## 7.1.5 Misconduct in Research

Biomedical and health research is intended to advance medical knowledge to benefit future patients. To achieve those goals physicians who are involved in such research maintain the highest standards of professionalism and scientific integrity.

Physicians with oversight responsibilities in biomedical or health research have a responsibility to ensure that allegations of scientific misconduct are addressed promptly and fairly. They should ensure that procedures to resolve such allegations:

- (a) Do not damage science.
- (b) Resolve charges expeditiously.
- (c) Treat all parties fairly and justly. Review procedures should be sensitive to parties' reputations and vulnerabilities.
- (d) Maintain the integrity of the process. Real or perceived conflicts of interest must be avoided.
- (e) Maintain accurate and thorough documentation throughout the process.
- (f) Maintain the highest degree of confidentiality.
- (g) Take appropriate action to discharge responsibilities to all individuals involved, as well as to the public, research sponsors, the scientific literature, and the scientific community.

# AMA Principles of Medical Ethics: I,III,V

*Opinion 7.1.5, Misconduct in Research, re-organizes content from previous guidance and associated background reports:* 

CEJA Report 9-A-04 Guidelines to prevent malevolent use of biomedical research

Report of the Judicial Council A-A-66 Declaration of Helsinki

# REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS $^{\ast}$

Subject:	Guidelines to Prevent Malevolent Use of Biomedical Research
Presented by:	Michael Goldrich, MD, Chair
Referred to:	Reference Committee on Amendments to Constitution and Bylaws (Mary W. Geda, MD, Chair)

1 INTRODUCTION

2

3 In February 1975, a group of leading scientists, physicians, and policymakers convened at 4 Asilomar, California, to consider the safety of proceeding with recombinant DNA research. The excitement generated by the promise of this new technology was counterbalanced by concerns 5 6 regarding dangers that might arise from it, including the potential for accidental release of genetically modified organisms into the environment. Guidelines developed at the conference to 7 8 direct future research endeavors had several consequences. They permitted research to resume, 9 bringing to an end the voluntary moratorium that the National Academy of Sciences (NAS) had instituted several months earlier. They also served to illustrate that the scientific community was 10 capable of self-governance, thereby securing public trust and persuading Congress not to institute 11 legislative restrictions.<sup>1</sup> Finally, they underscored the importance of weighing unforeseen risks 12 inherent in some research against potential benefits that may arise from these same endeavors. 13 14 15 In February 2000, a second meeting was held at Asilomar, bringing together members from the same groups, including some of the original attendees.<sup>2</sup> This meeting was held in honor of the 16

17 historic event's 25<sup>th</sup> anniversary and in recognition of the scientific community's increasing 18 attention to the potentially harmful applications of biotechnology in general – for example, to

facilitate the use of pathogens as deadly weapons.<sup>3</sup> Risk of this latter sort that arises not from

research *per se* but from its intentional misapplication for nefarious purposes constitutes the focus
of this report.

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The possibility that scientific research may generate knowledge with the potential for harmful as well as beneficial applications is not new. In recent years, however, it has become imperative to develop parameters within which to address such research, as heightened concerns have arisen from the threat of biochemical terrorism and warfare.

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28 BACKGROUND

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Physicians' involvement in biomedical research, whether clinical or pre-clinical, traditionally has
 been guided by a desire to help alleviate patient morbidity and mortality. In the AMA's *Principles* of *Medical Ethics*, research activities are grounded in obligations to advance scientific knowledge

and to contribute to the betterment of public health (*Principles V* and *VII*).<sup>4</sup> The Association's

<sup>&</sup>lt;sup>\*</sup> Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 more recent Declaration of Professional Responsibility, which has been supported by numerous

2 state and specialty medical societies, further encourages physicians to "work freely with colleagues 3 to discover, develop, and promote advances in medicine."<sup>5</sup>

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5 Though the fundamental goals of biomedical research may be morally sound, it remains that

6 researchers sometimes make discoveries that can be put to harmful, as well as beneficial, use.

7 Despite providing considerable guidance to ensure the ethical conduct of physicians engaged in

8 human subjects research,<sup>6</sup> the <u>Code of Medical Ethics</u> does not currently address the importance of

9 physicians playing a proactive role in trying to assess foreseeable consequences of their biomedical

10 research endeavors, nor does it offer a framework to assist them in doing so.

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12 In this, the Code's research guidelines may reflect the uneven impact of the Nuremberg Code, 13 which was drafted in response to wartime atrocities that Nazi physicians committed against captive 14 human subjects, under the guise of biomedical research. To prevent the recurrence of such 15 blatantly unethical "research," the Nuremberg Code set out ethical principles intended to guide all 16 future medical research involving human subjects. It focused largely on the requirement for 17 informed consent from all research subjects, rather than on possible ramifications of the research; 18 these were addressed only briefly in a statement that "experiment[s] should be such as to yield fruitful results for the good of society."<sup>7</sup> The requirement for consent has remained integral to 19 20 modern clinical research in the US. With regard to the latter provision, however, research has been 21 vetted only to ensure that it produces beneficial results, while neglecting to consider the harmful 22 ways in which the results could be misapplied. Arguably, this constituted a missed opportunity to develop normative guidance for the assessment of the goals and potential impact(s) of biomedical 23 24 research in general.

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- CLASSES OF RESEARCH WITH POTENTIAL FOR MALIGNANT APPLICATION 27

28 The development, production, stockpiling or use of biological weapons (BW) by any nation is 29 banned under the 1972 Biological and Toxin Weapons Convention (BTWC),<sup>8</sup> which has been signed by 167 nations, and ratified by 151.<sup>9</sup> Still, the World Medical Association (WMA) contends 30 that there remains "a need for the creation of and adherence to a globally accepted ethos that rejects 31 the development and use of biological weapons."<sup>10</sup> Moreover, according to the WMA, physicians 32 33 are morally obligated to play prominent roles in establishing such an ethos because biological and 34 toxin weapons (BTW) are intended to incapacitate or kill individuals, outcomes that are antithetical 35 to the professed duties of physicians. Moreover, as professionals entrusted by society to advance 36 human welfare, physician-researchers should actively speak out in condemnation of the creation 37 and use of BTW. As to participation in defensive weapons development, physicians should 38 consider the potential for offensive application of their research, and carefully weigh the risk of 39 misapplication against the risks associated with forgoing all weapons research.

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41 Additionally, researchers have begun to contend with the possibility that countless areas of biomedical research can lead to nefarious applications, and inadvertently may aid in the creation of 42 BW. A recent report from the US National Research Council (NRC), "Biotechnology Research in 43 an Age of Terrorism: Confronting the Dual-Use Dilemma,"<sup>11</sup> listed seven classes of "experiments 44

45 of concern" considered to be especially problematic due to their potential implications for the

creation and use of BW. Specifically, the NRC called attention to experiments that: 46

1 1. would demonstrate how to render a vaccine ineffective; 2 2. would confer resistance to the rapeutically useful antibiotics or antiviral agents; 3 3. would enhance the virulence of a pathogen or render a non-pathogen virulent; 4 4. would increase transmissibility of a pathogen; 5 5. would alter the host range of a pathogen; 6 6. would enable the evasion of diagnostic/detection modalities; 7 7. would enable the weaponization of a biological agent or toxin. 8 9 This list excludes many other areas of research that are less easily distinguished but equally 10 dangerous if misapplied. For example, researchers have been able to construct functional polio 11 virus particles de novo using relatively standard laboratory techniques and equipment, and freely available genetic information.<sup>12</sup> Though the potential danger of such an experiment has not been 12 overlooked,<sup>11</sup> many of the prerequisite experiments that allowed for it, such as the sequencing of 13 the polio virus genome, certainly could be considered innocuous. Similarly, genome sequencing of 14 many other pathogens, including those responsible for anthrax, Ebola hemorrhagic fever, and 15 bubonic plague, would not fall within the NRC's categorization; however, the publication of these 16 sequences in the open scientific literature,<sup>13</sup> while undeniably important to further understanding of 17 18 pathogenicity, could unintentionally facilitate the illegitimate creation and subsequent misuse of 19 these pathogens. 20 21 Categorical classifications run the risk of being either over- or under-inclusive, as a broad range of important and seemingly innocuous biomedical research could be used malevolently. This inherent 22 ambiguity necessitates that *all* biomedical research be ethically assessed. 23 24 25 PROFESSIONAL OBLIGATIONS OF PHYSICIAN-RESEARCHERS 26 27 It has been argued that pure scientific research is morally neutral and thus only its subsequent application should be subject to ethical scrutiny.<sup>14</sup> Many of the scientists whose discoveries in 28 29 atomic energy gave birth to nuclear weapons initially held this position. However, in the wake of 30 the bombings of Hiroshima and Nagasaki at the end of WWII, some of these same scientists openly 31 grappled with the possibility that they were ethically responsible in part for the destructive 32 applications of their findings. As their experience suggests, researchers may be morally accountable for harms that do not result from their research *per se*, but are borne of its applications. 33 34 35 Indeed, there is growing acceptance in the scientific community that scientists are obligated to 36 pursue knowledge both as an end in itself and as a means of improving the world for humankind. 37 For instance, the preface of the American Society for Biochemistry and Molecular Biology's 38 (ASBMB's) Code of Ethics states: 39 40 "Members of the ASBMB are engaged in the quest for knowledge in biochemical and 41 molecular biological sciences with the ultimate goal of advancing human welfare. 42 Underlying this quest is the fundamental principle of trust. The ASBMB encourages its 43 members to engage in the responsible practice of research required for such trust by 44 fulfilling the following obligations:... [including that] investigators [should] promote and follow practices that enhance public interest or well-being." 45

1 Similarly, in its Code of Ethics, the American Society for Microbiology (ASM) states that its 2 members should "aspire to use their knowledge and skills for the advancement of human 3 welfare."<sup>16</sup> With respect to the potential for malign use of research findings, the Council Policy Committee of the ASM goes further, in stating: 4 5 6 "...microbiologists will work for the proper and beneficent application of science and 7 will call to the attention of the public or the appropriate authorities misuses of 8 microbiology or of information derived from microbiology. ASM members are obligated 9 to discourage any use of microbiology contrary to the welfare of human kind."<sup>17</sup> 10 11 Unlike the ASBMB and the ASM, however, most scientific societies have not codified this notion 12 of social responsibility. Nonetheless, the obligation to preserve public trust extends to all 13 scientists, as a critical element of their collective professional responsibility. 14 15 Physician-researchers share in this obligation not only by virtue of their membership in the scientific community, but also because the preservation of public trust is a fundamental aspect of 16 medical professionalism, the moral duties of which bear upon the whole of their professional 17 18 conduct. The WMA has articulated this requirement in its Declaration of Washington on Biological Weapons, which states that "Physicians who participate in biomedical research have a 19 moral and ethical obligation to consider the implications of possible malicious use of their 20 21 findings."<sup>6</sup> Though this is an undeniably complicated undertaking, physician-researchers, who possess profound knowledge of their research and of human health and disease, are arguably in the 22 best position to assess the potential for and the ramifications of misapplications of their research. 23 24 25 Self-regulation 26 27 The Code states that "[t]he ultimate responsibility for the ethical conduct of science resides within 28 the institution (academic, industrial, public, or private) which conducts scientific research and with *the individual scientist* [emphasis added].<sup>"18</sup> In science as in medicine, individual responsibility is 29 a fundamental aspect of professionalism. To that end, physician-researchers need to understand 30 31 research ethics norms, such as scientific responsibility and integrity. Research ethics education, 32 beginning at the trainee level and extending throughout a career, can sensitize physician-33 researchers to the possibility for misapplications of scientific knowledge, and empower them to 34 make responsible assessments of the research used to generate it. Still, differences in opinion will 35 continue to arise. It is precisely because no one physician's ethical judgment is infallible that human subjects research protocols are vetted by Institutional Review Boards (IRBs). Similarly, 36 37 physician-researchers engaged in preclinical biomedical research should peer-review each others' 38 work. 39 40 Some experiments present such a degree of potential risk of harmful application that more rigorous 41 oversight may be warranted. The aforementioned NRC report firmly echoes this notion in its

42 proposal for a regulatory system that relies on both voluntary self-governance and scientific review 43 committees to provide oversight for "experiments of concern."<sup>11</sup> Other proposals have included

44 establishing registries, perhaps within the Centers for Disease Control and Prevention (CDC), of

45 researchers who are working with certain pathogens and toxins, and requiring that potentially

46 dangerous results, including inadvertent discoveries, be reported.<sup>3</sup>

To date, the US Department of Health and Human Services has created the National Science 1 2 Advisory Board for Biosecurity (NSABB) which, as part of its mandate, will develop guidelines 3 regarding appropriate oversight by local Institutional Biosafety Committees or federal officials of potentially harmful research.<sup>19</sup> Final authority over whether to accept these guidelines, however, 4 5 will reside with the federal departments and agencies that support the research. Already, classified 6 research, presumably for biodefense purposes, has been exempted from any guidelines developed 7 by the NSABB. 8

9 With the exception of research involving select agents or toxins identified by the CDC as posing a severe health threat,<sup>20</sup> formal oversight currently is mandatory only for studies and/or institutions that receive NIH funding for recombinant DNA research.<sup>21</sup> Though some privately-funded 10 11 research organizations voluntarily comply with current NIH research guidelines, and may elect to 12 13 comply with NSABB guidelines, they are not required to do so. The NSABB can seek to close the 14 significant gap in the current regulatory framework by extending the scope of federally regulated 15 research and encouraging the private sector to adopt the Board's system of oversight. Cooperation 16 between different countries' research bodies also should be promoted, since research increasingly is becoming a global enterprise. Physician-researchers will be able to play a leading role in calling 17 18 for the creation of and adherence to such global standards for research governance. 19

- 20 *Transparency*
- 21

22 In some cases, the dangers presented by research either cannot be fully appreciated before it is 23 conducted, or are the inevitable consequence of research of such importance that it must be allowed 24 to proceed nevertheless. Such dangers could be addressed by restricting the dissemination of 25 especially hazardous information. However, such restrictions may be undesirable for a number of 26 reasons. The Code, for example, emphasizes that timely publication of research is an essential element in the foundation of good medical care.<sup>22</sup> The elimination of openness in biomedical 27 28 research would not only create an aura of secrecy likely to compromise public trust in science, but 29 also would impede progress and innovation – notably within biodefense research,  $^{23}$  the development of vaccines and therapeutics necessary to effectively counter any use of BW.

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32 Under exceptional circumstances, it may be appropriate to limit accessibility to the results of 33 particular experiments. For example, the unexpected discovery of a means by which to engineer a 34 virus capable of infecting even immunized animals recently prompted a reexamination of openness in biomedical research,<sup>24</sup> on account of the potential to misuse the research's findings toward the 35 design of uniquely effective bioweapons. A group including scientist-authors, government 36 37 officials, and editors of major scientific journals was convened by the NAS to discuss these 38 concerns and issued a statement conceding that "there is information that, although we cannot now

- 39 capture it with lists or definitions, presents enough risk of use by terrorists that it should not be
- published."25 40
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42 Publication restrictions alone would likely prove ineffective, because scientific information is 43 disseminated not only through mainstream scientific literature, but also through presentations at 44 scientific meetings and increasingly on the Internet. Hence, it will be essential for members of the 45 scientific community, including physician-researchers, to consider the implications of presenting their data in any form. As an additional part of its mandate, the NSABB will be working with 46

stakeholders, including researchers and editors, to develop guidelines for the communication, in 47

1 any form, of potentially harmful research. In the absence of such guidelines, if there is any doubt 2 as to the propriety of open presentation, researchers would be wise to consult with colleagues in

- 3 deciding how to proceed.
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- 5 CONCLUSION
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7 Biomedical research is essential for providing means by which medicine can continue to advance 8 human welfare. For it to proceed responsibly, an overall ethical framework must be established 9 that seeks to balance the ability of biomedical research to generate medical innovations against 10 harms that may be incurred through its corruption, notably including its application to the 11 development of biological weapons. As scientists and medical professionals, physician-researchers should seek to play a major role in the creation of such a framework, and in the execution of any 12 13 steps that must be taken to fulfill the obligations it imposes. Chief among these steps is for physician-researchers to appreciate and advocate the need for diligence and moral fortitude in 14 assessing the ethical implications and foreseeable consequences of their research and the 15 dissemination of its findings.

- 16 17
- 18 RECOMMENDATIONS
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The Council on Ethical and Judicial Affairs proposes that the following recommendations be adopted and the remainder of this report be filed:

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Physicians who engage in biomedical research are bound by the ethical obligations of the
medical profession and also are required to meet responsibilities of the scientific
community. Beyond their commitment to the advancement of scientific knowledge and the
betterment of public health, physician-researchers must strive to maintain public trust in
the profession through their commitment to public welfare and safety, as demonstrated
through individual responsibility, commitment to peer review, and transparency in the
design, execution, and reporting of research.

- Biomedical research may generate knowledge with potential for both beneficial and
   harmful application. Before participating in research, physician researchers should assess
   foreseeable ramifications of their research in an effort to balance the promise of benefit
   from biomedical innovation against potential harms from corrupt application of the
   findings.
- In exceptional cases, assessment of the balance of future harms and benefits of research
  may preclude participation in the research; for instance, when the goals of research are
  antithetical to the foundations of the medical profession, as with the development of
  biological or chemical weapons. Properly designed biomedical research to develop
  defenses against such weapons is ethical.
- The potential harms associated with some research may warrant regulatory oversight.
  Physician-researchers have a responsibility not only to adhere to standards for research, but
  also to lend their expertise to the development of safeguards and oversight mechanisms,
  both nationally and internationally. Oversight mechanisms should balance the need to
  advance science with the risk of malevolent application.

After research has been conducted, consideration should be given to the risk of unrestricted
 dissemination of the results. Only under rare circumstances should findings be withheld,
 and then only to the extent required to reasonably protect against dangerous misuse.
 These ethical principles should be part of the education and training of all physicians
 involved in biomedical research.

(New HOD/CEJA Policy)

Fiscal Note: Less than \$500.00

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<sup>2</sup>.Russo E. (2000) Reconsidering Asilomar: Scientists See a Much More Complex Modern-day Environment. *The Scientist.* 14(7): 15.

<sup>3</sup> Tucker JB (2002) Viewpoint: In the shadow of anthrax: strengthening the biological disarmament regime. *The Nonproliferation Review*. IX(1): 112-121.

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<sup>5</sup> Declaration of Professional Responsibility: Medicine's Social Contract with Humanity. *In* Council on Ethical and Judicial Affairs, American Medical Association, *Code of Medical Ethics: Current Opinions*. Chicago, IL: AMA Press, 2003.

<sup>6</sup> CEJA Opinion 2.07, "Clinical Investigations."

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<sup>8</sup> Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction. (1972) *The Biological and Toxin Weapons Convention Website*. Available at: http://www.opbw.org [accessed January 15, 2004]

<sup>9</sup> List of States Parties/Signatories to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction. (November, 2003) Available at: <u>http://www.opbw.org/MSPs/BWC\_MSP2003\_INF.2.pdf</u> [accessed January 22, 2004]

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<sup>14</sup> See, for example, comments from L. Feiser, the chemist responsible for the invention of napalm, at: http://moderntimes.vcdh.virginia.edu/PVCC/mbase/docs/napalm.html [accessed January 9, 2004]

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<sup>17</sup> American Society for Microbiology. (2002) *Policy Guidelines of the Publications Board of the ASM in the Handling Of Manuscripts Dealing With Microbiological Sensitive Issues: Statement of the ASM Council Policy Committee*. Available at: <u>http://www.asm.org/Policy/index.asp?bid=5742</u> [accessed January 9, 2004] <sup>18</sup> CEJA Opinion 2.07, "Clinical Investigations."

<sup>19</sup> National Science Advisory Board for Biosecurity. Available at: http://biosecurityboard.gov/ [accessed March 10, 2004]

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<sup>21</sup> Steinbruner JD, Harris ED. (2003) Controlling dangerous pathogens. *Issues in Science and Technology* 19(3): 47-54.

<sup>22</sup> CEJA Opinion 9.08, "New Medical Procedures."

<sup>23</sup> See, for example, the National Institute of Allergy and Infectious Diseases (NIAID) Biodefense Research website, at: <u>http://www.niaid.nih.gov/biodefense/</u> [accessed January 23, 2004]

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 <sup>25</sup> Journal Editors and Authors Group (2003) Uncensored Exchange of Scientific Results. *Proc Natl Acad Sci*

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### **REPORTS OF STANDING COMMITTEES OF THE HOUSE OF DELEGATES**

### JUDICIAL COUNCIL

The following reports (A, C, D) were presented by Dr. E. G. Shelley, Vice Chairman. Report B, "Eulogy for James H. Berge, MD," appears on page 12. Report E, "Nominations for Affiliate Membership in the American Medical Association" appears on page 163.

### A. Declaration of Helsinki

During the past several years, the American Medical Association has given much attention to the subject of ethical guidelines for clinical medical investigation. A number of meetings have been held at which representatives of the Association and other organizations such as the American Federation for Clinical Research, the American Society for Clinical Investigation, the Central Society for Clinical Research, and the American College of Physicians, have discussed the desirability of adopting guidelines or standards or rules for clinical investigation. It is the consensus of knowledgeable individuals in this field that guidelines for medical clinical investigation should be developed and promulgated. It is the further thinking of these individuals, and the Judicial Council concurs in this thinking, that the Declaration of Helsinki adopted by the World Medical Association in 1954 is the expression of basic principles to which all honorable physicians and investigators can subscribe and may be accepted as guides to ethical conduct in medical investigation.

The Judicial Council has reviewed the Declaration of Helsinki and is of the opinion that it is in accord with the *Principles* of *Medical Ethics* of the American Medical Association. The Judicial Council, therefore, submits this Declaration to the House of Delegates with the recommendation that the House of Delegates endorse the Declaration of Helsinki as a guide to those who are engaged in clinical medical investigation.

### DECLARATION OF HELSINKI RECOMMENDATIONS GUIDING DOCTORS IN CLINICAL RESEARCH

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission. The Declaration of Geneva of the World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration" and the International Code of Medical Ethics declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest." Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to suffering humanity, the World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

#### I. Basic Principles

1. Clinical research must conform to the moral and scientific principles that justify medical research and should

be based on laboratory and animal experiments or other scientifically established facts. 2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of

a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

#### II. Clinical Research Combined with Professional Care

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity, the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

#### 111. Non-Therapeutic Clinical Research

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.
 Glinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued. The investigator or the investigating team should discontinue the research if, in his or their judgment, it may, if continued, be harmful to the individual.

REPORT OF REFERENCE COMMITTEE ON AMENDMENTS TO CONSTITUTION AND BYLAWS: On recommendation of the Reference Committee, the House voted to adopt Report A of the Judicial Council and Report M (p. 51) of the Board of Trustees and urged publication of the Declaration of Helsinki in state and local journals for the information of all physicians.

The following report was presented by Dr. Philip H. Jones, Chairman:

Report A of the Judicial Council and Report M (p. 51) of the Board of Trustees urge that the Declaration of Helsinki, already adopted by the World Medical Association, be endorsed by the House of Delegates as a guide to those who are engaged in clinical medical investigation. The Judicial Council report further indicates that the Declaration of Helsinki is in accord with the *Principles of Medical Ethics* of the American Medical Association.

### C. Special Report Concerning Unethical Hospital Assessments

At the Clinical Convention of the AMA House of Delegates in November 1965, the Pennsylvania delegation introduced resolution no. 13. The resolution reads as follows:

WHEREAS, A 'bed tax' has been imposed on doctors serving on the medical staffs of hospitals under the

guise of voluntary contributions to intern and resident educational programs; and WHEREAS, Physicians have lost their hospital privileges as a result of refusing to pay such 'contributions'; and

WHEREAS, Such taxes have been declared in violation of the *Principles* of *Medical Ethics* of the American Medical Association; Section 7, paragraph 9, which reads as follows;

"Compulsory Assessments, that is, assessments which, if not paid, would automatically cause doctors to lose staff membership, are not in the best traditions of ethical practice. It is not proper to condition medical staff membership on compulsory assessments for any purpose." (Judicial Council, 1962);

#### therefore be it

Resolved, That it is hereby declared to be a violation of the *Principles* of *Medical Ethics* of the American Medical Association for a physician, group or organization of physicians to take any action that imposes payment by physicians to a hospital for any purpose when such payment or nonpayment will, in any way, affect the granting or retention of hospital privileges to any physician.

The Reference Committee on Insurance and Medical Service, believing that the *Resolved* clause of resolution no. 13 broadens the area of previous Judicial Council opinions, recommended that resolution no. 13 be referred to the Judicial Council for consideration and such action as it deems necessary.

In 1952 the Judicial Council called attention to proposals whereby some hospitals suggested that physicians who utilize the hospital facilities pay to the hospital a percentage of the fees which they receive from their patients while being cared for in the hospital. The Council expressed its opinion that this was a form of fee splitting or sharing of professional fees with a lay organization which should not render professional services in the first place, but which in addition, has already levied its regular bill for the services which it legitimately rendered.

At the June 1958 Annual Convention of the Association, resolution no. 55 asked that the House of Delegates reiterate its position with regard to condemning compulsory assessments of members of medical staffs for building funds and the practice of required audits of staff members' financial records as a requisite for continued staff appointment. The Reference Committee on Medical Education and Hospitals recommended