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Πλήρης ενημέρωση, ελεύθερη συμμετοχή στην έρευνα: Προβληματισμοί στο πεδίο

Βασιλική Πετούση
Πανεπιστήμιο Κρήτης

Ημέρα για την ηθική και τη δεοντολογία στην έρευνα: Εφαρμογές των αρχών της ηθικής και της δεοντολογίας στην επιστημονική έρευνα

ΕΗΔΕ-ΠΑΜΑΚ, Διαδικτυακή συνάντηση
Παρασκευή 28/01/2022

Ενήμερη συναίνεση: *ἑκ τῶν ὧν οὐκ ἄνευ*

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Οι αρχές

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Κώδικας Νυρεμβέργης, 1949

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.

   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

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Διακήρυξη Ελσίνκι, 1964, 1975

(ανεξάρτητη επιτροπή αξιολόγησης ερευνητικών πρωτοκόλλων)

WMA

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

General Principles

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.

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.

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.

Risks, Burdens and Benefits

Vulnerable Groups and Individuals

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.

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

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.

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.

Research Registration and Publication and Dissemination of Results

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.

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Άλλα κείμενα (εντελώς ενδεικτικά)

- Council for International Organizations of Medical Sciences, International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002).
- Ευρωπαϊκή σύμβαση δικαιωμάτων του ανθρώπου
- Σύμβαση του Οβιέδο, 1997 Σύμβαση για την προστασία των ανθρωπίνων δικαιωμάτων και της αξιοπρέπειας του ανθρώπου σε σχέση με τις εφαρμογές της Βιολογίας και της Ιατρικής: Σύμβαση για τα ανθρώπινα δικαιώματα και τη βιοϊατρική. Ν2619/1999 (ΦΕΚ α 1332)
- Κώδικες Ηθικής και Δεοντολογίας της έρευνας.

Και ένα προϋπάρχον!

4. Any innovative therapy must be justified and performed in accordance with the principles of medical ethics and the rules of medical practice and theory. In all cases, the question of whether any adverse effects which may occur are proportionate to the anticipated benefits shall be examined and assessed. Innovative therapy may be carried out only it if has been tested in advance in animal trials (where these are possible).

5. Innovative therapy may be carried out only after the subject or his legal representative has unambiguously consented to the procedure in the light of relevant information provided in advance. Where consent is refused, innovative therapy may be initiated only if it constitutes an urgent procedure to preserve life or prevent serious damage to health and prior consent could not be obtained under the circumstances.

7. Exploitation of social hardship in order to undertake innovative therapy is incompatible with the principles of medical ethics.

13. While physicians and, more particularly, those in charge of hospital establishments may thus be expected to be guided by a strong sense of responsibility towards their patients, they should at the same time not be denied the satisfying responsibility (Verantwortungsfreudigkeit) of seeking new ways to protect or treat patients or alleviate or remedy their suffering where they are convinced, in the light of their medical experience, that known methods are likely to fail.

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Σύνθεση ηθικής, δεοντολογίας και ακεραιότητας της έρευνας

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Ακεραιότητα και ευθύνη στην έρευνα

Research Integrity

- General, abstract, second-order virtue connected to morality as a whole and not concerning specific actions (Beauchamp and Childress, 2001)
- Synonymous with high ethical standards (Background Paper of the Nuffield Council)
- Right to take independent stance towards values
- Interchangeable with responsible research and conduct
- Research behavior viewed from the perspective of professional standards (Steneck, 2006)
- Responsibility of researchers for the trustworthiness of their research (The Singapore Statement)

European Science Foundation

- Honesty in communication
- Reliability in performing research
- Objectivity
- Impartiality and independence
- Openness and accessibility
- Duty of care
- Fairness in references and credit
- Responsibility for future scientists and researchers

U.S. Department of Health & Human Services – The Office of Research Integrity

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.
(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
(d) Research misconduct does not include honest error or differences of opinion

ALLEA – All European Academies

Principles
- Reliability
- Honesty
- Respect
- Accountability

Good Research Practices
- Research Environment
- Training
- Research Procedures
- Safeguards
- Data Practices and Management
- Publication and Dissemination
- Reviewing, Evaluating and Editing

Violations of Research integrity
- Fabrication
- Falsification
- Plagiarism
- Other unacceptable practices

https://www.allea.org/wp-content/uploads/2018/06/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017-Digital_HE2_FINAL.pdf

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Ενημέρωση-συναίνεση

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Προϋποθέσεις ενήμερης συναίνεσης

- Πλήρης ενημέρωση
- Εκούσια παροχή
  - Χωρίς εξαναγκασμό ή πίεση
    - Ιεραρχική ή ιδιάζουσα άνιση σχέση ή σχέση εξάρτησης/υποστήριξης
  - Χειραγώγηση
    - Παραπλάνηση, επίκληση/αναφορά συνειδητά ή ασυνείδητα σε μη αυτόνομα, μη ορθολογικά στοιχεία του προσώπου
  - Κίνητρα
    - Υπερβολικά κίνητρα, ευπαθείς πληθυσμοί και ομάδες
  - Ικανότητα προς συναίνεση

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Περιεχόμενο ενημέρωσης

- Πλήρως κατανοητή γλώσσα και όροι
  - Περιγραφή στόχων, μεθόδων, επιπτώσεις/συνέπειες της έρευνας, φύση συμμετοχής, τυχόν οφέλη, κινδύνους ή ενόχληση
  - Ρητή αναφορά στο εθελοντικό της συμμετοχής, στο δικαίωμα άρνησης συμμετοχής και απόσυρσης συμμετοχής, δειγμάτων, δεδομένων, πληροφοριών από την έρευνα οποιαδήποτε στιγμή και χωρίς συνέπειες
  - Τρόπος συλλογής δειγμάτων ή δεδομένων, προστασία, καταστροφή ή επαναχρησιμοποίηση
  - Διαδικασίες αντιμετώπισης τυχαίων ή/και απροσδόκητων ευρημάτων (δικαίωμα να μη γνωρίζουν), πιθανότητα να επηρεάζουν και συγγενείς

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Σας ευχαριστώ!