Clinical research and publication ethics

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Tuskegee Syphilis Study
1932 to 1972

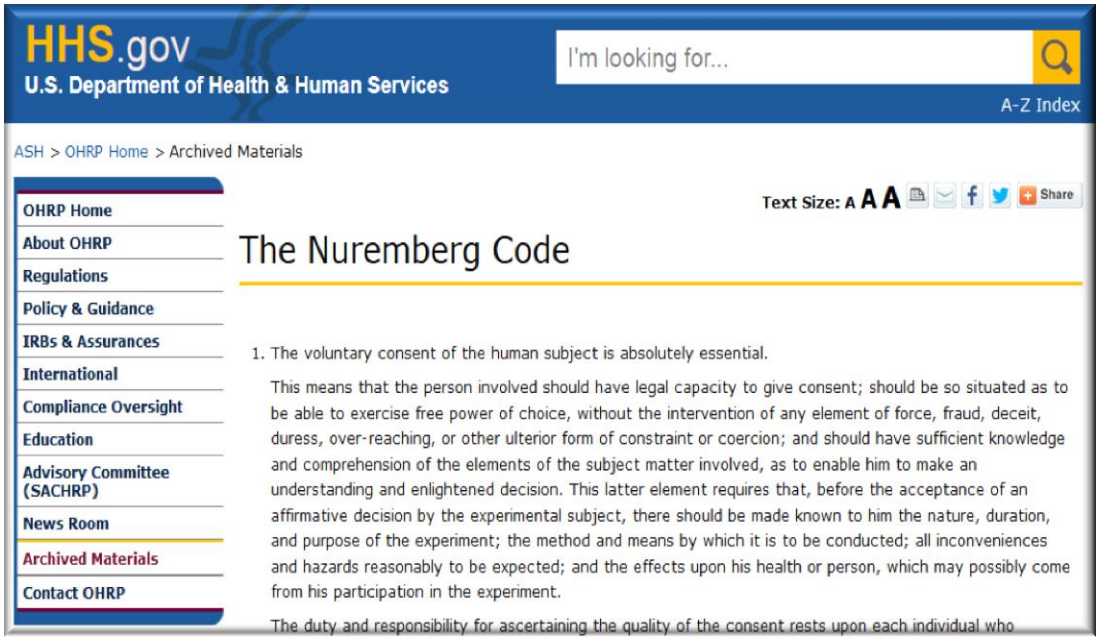
- Study the natural progression of untreated syphilis in rural African-American men in Alabama.
- Not told they were in a study.
- Treatment withheld.

http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx

Research ethics principles

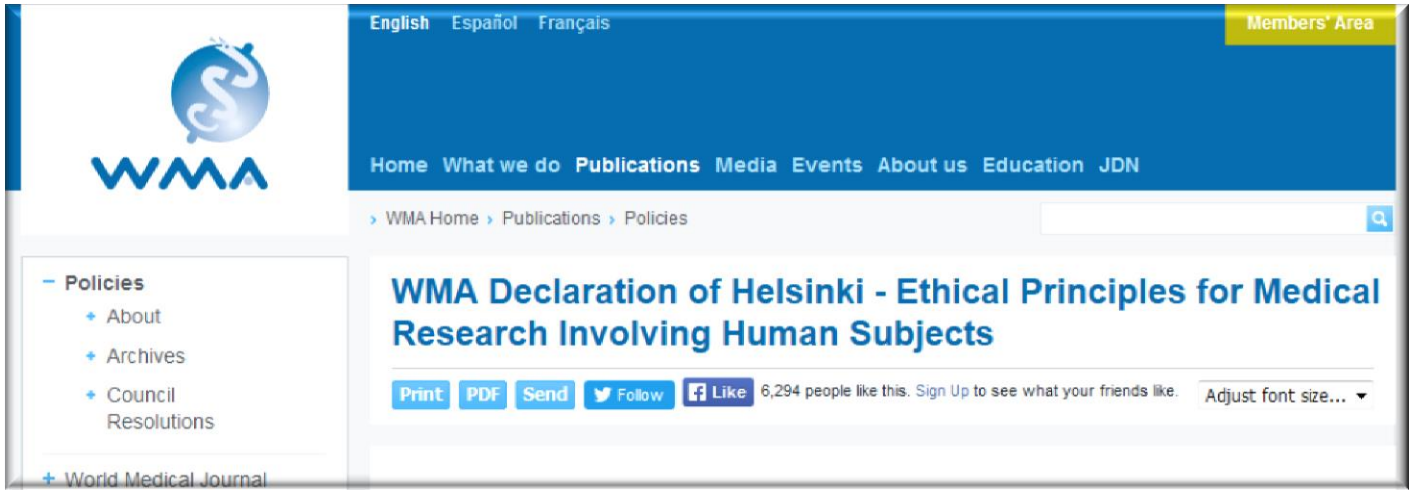
The Nuremberg Code
1947

Ten points that define legitimate medical research



http://www.hhs.gov/ohrp/archive/nurcode.html

The Declaration of Helsinki 1964



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

Regulations and law

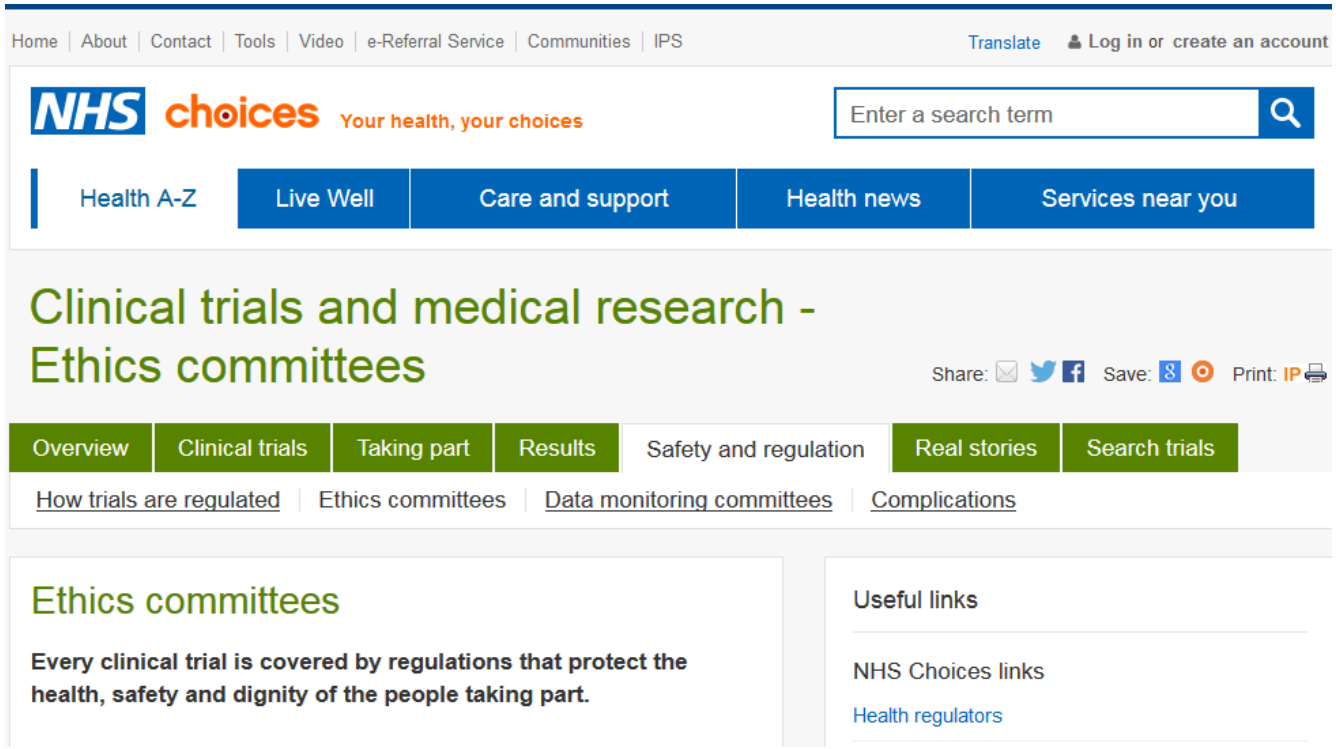
L 121/34 EN Official Journal of the European Communities 1.5.2001

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 4 April 2001

on the approximation of
relating to the impleme

https://www.mededcoventry.com/JDH/General_Information/EU_Directive.aspx

Requirements for ethical review of clinical research



COPE COMMITTEE ON PUBLICATION ETHICS

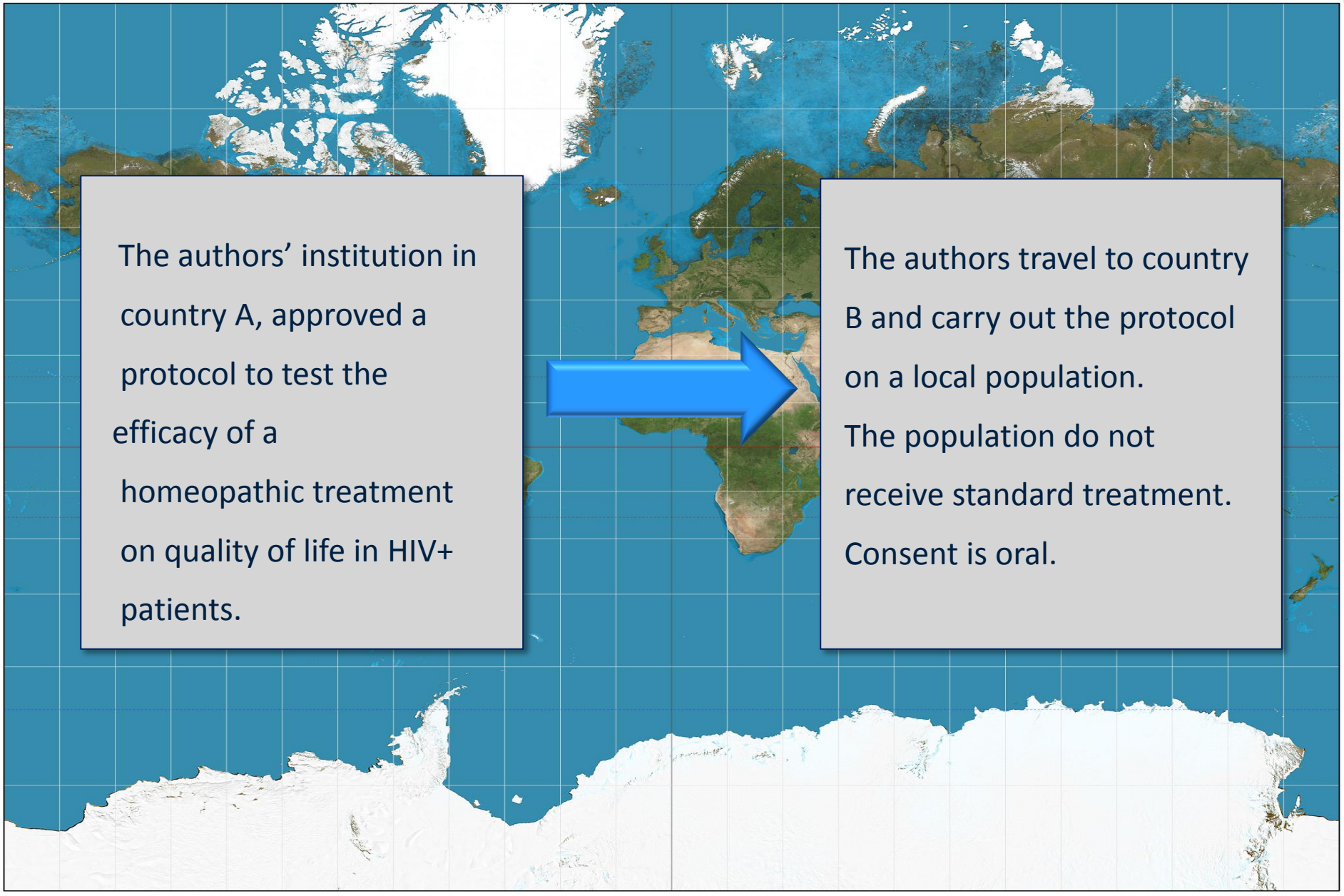
CODE OF CONDUCT FOR JOURNAL PUBLISHERS

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?

https://commons.wikimedia.org/wiki/File:Mercator_projection_SW.jpg Author Strebe.



https://commons.wikimedia.org/wiki/File:Mercator_projection_SW.jpg Author Strebe.

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?

http://www.theguardian.com/technology/2014/jun/30/facebook-emotion-study-breached-ethical-guidelines-researchers-say

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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