



AN INTRODUCTION TO ETHICS ISSUES AND PRINCIPLES IN RESEARCH INVOLVING HUMAN AND ANIMAL PARTICIPANTS

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1. BACKGROUND

Most research involving human beings is directed towards advancing human welfare, knowledge and understanding, and/or towards the study of social or cultural dynamics. Such work is undertaken for many reasons, for example: to alleviate human suffering, to validate social or scientific theories, to dispel ignorance, to analyse or evaluate policy, and to understand human behaviour and the evolving human condition.

Such research is primarily driven by the desire for new knowledge and understanding and may have a number of benefits. It may, for example, benefit research participants (e.g. improved treatments for disease/illness); research may also benefit both particular groups and society as a whole. That said, care must be taken to ensure that the benefits outweigh the risk of harm to research participants and it is for this reason – amongst others – that ethical frameworks have been developed to underpin research practice. Ethical frameworks are, however, developed within a continuously evolving social context which includes the need for research, moral imperatives and ethical principles, and the law; they are, however, subject to frequent change. Researchers must ensure that they are up-to-date and aware of legal requirements; one useful source of information is the National Research Ethics Service – NRES - (www.nres.nhs.uk). They are guided by one over-riding principle – the need to acknowledge and respect human dignity.

1.1 Academic Freedoms and Responsibilities

Researchers working in academia enjoy a number of important freedoms and privileges – the principle of academic freedom (UNESCO, 1997) - which are essential to maintain the independence of the higher education research community. These freedoms include freedom of inquiry and the right to disseminate their findings, freedom to challenge conventional thought and the opportunity to conduct research on human participants with public monies, trust and support.

However, researchers and institutions must also recognise that such freedom carries with it significant responsibilities, including the need to ensure that research involving human participants meets high scientific and ethical standards (Department of Health, 2001/2005, ESRC, 2005/2010) it also implies duties of honesty, integrity, objectivity, accountability and openness (Nolan Committee, 1995) alongside thoughtful inquiry, rigorous analysis, and the application of professional standards.

To further reinforce the importance of integrity in research, from 2014, the Higher Education Funding Council for England has made receipt of future research funding by Universities dependent upon compliance with the *Concordat on Research Integrity*.

2. RESEARCH INVOLVING HUMAN AND ANIMAL PARTICIPANTS

The conduct of researchers is under close scrutiny largely due to the potential for mistreatment of research participants and the demand for high quality and ethically appropriate research (Department of Health, 2001/2005, ESRC 2005/2010). Researchers have a clear responsibility to ensure that they recognise and protect the rights and general well-being of their participants, regardless of the nature of their research. Codes of practice in research provide guidelines that reinforce the basic principles of both human rights and ethics; many aspects are legally enforceable (Eby, 1985).

The Nazi atrocities during the Second World War significantly violated the basic principles of human rights as a result of which the first code of practice for ethical research was developed (Dempsey and Dempsey, 1992) (The Nuremburg Code of Ethical Practice). This provided the basis for the development of the Recommendations involving Human Subjects (Declaration of Helsinki) adopted by the World Medical Assembly in 1964 and most recently updated in 2013.

This clearly differentiates between therapeutic and non-therapeutic research (Levine, 1979) viz:

Therapeutic research: Research which offers participants an opportunity to receive an experimental treatment that may have beneficial effects (e.g. treatment with an experimental drug)

Non-therapeutic research: Research which permits the generation of knowledge that may benefit future generations but which is unlikely to benefit those involved.

The majority of research carried out in the University, by either staff or students, falls into the non-therapeutic category.

The Declaration of Helsinki (Appendix 1) illustrates the ethical issues that must be considered in undertaking research involving human participants. Such issues are based on respect for human dignity, autonomy (self-determination), truth (veracity) and justice. There must be no preferential advantage to potential participants and there must be no inducement to participate.

These considerations have been defined as reflecting the conflict between the protection of human rights and the generation of knowledge (Ford and Reuter, 1990). This means that researchers must take particular care to ensure that people are not exploited or harmed in any way by the conduct of research. This can be difficult to achieve since it is possible that work designed to generate knowledge that will ultimately have many benefits may, in the short-term at least, have, at best, no effect and, at worst, be clearly deleterious to those concerned (e.g. in clinical drug trials). Thus involving human participants in research places a significant emphasis on the principles of autonomy and informed consent and stresses the need for truth and disclosure of relevant information.

Respect for human dignity is, therefore, the cardinal ethical principle underlying research ethics and is intended to protect the interests and the physical, psychological or cultural integrity of the individual. This in turn reflects a number of important ethical principles which should underpin all research involving human beings.

Respect for the dignity of sentient animals is also ethically important. The use of animals in behavioural research and teaching, though usually non-invasive and involving observation only, can involve manipulation of the animals in order to answer the research questions. It is essential that any such manipulation carried out in studies at CCCU falls outside the scope of the Animals (Scientific Procedures) Act 1986. For further details of the University's requirements see Protocol for the Use of Sentient Animals in Research and Teaching (CCCU, 2011).

3. WHY DOES RESEARCH WITH HUMAN AND ANIMAL PARTICIPANTS REQUIRE ETHICAL APPROVAL?

Ethics approval for research with human participants is needed for the following reasons:

- To protect the rights and welfare of participants and minimise the risk of physical and mental discomfort, harm and/or danger from research procedures
- To protect the rights of the researcher to carry out any legitimate investigation as well as the reputation of the University for research conducted and/or sponsored by it
- To minimise the likelihood of claims of negligence against individual researchers, the University and any collaborating persons or organisations.
- Because Research Funding bodies and refereed journals increasingly require a statement of ethical practices in applications for research funds and/or as a condition for publication.

4. GUIDING ETHICAL PRINCIPLES UNDERPINNING RESEARCH

Such principles are designed to guide researchers in the planning and conduct of research and are based on a number of central and important ethical principles which reflect the common

standards, values and aspirations of the research community. Such factors will be taken into account in all ethical reviews whether this is carried out internally or externally.

4.1 Autonomy: This describes acknowledgement of the right of the individual to determine their own course of action in accordance with their own wishes and plans. Respect for individuals is expressed by recognising that their autonomy and right to self-determination underpin their ability to make judgements and decisions for themselves. Autonomy therefore underlies the need for informed consent.

4.2 Free and Informed Consent: Informed consent comprises three major elements - information, voluntariness and comprehension. When providing information researchers must ensure that participants are given sufficient detail about the nature of the research and the procedures involved; this should highlight the objectives of the study, potential risks and benefits and any alternative treatments must be made clear.

The concept of voluntariness has important implications. Consent must be freely given and may be withdrawn at any time. Undue influence may take the form of inducement, deprivation or the exercise of control, or authority over prospective participants. This is particularly important in research involving vulnerable people, and is absent if consent is secured by the order of authorities or as a result of coercion or manipulation.

Voluntary participation implies that participants make an informed choice while informed consent assumes that the information given is accurate. In practical terms, within an ethics review process, this translates into scrutiny of the process, rights, duties and requirements for free and informed consent by the research participant.

4.3 Veracity: Truthfulness is also central to obtaining informed consent since, without this, participants cannot exert their right to informed consent, justice or fairness (see below).

4.4 Respect for Vulnerable Persons: Vulnerable individuals, such as the old, the young, the sick or the mentally impaired, are entitled, on grounds of human dignity, caring, and fairness, to special protection against abuse, discrimination, deception or exploitation. Ethical obligations to vulnerable individuals in the conduct of research will often necessitate special procedures to protect their interests; these must be demonstrated where appropriate.

4.5 Privacy and Confidentiality: Each individual is entitled to privacy and confidentiality both on ethical grounds and in terms of the protection of their personal and sensitive data under the Data Protection Act (1998). Each person therefore has the freedom to decide the time, extent and circumstances under which they will withhold or share information. Standards of privacy and confidentiality protect the access, control and dissemination of personal information; such standards also help to protect mental or psychological integrity. All proposals must demonstrate that these principles will be upheld and the procedure to be followed in data storage and retention. Further details are available in the *Code of Conduct: Practice for Research Involving Human Participants* (CCCU, 2008), and *Data Protection in Research* (CCCU 2006).

4.6 Justice and Inclusiveness: In this context, justice connotes fairness and equity for all participants in research. In procedural terms, justice requires that ethics review processes involve methods that are fair and transparent, that established standards and procedures for reviewing research protocols are in place, and that the process be effectively independent.

Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice is directed towards ensuring that no segment of the population is unfairly burdened with the harms of research and, on the other, towards ensuring that no individual or group is neglected or discriminated against. The principle of justice thus

imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge.

4.7 Harms and Benefits: The analysis, balance and distribution of harms and benefits are central to research ethics. Modern research ethics requires a favourable harms-benefit balance so that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research participants, the informed assumption of harms and benefits, and the ethical justifications for competing research approaches.

It is acknowledged however, that, because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the magnitude and/or kind of benefits or harms associated with individual research projects. This imposes particular ethical obligations on researchers to ensure the scientific validity, design and conduct of their research.

- a. **Minimising Harm (Non-malificence):** This reflects the duty to avoid, prevent or minimise harm to others. In practice it means that research participants must not be subjected to any unnecessary risks of harm; their participation in research must be essential to achieving scientifically and socially important aims that cannot be achieved without the participation of human participants. The principle of minimising harm also requires that the research involve the smallest number of human participants and the smallest number of tests on these participants that will ensure scientifically valid data.
- b. **Maximising Benefit (Beneficence):** The principle of beneficence imposes a duty to benefit others and, in research, a duty to maximise net benefits. Care must be taken to ensure that the intention of research is to generate new knowledge that will produce benefits for participants themselves, for other individuals or for society as a whole, or for the advancement of knowledge.

5. PARTICIPANT-CENTRED PERSPECTIVE

To ensure that these principles are adhered to it is essential that a participant-centred approach is adopted. It must not be forgotten that research participants make a significant contribution to the progress and promise of research in advancing knowledge.

Collaboration between participants and researchers is important and helps to ensure that the interests of the participants are central to the work, that they will not be treated simply as objects and that their concerns will be listened to. It is recognised that, in some situations, a more formal separation between subject and researcher is needed due to the nature of a specific research design; this must, however, be clearly justified in any research proposal.

However, a participant-centred approach must also acknowledge that researchers and research participants may not always see the harms and benefits of a research project in the same way. Indeed, individual participants within the same study may respond very differently to the information provided in the free and informed consent process; this can be important and these individual perspectives must be considered. It is for this reason that lay members are included in all Research Ethics Committees.

This can have important practical implications. For example, researchers must recognise that those who are asked to participate in research by, for example, their caregiver (e.g., nurse, midwife or therapist) or teacher may be persuaded to participate by factors unrelated to the research itself rather than by any true assessment of the benefits and harms of participation. Care must be taken to ensure that this does not occur thus placing additional demands on the researcher for accuracy, candour, objectivity and sensitivity in informing potential participants about proposed research.

However, researchers and Research Ethics Committees must also recognise that there are legitimate situations in which research may be opposed to the interests of the research participants. This is particularly true of research in the social sciences and the humanities that is seeking to investigate policy or organisations for example; it may also apply to experimental studies involving a control group and/or the use of placebos. While it is crucial that such research is carried out according to professional standards, it should not be blocked through the use of harms/benefits analysis, because it may not involve collaboration with the research participants or because of the potentially negative nature of the findings; negative findings may be as important as positive ones in determining future policy.

6. ETHICAL ISSUES WITHIN THE RESEARCH PROCESS ITSELF

While many of the issues highlighted below will be central to peer review they will also be considered by Research Ethics Committees, as a judgement must be made as to whether the research is justified and whether it will contribute to the generation of knowledge. This aspect of the review will, therefore, focus on the balance between the level of intrusion into the lives of the participants and the need for the new and potentially valuable information that may be obtained.

When considering research involving human participants issues to be taken into account will include consideration of whether the research has been done before and whether there are consistent results in this area. This will be based on examination of the literature review and the justification of the need for the study.

6.1 Research design: Within the design of any study it is imperative that researchers ensure that potential harm to participants is reduced to the minimum possible level, whether such harm is physical, psychological or social in nature. Researchers must also acknowledge that, when experimental designs are adopted, some participants may act as controls and so not receive a potentially beneficial intervention. This should be taken into account in the consent process, and may be remedied once the study has been completed.

6.2 Sample: Decisions related to sampling may have a significant impact on the meaning that can be attributed to the findings. The size of the sample must therefore be considered and justified to ensure that it is sufficient to provide valid and generalisable results. Where the research is designed to enhance understanding, as in the case in some qualitative studies, this must be satisfactorily explained.

6.3 Data collection: The research design largely depends on the nature of the research question(s) and/or hypothesis(es) to be tested; care must be taken to ensure that these are appropriate. The design, in turn, will determine the methods of data collection to be used; these must be clearly described.

A number of ethical problems can arise in determining data collection techniques, for example in studies that are reliant on covert methods of data collection (e.g. participant observation); such approaches should be used only in rare circumstances where data simply cannot be collected in any other way. Similarly, within any interview, researchers must demonstrate their awareness of the power relationship that may exist between themselves and their participants and take steps to ensure that this is overcome.

6.4 Unforeseen needs: Clear plans must be in place to address particular needs that may arise during the course of any research but which may lie outside the researcher's knowledge, skills or expertise, bearing in mind the need for confidentiality. The subject's permission must be obtained before disclosing any information to a third party.

7. THE LAW

The law affects and regulates the standards and conduct of research involving human beings

in many ways (e.g. privacy and data protection, confidentiality, intellectual property) (see bibliography) while Human Rights legislation prohibits discrimination on a variety of grounds. All researchers must ensure that they comply with the current legal requirements. This can be challenging as the legal context for research involving human participants is constantly evolving and so subject to frequent change (see *Code of Conduct: Practice for Research Involving Human Participants* (CCCU, 2008) and www.nres.nhs.uk).

Clear indemnity arrangements must be in place in respect of claims for compensation in the case of negligent harm.

8. PUTTING THE PRINCIPLES INTO PRACTICE

The standards to be adopted when seeking Ethical Review within the University are set out in *Ethics Policy for Research Involving Human Participants* (CCCU, 2006). The procedures to be followed are outlined in *Ethical Procedures for the Conduct of Research involving Human Participants* (CCCU, 2007).

9. REFERENCES

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APPENDIX 1

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

[Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996; 52nd WMA General Assembly, Edinburgh, Scotland, October 2000; 53rd WMA General Assembly, Washington DC, USA, October 2002 (note of clarification added); 55th WMA General Assembly, Tokyo, Japan, October 2004 (note of clarification added); 59th WMA General Assembly, Seoul, Republic of Korea, October 2008, and 64th WMA General Assembly, Fortaleza, Brazil, October 2013.]

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 set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises 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 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 minimise 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 but 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 he or she freely agrees.

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 completely 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 authorised 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 is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised 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 authorised 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 authorised 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 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:

- Where no proven intervention exists, the use of 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 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 authorised 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.