Journal of Clinical Research & Bioethics
ISSN: 2155-9627
OPEN ACCESS Freely available online

Editorial

Ethical Guidelines

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INTRODUCTION

The goal of clinical research is to develop generalizable knowledge that improves human health or increases understanding of human biology. People that participate in clinical research make it possible to secure that knowledge. The trail to checking out if a replacement drug or treatment is safe or effective, for instance, is to check it on patient volunteers. But by placing some people in danger of harm for the great of others, clinical research has the potential to take advantage of patient volunteers. The aim of ethical guidelines is both to guard patient volunteers and to preserve the integrity of the science. The ethical guidelines in situ today were primarily a response to past abuses, the foremost notorious of which in America was an experiment in Tuskegee, Alabama, during which treatment was withheld from 400 African American men with syphilis in order that scientists could study the course of the disease. Various ethical guidelines were developed within the 20th century in response to such studies.

Some of the influential codes of ethics and regulations that guide ethical clinical research include:

* Nuremberg Code (1947)

* Declaration of Helsinki (2000)

* Belmont Report (1979)

* CIOMS (2002)

* U.S. Common Rule (1991)

GUIDELINES

Using these sources of guidance and others seven main principles are described as guiding the conduct of ethical research:

Social and clinical value: Every research study is meant to answer a selected question. Answering certain questions will have significant value for society or for present or future patients with a specific illness.

Scientific validity: A study should be designed during a way which will get a clear answer to the precious research question. This includes considering whether the question researchers are asking is answerable, whether the research methods are valid and feasible, and whether the study is meant with a transparent scientific objective and using accepted principles, methods, and reliable practices.

Fair subject selection: The first basis for recruiting and enrolling groups and individuals should be the scientific goals of the study not vulnerability, privilege, or other factors unrelated to the needs of the study.

Favorable risk-benefit ratio: Uncertainty about the degree of risks and benefits related to a drug, device or procedure being tested is inherent in clinical research — otherwise there would be little point to doing the research. And by definition, there's more uncertainty about risks and benefits in early-phase research than in later research.

Independent review: to attenuate potential conflicts of interest and confirm a study is ethically acceptable before it even starts, an independent review panel with no vested interest within the particular study should review the proposal and ask important questions.

Informed consent: For research to be ethical, most agree that individuals should make their own decision about whether or not they want to participate or continue participating in research. This is often done through a process of consent during which individuals are accurately informed of the aim, methods, risks, benefits, and alternatives to the research, understand this information and the way it relates to their own clinical situation or interests, and make a voluntary decision about whether to participate.

Respect for potential and enrolled subjects: Individuals should be treated with respect from the time they're approached for possible participation albeit they refuse enrollment during a study throughout their participation and after their participation ends. This includes:

• Respecting their privacy and keeping their private information confidential.

• Respecting their right to vary their mind, to make a decision that the research doesn't match their interests, and to withdraw without penalty.

• Informing them of latest information which may emerge within the course of research, which could change their assessment of the risks and benefits of participating.

• Monitoring their welfare and, if they experience adverse reactions, untoward events, or changes in clinical status, ensuring appropriate treatment and, when necessary, removal from the study.

• Informing them about what was learned from the research. Most researchers do an honest job of monitoring the volunteers' welfare and ensuring they're okay. they're not always so good about distributing the study results.

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Received: December 19, 2020**; Accepted:** December 26, 2020**; Published:** December 31, 2020

Citation: Gayatri M, (2020) Ethical Guidelines. J Clin Res Bioeth. S7: e001.