

# The Eighth Revision of the Declaration of Helsinki:

## What Should be Done?

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# Thanks

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- I have been a critic of the Declaration.
  - Inviting me to address the WMA during this revision process displays a deep commitment to openness and to considering views of critics.
  - You are to be admired and thanked.
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# Outline

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- Status of the Declaration
- Problems with the Current Version of the Declaration
- Recommendations for the Revised Declaration

# Status of the Declaration

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- Declaration of Helsinki stands as an honored guidance document on human subjects research.
- In 1964, it was pre-eminent.
- In 2012, it is not alone but in a crowded field.

# Status of the Declaration

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- A revision of the Declaration needs to accomplish two things:
  - Distinguish itself from other guidance documents.
  - Justify why it should be followed relative to other documents.

# Status of Declaration

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- Unlike other guidance documents, Declaration is short—35 paragraphs and just over 2000 words.
- The aim is to keep it as a short document— i.e. to be read in under 15 minutes.

# Status of Declaration

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- As a short document, the Declaration must be a statement of broad principles that guide reasoning about the ethics of human subjects research.
  - A broad Constitution requiring elucidation and interpretation.
  - Not detailed legislation or regulation.

# Status of Declaration

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- Consequently, the revision must be scrutinized to remove
  - Provisions that do not relate to human subjects research—e.g. animal research, impact of environment, and unproven interventions.
  - Detailed specifications of requirements—e.g. what should go into protocols, operations of REC, who is and is not vulnerable.



# Status of Declaration

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- Consequently, the revision must
  - Address everyone who is engaged in the research endeavor not just physicians. As a broad statement of principle it applies to all who participate in research.
  - Adopt broad language— “Separation of Church and State” “Equal Protection under the Law”

# Problems with the Declaration

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- The Declaration has grown from 11 provisions to 35 provisions.
- The provisions never reflected a coherent view of the ethics of research. It has always been an apparent random collection of provisions rather than a coherent framework.

# Problems with the Declaration

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- Past revisions of the Declaration have significantly changed the document and then changed it back.
- Seems as if there is no limit on the changes. If a Constitution, should aim for carefully worded document—not one that changes with the times.

# Problems with the Declaration

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- At least 6 major problems:
  - Confuses patient care and research
  - Disorganized bordering on incoherent.
  - Repetitive provisions
  - Contradictory provisions.
  - Contains vacuous statements
  - Makes ethical judgments that appear to lack justification.

# Problems with the Declaration

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- The introduction –especially provisions 3, 4, and 35—confuse patient care and research.
- Research subjects are not patients and do not have the same ethical entitlements.

# Problems with the Declaration

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- One consequence of the confusion is narrowing the audience for the Declaration to physicians and then stating that “other participants” are encouraged to adopt these principles.
- Also sanctions some types of non-research clinical interventions.

# Problems with the Declaration

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- Disorganization:
  - No coherent framework. Having a coherent framework does **not** mean Declaration has to adopt either a utilitarian or deontological philosophy, but it must have a view that it is articulating.
  - No clear rationale or logical flow informing the order of the provisions and how they connect.

# Problems with the Declaration

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- Risks-Benefits— provisions 8, 18, 20, 21, 27
- Informed consent—22, 24, 25, 26, 27, 28, 29 with three provisions—27-29— related to incompetent patients
- Why animals or environment or advice to editors?
- Why providing access to research for under-represented populations in the introduction?



# Problems with the Declaration

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- Why does registering a trial occur in the midst of provisions about risk and benefits?
- No clear specification of who has an obligation for fulfilling various provisions—eg providing post-trial access.

# Problems with the Declaration

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- Repetitive provisions
  - Voluntary consent in provision 22 and then again in 24 and maybe 34.
  - Relationship between value of research and risk in provisions 21 and 31.

# Problems with the Declaration

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- Contradictions
  - Addressed to physicians but then has provision addressed to authors, editors and publishers as well as to “other healthcare professional”.

# Problems with the Declaration

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- Well-being takes precedence over all other interests (provision 6), but in other places other interests—privacy, self-determination, benefits to communities—must be considered with no ordering of the interests—provision 11.

# Problems with the Declaration

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- Vacuous provisions
  - “most interventions involve risks and benefits.”
  - “It is the duty of physicians who participate in research to protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research information of research subjects.”

# Problems with the Declaration

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- There are many provisions that seem to lack ethical justification:
  - Why require such extensive disclosure of conflict of interest but not prohibit conflicts of interest or require they be managed?
  - Why require the research with unconscious patients be done only if the condition that prevents consent is the one being researched—unconsciousness post MI?

# Fixing the Declaration

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- Need careful and consistent wording of broad principles—avoiding elaboration of details
- Need to address all those engaged in research
- Need coherent framework
- Need to try to develop an enduring document.

# How to Fix the Declaration

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- 1) Begin with necessity for and purpose of medical research—provisions 5 and 7.
- 2) Emphasize the purpose of an ethical code on human subjects research—to protect subjects from exploitation and harm to their interests—health, well-being, self-determination, privacy—Combine provision 6, with relevant parts of 9 and 11.



# How to Fix the Declaration

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- 3) State to whom the ethical principles apply—e.g. everyone engaged in research.
  - 4) State that broad ethical principles require interpretation and application and that this will occur in individual country research regulations. This clarifies relation of Declaration to individual country laws.
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# How to Fix the Declaration

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- 5) State that research must be informed by science and conducted rigorously to produce valid and reliable data. Expand provision 12.
- 6) State that research needs to enroll people fairly—include under-represented, not target vulnerable, etc. Combine provisions 5, 17, 29, maybe 35

# How to Fix the Declaration

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- 7) Discuss the need to assess likelihood and magnitude of risks and benefits in quantitative manner and how to weigh risks and benefits of research. Refine provisions 8, 18, 20, 21,
- 8) Require elaboration of research protocol. Provision 14. Maybe less detail.

# How to Fix the Declaration

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- 9) Require independent review by research ethics committee. State when expedited review is permissible and when comprehensive review is appropriate. Revise provision 15.

# How to Fix the Declaration

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- 10) State qualifications and obligations of researchers—eg not only physicians, etc. Specify the requirements on conflict of interest—e.g. no conflict of interest or managed. Provision 16 and more. Consider shortening to principles rather than shopping list.

# How to Fix the Declaration

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11) Informed consent— divided into four provisions:

- Mentally competent
- Mentally incompetent
- Emergency research
- Human material and data.

Specify what it requires in terms of information, voluntariness (avoidance of coercion, etc).

# How to Fix the Declaration

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- 12) Specify researchers' ethical obligations including
- Protecting enrolled subjects of research
  - Data security and maintaining confidentiality of data,
  - Informing research subjects of results.
- 13) Compensation for research related injuries.

# How to Fix the Declaration

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- 14) Registration of research—might limit this to clinical research with greater than minimal risk
- 15) Public dissemination of results
- 16) Post-trial access to interventions.



# Conclusion

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- Declaration of Helsinki has a special place as guidance document.
- While in 1964 the Declaration was alone and preeminent, today it has significant competition from other documents.
- There is a need to clarify and specify its special role.

# Conclusion

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- The Declaration is to remain relevant and to remain a short document, then
  - It must become a broad statement of principles much like a Constitution.
  - This means it will be interpreted and specified by particular laws and regulations in countries.
- Thus the Declaration is “Constitution-like” and its form should reflect this.

# Conclusion

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- Currently Declaration does not reflect this role.
- Declaration has serious problems that have been compounded by revisions—  
incoherent structure, contradictions, unjustified provisions, too much detail to be a broad statement of principles.

# Conclusion

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- Reformat and refocus the Declaration.
- Given you an initial attempt at that reformulation.
- Careful, statement of principles is needed.