Post-Trial Obligations in the Declaration of Helsinki 2013

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Post-trial obligations in Declaration of Helsinki 2013

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CONICET-FLACSO-UBA

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Consensus on post-trial responsibility (PTR)

- Responsible transition
  - Responsibility towards participants does not end when trials end
- Joint responsibility
  - PTR shared by different agents in different stages
- On the rest “we agree to disagree”
  - Who owes what to whom and why?
  - No clear consensus on PTR identification and assignment to agents

WMA Declaration of Helsinki (DoH)

- Last version October 19th, 2013
- Previous versions no longer valid

Declaration of Helsinki (DoH) 2008

- Paragraph 33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

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Declaration of Helsinki (DoH) 2008

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	Post-trial access obligations to individual research participants				
DoH	1. Care after research		2. Other appropriate benefits	3. Relevant information after research	"Strength" of text (Macklin 2013)
	1.1. Study intervention	1.2. Other appropriate care			
2008	☺	☺	☹	☺	

1. Care after research

Jay Weinstein + imatinib (Glivec™) (2005)

Phil Marino for *The New York Times*

2. Care after research

Dr. Brian Druker, Carolyn Blasdel & Jay Weinstain (25 de julio, 2007)

Andrew Holtz for *The Oncology Times* *Interview*

3. Relevant information after research

‘Our cars get recalled,” noted one participant with experience in five trials”.(Sofaer et al. 2009)

Access to relevant information

- “[...] these people took our drugs for us to see what was going on, and a year down the road we found out, oh, by the way, these might kill you. Hey, maybe we ought to call them and let them know!”. (Sofaer et al. 2009)
  - Participant complains of learning about Vioxx® adverse effects only from the media (Sofaer et al. 2009)
  - Other relevant information? Holzer (2015)

Declaration of Helsinki (DoH) 2013

- Post-Trial Provisions. 34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

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2013					

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2008					
2013					

☺ Positive aspects of DoH 2013

1. Reference to “other benefits” removed
   - It was a blank check (Mastroleo 2013)
2. Responsible agents identified
   - Open-ended list? (Mastroleo 2015)
3. Post-trial tied to participants health needs
4. Disclosure of post-trial plans in informed consent process

☹ Negative aspects of DoH 2013

1. The term “access to other appropriate care” was removed
   - More research needed on implementation (Mastroleo 2015)
2. Limitation of access to relevant information after research to “general outcome and results”
   - Why? (Mastroleo 2015)

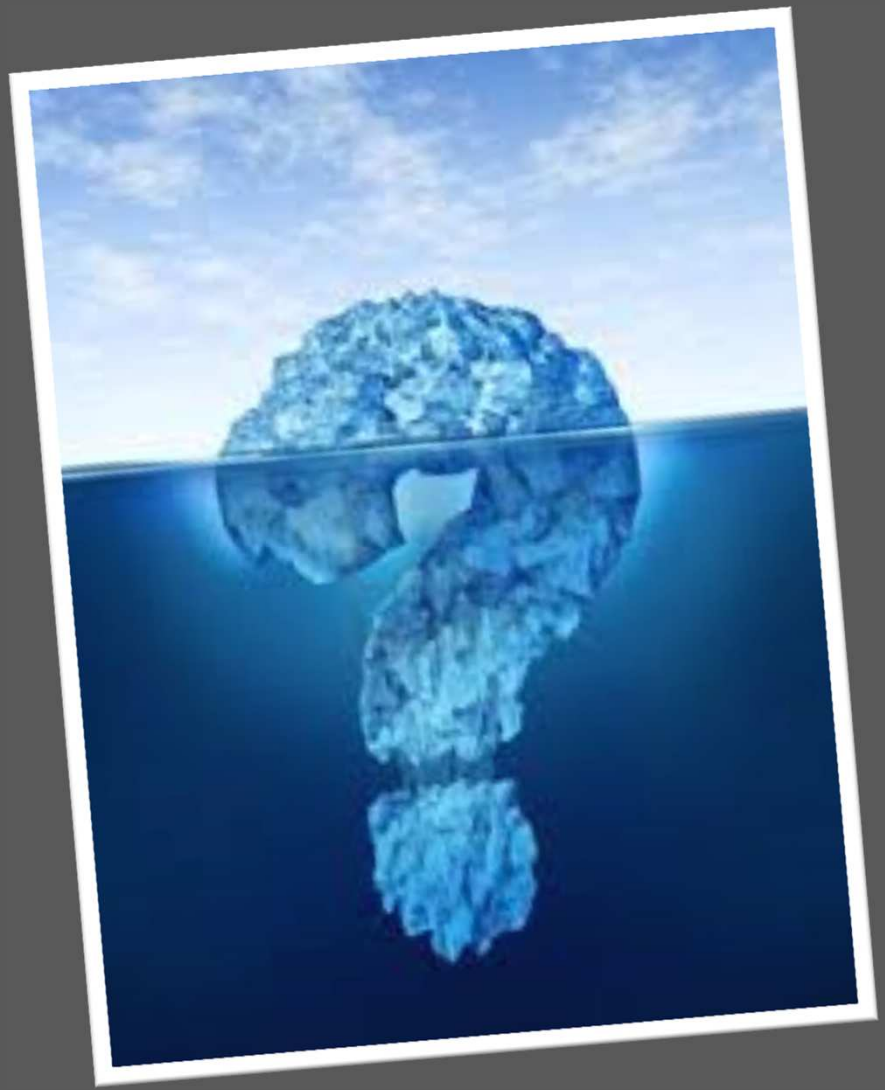
😐 Other aspects of DoH 2013

1. Internal inconsistency on relevant information
   - The reference hidden in #26
   - DoH 2013 draft was part of Post-trial provisions #34

Remaining concerns

- Undue inducement? False hopes?
- Golden hand-cuffs?
- Proper regulation and implementation?

Post-trial ethics?



Vielen Dank!

Milstein and Kohler (1984)

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Articles

http://philpapers.org/

http://www.academia.edu/

Acknowledgments

APENDIX

3. Relevant information after research

References

- Baker, R (2005) “International Bioethics And Human Rights: Reflections On A Propose Universal Declaration On Bioethics And Human Rights”, Politics and Ethics Review, 1(2):188-96.
- Bazin, H. (2011). *Vaccination: a history from Lady Montagu to genetic engineering*. John Libbey Eurotext.
- Emanuel, E., David Wendler, and C. Grady. "An ethical framework for biomedical research." *The Oxford textbook of clinical research ethics* (2008): 123-135.
- Grady, C. (2014) «Ethical and Regulatory Aspects of Clinical Research” http://videocast.nih.gov/summary.asp?Live=14685&bhcp=1
- Katz, J. (1972). *Experimentation with human beings: The authority of the investigator, subject, professions, and state in the human experimentation process*. Russell Sage Foundation.
- Kitcher, P. (2004). *Science, truth, and democracy*. Oxford University Press.
- London, A. "Responsiveness to host community health needs." Emanuel et al. (eds.) *The Oxford Textbook of Clinical Research Ethics.* (2008):737-744
- Mastroleo, I. (2011). La evaluación de la investigación científica en las sociedades democráticas: Kitcher, Rawls y el enfoque de las verdades científicas significativas. *Revista Redbioética/UNESCO*, *2*(4), 43-60.

	Post-trial access obligations to individual research participants				
DoH	1. Care after research		2. Other appropriate benefits	3. Relevant information after research	"Strength" of text (Macklin 2013)
	1.1. Study intervention	1.2. Other appropriate care			
1964-1996	☹	☹	☺	☹	| | | |
2000	☺	☹	☺	☹	| | | |
2004	☺	☺	☺	☹	| | | |
2008	☺	☺	☹	☺	| | | |
2013	☺	☹	☺	😐	| | | |

DoH	Post-trial access obligations to individual research participants				
	1. Care after research		2. Other appropriate benefits	3. Relevant information after research	"Strength" of text (Macklin 2013)
	1.1. Study intervention	1.2. Other appropriate care			
1964-1996	☹	☹	☺	☹	| | | |
2000	#30	☹	☺	☹	| | | |
2004	#30 +note	#note	☺	☹	| | | |
2008	#33	#33	#33	#33	| | | |
2013	#34	☹	☺	#26	| | | |

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1964-1996	☹	☹	☹	☹	-
2000	#30	☹	☹	☹	| | | |
2004	#30 +note	#note	☹	☹	| |
2008	#33	#33	#33	#33	|
2013	#34	☹	☹	#26	| | |

DoH	Post-trial access obligations to individual research participants			
	1. Care after research		2. Other appropriate benefits	3. Relevant information after research
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1964-1996	☹	☹	☹	☹
2000	☺	☹	☹	☹
2004	☺	☺	☹	☹
2008	☺	☺	☺	☺
2013	☺	☹	☹	😐

	Post-trial obligations to individual participants			
DoH	1. Obligations of care after research		2. Other appropriate benefits	3. Obligations of access to information after research
	1.1. Study intervention	1.2. Other appropriate care		
1964-1996	X	X	X	X
2000	#30	X	X	X
2004	#30 +note	#note	X	X
2008	#33	#33	#33	#33
2013	#34	X	X	#26

Declaration of Helsinki 2000

- Paragraph 30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

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Declaration of Helsinki 2004

- Note of clarification on paragraph 30 of the WMA Declaration of Helsinki [2000]. The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

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Declaration of Helsinki 2008

- Paragraph 33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

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Declaration of Helsinki 2013

- Post-Trial Provisions. 34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Only valid version

Declaration of Helsinki 2013

- Informed consent. 26. […] All medical research subjects should be given the option of being informed about the general outcome and results of the study.

Only valid version

Declaration of Helsinki 2013

- Informed consent. 26. “In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of […] post-study provisions […]”

[Relevant information after research]

- […] All medical research subjects should be given the option of being informed about the general outcome and results of the study.

Only valid version

Declaration of Helsinki 2013

- Vulnerable Groups and Individuals. 20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Only valid version