



World Water Safety

INTERNATIONAL LIFE SAVING FEDERATION

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MEDICAL POSITION STATEMENT - MPS 14

ETHICS IN RESEARCH INVOLVING HUMAN SUBJECTS

BACKGROUND

Research ethics govern the standards of conduct for scientific researchers. It is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants.

As such, all research involving human beings should be reviewed by an ethics committee to ensure that the appropriate ethical standards are being upheld. Discussion of the ethical principles of beneficence, justice and autonomy are central to ethical review. ^[1]

The World Health Organisation has developed a document for individuals and organisations involved in health-related research with human participants. “Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants” (2011) ^[2]

Ethics guidance for research involving human participants has been developed and disseminated by numerous organisations and agencies at international, regional, and national levels over the past 50 years. ^{[4], [5]} Adherence to these guidelines helps to promote the ethical conduct of research and enhances and protects the rights and wellbeing of research participants and communities.

A core component of all contemporary research ethics guidelines is that research should be subject to prior ethical review by a competent Research Ethical Committee. Such review is intended to ensure that the ethical principles and practices put forward in the guidelines will be followed in the proposed research.

STATEMENT

1. The International Life Saving Federation encourages research in the field of lifesaving, particularly in those areas that have been, or may in the future be, the subject of medical position statements.

2. The Committee has a duty to ensure that any research work being undertaken in its name, or with its agreement, has received independent ethics approval. Ideally, this should be from a committee that meets the "WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants".

The WHO guidelines are contained in 10 statements as listed below:

STANDARDS AND OPERATIONAL GUIDANCE FOR ETHICS REVIEW OF HEALTH-RELATED RESEARCH WITH HUMAN PARTICIPANTS AS OUTLINED BY THE WORLD HEALTH ORGANISATION

1. **STANDARDS FOR THE RESEARCH ETHICS REVIEW SYSTEM**
Standard 1: Responsibility for establishing the research ethics review system
2. **STANDARDS AND GUIDANCE FOR ENTITIES THAT ESTABLISH RESEARCH ETHICS COMMITTEES**
Standard 2: Composition of research ethics committees
Standard 3: Research ethics committee resources
Standard 4: Independence of research ethics committees
Standard 5: Training the research ethics committee
Standard 6: Transparency, accountability, and quality of the research ethics committee
3. **STANDARDS AND GUIDANCE FOR MEMBERS OF THE RESEARCH ETHICS COMMITTEE**
Standard 7: Ethical basis for decision-making in research ethics committees
 - a. Scientific design and conduct of the study
 - b. Risks and potential benefits
 - c. Selection of study population and recruitment of research participants
 - d. Inducements, financial benefits, and financial costs
 - e. Protection of research participants' privacy and confidentiality
 - f. Informed consent process
 - g. Community considerationsStandard 8: Decision-making procedures for research ethics committees
4. **STANDARDS AND GUIDANCE FOR THE SECRETARIAT, STAFF, AND ADMINISTRATION OF THE RESEARCH ETHICS COMMITTEE**
Standard 9: Written policies and procedures
 - a. Membership of the committee
 - b. Committee governance
 - c. Independent consultants
 - d. Submissions, documents required for review, review procedures, and decision-making
 - e. Communicating a decision
 - f. Follow-up reviews and monitoring of proposed research
 - g. Documentation and archiving
5. **STANDARDS AND GUIDANCE FOR RESEARCHERS**
Standard 10: Researchers' responsibilities
 - a. Submitting an application for review
 - b. Conduct of research
 - c. Safety reporting
 - d. Ongoing reporting and follow-up

- e. Information to research participants

ANNEXURE 1

- Guidelines and codes of best practice
- Statutes and regulations

ANNEXURE 2

- Guidance for developing terms of reference for the Secretariat of the research ethics committee

ANNEXURE 3

- Guidance for developing written procedures for the research ethics committee

- a. Membership of the Committee
- b. Committee governance
- c. Independent consultants
- d. Submissions, documents required for review, review procedures, and decision-making
- e. Communicating a decision
- f. Follow-up reviews and monitoring of proposed research
- g. Documentation and archiving

GLOSSARY

LEVEL OF EVIDENCE

This document is based on expert consensus.

POTENTIAL CONFLICT OF INTEREST STATEMENT

None of the participants in the consensus process leading to this position statement has a conflict of interest with the stakeholder industry, technology, persons or organisations that are identified and/or impacted by the position statement.

REFERENCES

1. World Health Organisation - Ethical standards and procedures for research with human beings
2. World Health Organisation. "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants" (2011) <http://www.who.int/ethics/research/en/>
3. International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)
4. Declaration of Helsinki - World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
5. Australian Government National Health and Research Council - National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015

Original Policy Statement approved by the ILS Board of Directors on 20/09/2006 and 03/09/2016.