MENU

PATIENT RIGHTS

What Is the Declaration of Helsinki?

By Brandon Peters, MD | Updated on October 27, 2020

Fact checked by Marley Hall

Medical research in humans depends on important ethical considerations to ensure the protection of the research subjects. One of the most important guiding statements is the Declaration of Helsinki. Learn about its origins and revisions, the principles outlined, and how human research is informed by it.

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Introduction

by the 18th Assembly of the World Medical Association in Helsinki, Finland in June 1964.[1] It was developed from 10 principles first stated in 1947 in the Nuremberg Code and further incorporated elements from the Declaration of Geneva (made in 1948), a statement of the ethical duties of physicians.

It has been subsequently amended by nine general assemblies of the association, at meetings extending from 1975 to 2013. Though addressed primarily to physicians, its principles provide an ethical foundation that is used by all involved in medical research involving human subjects.

General Guiding Principles

There are several general guiding principles that lay the foundation for the ethical standards further detailed in the statement. These guiding principles include:

Protecting Patient Health

In line with the Hippocratic Oath, espousing the belief to "First, do no harm" (*Primum, non nocere*), and the Declaration of Geneva that emphasizes "the health of my patient will be my first consideration," the first priority is to act to promote the health and well-being of patients who are involved in medical research. The research must be designed to reduce potential harm so that it does not exceed the anticipated benefits and it may never supersede these protections.

Knowledge Cannot Trample Rights

The purpose of medical research is to generate new knowledge to better understand the causes, development, and effects of diseases as well as to improve both diagnosis and treatment. According to the Declaration of Helsinki, "This goal can never take precedence over the rights and interests of individual research subjects." Physicians involved in medical research must protect:

Life

Integrity
Right to self-determination (autonomy)
Privacy
Confidentiality of personal information [1]

In order to achieve this, specific considerations must be taken into account.

Additional Considerations

Medical research involving humans should only be conducted by individuals with appropriate scientific and ethical education, training, and qualifications. In most cases, this should be supervised by a qualified physician or healthcare professional. When the research is conducted, it must also minimize potential harm to the environment. Underrepresented groups should be provided adequate access to the research opportunities. If harm occurs, appropriate compensation and treatment for subjects must be provided.

Following Local Regulatory Norms

Physician scientists must also take into account their local ethical, legal, and regulatory norms and standards for research involving human subjects. These requirements should not diminish the protections set forth in the Declaration of Helsinki, but additional protections may be afforded.

Specific Sections

There are 10 specific topic areas addressed within the Declaration of Helsinki as it presently exists, outlined as follows:

Risks, Burdens and Benefits

Medical research must only be conducted if the importance of the findings outweigh the risks and burdens to the research subjects. This involves reflecting on the impacts on the individual participating, as well as the potential benefits to them and others who may be similarly affected by the

stopped.

Vulnerable Groups and Individuals

Special protections must be implemented to protect some individuals and groups who are particularly vulnerable with a higher likelihood of becoming wronged or incurring additional harm due to their status. These groups may include minor children, the imprisoned, those with intellectual or physical disabilities, as well as racial or ethnic minorities who may face systemic injustice.

Scientific Requirements and Research Protocols

The basis for medical research must rest in sound scientific inquiry. This requires thorough knowledge of the existing scientific literature, other relevant sources of information, and techniques of experimentation. The study design must be clearly described and justified in the research protocol. It is important to disclose information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects, and compensation for harm. [1]

Research Ethics Committees

Prior to the start of the study, the research protocol must be submitted for review by an independent research ethics committee, often an assigned institutional review board. This committee usually consists of qualified experts who transparently provide comment, guidance, and approval of research. Monitoring information may be provided in an ongoing fashion to the committee, especially reporting of serious adverse events. The protocol may not be amended without the committee's knowledge and approval. At the study's conclusion, the researchers submit a final report to the committee that includes a summary of the findings and conclusions.

Privacy and Confidentiality

Personal information must be kept confidential and the privacy of participating research subjects must be protected.

Participation in medical research must be voluntary and informed consent should be obtained in writing from those who are able to provide it. As part of the consent process, information must be provided about the following:

Study aims
Methods
Funding sources
Conflicts of interest
Institutional affiliations
Anticipated benefits
Potential risks
Study outcomes
Post-study provisions

A potential research subject may initially refuse to participate and has the right to withdraw consent at any time without reprisal. Further considerations exist for those who are incapable of giving informed consent due to mental or physical incapacity, such as obtaining the consent from a legally authorized representative, and are outlined in the Declaration of Helsinki.

Use of Placebo

As a general rule, new interventions must be tested against the existing gold standard, the best proven treatment that presently exists. In rare cases, the new intervention may be compared to a placebo (no intervention) when no proven intervention exists or if there is a compelling reason to determine the efficacy or safety of the intervention and there is deemed to be no additional risk to abstaining from treatment.

Post-Trial Provisions

If an intervention is identified as beneficial within a trial, provision for post-trial access for all participants should be offered.

Research Registration and Publication and Dissemination of Results

ethical obligation to disseminate the results. These reports must be complete and accurate. Negative or inconclusive results, as well as positive findings, must be disclosed.

Unproven Interventions in Clinical Practice

When a proven intervention does not exist, a physician may use an unproven intervention after appropriate considerations that incorporate professional judgment, expert advice and committee oversight, and informed consent. The research must be designed to evaluate its safety and efficacy with findings made publicly available.

A Word From Verywell

Research in human subjects requires careful ethical considerations. The Declaration of Helsinki is an important set of guidelines that inform these reflections. It is the foundation for scientific efforts the world over, protecting those who nobly participate in medical research to benefit not only the health of themselves but also others who may be similarly afflicted. These ethical principles and protections ensure research is done in a way that ensures the best possible outcomes for all.

1 Source

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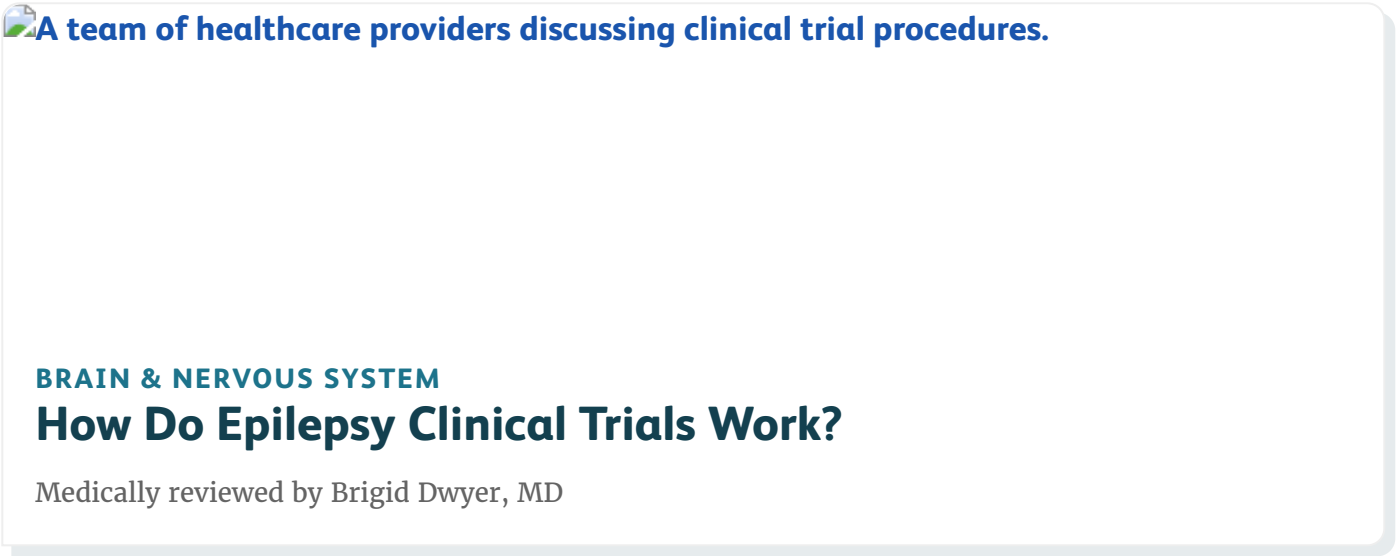

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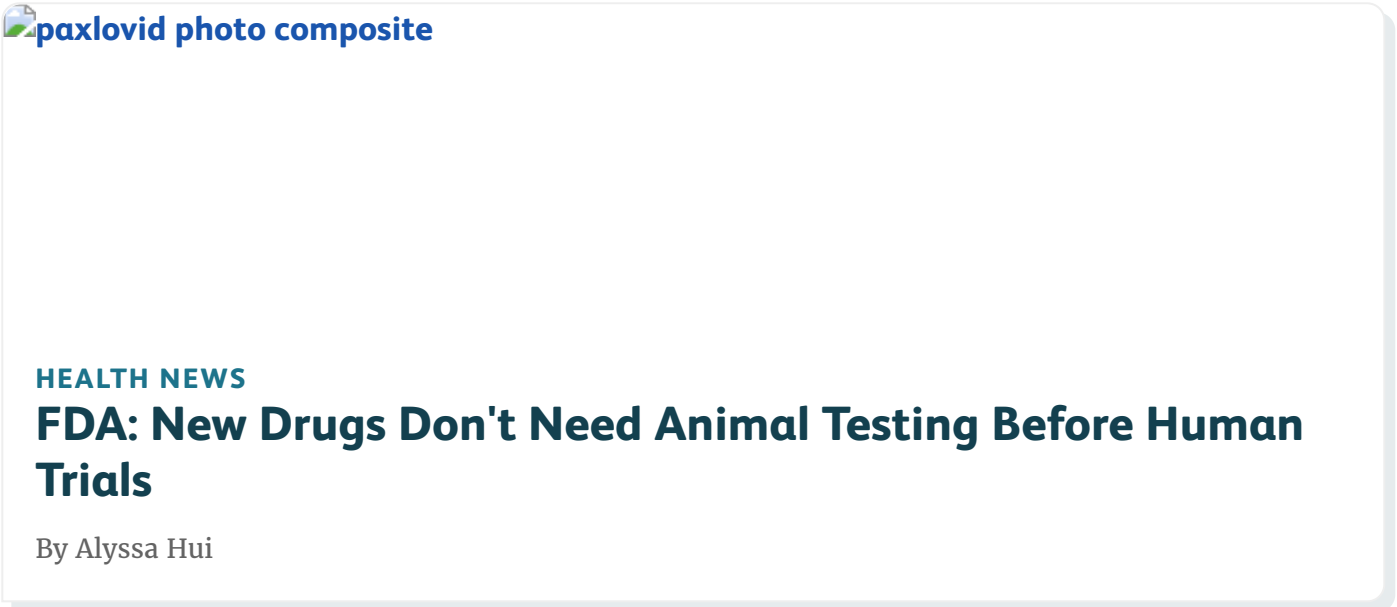

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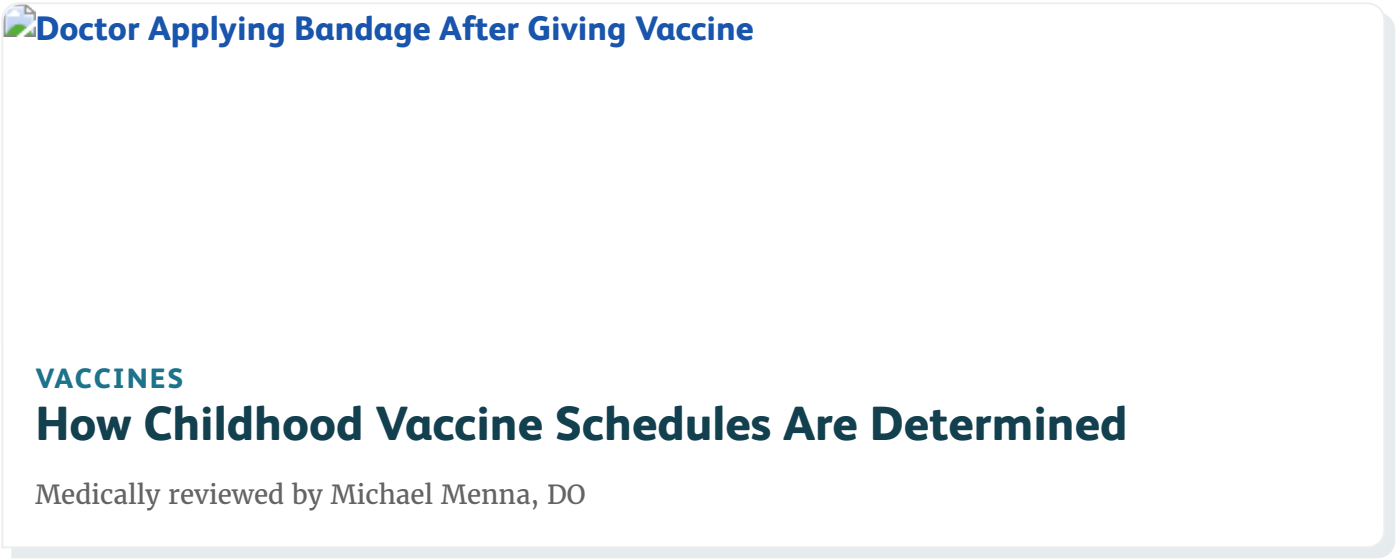

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