

HUMAN RESEARCH ETHICS

CMDA recognizes the mandate God gave to be wise stewards over our world (Gen 1:28ⁱ). We also delight in responding to God's call to alleviate suffering. Research on human subjects is often an appropriate way to accomplish these ends. Research on humans should never intend to harm the subject and any harm caused to the patient must only be allowed with the expectation or the achievement of a greater benefit for the patient.ⁱⁱ

Research involving human beings is invaluable, and it provides important new information as well as broad benefits for mankind. Scientific rigor and ethical principles – providing for the respect and dignity of human life – are paramount in this research. CMDA believes Scripture (Matt 22:37-40ⁱⁱⁱ) provides the moral foundation that informs these ethical decisions.^{iv}

There are recognizable and intangible benefits to research subjects. Some patients near the end of life, and healthy volunteers, knowing that they will not benefit personally from the research are willing to participate for the benefit of others.

Research involving human beings has a domestic and an international history of abuse (for example, the Tuskegee Syphilis Study and the Nazi atrocities of World War II) that must be remembered. Learning from the past moral violations in human research is essential to safeguard future endeavors. The Nuremberg Code, the Declaration of Helsinki, and the Belmont Report are historical documents that addressed past abuses of human beings.

Human research ethics involves institutions, investigators, sponsors, subjects, and data. Research ethics is necessary to provide guidelines and boundaries for research teams and sponsoring organizations in order to protect human subjects from harm. This is especially needed when research crosses biologic, economic, social, ethnic and cultural boundaries.

The participants – human beings made in the image of God (Gen 1:27^v) – must be treated as unique and special creations and the researchers must exercise compassion, dignity, fairness, and respect for human beings.

- Research should only be conducted if the proposed benefit outweighs the burdens and risks to the human subjects. Vulnerable populations – such as children and prisoners – must be granted additional protection
- Informed consent must be obtained in advance from the participant or appropriate proxy^{vi}
- Participation must be voluntary, and researchers must make conscientious effort to avoid coercive situations. Coercive situations may arise in the context of disparities such as wealth, social (or institutional) class, education, age, gender, ethnicity and race
- Participants must be allowed to terminate their participation in the trial at any time without reprisal

The research team must be cognizant of its obligations and act appropriately. (1 Cor 4:2^{vii})

- Research studies must ask a question of significant importance for human benefit and health, and must be designed to obtain unbiased data and be sufficiently powered for statistical significance
- Research studies should be reviewed by an Institutional Review Board, and they must be assessed for predictable risks and burdens, maximizing the foreseeable benefits
- Potential conflicts of interest, at any level (e.g., institutional review board, the research subject, the publishing journal, and/or the sponsor) must be disclosed, and they must be adequately addressed
- Conflicts of interest arise when the researcher has a dual relationship with the subject (as investigator and treating clinician), and as such, the researcher must act in the best interest of the subject
- Placebo and non-treatment trials are not permitted when a proven therapy is available and omission of a proven therapy would result in harm^{viii}
- All results, including beneficial and non-beneficial data, must be openly reported without bias
- Confidentiality of the subjects must be maintained
- Fabrication, falsification, and plagiarism are to be assiduously avoided and punished
- Responsibility and appropriate care for subjects suffering adverse research outcomes must be provided
- Authorship criteria and credentialing must be accurately reported

Research performed in any country or culture requires that:

- Researchers and host authorities share responsibility for the protection of the research subjects in accordance with their human dignity as bearers of the image of God.
- The research study must be responsive to the health needs of its people
- Research results and ensuing benefits should extend to the people of the host country
- Neither research location nor selection of subjects should be chosen to take advantage of a lower research standard

Research study information should be disclosed to the public when:

- Results are scientifically valid
- Research findings offer therapeutic implications for the study population or the study condition
- Important new data (positive or negative) have been discovered

Research study information may be withheld when research is incomplete and premature disclosure would compromise the study validity

Research studies must be discontinued when:

- Clear and unequivocal improvement or harm in the study group is identified
- Research protocols have been irrevocably compromised

Conclusion

CMDA endorses research using human subjects with proper consent if the studies are transparent in design and implementation, providing it is protective and non-exploitive. CMDA believes that human subject research, with the above conditions, respects God's design of human beings made in His image.

ⁱ Genesis 1:28 - God blessed them and said to them, "Be fruitful and increase in number; fill the earth and subdue it. Rule over the fish of the sea and the birds of the air and over every living creature that moves on the ground."

ⁱⁱ See CMDA Statement on "Biblical Model for Medical Ethics"

ⁱⁱⁱ Matthew 22: 37-40 - Jesus replied: " 'Love the Lord your God with all your heart and with all your soul and with all your mind.' This is the first and greatest commandment. And the second is like it: 'Love your neighbor as yourself.' All the Law and the Prophets hang on these two commandments."

^{iv} See CMDA Statement on "Human Life: Its Moral Worth"

^v Genesis 1: 27 - So God created man in his own image, in the image of God he created him; male and female he created them.

^{vi} See CMDA Statements on "Fetal Tissue for Experimentation and Transplantation" and " Human Stem Cell Research and Use"

^{vii} I Corinthians. 4:2 - Now it is required that those who have been given a trust must prove faithful.

^{viii} Placebo-controlled trials are valuable in many research situations. However, it is not ethical to conduct non-treatment trials in conditions known to be progressive or lethal (e.g., syphilis and cancer) when effective treatments are available.

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