

Thinking Ahead

26-29 June 2012

11th World Congress of Bioethics
International Association of Bioethics

Rotterdam

Bioethics for the Future. The Future of Bioethics. Challenges, Changes, Concepts.



WMA Satellite Meeting The future of the Declaration of Helsinki

The new Declaration of Helsinki and the use of placebo in clinical trials: controversy still remains

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The new Declaration of Helsinki and the use of placebo in clinical trials: controversy still remains

- **Declaration of Helsinki** – strengthen measures to protect research subjects

- **Letter from Brasilia (2000):**

“The Declaration of Helsinki should be maintained as an overall set of concise principles. Even though the Declaration of Helsinki is the responsibility of the World Medical Association, the document should be considered the **property of all humanity**”

Human, Fluss, 2000

The new Declaration of Helsinki and the use of placebo in clinical trials: controversy still remains

- 1964 Declaration of Helsinki – worldwide accepted document
 - 1975 (Tokyo)
 - 1983 (Venice)
 - 1989 (Hong Kong)
 - 1996 (Somerset West)
 - 2000 (Edinburgh)
 - ...
 - 2002 (Washington)
 - 2004 (Tokyo)
 - ...
- 2008 Declaration of Helsinki – controversy (Seoul)



The new Declaration of Helsinki and the use of placebo in clinical trials: controversy still remains

- **DoH (2008) - § 32:** “The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
 1. The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
 1. Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option”.

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BRAZIL OFFICIAL BAN (2008 ...)

- **National Committee of Research Ethics (CONEP) : Resolution 404 (Aug 1st, 2008)**
- **DoH (2000) :** “The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention. This does not exclude the use of placebo, or no treatment, where no current proven intervention exists”.

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- **What are the options for the PLACEBO use debate?**

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- **What are the options for the PLACEBO use debate?**
 - a) **When Placebo IS Acceptable:**
Vitamin D Clinical Trial

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- **What are the options for the PLACEBO use debate?**
 - When Placebo IS Acceptable:**

Vitamin D Clinical Trial
 - When Placebo is NOT Acceptable:**

Tuskegee (1972)
HIV Transversal Contamination (1996)

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- **What are the options for the PLACEBO use debate?**
 - a) When Placebo IS Acceptable:**

Vitamin D Clinical Trial
 - b) When Placebo is NOT Acceptable:**

Tuskegee (1972)
HIV Transversal Contamination (1996)
 - c) When Placebo CHANGES Gold-Standard:**

CAST (1986) – Cardiac Arrhythmia Suppression Trial

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- **Controversy remains – radicalisms**

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Versus

ICH

International Conference of Harmonisation

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CFM and CONEP – Brazil

CFM (Federal Council of Medicine)
CONEP (National Committee of Research Ethics)

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Declaration of Helsinki

The new Declaration of Helsinki and the use of placebo in clinical trials: controversy still remains

- **Declaration of Helsinki – common ground**
- **Placebo use**
 - a) **pragmatic**
 - b) **idealistic**

NOT!

The new Declaration of Helsinki and the use of placebo in clinical trials: controversy still remains

- **Declaration of Helsinki – common ground**
- **Placebo use**

c) case – by – case

Thank You.