



# Revising the Declaration of Helsinki Points to Consider

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## **TRREE – FMH**

WMA Conference

Cape Town, South Africa

December 6, 2012

# Overview



- TRREE – FMH position statements
- Clarification of the relation between the DoH and the law
  - Legal order – ethical reasoning
  - Normative density
  - Nature of the DoH
- Why is there a mix of principles and detailed rules in the DoH and what to do about it
- Conclusions

## TRREE – FMH position statements



**TRREE**

- If there is no urgency for the revision of a law, it is urgent not to revise it **(FMH – TRREE)**
- If specific issues deserve more detailed guidances, they should be covered in a separate set of documents **(FMH – TRREE)**
- The placebo rule must be maintained (and even strengthened) **(FMH – TRREE)**
- The consultation process should be open to non-English speaking stakeholders, with special attention to interested parties in developing world **(TRREE – NHREC Cameroon – FCRM Congo – Odile Ouwe Missi Oukem, Niger – Dr. Morenike Ukpong, Nigeria – etc.)**

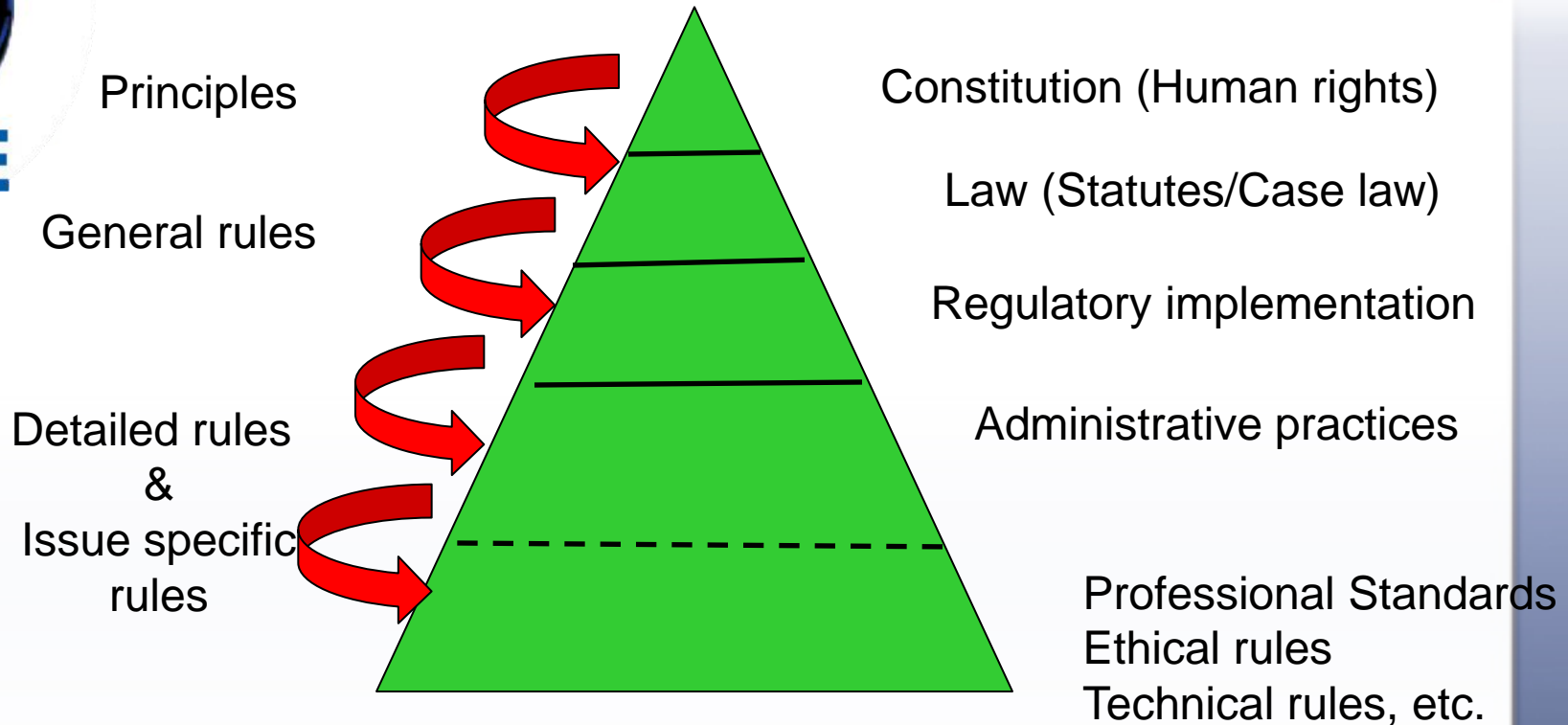
# Clarification of the relation between the DoH and the law: Preamble



- The law is not limited to the legislation and case law
- Research ethics is not limited to code of ethics such as the DoH or professional standards such as the ICH – GCP

The value of the DoH is not based primarily on the fact that it was adopted by the WMA, but on the fact that it reflects the applicable ethical principles in the field.

# Parallelism between the legal order and ethical reasoning (a theoretical view)



«Ethical reasoning is, and ought to be, hierarchical and deductive»

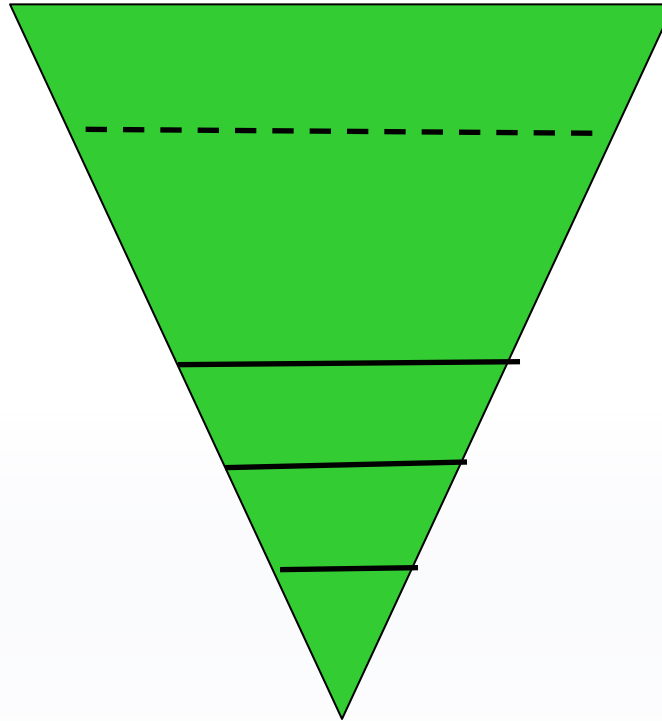
(Robert Levine on the Belmont Report)



## Normative density (rule of law)

- Every rule or norm is characterized by its normative density. This includes two elements:
  - Specificity
  - Clarity
- The more specific and the more detailed is a rule, the higher is its normative density

# The pyramid of norms (a pragmatical view)



At the light of the concept of normative density, the hierarchy of norms is reversed.



## Nature of the DoH

- The DoH is focusing on principles. It may be considered as the Constitution of research ethics.
- The normative density of the DoH is low
- It requires more detailed rules to be implemented
- In principle, those rules of implementation do not belong to the DoH as they are not principles...



## Why is there a mix of principles and specific rules in the DoH?



- The DoH is not merely an academic document. It is the product of history, lobbying from various stakeholders, of the development strategy of the WMA, etc.
- Its present structure and content is the expression of a careful consensus within the medical profession and also the research community, the RECs and competent authorities worldwide



## Why rules exist?

- Rules exist because they are violated
- The violation of a legal or ethical rule precedes its adoption
  - The placebo rule hurts the interests of those wanting research to go faster but it contradicts the Council of Europe and EU principle of the primacy of the interests of the participants v. the sole interests of science or society



## Conclusions

- The WMA should only revise the provisions that do create problems.
- The fact that a principle requires more detailed instruction to be implemented does not mean the principle should be revised.
- For emerging issues or issues requiring more detailed rules, the WMA should adopt guidance documents separated from the DoH which should be implemented in the light of the DoH (cf. Council of Europe Convention of Human Rights and Biomedicine and its additional protocols).



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