

**Lost in delusion:  
Reflections on the Article: “The 50th Anniversary of the Declaration of Helsinki.  
Progress but Many Remaining Challenges”**

**La ilusión perdida:  
Reflexiones sobre el artículo: “El cincuenta aniversario de la Declaración de  
Helsinki. Progreso pero muchos retos pendientes”**

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**Abstract**

This year marks the 50th anniversary of the Declaration of Helsinki. In this paper the last revision of the Declaration is discussed. Instead of addressing separately each revision that has been made, the author discusses the Declaration from the vantage point of Ezekiel Emanuel et al.'s critique of the current version. Four substantial points in their critique are the focus of attention: informed consent and confidentiality pertaining to biological samples; the primacy principle of the human being in research; research conducted in cash-poor communities and the use of placebo. The author shares Emanuel et al. critiques of the Declaration's restricted view with regard to who is its primary addressee, i.e. physicians. However, the author argues that Emanuel et al.'s substantial critique is built on shaking foundations, and that their suggestions for revisions reflect a normative view that is at odds with fundamental human rights and with several normative core commitments in medical and health related research.

Keywords: Declaration of Helsinki, Emanuel critique, human rights, normative view

**Resumen**

Este año se cumple el 50 aniversario de la Declaración de Helsinki. En este trabajo se discute la última revisión de dicha Declaración. En lugar de abordar por separado cada revisión que se haya hecho, el autor discute el punto de vista sobre la Declaración de Ezekiel Emmanuel y otros críticos de la versión actual. Se abordan cuatro puntos sustanciales de la crítica: el consentimiento informado y la confidencialidad en relación con las muestras biológicas, el principio de la primacía del ser humano en investigación, la investigación llevada a cabo en comunidades efectivamente pobres y el uso del placebo. El autor comparte la crítica de Emanuel y otros acerca de que las frecuentes revisiones socavan la autoridad de la Declaración y simpatiza en consecuencia con su crítica respecto de la visión restringida de la misma en relación con quiénes son sus principales destinatarios, es decir los médicos. Sin embargo el autor argumenta que la crítica sustancial de Emmanuel y otros se sostiene sobre fundamentos poco firmes y que sus sugerencias de revisión reflejan una visión normativa que contradice los derechos humanos fundamentales y compromisos normativos básicos en investigación médica y en la relacionada con la salud.

Palabras clave: Declaración de Helsinki, crítica de Emanuel, derechos humanos, visión normativa

**Resumo**

Este ano completa 50 anos da Declaração de Helsinki. Neste trabalho se estuda a última revisão de tal Declaração. Em vez de analisar separadamente cada revisão feita, o Autor discute o ponto de vista da Declaração de Ezekiel Emmanuel e outros críticos sobre a versão atual. São considerados quatro pontos substanciais da crítica: o consentimento informado e a confidencialidade em relação às amostras biológicas, o princípio da primazia do ser humano na pesquisa, a pesquisa entre comunidades efetivamente pobres e o uso do placebo. O autor concorda com a crítica de Emanuel e outros de que as frequentes revisões minam a autoridade da Declaração, e se simpatiza consequentemente com sua crítica sobre a visão restrita quanto àqueles que são seus principais destinatários, ou seja, os médicos. O Autor argumenta, porém, que a crítica substancial de Emanuel e outros se sustenta sobre

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fundamentos pouco sólidos e que suas sugestões de revisão refletem uma visão normativa que contradiz os direitos humanos fundamentais e compromissos básicos em pesquisas médicas e nas relacionadas com a saúde.

Palavras Chave: Declaração de Helsinki, crítica de Emanuel, direitos humanos, visão normativa

## Introduction.

On May the 4th 2013 Ezekiel J. Emanuel, the former Director of the NIH's Department of Clinical Bioethics and vociferous spokesman for the scandalized notion of "fair benefit" in clinical research ethics, published a paper in the *Lancet* stating: "Next year will mark the 50th anniversary of the Declaration of Helsinki. Consequently, the World Medical Association (WMA) is developing its eighth version of the Declaration. This anniversary presents an excellent opportunity to reconsider the problems of the Declaration and how they can be remedied to ensure the document retains its prominent status" (Emanuel, 2013, pp. 1532-1533). According to Emanuel, while the 1964 version of the Declaration with its 11 articles and 713 words was a unique normative document, the numerous revisions of the Declaration throughout the years have turned it into a document three times as big both in terms of articles (in total 35) and words (2045) and with a whole range of problems in need of being rectified:

"it has an incoherent structure; it confuses medical care and research; it addresses the wrong audience; it makes extraneous ethical provisions; it includes contradictions; it contains unnecessary repetitions; it uses multiple and poor phrasings; it includes excessive details; and it makes unjustified, unethical recommendations" (Emanuel, 2013, p. 1533).

At the same time the author criticizes the frequency with which the Declaration has been undergoing revision, since this undermines its normative authority: "to be authoritative, the Declaration must aspire to what might be considered 'tentative immortality'" (Emanuel, 2013, p. 1533). A reasonable interpretation of this verdict is that the Declaration is only in need of revisions when it does not comply with the normative convictions of Mr. Emanuel!

Six months later, when the latest revision of the Declaration was released, Emanuel together with

Joseph Millum and David Wendler, published an opinion paper in *JAMA*, hailing the significant improvements that had been made, while at the same time arguing for the need of rectifying a whole range of remaining inadequacies, confusions and mistakes and doing away with conflicting, inconsistent, unclear and problematic forms of guidance (Millum, Wendler and Emanuel, 2013).

I share Emanuel and his colleagues' critique about frequent revisions undermining the authority of the Declaration, and I also sympathize with their critique of the Declaration's restricted view with regard to who is its primary addressee, i.e. physicians, since this reflects a denial of the fact that the number of physicians involved in medical and health related research involving human subjects is steadily decreasing compared to researchers with other forms of background training. On most substantial points, however, I strongly disagree with their suggestions for revisions, because they reflect a normative view that may be digestable within a US-context but is at odds with several normative core commitments in medical and health related research. In my analysis of their critique I focus the attention on: a) informed consent and confidentiality pertaining to biological samples; b) the primacy principle of the human being in research; c) research conducted in cash-poor communities and d) the use of placebo.

## The treatment of informed consent and confidentiality pertaining to biological samples

The authors criticise the revised Declaration for not providing

"...guidance on when it can be appropriate to ask participants to give broad consent for their biological samples to be used in a wide range of future studies, rather than seeking consent for each specific study. This is a pressing issue on which

researchers need clear guidance” (Millum, Wendler and Emanuel, 2013: p. 2143).

There is no reference what so ever in their opinion paper to the bulk of scholarly literature having discussed and criticised the move from individual express consent to conceptions of so-called broad and even ‘open consent’ in this context. This, in fact, is a tendency throughout the paper, since the authors in their critique of the Declaration only refer to papers written by themselves or to proponents reproducing their own views.

The legal and bioethics debates on consent requirements for collecting, storing and utilising human biological material for purposes of basic and applied research have already managed to pass through three ostensibly dissimilar stages: During the last two decades or so, a mudslide of research papers, policies and guidelines have been produced advocating anything from (1) presumed consent (Galcher and Steffanson, 2000), (2) expressed full-blown informed consent (Knoppers and Laberge, 1989; Beskow, Burke, Mertz et al., 2001; Mertz, McGee and Sankar, 2003); to the current mode of (3) broad consent (Hansson, Dillner, Bartram, Carlson and Helgesson, 2006; Hansson, 2009).

Confidentiality is often portrayed as the crux of ethical challenges arising from research biobanking. While securing the confidentiality of data, information and knowledge derived from donated biological material and other data sources often is thought of in purely technical terms (Hansson, Dillner, Bartram, Carlson and Helgesson, 2006, p. 267; Hansson, 2009, p. 8), it is important to remember that confidentiality is also a fundamental right, involving corresponding obligations held by researchers, affiliated institutions and biobank employees. Unauthorised use and abuse of donations not only can have profound negative impacts on the personal life of donors, but may also be problematic for the proper functioning of democratic societies. As such, research biobanks and their affiliated institutions have an obligation to ensure that data, information and knowledge is handled in a manner that minimises the risk to donors, while providing benefits to society. By conforming to strict data security measures and ethical standards, it is thought that donors to research bio-

banks will be well-protected from potential harms arising from research biobanking. Such potential harms include psychosocial harms occurring from being exposed to risk information pertaining to one’s own probability of developing diseases, either divulged from a biobank or from close relatives that have chosen to receive this kind of information, and discriminatory harms, including loss of job opportunities and exclusion from life insurance policies and healthcare benefits.

To prevent such and similar unintended harms from taking place, it is crucial that donors, as well as their implicated biological relatives can exercise their basic rights to self-determination and confidentiality, in a research context often expressed as the primacy of the human being, i.e. that the interests and welfare of the human being should have priority over the sole interest of science or society (UNESCO, 2005, Article 3.2; Council of Europe, 1997, §2). It is for these reasons that the suggestion of Emanuel et al. of asking participants to give broad consent for their biological samples needs critical scrutiny, because the problem with this conception is not only that it is at odds with the premises of information and understanding underlying the principle of informed consent (Árnason, 2004, p. 41; V; Hofmann, 2009), but that confidentiality as a right is turned into technically manageable forms of risk (Hansson, Dillner, Bartram, Carlson and Helgesson, 2006, p. 267):

“Consistency with current practice lends further support to the idea that sample donors should be entitled to give broad consent and consent to future research, provided that the risks of harm are well controlled by a secure coding system and by secrecy laws that protect the confidentiality of personal information.”

The authors behind this quote are writing in a time when it is becoming increasingly clear that the problem of confidentiality cannot be reduced into technically manageable forms of risk (McGuire and Gibbs, 2006; Lowrance and Collins, 2007; Lunshof, Chadwick, Vorhaus and Church, 2008), yet three years later one of these authors reiterates the same premise in his argument, even though the problem of handling access to research biobanks has proved to be everything

but solvable by way of simple instructions (Hansson, 2009):

“With broad consent emerging as the generally preferred solution for biobank studies and simple instructions available for coding that will protect the privacy of donors there is a good climate for international collaboration that may make progress in biobank research for the benefit of future patients through prevention and treatment.”

This problem becomes even clearer when turning the attention to the most recent sibling of this model, the ‘open consent’ model proposed by Lunshof and co-authors (Lunshof, Chadwick and Church, 2008). Because contrary to what they want us to believe, the right to confidentiality does not pose a problem to research biobanking and genomic science; it is this research endeavour that poses a problem for confidentiality. Lunshof et al. claim that “the empirical facts of genomic science change too fast for the reflection of ethics to keep pace with it” (Lunshof, Chadwick and Church, 2008, p. 406), and that consequently biomedical research ethics is in need of a “revision” of some of its key concepts, such as confidentiality and consent. Their suggested way out of this conceptual quagmire does not, however, represent a revision of these concepts to make them comply with a scientific reality undergoing rapid change, but rather a depletion of these concepts of any moral bearing. ‘Open consent’, if not a contradiction in terms, is a moral illusion disguised as a “pragmatic” device to serve the narrow interests of closed researcher mindsets. It represents the inevitable end of a language game, which aims at overcoming the moral primacy of the human being in research by installing the priority of scientific and societal interests in its stead. However, there is little use for balancing the purported interests of researchers against those of the individual donor when what are at stake are the basic rights and freedoms of donors, and the preconditions necessary for these rights to be exercised. For these reasons Emanuel et al’s proposal that “it can be appropriate to ask participants to give broad consent for their biological samples to be used in a wide range of future studies, rather than seeking

consent for each specific study” (Millum, Wendler and Emanuel, 2013, p. 2143), cannot be understood otherwise than as an attempt at lending an ear to the most powerful players in this field, i.e. the biobank research community, their consortia of biobanks, and biobank investors playing at their back stage.

### **The treatment of the primacy principle of the human being in research**

Article 8 of the revised Declaration states: “While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects” (WMA, 2013). Also in relation to this core principle in medical and health related research, which has served as a normative bedrock in the Declaration since its inception, Emanuel et al find reason for depleting it of moral bearing. Because according to their distorted reading, the primacy of the individual’s rights and interests does not apply in research situations where “... the net risks to participants’ interests are low and the benefits to society are sufficiently large” (Millum, Wendler and Emanuel, 2013, p. 2143). They provide no argument what so ever to support this view, and no example of a kind of research where one would be able to show that it is in compliance with these epistemological preconditions, i.e. that it would yield large benefits to society at low risks to participants. The kind of research that seems to lurk behind their flawed argumentation is research pertaining to the use of human biological samples. The empirical evidence for this research being in compliance with the epistemological preconditions here mentioned, is, however, still only wishful thinking.

### **The treatment of research conducted in cash-poor communities**

The authors criticise the Declaration for being confused and mistaken about the principle of vulnerability and what it entails to provide vulnerable individuals and groups with “...appropriate protection and the appropriate means to achieve these protections” in a research context (Millum, Wendler and Emanuel, 2013, p. 2144). According to their reading of vulnerability, it is important to dis-

tinguish between vulnerability caused by poverty and limited access to medical services and vulnerability caused by being at higher risk of harms because of serving as a research participant. I have no problem accepting this differentiation, but the normative answer Emanuel et al. propose to justify the inclusion of poor populations suffering from inadequate access to medical services in clinical studies - the fair benefit mantra - is not the solution to exploitation in such situations, rather it is the problem; since it represent a subtle way of increasing the level of exploitation of impoverished populations in clinical research, and notably in the interest of science and society. Says Emanuel et al. (Millum, Wendler and Emanuel, 2013, p. 2144):

“Providing fair benefits is the goal. The means to achieve it vary. In only a limited number of clinical trials, the requirement that vulnerable groups should benefit “from the knowledge, practice, or interventions that result from the research” (paragraph 20) along with the requirement that participants have posttrial access to interventions identified as beneficial (paragraph 34) can provide fair benefits, but only with respect to phase 3 trials in which an experimental intervention is found to be more effective. When research does not prove an intervention effective - phase 1 and 2, and negative phase 3 research trials - participants from poor countries with limited access to medical services are unlikely to benefit at all from these requirements. In these cases, a research project might supply clean water, new clinics, or build local medical and research capacity. If this level of benefits is fair, then the research will not be exploitative”.

Contrary to Article 20 of the Declaration, which states that research with impoverished populations can only be “...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”, and in addition these groups “...stand to benefit from the knowledge, practices or interventions that result from the research” (WMA, 2013), Emanuel et al. try to justify

the use of such individuals and populations even in research that has no relevance what so ever for the health needs of these individuals and populations. And the rhetorical way offered to justify these forms of exploitation is the normative quick-fix called ‘fair-benefit’. The theoretical underpinnings of this stance have been developed by Alan Wertheimer (Wertheimer, 2008) This author asserts that any research involves a transaction in which two aspects should be taken into account:

- The participants’ voluntary nature, especially of the most vulnerable part of the transaction
- The way in which the “benefits” are distributed between the two parties interacting

This assertion, on which the so-called fair benefit approach is based, makes a distinction between “harmful exploitation” and “mutually advantageous exploitation” (Wertheimer, 2008, pp. 67-78):

“By mutually advantageous exploitation, I refer to those cases in which both parties (the alleged exploiter and the alleged exploited) reasonably expect to gain from the transaction as contrasted with the pre-transaction status quo.... I shall generally presume that mutually advantageous transactions are also consensual”.

Supporters of this stance have assigned strong importance not to “what” is at stake but “how much.” They state that oppression, attack, deception, betrayal, coercion, or discrimination may be harmful to people, but it is not exploitation. From this vantage point, A exploits B when B receives an unfair level of benefits as a consequence of the interaction between A and B (Participants in the 2001 conference on ethical aspects of research in developing countries, 2004). Fairness is related to the burden to be borne by B and the amount of benefits to be received by A, something which applies to biomedical research.

The fair benefit approach relies on premises that violates a precondition that has been an integral part of research ethics guidelines since the inception of the Declaration, i.e. that concept of benefit and the concept of risk are interconnected, imply-



ing that the forms of risk and benefit that should be included in the epistemic equation are the risks and benefits directly related to being involved in a study and resulting from the knowledge, practice, or interventions that emerge from the study. To the discontent of Emanuel et al. this inter-connectedness between risk and benefit is clearly reflected in Article of 20 of the Declaration.

At first reading the fair benefit approach seems to be restricted to discussing procedures at the microlevel of best achieving mutually advantageous forms of transactions between consenting and collaborative parties. The existing background injustice is taken as a fact of the world, implying that this position "...accepts the status quo in the host community as the appropriate 'normative baseline' against which proposed research initiatives" should be evaluated (London, 2005, p. 27). However, as observed by several critiques, this position profits directly from this background injustice by forcing poor communities and impoverished populations to enter into negotiations about the distribution of benefit in "...situations of enormous inequality of bargaining power" (Ballantyne, 2010, p. 28), an with little likelihood of producing "...outcomes that satisfy the minimal conditions of fairness that the proponents of this view themselves endorse" (London and Zollman, 2010, p. 41). Negotiations in such a situation of enforced consent, can hardly ever be said to comply with the requirements of appropriate consent procedures. The fair benefit approach does not, however, only violate the requirements of informed consent; in addition, it gives legitimacy to the establishment of forms of collaboration that are clearly exploitative on the part of science of impoverished communities, and in ways that are at odds even with their own notion of 'mutually advantageous exploitation', as the conditions of an appropriately informed consent to the transaction cannot be said to have been met. Third and last, but not the least, the fair benefit approach may lead to situations where leaders of impoverished communities are tempted to sacrifice some of their individuals as research participants for the negotiated benefits of the community serving as host for internationally sponsored research projects. Examples of such benefits may be ancillary health services, health care capacity development or even employment and economic activity,

or as suggested by Emanuel et al.: "...clean water, new clinics, or build local medical and research capacity" (Millum, Wendler and Emanuel, 2013, p. 2144). Thus it becomes clear that the introduction of the fair benefit approach into international research ethics not only risks undermining the normative bedrock of clinical and health related research; contrary to its name, this language also paves the way for a double form of exploitation of impoverished communities; first, on the level of interaction between science and community leaders, and second, on the level of interaction between community leaders and groups of ailing patients in the same communities 'encouraged' to enroll in the hosted studies for societal reasons.

### **The treatment of Article 33. Use of Placebo.**

Emanuel et al. are also displeased with the revision of the article on the Use of Placebo in the Declaration, i.e. Article 33. The last clause of the 2008 version of this article (Article 32) on the use of placebo states (WMA, 2008):

"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".

In the current version of the Declaration this clause reads as follows (WMA, 2013):

"Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option".

To this revision Emanuel et al. comment (Millum, Wendler and Emanuel, 2013, p. 2144):

“How to interpret this last clause is unclear. The danger is that it may preclude vital research that promises to improve the condition of the worst off... A future and better declaration should allow such trials under strict conditions, especially when no patients are deprived of treatment they would otherwise receive and the research has the potential to save lives and improve the care of poor populations”.

I agree with Emanuel et al. that this last clause remains unclear. But my concern is the opposite of theirs, and notably because of the change in the clause from “any risk” to “additional risks”, because this may be interpreted as a silent acceptance of a double moral standard, i.e. that the status quo level of risk – or background risk – subjects in the control group are exposed to if not given access to the best proven treatment, is not to be included in the equation of risk assessment.

## Concluding remarks

In their conclusion Emanuel et al. state (Millum, Wendler and Emanuel, 2013, p. 2144):

“The revised Declaration of Helsinki represents a significant improvement over previous versions. Creating an international document to guide research around the world is an enormously difficult and complicated task. Nevertheless, important problems and some confusion remain in this 50th-anniversary declaration. The definitive guidance on research ethics and even better protection for research participants await responses to the Declaration of Helsinki’s remaining challenges”.

Viewed from the vantage point of fair benefit approach, these authors have been advocating for years, it is understandable that they have problems digesting the current version of the Declaration of Helsinki. On the other hand, for those championing an international normative framework of research ethics not disfigured by an underlying double moral standard, the current ver-

sion represents a first small step back to a normative position in compliance with respect for human dignity, human rights, and fundamental freedoms as expressed in the Universal Declaration on Bioethics and Human Rights. What remains to be rectified for this to be the case is a rewording of Article 33, so that it becomes crystal clear that the Declaration no longer accepts a double moral standard with regard to the use of placebo.

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