



# Clinical research and publication ethics

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## Tuskegee Syphilis Study 1932 to 1972

- Study the natural progression of untreated syphilis in rural African-American men in Alabama.
- Not told they were in a study.
- Treatment withheld.



[http://www.tuskegee.edu/about\\_us/centers\\_of\\_excellence/bioethics\\_center/about\\_the\\_usphs\\_syphilis\\_study.aspx](http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx)

# Research ethics principles

## The Nuremberg Code 1947

Ten points that define  
legitimate medical research

**HHS.gov**  
U.S. Department of Health & Human Services

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**The Nuremberg Code**

1. The voluntary consent of the human subject is absolutely essential.  
This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who

# The Declaration of Helsinki 1964

The screenshot displays the World Medical Association (WMA) website. At the top, there are language options: English, Español, and Français, along with a Members' Area link. The main navigation bar includes Home, What we do, Publications, Media, Events, About us, Education, and JDN. The breadcrumb trail shows WMA Home > Publications > Policies. The main content area features the title "WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects" with options to Print, PDF, Send, Follow, and Like (6,294 people like this). A search bar is visible on the right. On the left, a sidebar lists Policies, About, Archives, and Council Resolutions, with a link to the World Medical Journal at the bottom.

<http://www.wma.net/en/30publications/10policies/b3/>

# Regulations and law

L 121/34

EN

Official Journal of the European Communities

1.5.2001

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 4 April 2001  
on the approximation of  
relating to the impleme



legislation.gov.uk

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Title:  Year:  Number:  Type: All Legislation (excluding draft)

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## The Medicines for Human Use (Clinical Trials) Regulations 2004

2004 No. 1031 ▶ PART 1 ▶ Regulation 2

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**What Version** ? **Status:** This is the original version (as it was originally made). This item of legislation is currently

# Requirements for ethical review of clinical research

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## Clinical trials and medical research - Ethics committees

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[How trials are regulated](#) | [Ethics committees](#) | [Data monitoring committees](#) | [Complications](#)

### Ethics committees

Every clinical trial is covered by regulations that protect the health, safety and dignity of the people taking part.

### Useful links

[NHS Choices links](#)

[Health regulators](#)



## CODE OF CONDUCT FOR JOURNAL PUBLISHERS

**Publishers should work with journal editors to:**

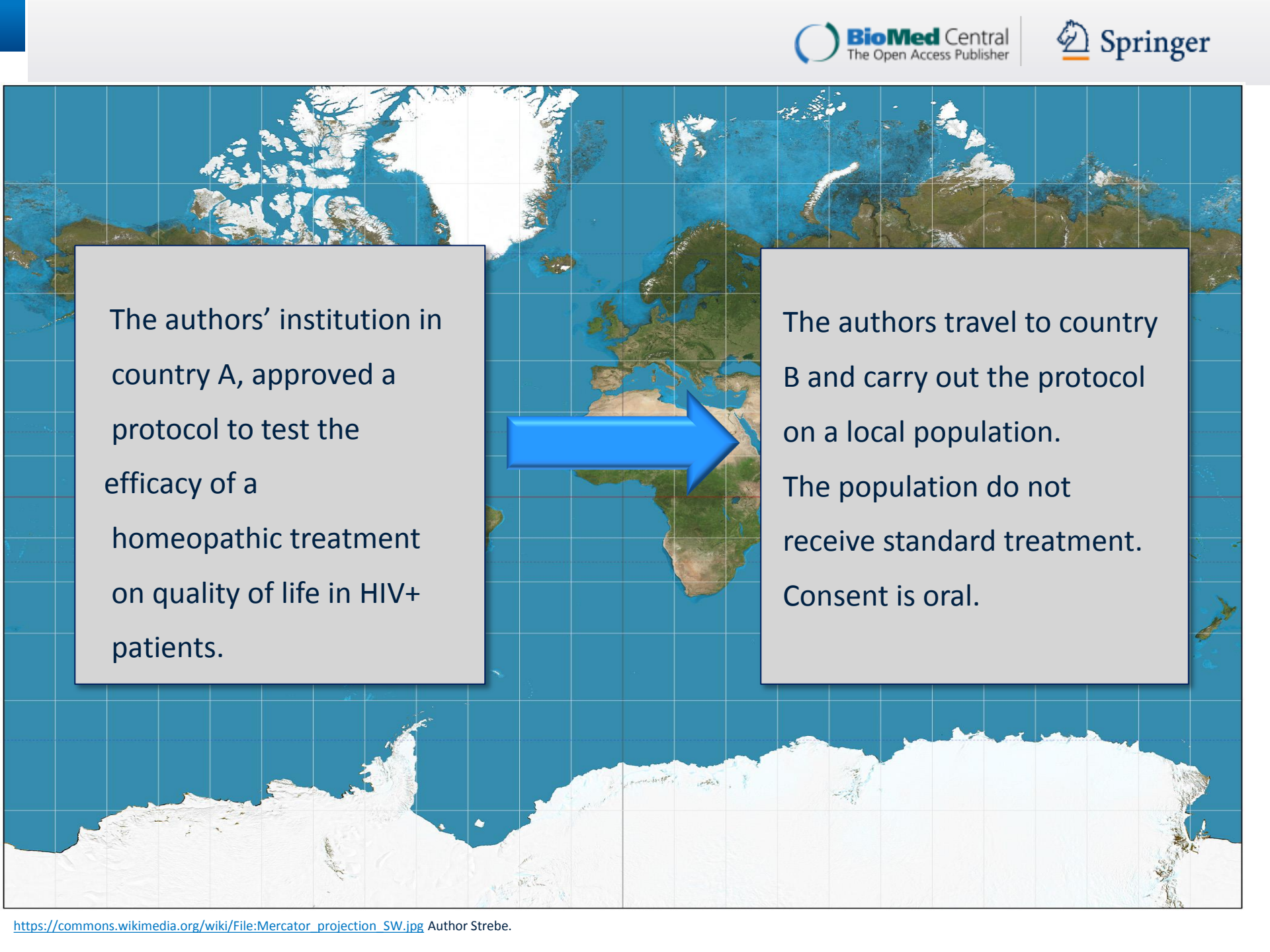
- **Set journal policies appropriately and aim to meet those policies, particularly with respect to:**
  - **Research ethics, including confidentiality, consent, and the special requirements for human and animal research**

**What are the challenges for  
journal editors and publishers?**





**Guidelines and expectations are not shared throughout the world.**



The authors' institution in country A, approved a protocol to test the efficacy of a homeopathic treatment on quality of life in HIV+ patients.

The authors travel to country B and carry out the protocol on a local population. The population do not receive standard treatment. Consent is oral.



## What can the editor do?

Not reject

Pursue as far as possible

Ask authors for an explanation

Ask the ethics committee

Ask the funders

Ask the Department of Health

Ask medical regulatory organisations

**Journals and publishers can feel powerless.**

## Another example

A protocol for a randomised trial is submitted.

The protocol has the necessary approvals from the authors' institution.

The participants will be randomised to a treatment for which there is new evidence of potential harm to those who have a history of heart disease.

# What can the editor do?

## Points to consider

- The study has not yet begun.
- If it is allowed to continue, participants will be exposed to a potential risk.

- New evidence of potential harm of the intervention.
- The editor asked the authors to talk to their ethics committee.
- The ethics committee asked for modifications to the protocol to avoid at risk patients from taking part.
- The authors changed their protocol.
- The journal eventually published the revised protocol.

Sometimes journal editors and publishers do  
do have the power to change things.



**There are scenarios that are not covered  
by guidelines.**

## Another example

A group of researchers published a study about the possible role of an infective agent on the development of a childhood ailment.

The study was published 17 years ago, but no-one has since performed a similar study.

The editor is alerted that the authors did not obtain approval from an ethics committee at the time of the study, although their institution did have an ethics committee at the time.

The authors have funding for further research.

# What can the editor do?

## Points to consider

- The conduct of the study complied with ethical principles.
- Although the data are 17years old, no-one has done a similar study since.
- There is a potential public health issue.
- There is interest in further research in the same area.
- If the article is retracted, the funding could be withdrawn.

The editor contacted the authors' institutional ethics committee.

The committee said it would have approved the study.

The editor decided to leave the article published and published an erratum explaining the lack of ethics approval and the editor's decision.

# New challenges

## Facebook

### Facebook emotion study breached ethical guidelines, researchers say

Lack of 'informed consent' means that Facebook experiment on nearly 700,000 news feeds broke rules on tests on human subjects, say scientists

[Poll: Facebook's secret mood experiment: have you lost trust in the social network?](#)



# Conclusion

**Acknowledge our collective responsibility.**

**Not all research that ticks the policy boxes is ethical.**

**Not all research that does not tick the policy boxes is unethical.**

# How can publishers support editors?

Raise awareness.

Provide resources, training and guidance.

Pursue issues.

Encourage retraction of unethical research.



# Thank you

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