire, care for, use, and dispose of all animals in compliance with all relevant laws and regulations. Where such regulations are inadequate for the very young animals, we will use special procedures that minimize discomfort, pain and distress.



## **Four principles guide the use of animal research:**

(1) Animals are used to enable researchers to answer questions and solve problems that cannot realistically be addressed without their use.

(2) Animals are treated humanely during all phases of research. When experimental procedure requires stressful stimulation, it will be applied judiciously to meet the objective of the experiment while minimizing distress.

(3) Healthy animals are the best subjects for studies on live animals; they give the most reliable data, thereby reducing the overall number of animals needed to provide meaningful and reliable experimental findings.

(4) The primary investigator responsible for day-to-day conduct of the research is responsible for appropriate care and use of each animal. Personnel working with animals should be supervised by well-trained and experienced scientists who are familiar with government regulations and aided by a veterinary staff, trained animal care technicians and appropriate institutional facilities and policies. Members of ISDP subscribe to the guidelines for use of animals developed by organizations such as the American Psychological Association, Animal Behavior Society, and Society for Neuroscience. However, members of ISDP frequently apply treatments to or make measurements on fetal and neonatal animals. We recognize that very young animals have limited behavioral and physiological special needs for maintenance of body temperature, adequate nutrition, and social development. Therefore, we will use additional vigilance to ensure that conditions for the care and use of very young animals minimize discomfort.

A copy of these principles should be posted in laboratories where members of ISDP conduct research.

## **World Medical Association Declaration of Helsinki**

### **Ethical Principles for Medical Research Involving Human Subjects**

Adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

[A. Introduction.](#)

[B. Basic Principles for all Medical Research.](#)

[C. Additional Principles for Medical Research Combined with Medical Care.](#)

### **A. Introduction**

The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

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## **B. Basic Principles for all Medical Research**

It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

The subjects must be volunteers and informed participants in the research project.

The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

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### **C. Additional Principles for Medical Research Combined with Medical Care**

The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.

At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgment it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.