Fundamental Principles for Research Involving Human Subjects

1. Physicians conducting medical research have a fundamental duty to protect the life, health, privacy, and dignity of all human participants.
2. Research involving human subjects must adhere to widely accepted scientific standards. It should be grounded in a comprehensive understanding of existing scientific literature, relevant data sources, and appropriate preliminary work, including laboratory studies and, where applicable, animal experimentation.
3. Researchers must exercise due caution in studies that may impact the environment. The welfare of animals used in research must also be respected.
4. Every research procedure involving human participants must be clearly outlined in a written protocol. This protocol must be submitted for review, comment, and, where necessary, approval by an independent ethics committee. This committee must operate free from influence by the investigator, sponsors, or other external parties and should comply with the laws and regulations of the host country. The committee must have the authority to oversee ongoing studies. Researchers are responsible for providing monitoring updates, particularly in cases of serious adverse events. Information on funding sources, sponsorship, institutional affiliations, conflicts of interest, and subject incentives must also be disclosed to the committee.
5. The research protocol must explicitly state the ethical considerations involved and demonstrate adherence to the principles of this Declaration.
6. Human subject research must be conducted by scientifically qualified individuals and supervised by a medically competent professional. Responsibility for participant welfare must rest solely with medically trained personnel, never with the participants themselves, regardless of consent.
7. Every study involving human subjects must be preceded by a thorough risk-benefit analysis. This includes predictable risks and burdens compared to anticipated benefits for the participant or others. Healthy volunteers may still participate, and all study designs should be made publicly accessible.
8. Physicians must not initiate research unless they are confident that the risks have been thoroughly assessed and can be responsibly managed. Investigations should be terminated if risks outweigh potential benefits, or if conclusive, beneficial results are obtained.
9. Research should only proceed if the value of the objective justifies the inherent risks and burdens to participants. This is especially crucial when healthy volunteers are involved.
10. Research is ethically acceptable only if there is a reasonable expectation that the population involved will benefit from the findings.
11. Participation must be entirely voluntary and based on fully informed consent.
12. The right of participants to preserve their personal integrity must always be respected. All necessary steps must be taken to safeguard privacy, maintain confidentiality, and minimize any physical or psychological impact of the research.
13. All prospective participants must be thoroughly informed of the study's goals, methodology, funding sources, potential conflicts of interest, institutional affiliations, expected benefits, possible risks, and any associated discomfort. They must be made aware of their right to refuse or withdraw from the study at any time, without penalty. Once comprehension is confirmed, informed consent must be obtained, preferably in writing. If written consent is not feasible, a formal, witnessed record of verbal consent is required.
14. When the subject is in a dependent relationship with the physician or may be subject to coercion, special care must be taken to obtain informed consent. In such cases, consent should be obtained by an impartial and knowledgeable physician who is not involved in the study.
15. For individuals who are legally incompetent or physically or mentally incapable of giving consent—including minors—consent must be obtained from a legally authorized representative, in accordance with local laws. These individuals should only be included in research when it is essential for advancing the health of the population they represent and when the research cannot be conducted with competent individuals.
16. When legally incompetent individuals, such as minors, are capable of providing assent, this assent must be obtained alongside consent from their legal representative.
17. Research involving individuals who cannot give consent—directly or via a proxy—may only be conducted if their condition is an essential characteristic of the research population. The justification for including such participants must be clearly detailed in the study protocol and submitted for ethical review. Where possible, consent to continue participation must be obtained as soon as feasible from the individual or a legally authorized surrogate.
18. Both authors and publishers share ethical responsibilities. Researchers are required to report their findings accurately. Both positive and negative results should be published or otherwise made publicly accessible. Sources of funding, institutional affiliations, and potential conflicts of interest must be disclosed. Studies that fail to comply with the principles of this Declaration should not be accepted for publication.

Additional Principles for Research Combined with Medical Care

1. Physicians may combine medical care with research only when the research is justified by its potential preventive, diagnostic, or therapeutic value. In such cases, additional protections are required for the patients involved as research subjects.
2. The benefits, risks, burdens, and efficacy of any new method must be tested against those of the best available preventive, diagnostic, or therapeutic interventions. Placebos or the absence of treatment may be used in studies only where no proven method exists.
3. Upon completion of the study, every participant must be assured access to the best proven interventions identified through the research.
4. Physicians must clearly inform patients which aspects of their care are part of the research. A patient's refusal to participate must never compromise the physician–patient relationship.
5. When no proven preventive, diagnostic, or therapeutic options exist—or when existing ones have failed—the physician, with informed patient consent, must be free to use unproven or novel methods if there is reasonable hope of benefit. Where feasible, these interventions should become subjects of research to evaluate their safety and effectiveness. All new data should be documented and, where appropriate, published. The principles of this Declaration must continue to be observed in such cases.