Overview of the revision process of the 2024 Declaration of Helsinki: Part 2 - General descriptions and some highlights

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(My personal view, not from WMA side; Not representing any organisation)

Slide 1: Cover

Thank you everyone for participation. My name is Chieko Kurihara, Kanagawa Dental University, one of the organizers and will present overview of the revision process of the 2024 Declaration of Helsinki, General descriptions and some highlights. All the content is my personal view not from WMA side, Not representing any organization.

Slide 2: Chieko Kurihara, Self-introduction

I am working at National Research Institute, as Vice-chair of Research Review Board. I am engaged in Ethics Working Group of the IFAPP also engaged in ICRP's activity of developing international ethics documents.

Slide 3: Contents: Background

Slide 4: Springer book

I have been engaged in the discussions of the DoH since 2000 revision from external position from the WMA, and most recently published this book as a leading editor collaborating with co-editors prof Greco and Prof Ames Dhai. Ames Dhai will attend the second day of this webinar August 26. The book title is *Ethical innovation for global health: pandemic, democracy and ethics in research*. Published from Springer last November. This book acquired 2,700 downloads in 109 countries worldwide during 8 months form publication. Then we planned NEXT publication within next year, to discuss about the new version of the DoH.

Slide 5: World Medical Association (WMA) Declaration of Helsinki (DoH)

DoH new version will be adopted in October, there were 2 times of public consultations. I led two times of comment submissions from IFAPP Ethics WG members which was not officially representing IFAPP. And today's presentation is my personal view not representing IFAPP.

Slide 6: WMA Regional Meetings

There were WMA's Regional meetings discussing several topics. IFAPP President Varvara

Baroutsou was invited to discuss new clinical trial design. She will attend the next day of this webinar. I was invited to coming Washington DC meeting held on August 15 and 16, focusing on advocacy and communications, this is representing IFAPP Ethics WG.

Slide 7: Contents: Key changes in the draft revision of the DoH and My opinions (Phase 2 consultation version)

Slide 8: Paragraph 1 Scope

Through the document the word “human subject” is changed to “human participant”. Because this is the same as ICH GCP Renovation, the impact of the DoH is not so much.

Slide 9: Paragraph 2 Scope of obliged persons

Another point is that recommendation to non-physician researchers became strengthened. This is in line with the IFAPP’s position.

Slide 10: Paragraph 7 Community engagement (New)

One of the highlights is the new paragraph on Community engagement. It is important to stress that research takes place in the context of various structural inequities. Meaningful community engagement is recommended to avoid inequities in the conduct and result implementation of the research.

Slide 11: Paragraph 6～8 Purpose of research

Next about the purpose of research that can never take precedence over the rights and interest of individual research participants. This core principle of the DoH is not changed. A new paragraph states even in the public health emergency the principles in the DoH does not change. The word Social Value was added in the first draft as the ultimate goal of research but it was deleted in the second draft. It was disappointing because social value is established concept in the CIOMS 2016 guidelines for health research.

Slide 12: Paragraph 19 Vulnerability

There is also an extensive discussions on vulnerability. The world trend is changing from stereotypical categorization of vulnerable groups such as children, pregnant women, to context-based vulnerability, which means vulnerability is changing up to the situations. Another point is to promote inclusion of vulnerable people in research rather than protection by means of excluding them. This is because better health of vulnerable people needs more inclusion in research with strengthened protection. This is already clearly discussed in CIOMS.

Slide 13: Paragraph 21 Scientific requirements

Another interesting point is to include new word “research waste”. This is because during the COVID-19 pandemic many meaningless research results were published. Something missing is that there is no mention of prevention of scientific misconduct.

Slide 14: Paragraph 23 REC, strengthened

Research ethics committee's function is strengthened. Most importantly, in case of international research both in sponsoring and host country reviews are required.

Slide 15: Paragraph 25～32 Informed Consent

In terms of informed consent electronic documentation comes to be mentioned.

Slide 16: Paragraph 32 Informed consent for the collection, storage, secondary use of biological material and data

This is the most important highlight of this revision. During the process you obtain informed consent of research participant, if there is a possibility of future secondary use of the data/materials from the research, you have to adhere to the Declaration of Taipei. The content of the DoT is not easy, not limited to privacy protection or security, you have to consider handling of incidental findings, intellectual property rights and material transfer agreement. We have to learn more about the Declaration of Taipei.

Slide 17: Paragraph 33 Conditions of placebo study

Condition of placebo study when there is a proven intervention is the most controversial points of debates. Unfortunately there seems to be no change at this moment. Since 1975 to 2000 the DoH describes physician's duty to provide best-proven intervention even in comparative study. However, according to the ICH E10 guidelines in 2000, the DoH changed its position to Utilitarian pragmatism to allow placebo study when there is a proven intervention if there is no increase of risk of serious or irreversible harm. On the other hand, CIOMS guideline 2016 takes a different risk threshold "minor increase above minimal risk". IFAPP members paper for which I am a leading author supported this CIOMS position of risk minimization

Slide 18: Paragraph 34 Post-trial access

- **"Post-trial access":** ethical standard, first included in the 2000 version of the DoH, of ensuring that participants in a trial are provided with an intervention proven to be effective in that trial, at the completion.
- In the case of a placebo trial, the intervention shown to be effective would be made available to participants in the placebo arm.
- In any study design, a participant who still needs the study intervention at the end of the study should be provided with this intervention after the end of the study.
- Without post-trial access, the trial participants are being **exploited**.
- However, sometimes it is difficult for the sponsor to provide access because of the time gap before regulatory approval.

Slide 19: Paragraph 34 Post-trial access

- Because of these difficulties, since 2004 "post-trial access" has become an item to be described in the protocol and informed consent, whether or not there is post-trial

access.

- In the 2024 revision (draft), the requirements for "post-trial access" are strengthened, but there is an excuse: "Exceptions to these provisions must be approved by a research ethics committee".
- Argument of IFAPP members: (not official statement of IFAPP)
  Post-trial access should be available to:
    - Participants who still need the trial intervention
    - People in the trial host community
    - Those most in need worldwide

Slide 20: Paragraph 2 Scope of obliged persons

Thank you for your attention! We hope that you visit these websites to upload continuous discussions.

Registration for the second day, August 26 is still now open, so please share this information to your friends.

I will share this slide with today's participants, soon.

And video-recording of this and previous webinars are available from this website.

Looking forward to further opportunities of discussions! Thank you very much.