Ethical issues in clinical research

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TODUA CLINIC

Acad. F. Todua Medical Centre - Research Institute of Clinical Medicine

Iv. Javakhishvili Tbilisi State University


PAULA STRADIŅA
KLĪNISKĀ UNIVERSITĀTES SLIMNĪCA
AUKC
1910


Ārlietu ministrija


UNIVERSITAS TPHILISENSIS
1918

TODUA CLINIC

NO CONFLICT OF INTEREST TO DECLARE

- The purpose of medical research in humans is to understand the causes of diseases, determine their effects, and improve measures for prevention, diagnosis, and treatment of diseases.

- Clinical research should be based on ethical standards that respect the research participants and protect their health and rights.

- Researchers must protect the safety, dignity, self-determination, and confidentiality of personal information of research participants.

- In addition, clinical research should be conducted and published under the authorized standards of scientific integrity.

The 1947 judgment against Nazi doctors is recognized as the cornerstone of modern research ethics.

The 10-statement Nuremberg Code emphasizes the importance of sound scientific research protocols and informed consent.

Despite this, several reports of unethical medical studies conducted without informed consent on vulnerable research participants have been published since the early 1960s. Such unethical events have emphasized the need for informed consent of the research participants and required the researcher to take responsibility for the potential risks of the research.

Among several declarations related to research ethics, the Declaration of Helsinki published by the World Medical Association in 1964 has undergone revision and is now accepted as an ethical principle in medical research involving humans.

The major changes in the latest revision published in 2013 are compensation for clinical trial-related injuries, approval for use of placeboes in clinical trials, protection of vulnerable populations, and post-trial provisions.

No.	Statatments
1	Voluntary consent to be based on sufficient knowledge of the nature, duration, purpose, methods, inconveniences, hazards, and effects of the research.
2	Research would yield fruitful results for the good of society not procurable by other methods.
3	Research to be based on animal research and prior knowledge.
4	All unnecessary physical or mental suffering and injury to be avoided.
5	No experiment be conducted in which death or disabling injury will occur (except where physicians were also subjects).
6	Degree of risk would not exceed that determined by the humanitarian importance of the problem to be solved.
7	Preparation and facilities be provided to protect subjects against even the remote possibility of injury, disability, or death.
8	The research be conducted by scientifically qualified persons and require the highest degree of skills and care.
9	Subjects be free to bring an experiment to an end if they reached the physical or mental state where continuance seemed impossible.
10	Researchers be prepared to terminate the experiment if they had cause to believe, in their good faith, skill, and judgment, that continuation was likely to result in injury, disability, or death to a subject.

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Research ethics committee

Prior to initiation of the study, the study protocol must be submitted to a qualified research ethics committee for review and approval.

The committee should be neutral and transparent, and there should be no conflict of interest with the researchers or institutions sponsoring the research.

The committee should be able to monitor the research process, and the researcher should provide necessary information when requested by the committee.

If protocol violations or adverse events occur during the study, they must be reported to the committee according to the established regulations.

The committee should resolve or refer the issues for resolution and may terminate or suspend the research when deemed to have significant ethical violations or higher-than-expected risks.

Considerations in human participants

1) Risk and benefits
Clinical research can only be conducted when the research objective outweighs the risk to the research participants. All clinical studies should be conducted only after a full evaluation of the potential risks and benefits for the study participants. Researchers should come up with measures to minimize the risks and also must continuously monitor and record the risk factors.

2) Privacy and confidentiality
In clinical research, privacy is an individual's right to make decisions on the information about an individual's physical condition, thoughts and feelings, and social networks shared with researchers. Confidentiality in clinical research means that the personal information of the research participant must be protected, and that there are restrictions on the method and timing of exposure to third parties.

3) Informed consent
Individuals participating in the study should be fully informed about the study and its risks and voluntarily provide their informed consent. All research participants should receive appropriate information about the overall research, such as the purpose, method, expected benefits and risks, and possible conflicts of interest. They should be aware that they may refuse to participate in the study and may withdraw their consent at any time. If a potential study participant is unable to provide informed consent, it must be obtained through a legally authorized representative. Consent must be obtained from a legally authorized representative as soon as possible to maintain participation in the study.

Publication ethics

1. Transparency and protection of research participants
Editors of journals should state the editorial policy to let the authors disclose sources of funding for research or publication. The submitted manuscript should state that the study was approved by the research ethics committee or institutional review board, and that it was undertaken with informed consent from the research participants.

2. Authorship
Authorship has significant academic, social, and financial implications as well as responsibility for published work. The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following four criteria: (1) substantial contributions to the conception or design of the work or the acquisition, analysis, and interpretation of data for the work; (2) drafting the work or revising it critically for important intellectual content; (3) final approval of the version to be published; or (4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Misconduct in research and publication

1. Fabrication/falsification

Fabrication is inventing data or results, while falsification is an act of omission or alteration of research materials, process, and data. Such misconduct is considered the most serious violation in clinical research, as it seriously impairs trust in the research as a whole.

2. Plagiarism

The word “plagiarism” stems from Latin word, “plagiarius” (an abductor) and “plagiare” (to steal). The World Association of Medical Editors defines plagiarism as the use of published or unpublished ideas or words (or other intellectual property) from others without attribution or permission and presenting them as new and original rather than derived from an existing source. Plagiarism can be categorized as direct (plagiarism of the text), mosaic (borrowing ideas and opinions from the original source and a few verbatim words or phrases without crediting the author), and self-plagiarism. In particular, self-plagiarism is using a part of the authors’ previously published work without mentioning the original article.

3. Overlapping publications

Duplicate submission of the same manuscript simultaneously to more than one journal is prohibited. Duplicate publication of a prior publication with substantial overlap without reference or related statement is another misconduct in clinical research Journals may decide to accept re-publication of previously published studies with accurate translations in other languages.

Ethics related to clinical research under contract

- Clinical research conducted under contract and funded by pharmaceutical or medical device companies or biotechnology companies has increased in recent years.
- Clinical research that is based on contractual relationships may affect the independence of researchers, the safety of the research participants, and the integrity of the research.
- The ICMJE has pledged not to review or publish studies based on contracts that restrict independent access to and analysis of research data and free publication of research results.
- Even if the research result is negative for the sponsoring company, the researcher should be free to analyze and publish the data.
- The research plan must be verified in advance by the institutional review board so that the research design, method, statistical analysis of the results, and the derivation of results are not affected by competing interests.
- It is also essential to pre-evaluate whether patient safety and confidentiality are sufficiently guaranteed.
- The budget required for the research should be sufficient to enhance the completeness of the research, but it should also be evaluated to determine whether it is excessive based on reasonable judgment criteria.

Conclusion

Every medical or clinical study that includes human participants should be designed and conducted to achieve scientific integrity as well as to follow ethical principles to protect the health, safety, and well-being of the participants.
Publication of the studies should follow ethical guidelines that are based on truth. It is also mandatory to educate investigators, members of the research team, and medical students about these ethics for sound persistence of medical science.

Resolution by the Government of Georgia

#380 as of 20 July 2022, Tbilisi

About the rule and the conditions of issuance of the permits for clinical trial of the pharmacological product, pharmaceutical manufacturing, authorized drug store, import and export of the medical products due to special control
Regarding the changes made in Georgian government resolution# 335 as of 16July2019

Clinical research organization in Georgia

No centralize ethics committees in Georgia – only LECs

Fast start-up/regulatory timelines – compare to EU countries

More then 20 CROs are operating – start-up/regulations/monitoring/safety

About 45 ongoing clinical studies an more then 350 closed studies at the Touda Clinic last 20 years

Education, Competences & Opportunities of Health care Professionals in the Region

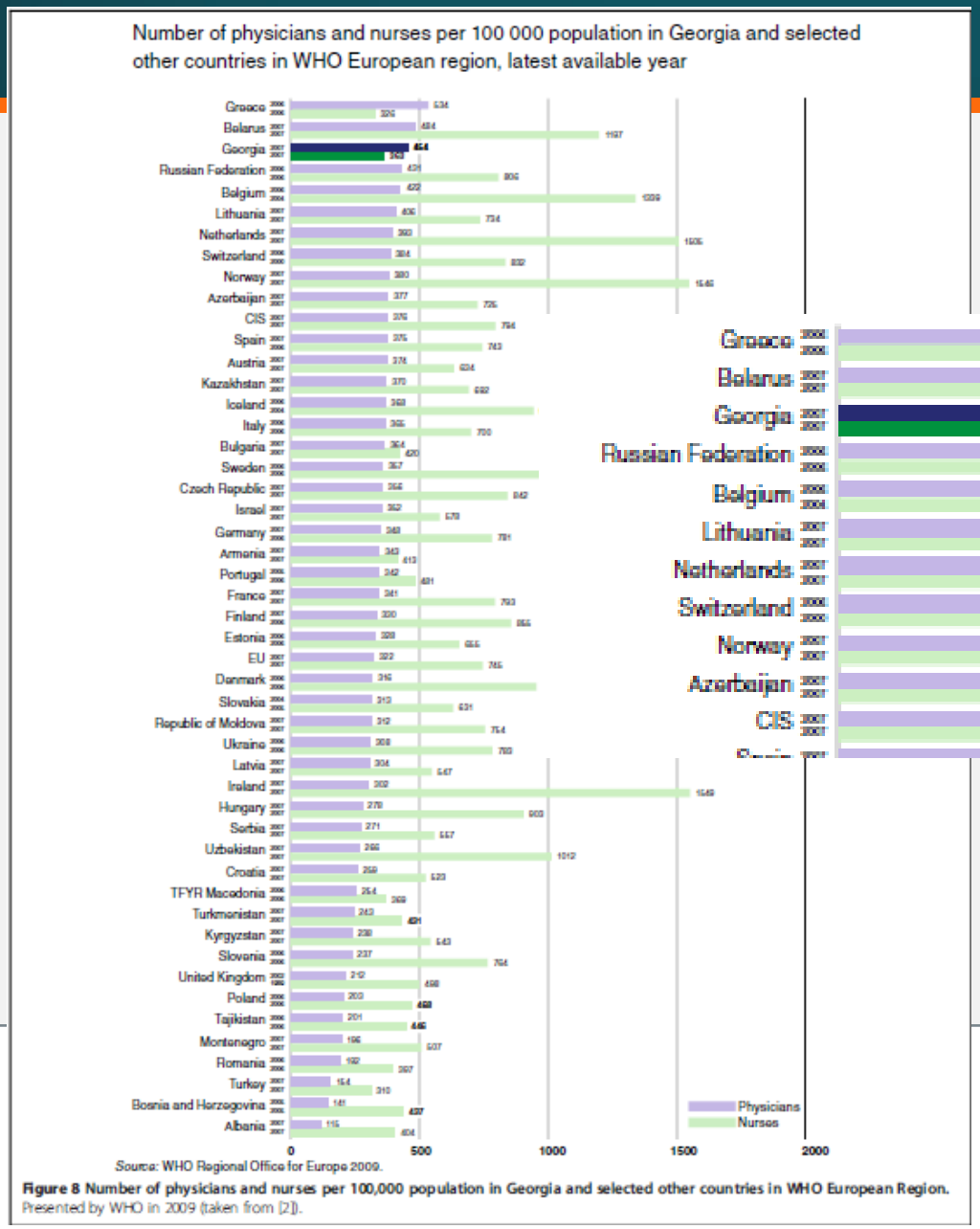
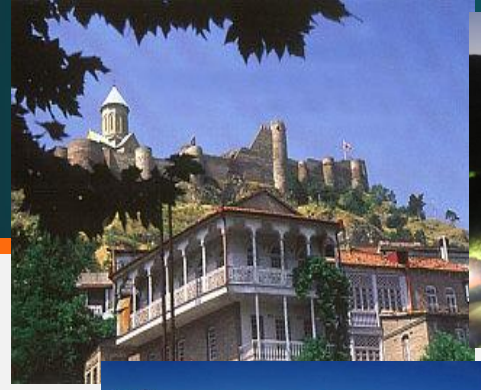
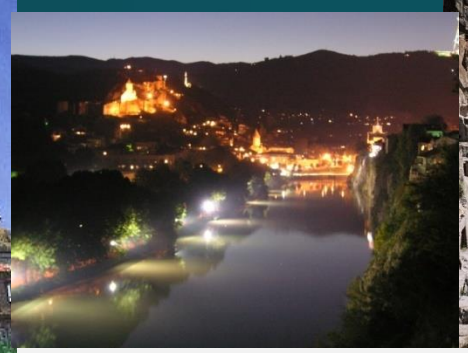
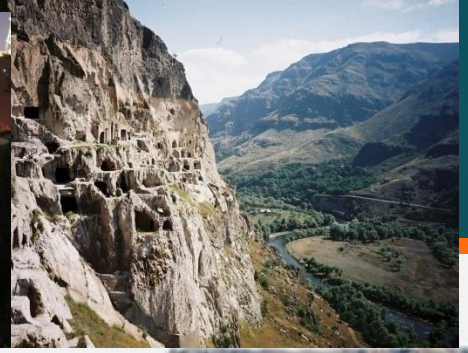
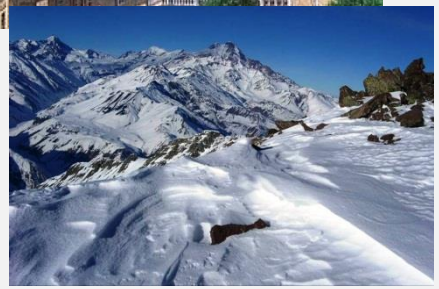


Figure 8 Number of physicians and nurses per 100,000 population in Georgia and selected other countries in WHO European Region. Presented by WHO in 2009 (taken from [2]).





Thank You for Attention!

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