ISSID code of conduct

ISSID is a welcoming, inclusive and tolerant organisation where diverse views are respected. This code protects members' interests, ensures that members produce and discuss high-quality work, and that interactions between members are appropriate, productive and enjoyable

Respect

We expect members to deal sensitively with others in person, online and in print, recognising that academic differences and differences of opinion must not translate into personal disputes. Members must not abuse their authority or engage in any form of bullying or harassment, physical or verbal conduct which a reasonable person would deem to be unwelcome, offensive, humiliating, or intimidating.

Professionalism

We expect members to act within ISSIDs best interests and refrain from conduct which could damage ISSIDs reputation. Members must also abide by the "ISSID Vision" when this is published on the Society website. Researchers should abide by the European Code of Conduct for Research Integrity and the ethical principles of the Declaration of Helsinki which are appended to this document. Research projects should be performed within the member's area of competency and be accurately and impartially designed, analysed, interpreted and reported.

Complaints and concerns

Members who experience or witness any breach of these principles should report it to one of the ISSID Directors, and/or the conference organiser. All complaints and concerns will be investigated by the Board of Directors as laid out in Section 5.17 of the Society by-laws (2023). These also explain the sanctions that the Society may apply should the complaint be upheld, in

addition to any civil or criminal action. The name of the complainant will be kept confidential if requested.

Insurance and liability

ISSID, its Directors and the host institution do not accept liability for any injury, loss, or damage incurred by attendees during any conference or event organised by the Society. All attendees are advised to arrange personal insurance coverage for any risks associated with their participation in the conference/event, including travel, health, and personal belongings insurance. By registering for the conference/event, delegates acknowledge and accept this disclaimer of liability.

Annex A: European Code of Conduct for Research Integrity

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Preamble

Research is the quest for knowledge obtained through systematic study, thinking, observation, and experimentation. While different disciplines may use different approaches, they each share the motivation to increase our understanding of ourselves and the world in which we live. Therefore, "The European Code of Conduct for Research Integrity" applies to research in all scientific and scholarly fields.

Research is a common enterprise, carried out by many different actors in academic, industry, and other settings. It involves collaboration, direct or indirect, which often transcends social, political, and cultural boundaries. It is underpinned by the freedom to define research questions and develop theories, gather empirical evidence, and employ appropriate methods in an impartial way. Therefore, research draws on the work of the community of researchers and should develop independently of pressure from commissioning parties and from ideological, economic, or political interests.

Research integrity is crucial to preserving the trustworthiness of the research system and its results. It encompasses the basic responsibility of the research community to formulate the principles of research, to define the criteria for proper research behaviour, to maximise the quality, reliability, and robustness of research and its results, and to respond adequately to threats to, or violations of, good research practices. Research results in this context include, but are not limited to, publications, data, metadata, protocols, code, software, images, artefacts, and other research materials and methods. The primary purpose of this European Code of Conduct is to help realise this responsibility and to serve the research community as a framework for self-regulation.

The research community encompasses a broad range of stakeholders including individual researchers, research teams, and research support staff. It also includes the institutions and organisations that enable research, such as research performing organisations, research funders, academies, learned societies, editors and publishers, and other relevant bodies. The European Code of Conduct describes professional, legal, societal, ethical, and moral responsibilities of the different actors in different settings, including those who define and implement the priorities and criteria for research funding, assessment, and publication. It acknowledges the role of institutions and organisations in facilitating good research practices through appropriate policies, processes, resources, and infrastructure.

Interpretation of the values and principles that regulate research may be affected by social, political, or technological developments and by changes in the research environment. Such changes since the 2017 edition of the European Code of Conduct include the development and application of technologies in research in new ways, and the use and impact of social media to share and disseminate research results. The 2023 edition also takes account of changes in data management practices, the General Data Protection Regulation (GDPR), and recent developments in Open Science and research assessment. The 2023 edition of the European Code of Conduct also reflects a new awareness of the importance of research culture in enabling research integrity and implementing good research practices.

An effective European Code of Conduct for the research community promotes an ethical mindset. Its principles are relevant across the research system and in all disciplines and are applicable to publicly funded and private research. It can be the basis for local, national, and discipline-specific policies and guidelines, and applies to existing and new research practices such as citizen science or participatory research. Each stakeholder within the research community needs to take active responsibility for observing and promoting these practices and the principles that underpin them.

This document is an updated version of the 2017 edition of the European Code of Conduct for Research Integrity, developed by the European Federation of Academies of Sciences and Humanities (ALLEA). It is updated periodically to take account of evolving concerns and emerging areas so that it can continue to be fit for purpose in guiding the research community towards good research practice.

1. Principles

Good research practices are based on fundamental principles of research integrity. They guide individuals, institutions, and organisations in their work as well as in their engagement with the practical, ethical, and intellectual challenges inherent in research.

These principles include:

- ***Reliability*** in ensuring the quality of research, reflected in the design, methodology, analysis, and use of resources.
- ***Honesty*** in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full, and unbiased way.
- ***Respect*** for colleagues, research participants, research subjects, society, ecosystems, cultural heritage, and the environment.
- ***Accountability*** for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider societal impacts.

2. Good Research Practices

This section describes good research practices in the following contexts:

- Research Environment
- Training, Supervision, and Mentoring
- Research Procedures
- Safeguards
- Data Practices and Management
- Collaborative Working • Publication, Dissemination, and Authorship
- Reviewing and Assessment

2.1 Research Environment

- Research institutions and organisations promote awareness and resource incentives to ensure a culture of research integrity.
- Research institutions and organisations create an environment of mutual respect and promote values such as equity, diversity, and inclusion.
- Research institutions and organisations create an environment free from undue pressures on researchers that allows them to work independently and according to the principles of good research practice.
- Research institutions and organisations demonstrate leadership in clear policies and procedures on good research practice and the transparent and proper handling of suspected

research misconduct and violations of research integrity.

- Research institutions and organisations actively support researchers who receive threats and protect bona fide whistleblowers, taking into account that early career and short-term employed researchers may be particularly vulnerable.

- Research institutions and organisations support appropriate infrastructure for the generation, management, and protection of data and research materials in all their forms that are necessary for reproducibility, traceability, and accountability.

2.2 Training, Supervision, and Mentoring

- Research institutions and organisations ensure that researchers receive rigorous training in research design, methodology, analysis, dissemination, and communication.

- Research institutions and organisations develop appropriate and adequate training in ethics and research integrity to ensure that all concerned are made aware of the relevant codes and regulations and develop the necessary skills to apply these to their research.

- Senior researchers, research leaders, and supervisors mentor their team members, lead by example, and offer specific guidance and training to properly develop and structure their research activities.

- Researchers across the entire career path, from junior to the most senior level, undertake training in ethics and research integrity.

2.3 Research Procedures

- Researchers take into account the state-of-the-art in relevant fields when developing research ideas.

- Researchers design, carry out, analyse, and document research in a careful, transparent, and well-considered manner.

- Research protocols take account of, and are sensitive to, relevant differences among research participants, such as age, gender, sex, culture, religion, worldview, ethnicity, geographical location, and social class.

- Researchers make proper and conscientious use of research funds.

- Researchers share their results in an open, honest, transparent, and accurate manner, and respect confidentiality of data or findings when legitimately required to do so.

- Researchers report their results and methods, including the use of external services or AI and automated tools, in a way that is compatible with the accepted norms of the discipline and facilitates verification or replication, where applicable.

2.4 Safeguards

- Researchers, research institutions, and organisations comply with relevant codes, guidelines, and regulations.

- Researchers handle research participants and subjects (be they human, animal, cultural, biological, environmental, or physical) and related data with respect and care, and in accordance with legal provisions and ethical principles.

- Researchers have due regard for the health, safety, and welfare of the community, of collaborators, and others connected with their research.

- Researchers recognise and weigh potential harms and risks relating to their research and its applications and mitigate possible negative impacts.

- Researchers overseeing projects that cross professional boundaries, such as citizen science or participatory research, take responsibility for ensuring research integrity standards, oversight, training, and safeguards.

2.5 Data Practices and Management

- Researchers, research institutions, and organisations ensure appropriate stewardship,

curation, and preservation of all data, metadata, protocols, code, software, and other research materials for a reasonable and clearly stated period.

- Researchers, research institutions, and organisations ensure that access to data is as open as possible, as closed as necessary, and where appropriate in line with the FAIR Principles (Findable, Accessible, Interoperable and Reusable) for data management.

- Researchers, research institutions, and organisations are transparent about how to access and gain permission to use data, metadata, protocols, code, software, and other research materials.

- Researchers inform research participants about how their data will be used, reused, accessed, stored, and deleted, in compliance with GDPR.

- Researchers, research institutions, and organisations acknowledge data, meta- data, protocols, code, software, and other research materials as legitimate and citable products of research.

- Researchers, research institutions, and organisations ensure that any contracts or agreements relating to research results include equitable and fair provisions for the management of their use, ownership, and protection under intellectual property rights.

2.6 Collaborative Working

- All partners in research collaborations take responsibility for the integrity of the research and its results.

- All partners in research collaborations formally agree at the outset, and monitor and adapt as necessary, the goals of the research and the process for communicating their research as transparently and openly as possible.

- All partners in research collaborations formally agree at the outset, and monitor and adapt as necessary, the expectations and standards concerning research integrity, the laws and regulations that will apply, protection of the intellectual property of collaborators, and procedures for handling conflicts and possible cases of misconduct.

- All partners in research collaborations are consulted and formally agree on submissions for publication of research results and other forms of dissemination or exploitation of the results.

2.7 Publication, Dissemination, and Authorship

- Authors formally agree on the sequence of authorship, acknowledging that authorship itself is based on: (1) a significant contribution to the design of the research, relevant data collection, its analysis, and/ or interpretation; (2) drafting and/or critical reviewing the publication; (3) approval of the final publication; and (4) agreeing to be responsible for the content of the publication, unless specified otherwise in the publication.

- Authors include an 'Author Contribution Statement' in the final publication, where possible, to describe each author's responsibilities and contributions.

- Authors acknowledge important work and contributions of those who do not meet the criteria for authorship, including collaborators, assistants, and funders who have enabled the research.

- Authors disclose any financial and nonfinancial conflicts of interest as well as sources of support for the research or the publication.

- Authors and publishers promptly issue corrections or retract publications, if necessary, the retraction processes are clear and the reasons stated, and authors are given credit for issuing corrections post-publication.

- Authors, research institutions, publishers, funders, and the research community acknowledge that negative results can be as relevant as positive findings for publication and dissemination.

- Authors are accurate and honest in their communication to colleagues, policymakers, and society at large.

- Authors are transparent in their communication, outreach, and public engagement about assumptions and values influencing their research as well as the robustness of the evidence, including remaining uncertainties and knowledge gaps.

- Authors adhere to the same criteria as those detailed above whether they publish in a subscription journal, an open access journal, or in any other publication form, including preprint servers.

2.8 Reviewing and Assessment

- Researchers take seriously their commitment and responsibility to the research community through refereeing, reviewing, and assessment, and this work is recognised and rewarded by researchers, research institutions, and organisations.

- Researchers, research institutions, and organisations review and assess submissions for publication, funding, appointment, promotion, or reward in a transparent and justifiable manner, and disclose the use of AI and automated tools.

- Reviewers and editors declare any actual or perceived conflicts of interest and, when necessary, withdraw from involvement in discussion and decisions on publication, funding, appointment, promotion, or reward.

- Reviewers maintain confidentiality unless there is prior approval for disclosure.

- Reviewers and editors respect the rights of authors and applicants, and seek permission to make use of the ideas, data, or interpretations presented.

- Researchers, research institutions, and organisations adopt assessment practices that are based on principles of quality, knowledge advancement, and impact that go beyond quantitative indicators and take into account diversity, inclusiveness, openness, and collaboration where relevant.

3. Violations of Research Integrity

It is of crucial importance that researchers master the knowledge, methodologies, and ethical practices associated with their field. Failing to follow good research practices violates professional responsibilities. It damages the research processes, degrades relationships among researchers, undermines trust in and the credibility of research, wastes resources, and may expose research participants and subjects, users, society, or the environment to unnecessary harm.

3.1 Research Misconduct and other Unacceptable Practices

Research misconduct is traditionally defined as fabrication, falsification, or plagiarism (the so-called FFP categorisation) in proposing, performing, or reviewing research, or in reporting research results:

- ***Fabrication*** is making up data or results and recording them as if they were real.
- ***Falsification*** is manipulating research materials, equipment, images, or processes, or changing, omitting, or suppressing data or results without justification.
- ***Plagiarism*** is using other people's work or ideas without giving proper credit to the original source.

There are further violations of good research practice that distort the research record or damage the integrity of the research process or of researchers. In addition to violations of the good research practices set out in this European Code of Conduct, examples of other unacceptable practices include, but are not confined to:

- Allowing funders, sponsors, or others to jeopardise independence and impartiality in the research process or unbiased reporting of the results.
- Misusing seniority to encourage violations of research integrity or to advance one's own career.
- Delaying or inappropriately hampering the work of other researchers.
- Misusing statistics, for example to inappropriately suggest statistical significance.
- Hiding the use of AI or automated tools in the creation of content or drafting of publications.
- Withholding research data or results without justification.
- Chopping up research results with the specific aim of increasing the number of research publications ('salami publications').
- Citing selectively or inaccurately.
- Expanding unnecessarily the bibliography of a study to please editors, reviewers, or colleagues, or to manipulate bibliographic data.
- Manipulating authorship or denigrating the role of other researchers in publications.
- Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original ('self-plagiarism').
- Establishing, supporting, or deliberately using journals, publishers, events, or services that undermine the quality of research ('predatory' journals or conferences and paper mills).
- Participating in cartels of reviewers and authors colluding to review each other's publications.
- Misrepresenting research achievements, data, involvement, or interests.
- Accusing a researcher of misconduct or other violations in a malicious way.
- Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.

In their most serious forms, unacceptable practices are sanctionable, but at the very least every effort must be made to prevent, discourage, and stop them through

training, supervision, and mentoring and through the development of a positive and supportive research environment.

3.2 Dealing with Violations and Allegations of Misconduct

National and institutional guidelines differ as to how violations of good research practice and allegations of misconduct are handled.

However, it is always in the interest of society and the research community that violations are handled in a fair, consistent, and transparent fashion. The following principles need to be incorporated into any investigation process:

- Anyone accused of research misconduct is presumed innocent until proven otherwise.
- Investigations are fair, comprehensive, and conducted expediently, without compromising accuracy, objectivity, or thoroughness.
- The parties involved in the investigation declare any conflict of interest that may arise during the investigation.
- Measures are taken to ensure that investigations are carried through to a conclusion.
- Investigations are conducted confidentially in order to protect those involved.
- Institutions protect the rights of bona fide whistle-blowers during investigations and ensure that their career prospects are not endangered.
- General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity.
- Persons accused of research misconduct are given full details of the allegation(s) and are allowed a fair process for responding to allegations and presenting evidence.
- Investigations into research misconduct consider the role of both individuals and institutions contributing to the breach of good research practice.
- Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.
- Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct.

Annex B: WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS

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
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clari cation added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clari cation added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008 64th WMA General Assembly, Fortaleza, Brazil, October 2013 and by the 75th WMA General Assembly, Helsinki, Finland, October 2024

PREAMBLE

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human participants, including research using identifiable human material or 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. While the Declaration is adopted by physicians, the WMA holds that these principles should be upheld by all individuals, teams, and organizations involved in medical research, as these principles are fundamental to respect for and protection of all research participants, including both patients and healthy volunteers.

GENERAL PRINCIPLES

3. The WMA Declaration of Geneva binds the physician with the words, “The health and well-being of my patient will be my first consideration,” and the WMA International Code of Medical Ethics declares “The physician must commit to the primacy of patient health and well-being and must o er care in the patient’s best interest.”

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 participants.

   Even well-proven interventions should be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.

6. Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights.

   Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.

   Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results.

7. The primary purpose of medical research involving human participants is to generate knowledge to understand the causes, development and effects of diseases; improve preventive, diagnostic and therapeutic interventions; and ultimately to advance individual and public health.

   These purposes can never take precedence over the rights and interests of individual research participants.

8. While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, autonomy, privacy, and confidentiality of personal information of research participants. The responsibility for the protection of research participants must always rest with physicians or other researchers and never with the research participants, even though they have given consent.

10. Physicians and other researchers must consider the ethical, legal and regulatory norms and standards for research involving human participants in the country or countries in which the research originated and where it is to be performed, 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 participants set forth in this Declaration.

11. Medical research should be designed and conducted in a manner that avoids or minimizes harm to the environment and strives for environmental sustainability.

12. Medical research involving human participants must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Such research requires the supervision of a competent and appropriately qualified physician or other researcher.

    Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.

13. Groups that are underrepresented in medical research should be provided 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 will not adversely affect the health of the patients who serve as research participants.

15. Appropriate compensation and treatment for participants 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 participants may only be conducted if the importance of the objective outweighs the risks and burdens to the research participants.

17. All medical research involving human participants 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 and burdens must be implemented. The risks and burdens must be continuously monitored, assessed, and documented by the researcher.

18. Physicians and other researchers may not engage in research involving human participants unless they are confident that the risks and burdens have been adequately assessed and can be satisfactorily managed.

    When the risks and burdens are found to outweigh the potential benefits or when there is conclusive proof When the risks and burdens are found to outweigh the potential benefits or

when there is conclusive proof of definitive outcomes, physicians and other researchers must assess whether to continue, modify or immediately stop the research.

Individual, Group, and Community Vulnerability

19. Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm. When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities. Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion. In order to be fairly and responsibly included in research, they should receive specifically considered support and protections.

20. Medical research with individuals, groups, or communities in situations of particular vulnerability is only justified if it is responsive to their health needs and priorities and the individual, group, or community stands to benefit from the resulting knowledge, practices, or interventions. Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, or when excluding them would perpetuate or exacerbate their disparities.

Scientific Requirements and Research Protocols

21. Medical research involving human participants must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and avoid research waste. The research 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 all medical research involving human participants 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 aims, methods, anticipated benefits and potential risks and burdens, qualifications of the researcher, sources of funding, any potential conflicts of interest, provisions to protect privacy and confidentiality, incentives for participants, provisions for treating and/or compensating participants who are harmed as a consequence of participation, and any other relevant aspects of the research.

    In clinical trials, the protocol must also describe any post-trial provisions.

Research Ethics Committees

23. The protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the research begins. This committee must be transparent in its functioning and must have the independence and authority to resist undue

influence from the researcher, the sponsor, or others. The committee must have sufficient resources to fulfil its duties, and its members and staff must collectively have adequate education, training, qualifications, and diversity to effectively evaluate each type of research it reviews.

The committee must have sufficient familiarity with local circumstances and context, and include at least one member of the general public. It must take into consideration the ethical, legal, and regulatory norms and standards of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research participants set forth in this Declaration.

When collaborative research is performed internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host countries.

The committee must have the right to monitor, recommend changes to, withdraw approval for, and suspend ongoing research. Where monitoring is required, the researcher must provide information to the committee and/or competent data and safety monitoring entity, especially 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 research, the researchers must submit a final report to the committee containing a summary of the findings and conclusions.

Privacy and Confidentiality

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

Free and Informed Consent

25. Free and informed consent is an essential component of respect for individual autonomy. Participation by individuals capable of giving informed consent in medical research must be voluntary. Although it may be appropriate to consult family members or community representatives, individuals capable of giving informed consent may not be enrolled in research unless they freely agree.

26. In medical research involving human participants capable of giving informed consent, each potential participant must be adequately informed in plain language of the aims, methods, anticipated benefits and potential risks and burdens, qualifications of the researcher, sources of funding, any potential conflicts of interest, provisions to protect privacy and confidentiality, incentives for participants, provisions for treating and/or compensating participants who are harmed as a consequence of participation, and any other relevant aspects of the research.

    The potential participant must be informed of the right to refuse to participate in the research or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information and communication needs of individual potential participants as well as to the methods used to deliver the information.

After ensuring that the potential participant has understood the information, the physician or another qualified individual must then seek the potential participant's freely given informed consent, formally documented on paper or electronically. If the consent cannot be expressed on paper or electronically, the non-written consent must be formally witnessed and documented.

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

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

28. In medical research involving human participants incapable of giving free and informed consent, the physician or other qualified individual must seek informed consent from the legally authorized representative, considering preferences and values expressed by the potential participant.

    Those persons incapable of giving free and informed consent are in situations of particular vulnerability and are entitled to the corresponding safeguards. In addition to receiving the protections for the particularly vulnerable, those incapable of giving consent must only be included if the research is likely to either personally benefit them or if it entails only minimal risk and minimal burden.

29. When a potential research participant who is incapable of giving free and informed consent is able to give assent to decisions about participation in research, the physician or other qualified individual must seek that assent in addition to the consent of the legally authorized representative, considering any preferences and values expressed by the potential participant. The potential participant's dissent should be respected.

30. Research involving participants 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 or other qualified individual must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the research may proceed without informed consent provided that the specific reasons for involving participants with a condition that renders them unable to give informed consent have been stated in the research protocol and the research has been approved by a research ethics committee.

    Free and informed consent to remain in the research must be obtained as soon as possible from a legally authorized representative or, if they regain capacity to give consent, from the participant.

31. The physician or other researcher must fully inform potential participants which aspects of their care are related to the research. The refusal of a patient to participate in research or the

patient's decision to withdraw from research must never adversely affect the patient-physician relationship or provision of the standard of care.

32. Physicians or other qualified individuals must obtain free and informed consent from research participants for the collection, processing, storage, and foreseeable secondary use of biological material and identifiable or re-identifiable data. Any collection and storage of data or biological material from research participants for multiple and indefinite uses should be consistent with requirements set forth in the WMA Declaration of Taipei, including the rights of individuals and the principles of governance. A research ethics committee must approve the establishment and monitor ongoing use of such databases and biobanks.

    Where consent is impossible or impracticable to obtain, secondary research on stored data or biological material may be done only after consideration and approval of 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:

- If no proven intervention exists, the use of placebo, or no intervention, is acceptable; or
- If for compelling and scientifically sound methodological reasons the use of any intervention other than the best proven one(s), the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention; and the participants who receive any intervention other than the best proven one(s), 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, post-trial provisions must be arranged by sponsors and researchers to be provided by themselves, healthcare systems, or governments for all participants who still need an intervention identified as beneficial and reasonably safe in the trial. Exceptions to this requirement must be approved by a research ethics committee. Specific information about post-trial provisions must be disclosed to participants as part of informed consent.

Research Registration, Publication, and Dissemination of Results

35. Medical research involving human participants must be registered in a publicly accessible database before recruitment of the first participant.

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 participants and are accountable for the timeliness, 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. When an unproven intervention is utilized in an attempt to restore health or alleviate suffering for an individual patient because approved options are inadequate or ineffective and enrolment in a clinical trial is not possible, it should subsequently be made the object of research designed to evaluate safety and efficacy. Physicians participating in such interventions must first seek expert advice, weigh possible risks, burdens, and benefits, and obtain informed consent. They must also record and share data when appropriate and avoid compromising clinical trials. These interventions must never be undertaken to circumvent the protections for research participants set forth in this Declaration.