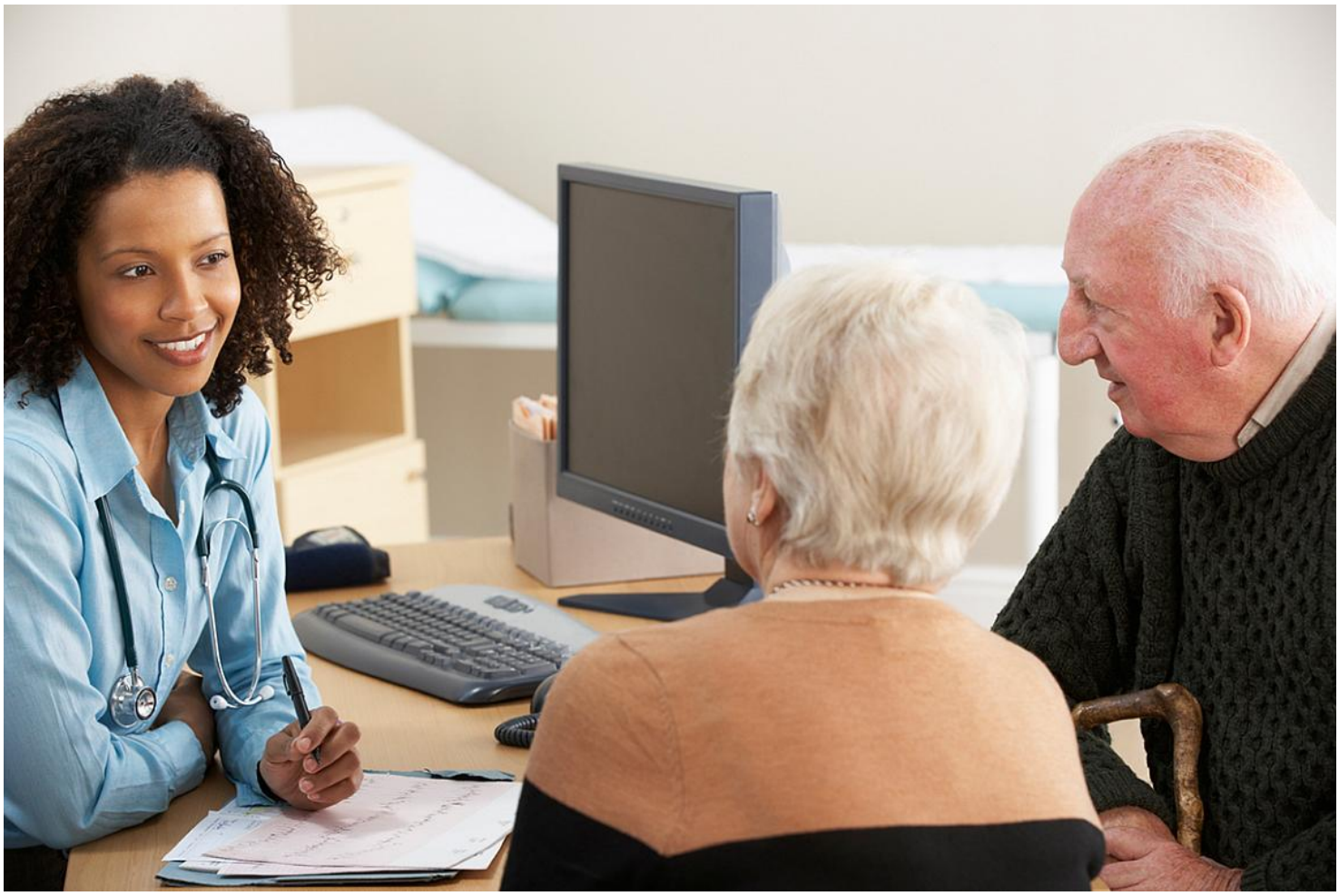
NIH CLINICAL RESEARCH TRIALS AND YOU

Guiding Principles for Ethical Research

Pursuing Potential Research Participants Protections



"When people are invited to participate in research, there is a strong belief that it should be their choice based on their understanding of what the study is about, and what the risks and benefits of the study are," said Dr. Christine Grady, chief of the NIH Clinical Center Department of Bioethics, to Clinical Center Radio in a podcast.

Clinical research advances the understanding of science and promotes human health. However, it is important to remember the individuals who volunteer to participate in research. There are precautions researchers can take – in the planning, implementation and follow-up of studies – to protect these participants in research. Ethical guidelines are established for clinical research to protect patient volunteers and to preserve the integrity of the science.

NIH Clinical Center researchers published seven main principles to guide the conduct of ethical research:

- **Social and clinical value**
- **Scientific validity**
- **Fair subject selection**

- **Favorable risk-benefit ratio**
- **Independent review**
- **Informed consent**
- **Respect for potential and enrolled subjects**

Social and clinical value

Every research study is designed to answer a specific question. The answer should be important enough to justify asking people to accept some risk or inconvenience for others. In other words, answers to the research question should contribute to scientific understanding of health or improve our ways of preventing, treating, or caring for people with a given disease to justify exposing participants to the risk and burden of research.

Scientific validity

A study should be designed in a way that will get an understandable answer to the important research question. This includes considering whether the question asked is answerable, whether the research methods are valid and feasible, and whether the study is designed with accepted principles, clear methods, and reliable practices. Invalid research is unethical because it is a waste of resources and exposes people to risk for no purpose

Fair subject selection

The primary basis for recruiting participants should be the scientific goals of the study — not vulnerability, privilege, or other unrelated factors. Participants who accept the risks of research should be in a position to enjoy its benefits. Specific groups of participants (for example, women or children) should not be excluded from the research opportunities without a good scientific reason or a particular susceptibility to risk.

Favorable risk-benefit ratio

Uncertainty about the degree of risks and benefits associated with a clinical research study is inherent. Research risks may be trivial or serious, transient or long-term. Risks can be physical, psychological, economic, or social. Everything should be done to minimize the risks and inconvenience to research participants to maximize the potential benefits, and to determine that the potential benefits are proportionate to, or outweigh, the risks.

Independent review

To minimize potential conflicts of interest and make sure a study is ethically acceptable before it starts, an independent review panel should review the proposal and ask important questions, including: Are those conducting the trial sufficiently free of bias? Is the study doing all it can to protect research participants? Has the trial been ethically designed and is the risk–benefit ratio favorable? The panel also monitors a study while it is ongoing.

Informed consent

Potential participants should make their own decision about whether they want to participate or continue participating in research. This is done through a process of informed consent in which individuals (1) are accurately informed of the purpose, methods, risks, benefits, and alternatives to the research, (2) understand this information and how it relates to their own clinical situation or interests, and (3) make a voluntary decision about whether to participate.

Respect for potential and enrolled participants

Individuals should be treated with respect from the time they are approached for possible participation — even if they refuse enrollment in 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 change their mind, to decide that the research does not match their interests, and to withdraw without a penalty
- informing them of new information that might emerge in the course of research, which might change their assessment of the risks and benefits of participating
- monitoring their welfare and, if they experience adverse reactions, unexpected effects, or changes in clinical status, ensuring appropriate treatment and, when necessary, removal from the study
- informing them about what was learned from the research

More information on these seven guiding principles and on bioethics in general

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