

## **INSTRUCTIONS FOR AUTHORS**

### **UNDERSEA and HYPERBARIC MEDICINE Journal**

**The Journal of the Undersea & Hyperbaric Medical Society, Inc.**

***Updated September 2025***

## **OVERVIEW**

*UHM* will not consider simultaneous submissions nor papers that have not been released from consideration by other journals. In the case of papers that have been reviewed and released by another journal, *UHM* reserves the right to request reviews and editor comments from the other journal(s) during its consideration of the paper.

Submissions inconsistent with these guidelines will be returned to the corresponding author for revision before being reviewed.

Uncorrected proofs will be posted on the Journal's webpage after acceptance until they appear in the Journal. All articles will be open access 12 months after publication.

## **LANGUAGE**

The language of the Journal is standard American English. Papers must be written in a clear, concise style for the best chance of acceptance. *UHM* does not provide translation or writing services; authors who are not fluent in the language should have the manuscript edited before submission by a native English speaker or professional language editor.

The Journal will decline to review manuscripts that are not written clearly enough for an informed reader to follow the line of argument.

## **Generative Artificial Intelligence (GAI)**

The use of GAI, in any capacity, is discouraged, and GAI (e.g., ChatGPT) may not be named in the author line. Use of GAI must be disclosed in the cover letter and manuscript.

## **MANUSCRIPT GUIDELINES**

Membership in the Undersea and Hyperbaric Medical Society is not a prerequisite for publication in *UHM*. Manuscripts are accepted for publication on the condition that they are contributed solely to *UHM*. Authors submitting a manuscript do so with the understanding that if it is accepted for publication, copyright is assigned exclusively to the UHMS.

Acceptance of a manuscript is based on originality and quality of the work as well as clarity of presentation. An editor will review the manuscript, and one or more external impartial reviewers will be asked to evaluate each manuscript for significance and scientific soundness.

## PROOFS and FEES

Proofs are sent to the corresponding authors via email in a PDF format and are to be checked carefully. The corresponding author is the responsible party for signing off on proofs. During this process, *UHM* makes the reasonable assumption that the corresponding author will consult with all co-authors or be designated by the co-authors to act on their behalf.

Authors must clearly indicate necessary changes on the galley or an accompanying Word document, with corrections set in color text or highlighting. Proofs must be sent back within the time specified. A paper may be rescheduled if the delay warrants. Authors whose original papers are accepted for publication in *UHM* can publish for no fee.

## TREATMENT OF SUBJECTS

The UHMS endorses the principles of the Declaration of Helsinki on the treatment of human subjects and the guiding principles in the care and use of animals approved by the Council of the American Physiological Society. Studies using human subjects or animals must clearly indicate that the study was reviewed and approved by the appropriate group or agency in the methods section and on the title page. The name of the approving body and the approval number must be included.

## TYPES OF ARTICLES IN THE JOURNAL

The *Undersea and Hyperbaric Medicine Journal* strives to provide unbiased scientific information and fair analyses through its publication of the following types of papers.

**Research articles/reports** should not exceed 6,000 words and have approximately 25 references, four tables, and four figures. Papers in this category should cover the results of experimental, theoretical, and clinical investigations on topics important to the understanding of undersea, submarine, and hyperbaric medicine. Short reports that make a substantial scientific contribution and extensive studies will be considered.

**Review articles** should not exceed 6,000 words and have up to 150 references. Longer reviews of exceptional quality and relevance may be submitted with prior approval from the Chief Editor. These texts may cover scientific and practical subjects and may express the personal opinions of the author, backed by documentation. *Systematic reviews must be registered prospectively with PROSPERO (<https://www.crd.york.ac.uk/prospero/>) or similar, and the registration number must be included in the abstract and methods.* For systematic reviews, it is strongly recommended that a medical librarian be involved with the development and execution of the literature search. Systematic reviews and meta-analyses must be reported using the most recent [PRISMA guidelines](#) (currently the 2020 edition).

**Short communications** should not exceed 3,000 words, with approximately 12 references and a combined total of four tables/figures. This category includes:

**Clinical communications and clinical case reports** should not exceed 3,000 words, with approximately 12 references and a combined total of four tables/figures. These papers should comprise observations of an exceptionally revealing nature and include a short introduction to provide perspective, details of the case, and a discussion that includes references to pertinent literature.

**Letters to the editor** should not exceed 400 words and contain no more than five references. Letters include discussion of scientific papers that have appeared in the Journal or scientific issues of interest to the Journal's readers. Letters should include an informative title and be as short as possible. No more than three authors can sign a letter.

## **PREPARATION OF MANUSCRIPTS**

The overriding principles for papers considered for *UHM* are that the text is correct and unambiguous, clear, and concise. When writing, the active voice is generally preferable to the passive voice. Parallel construction of groups of like items and/or concepts aids in comprehension. Abbreviations and acronyms should not be overused, should be clearly defined at first appearance in the abstract and the text, and should be avoided in the title. There should be no repetition of information in the Discussion section that has already appeared in Results.

All accepted manuscripts are subject to final editing by the editors to improve readability and conserve space.

## **MANUSCRIPT REQUIREMENTS:**

**Submission:** Manuscripts must be submitted electronically through the online submission and review system, Manuscript Manager, at: <https://www.manuscriptmanager.net/uhm>. Individuals submitting papers will be guided in the submission process, including full and short titles, keywords, conflict of interest statements, author names, affiliations, and email addresses—direct submission inquiries to the Managing Editor.

**Text requirements:** *Undersea and Hyperbaric Medicine* participates in the agreement established by the International Committee of Medical Journal Editors as outlined in Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ann Intern Med. 1988; 108:258-265 and Br Med J 1988; 296:401-405.

**Title page:** A title page that is separate from the manuscript should include the following.

- title of no more than 85 characters, including spaces;
- - each author's full name
- highest clinical degree/certification, followed by the highest academic degree, and the following: CHT, CHRN, DMT;

- laboratory or institution of origin;
- city, state, and country
- a running head, not to exceed 50 characters, including spaces;
- full contact info for the corresponding author, including telephone, complete postal address, and email

The maximum number of authors is eight without justification by the corresponding author and approval of the editor.

Titles should be informative. The implication that a manuscript is one of a series of related papers is discouraged (e.g., "Decompression sickness studies I"). Avoid titles that pose questions.

**Place this information on the title page.**

**Funding details:** Please supply all details required by your funding and grant-awarding bodies as follows:

***For single agency grants:*** This work was supported by the [Funding Agency] under Grant [number xxxx].

***For multiple agency grants:*** This work was supported by the [Funding Agency #1] under Grant [number xxxx]; [Funding Agency #2] under Grant [number xxxx], etc.

***No extramural funding must be indicated.***

***IRB/IACUC approval:***

Indicate the body providing ethics approval and the approval number

List the date of ethics approval

List the date the first subject was enrolled

Indicate the page of your manuscript where ethics approval is indicated

***Word count:*** Excluding references and tables

***Number of references***

**Abstracts:** A structured abstract must be 250 words or fewer, suitable for abstracting agencies without rewording. *For research papers and short communications*, the following headings must be used: Background, Methods, Results, and Conclusions. For case reports, the following headings should be used when possible: Rationale, Patient presentation, Diagnosis, Outcome, Lessons.

**Keywords:** Include three to six keywords separated by semicolons that are not contained within the title.

**Key points:** An informative summary of two to three lines describing the paper's content must be provided for use in the table of contents.

**Sections:** The manuscript must be divided into Introduction, Methods, Results, and Discussion. A limitations section should be included in the discussion section. Long stretches of text should be broken into suitable paragraphs and subheadings, but subheadings should not be overused. Obscure symbols and excessive use of abbreviations should be avoided.

**Statistical methods:** These should be described in the Methods section. Information about presentation of statistical material can be found in: Bailar J, Mosteller F. Guidelines for statistical reporting in articles for medical journals: amplifications and explanations. *Adv Intern Med* 1988; 108: 268-273.

Reporting significance: precise p-values should be reported when possible. P-values should be reported as a lower case "p" and the numeric value preceded by a "0". For p-values of 0.01 and greater, report the value to two decimals. For p-values of 0.001 to 0.01, report the value to three decimals. For p-values less than 0.001, report the value as "<0.001".

**Figures:** ***Figures may not be embedded in the manuscript;*** however, please indicate within the text where they should be placed. Figures should be high-quality (1200 dpi for line art, 600 dpi for grayscale, and 300 dpi for color, at the correct size). Figures should be supplied in one of our preferred file formats: PDF, JPEG, or TIFF. Microsoft Word (.doc or .docx) files are acceptable for figures that have been drawn in Word. Color images are allowed only in cases where their removal makes the image uninterpretable, such as diagnostic images. Figures created in Microsoft Excel are discouraged.

Depictions of US Navy hyperbaric treatment tables will not be accepted as figures unless the treatment was modified in the study/case report. Indicate the treatment table used in the text and cite the current version of the US Navy Dive Manual.

**Depiction of animals:** Animals must be depicted only by line drawings or other forms of animation. It is the Journal's policy not to publish photographs of animal subjects.

**Depiction of patients:** *UHM* publishes only photos of subjects who have provided express written permission to the author to do so. The authors must specifically document this in an article in which such images are included. Lack of specific consent requires a de-identified photo (i.e., with a black box obscuring the identity of the subject).

**Tables:** Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table without reference to the text. *Tables may not be embedded in the manuscript.* Please supply editable tables in a Microsoft Word (.doc or .docx) file.

## REFERENCES

Citations in the reference list are to be in the form used by the U.S. National Library of Medicine (PubMed). Do not list PMID or PMC numbers in the references. Do not list a DOI reference unless the article is published in an online-only journal. Authors are responsible for supplying complete references and verifying them against the original documents. References must be numbered consecutively in the order in which they first appear in the text and identified in the text by Arabic numerals in parentheses or brackets. References cited only in tables or legends should be numbered in accordance with a sequence corresponding to the first mention of the table or figure in the text.

When citing web links in the text, please consider them as references, as seen below, and number them as noted above.

- NASA Astrophysics Data System. <<http://adswww.harvard.edu/>>
- The Handle System. <<http://handle.net/>>

Manuscripts that have been accepted but are not yet in print should be cited in the reference list as regular references, with "Forthcoming + publication year" in place of journal pages. Manuscripts listed electronically before they are printed should be cited as "epub ahead of print." Citations such as unpublished observations, personal communication, manuscript in preparation, or to be published are not to appear in the reference list, although reference to such a communication, if it exists in written form, may be cited in the text in parentheses. References to government reports should only be cited if such reports are readily available to all readers.

**Authors:** List names and initials of all authors. Examples:

- Kemper TC, de Jong VM, Anema HA, van den Brink A, van Hulst RA. Frostbite of both first digits of the foot treated with delayed hyperbaric oxygen: a case report and review of the literature. *Undersea Hyperb Med.* 2014 Jan-Feb;41(1):65-70.
- Lee CH, Choi JG, Lee JS, Lee Y, Kim H, Kim YS, Cha YS. Seizure during hyperbaric oxygen therapy: experience at a single academic hospital in Korea. *Undersea Hyperb Med.* 2021 First Quarter;48(1):43-51.
- Gonnering RS, Kindwall EP, Goldmann RW. Adjunct hyperbaric oxygen therapy in periorbital reconstruction. *Arch Ophthalmol.* 1986 Mar;104(3):439-43.

**Equations:** Equations should appear in the text in an appropriate type style (*italics*, **bold**, etc.). Authors should carefully distinguish between capital and lower-case letters, Roman and Greek characters, and letters and numerals. Number equations sequentially, in parentheses on the left edge of the text. All constituent terms should be defined when they initially appear. Authors are responsible for the correct formatting of each term in the equation. Equations should be considered camera-ready when they are submitted.

**Acknowledgments:** Acknowledgments of persons who aided in the work and of funding agencies, along with any other special considerations about the paper, should appear at the end of the text, before references. This information will be blinded during the review process.

**Footnotes:** Footnotes to material in the text are not allowed. Footnotes to tables are acceptable and should be identified in sequence by lower-case letters of the alphabet in italic superscript.

**Units of measure:** The Système Internationale d'Unités (SI units) format should be used to express measurements of pressure, depth, length, weight, time, temperature, energy, power, force, and concentration per: Standard Practice for Use of the International System of Units (SI) Document E380-89a, American Society for Testing and Materials, Philadelphia, Pa. 1989.

If the subject matter makes it appropriate to use non-SI units such as fsw, msw, atm, or bar, a parenthetical conversion to pascals, kilopascals, or megapascals should accompany the first mention of a pressure value in the abstract and the text. Units of fsw and msw should not be used to express partial pressure or when the nature of the subject matter requires precise evaluation of pressure. After all units, authors must include a parenthetical (a) or a parenthetical (g) to indicate whether units are in absolute or gauge terms.

The proper method for the expression of other units or appreciations may be found in Br Med J. 1978; 1:1334-1336 and Aviat Space Environ Med. 1984; 55: 93-100.

## **AUXILIARY PUBLICATIONS**

Auxiliary information includes detailed tables, appendices, mathematical derivatives, extra figures, and other supplementary matter deemed too voluminous to be included in the journal article. Such material may be submitted for deposition with the American Society for Information Sciences (ASIS), National Auxiliary Publication Service, at no charge. The editorial office deposits the information with the author's consent, and a footnote will appear in the published article to show that photoprint or microfiche copies are available at a moderate cost.

In some instances, additional material will be posted in the online version of the paper.

*Revised November 2023*

## **SCOPE OF THE JOURNAL**

*Undersea and Hyperbaric Medicine* Journal accepts manuscripts for publication related to the areas of diving research and physiology, hyperbaric medicine and oxygen therapy, submarine medicine, naval medicine, and clinical research related to the above topics. To be considered for *UHM*, scientific papers must deal with significant and new research in an area related to biological, physical, and clinical phenomena related to the above environments.

The following types of papers are published: research articles/reports (theoretical and experimental); review articles; short communications (which may include current issues and technical communications); clinical communications and clinical case reports; proceedings from symposiums or workshops; letters to the editor; and book reviews. For specific information, see 'Instructions for Authors.'

Reports of major contributions or symposiums will be considered and may be published as supplements to regular issues. Authors are referred to "Instructions for Authors" for more details on the categories of papers.

Undersea and Hyperbaric Medicine is abstracted and/or indexed in Chemical Abstract Service, Excerpta Medica, Oceanic Abstracts, Bioscience Information Service of Biological Abstracts, Current Contents, Index Medicus, PubMed, EBSCO, Scopus, and Current Awareness in Biological Sciences.

On file in the administrative offices of the Society are two documents pertaining to Institutional Review Board regulations, CFR50 and 21cfr56. The UHMS, as publisher of the UHM journal, acknowledges that all human research requires informed consent and IRB approval in accordance with the laws of the country in which the work was performed. This includes abstracts as well, since they are published in UHM.

The Society endorses the principles embodied in the Declaration of Helsinki (following). It expects that all investigations involving man reported in its journal will have been conducted in conformity with these principles.

## **DECLARATION OF HELSINKI**

### **Preamble**

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole, and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.



## **General Principles**

3. The Declaration of Geneva of the WMA 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 in the patient's best interest when providing medical care."
4. It is the duty of the physician to promote and safeguard the health, well-being, and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
5. Medical progress is based on research that ultimately must include studies involving human subjects.
6. The primary purpose of medical research involving human subjects is to understand the causes, development, and effects of diseases and improve preventive, diagnostic, and therapeutic interventions (methods, procedures, and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.
7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.
10. Physicians must consider the ethical, legal, and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal, or regulatory requirement should reduce or eliminate any of the protections for research subjects outlined in this Declaration.
11. Medical research should be conducted in a manner that minimizes possible harm to the environment.
12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training, and qualifications. Research on patients or

healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided with appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic, or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

### **Risks, Burdens, and Benefits**

16. In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed, and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify, or immediately stop the study.

### **Vulnerable Groups and Individuals**

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices, or interventions that result from the research.

## **Scientific Requirements and Research Protocols**

21. 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 adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects, and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

## **Research Ethics Committees**

23. The research protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor, and any other undue influence, and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed, as well as applicable international norms and standards. Still, these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

## **Privacy and Confidentiality**

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

## **Informed Consent**

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless they freely agree.

26. In medical research involving human subjects capable of giving informed consent, 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, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study, the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations, the informed consent must be sought by an appropriately qualified individual who is entirely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent can give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances, the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent, provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the

study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorized representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage, and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations, the research may be conducted only after consideration and approval by a research ethics committee.

### **Use of Placebo**

33. The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of a placebo, or no intervention, is acceptable; or

Where, for compelling and scientifically sound methodological reasons, the use of any intervention less effective than the best proven one, the use of a placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

### **Post-Trial Provisions**

34. In advance of a clinical trial, sponsors, researchers, and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

### **Research Registration and Publication and Dissemination of Results**

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors, and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the

publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

### **Unproven Interventions in Clinical Practice**

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement, it offers hope of saving life, re-establishing health, or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.