

Revised CIOMS research ethics guidance: On the importance of process for credibility

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Abstract

This paper reviews the 2016 CIOMS International Ethical Guidelines for Health-related Research Involving Humans. I argue that these new guidelines constitute a significant improvement over the guidelines they replace. However, the procedures put in place by CIOMS resulted in an authoring group consisting of a majority of authors and advisors hailing from the global North, while the guidelines squarely aim at influencing policies in the global South. I question CIOMS' strategy to produce a consensus-based document, and raise concerns about frequent appeals to authority designed to establish the credibility of these guidelines and the processes that led to them. It is unclear why it should be the role of a small organisation such as CIOMS to try to guide the research ethics policies in countries of the global South.

Introduction

CIOMS, the Council for International Organisations of Medical Sciences, is arguably best known among people with an interest in research ethics for two sets of ethical guidelines pertaining to epidemiological research and biomedical research involving human participants, respectively. In late 2016, the organisation published new sets of guidelines, broader in scope and covering the areas previously targeted by the two older sets of guidance documents.

This paper will avoid the temptation to produce a point-by-point discussion of the new guidelines. It will also avoid the temptation – it's a big temptation – to produce rebuttals to guidance points that I think are both ill-informed and misguided (such as Guideline 20 on research in disasters and disease outbreaks). Rather, my objective is to flag inevitable procedural and credibility problems these and similar guidelines face, problems that should make us reconsider the value of producing such documents, well-intentioned as they usually are.

The CIOMS *International Ethical Guidelines for Health-related Research Involving Humans* (1) is a substantial document comprising 25 short guideline chapters, and four appendices.

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Given the guidelines' broader scope, now encompassing the issues formerly discussed in two distinct guidance documents, the interested reader will find in this edition anything from traditional content such as informed consent, standards of care in a trial, conflicts of interest, content on particular participant groups such as children and women; to topics including the social value of research, the collection, storage and use of data, and public accountability of research. In the words of the document's authors: "The current scope is confined to the classic activities that fall under health-related research with humans, such as observational research, clinical trials, biobanking and epidemiological studies."(1: p ix)

But is it ethics?

Let us start this brief review of the CIOMS' effort by asking whether this booklet with its 25 guidelines and numerous appendices qualifies as an ethical guideline. This takes us to the question of what exactly distinguishes an ethical guideline from a guideline that is not an ethics document. Ethics serves essentially two functions: to provide action guidance on ethical questions or problems, and to provide a justification for this guidance that is uncontroversially ethical in nature. It is important to keep this in mind when one looks at ethical guidance documents, declarations and whatever else is these days liberally issued under the cover of "ethics" by a flurry of national and international organisations. The authors of the CIOMS document clearly have a good understanding of the requirements of ethics, yet their attempts at providing ethical justifications for their guidance points remain sketchy at best. Oftentimes, no ethical justifications for guidance points are provided, on other occasions limited efforts are being made (eg Guideline 3: Equitable Distribution of Benefits and Burdens in the Selection of Individuals and Groups of Participants in Research). Each guidance point is accompanied by a brief explanatory commentary. These commentaries also prove quite valuable as they usually clarify or define the meaning of particular terms used in a given guideline. This distinguishes the CIOMS guideline to a limited extent from, say, the World Medical Association's Declaration of Helsinki, which is entirely authoritarian in nature, in that it derives its normative punch *not* from its superb ethical justifications (because there are none to be found in it), but from the authority of the World Medical Association.

Past to present – appeals to authority

A bit of history might be of interest to the reader of this journal. CIOMS, historically, put itself forward as the organisation that would interpret the guidance given in the Declaration of Helsinki, and it derives much of its current-day standing from

being that interpreter. CIOMS, even today, is in reality not much more than a naked emperor. It counts only 13 actual international organisations of medical sciences as its members, among them the International Society of Audiology. Despite its name, CIOMS also counts national medical associations among its members, virtually all of whom hail from the global North (2). Of course, anyone not hugely impressed by the bombastic acronym that CIOMS is, could not have helped but wonder what drove this little-known organisation to decide that it is its job to make sense of another organisation's guidance document. It turns out this decision was a smart strategic move of the CIOMS Executive at the time, because it made itself known to a wider audience as an organisation with expertise in research ethics. Fast forward to 2016, CIOMS now implicitly says good-bye to that odd claim of being the authoritative interpreter of another organisation's document on matters of research ethics. It now makes a seemingly grander claim, which is more modest at the same time. Its immediate-past president, bioethicist Professor Hans van Delden of Utrecht University's Medical Centre, states that "these guidelines [are] ... based on authoritative ethical guidance documents, such as the World Medical Association's Declaration of Helsinki and UNESCO's Universal Declaration on Bioethics and Human Rights"(3). "Based" is not quite the same as being the authoritative interpretation, which arguably makes the new document more modest in terms of the influence it aims to command. The claim also seems, by the same token, more grand even in its vagueness. What exactly it means that the CIOMS guidelines are "based" on these documents remains mercifully a mystery. What is clear is that CIOMS thinks it has somehow distilled the relevant content from these documents and then fed whatever that process produced somehow into its own guidance document. On a fair number of possible interpretations, this seems to suggest that the CIOMS document would be more relevant than each of these two documents on its own, not least due to its comprehensiveness. The CIOMS writers also state that the objective of the guidelines "is to provide internationally vetted ethical principles and detailed commentary on how these principles should be applied."(3). This suggests that CIOMS has finally emancipated itself from its original sin and does not claim any longer to be the authoritative interpreter of another organisation's documents. Progress has been made. The CIOMS guidelines, despite the vague embrace of WMA and UNESCO, stand on their own feet, and so they should! The document before us is, by a long stretch, intellectually more coherent and qualitatively superior to the content either the WMA or UNESCO proffer to the public as ethical declarations on matters of research and bioethics. In fact, the function of van Delden describing the WMA and UNESCO documents as "authoritative" seems, at best, an appeal to authority as opposed to reasoned justification. Anyone with an interest in research ethics will be aware of the controversies surrounding the WMA's Declaration of Helsinki and its wholesale rejection by influential players, including US government agencies. The UNESCO bioethics and human rights declaration is virtually ignored by professional bioethicists in their academic outputs, largely due to its

mediocre quality. Declaring these documents authoritative does not make them authoritative. Let the buyer beware.

Process and representation matter

It is well worth your time to read how the group approached its content development (1: pp xi-xii). Apparently, and commendably so, an extensive review of existing guidelines as well as content in leading specialist journals was undertaken, and then some sort of deliberation took place with a view to establishing a consensus. Remarkably, if no consensus could be reached, the authoring team of the guidelines decided to leave the content from the guidelines it was meant to replace, in place. It is unclear why that was preferable to a vote decided by a however significant majority margin.

Let me be clear, these ethical guidelines are not ethical guidelines in at least one sense: they must not be confused with a typical academic ethical analysis, where a particular ethical theory or concept would be rigorously applied to the kinds of questions the CIOMS' authoring group was concerned with. Rather, what we have is an eminently political document where votes took place and compromises were reached, and where consensus was the name of the game. That matters to any analysis of the content provided therein, because this guidelines writing project clearly was not an academic enterprise but a policy-oriented, political enterprise.

Since this is a policy document as much as it is an ethical guideline, it is important to discern who is targeted by it (ie who should be guided by it), who actually wrote it, and how those who wrote it became authors, as opposed to others who were not invited to become authors of these guidelines. To answer the first question: The main target of these guidelines are regulators in countries of the global South where insufficient local expertise is thought to exist to draft research ethics guidelines competently. Countries like, for instance, Canada that have sufficient home-grown expertise produce their own guidelines¹, are unlikely to see the need to turn to a group like CIOMS to establish their research ethics guidelines. The same might not be true for, say, Côte d'Ivoire. Seeing that this guidelines writing activity was not primarily an academic enterprise, but a policy development activity aimed at countries of the global South, it begins to matter a great deal who was provided with a seat at CIOMS' authoring group's table, so to speak. My breakdown based on the information CIOMS published about that group (1: pp 107-11), is given in Table 1.

In my reading then, even though it reportedly and admirably achieved parity in terms of the sexes, the authoring group of these guidelines consisted of 8 members hailing from the global North, and 4 members hailing from the global South. Of the four members situated in countries of the global South, arguably only two members were located in countries where a significant amount of the kind of research these guidelines are concerned with is taking place. Strangely, Central America and China are completely missing in action, despite the growing number of foreign-funded health research projects undertaken

Table 1:
Composition of CIOMS revised guidance working group

Country	No. of Members
Global North	8
Lithuania	1
Netherlands	2 (chair+secretary)
Switzerland	1
United Kingdom	2
USA	2
Global South	4
Brazil	1
Burkina Faso	1
India	1
Senegal	1

in these locales (4: p 14). Equally surprising is the absence of a South African member on the authoring group, given the extensive experience South Africa, especially, has with hosting multinational clinical trials, and the superb quality of some of the research ethics committees in that country.

Apparently there was also a group of advisors, all of whom hailed from countries of the global North (1: pp 110-11).

Much has been made by some members of that group, and by CIOMS, of their capacity to represent or somehow symbolise the cultures of the societies they are hailing from. As van Delden writes, "the composition of the Working Group ensured that different cultural perspectives were present." (5). It is truly puzzling what CIOMS could have possibly meant when it also stated that "one of the members represented the perspective of research participants." (5). This claim is close to nonsensical. Unless past research participants have been surveyed on the issues the guidelines are concerned about, and the results of that survey were represented by said members, it simply is not the case that "the perspective of research participants" was represented. What was represented was the perspective of said member of the authoring committee, no more, no less. This person's views may have been – never, sometimes, or always – representative of other research participants, but the odds are that nobody knows how representative this particular member of the committee was with regard to that claimed constituency. The same holds true for comments the group received from individuals, and individuals hailing from particular organisations, when it asked for comments on an initial draft. CIOMS immediate-past president, Professor van Delden, writes, "the commentators represented all parts of the world." (5). The fact of the matter is that these commentators hailed from "all parts of the world", but that does not necessarily make their views in any meaningful way representative. Individuals would have represented their valuable individual views, some of those representing particular organisations would have done just that, even though I have some doubts that those organisations have actually engaged in consultations of their members' views on the CIOMS draft document.

Language matters; here it is used to bolster unjustifiable claims about the weight of the authoring group's representativeness

vis à vis particular regions and cultures. It is remarkable that an international organisation drafts guidelines aimed primarily at the global South, while relying on an authoring group consisting in a 2:1 ratio of members residing in the global North. This grates, particularly because the global South these days has many professionals who would have been capable of producing a document such as this. We will never know what guidelines written by them would have looked like.

This CIOMS authoring group included a large number of fairly senior and internationally very experienced bioethicists who are all too familiar with the concerns I have just flagged. Their answer, seemingly, is an appeal to authority. Appeals to authority are always terrible ideas. They carry no normative weight. In this case it is an appeal to the authority of an opaque committee (yes, another committee) at the World Health Organisation. This Committee is called, you could not invent a better name, the *Guidelines Review Committee*. It approved the CIOMS revision process. Transparency is, of course, of great significance when it comes to activities such as these, and CIOMS has made very significant strides for the better since its old guidelines were produced. However, when I tried to find out who the people were on the WHO *Guidelines Review Committee*, there was no information about them to be had on the WHO website (6). So, in essence, unknown people of an unknown WHO committee assure us that all is well with CIOMS procedures. Case closed. It is difficult to take this quite seriously. CIOMS cannot be faulted for trying; the reality is that the production of such documents, if they are meant to have any credibility at all, perhaps requires these sorts of activities, but evidently they are insufficient to establish that all is well in terms of process.

I have argued, quite some years back, commenting again on so-called ethical guidance documents, that "a policy document of this sort should be based on a transparent method of working as far as the discussions (including selection of participants) and the utilisation of the input provided by professionals and the interested public are concerned. Also, seeing that in this particular instance the ramifications would be most severe for participants in developing countries, substantially greater efforts should be put into ensuring that the developing world-based delegates at consultative meetings are truly representative of their constituents. This would require that members of the same socioeconomic groups of patients affected by a given guideline be consulted in a meaningful way. Not all, but some ethical guidelines lack rational justifications for the substantive guidance provided. Justification of the policy guidance proposed should be mandatory for any document wanting to be taken seriously. We should certainly not accept views from the WMA or any other organisation as if they were somehow ex cathedra." (Schuklenk, 2004) (7). My concerns then remain my concerns today.

The trouble with ethics by committee consensus

CIOMS is correct when it notes, possibly anticipating the above concerns, "ultimately, the validity of the ethical positions in

these Guidelines hinges on the strength of the arguments." You would find it difficult to find an ethicist disputing this statement. Unfortunately, CIOMS seems to ignore that insight, given what it tells us about how the content was actually settled on. Apparently the authoring committee "members deliberated until they had reached a well-argued consensus. If no such consensus was reached, the previous text in the 2002 Guidelines remained in place."(5). The validity of an ethical argument is, of course, not established by reaching a consensus, or by leaving an old text in place that other people managed to agree on (assuming the old text was settled on by similar means and not by chairperson fiat).

As the South African philosopher David Benatar has shown, consensus-finding activities are most likely to translate into a minimal consensus (8). Such efforts are also likely to result in incoherent guidance, where everyone on the committee gets their bit of satisfactory verbiage. Take as an example – I beg your forgiveness for breaking my promise not to undertake a detailed analysis of individual guidelines – the guidance given on pregnant and breastfeeding women as research participants. CIOMS tells us unequivocally that such women *must* not be enrolled in research that is not designed to benefit them individually and that features a greater than minimal risk. Helpfully the CIOMS authoring committee explains that "'must' has been used to attach greater moral weight to requirements when compared to 'should.'" (1: p xii). So, pregnant women *must* not be enrolled. That is as clear a statement as it gets, or so you would think. Right after making this categorical statement the CIOMS authors can be seen busily rowing in the opposite direction. They write, "When the social value of the research for pregnant or breastfeeding women or their fetus or infant is compelling, and the research cannot be conducted in non-pregnant or non-breastfeeding women, a research ethics committee may permit a minor increase above minimal risk." (1: p 71). I am not taking a stance here on whether that would be an ethically defensible stance, my objective is to flag the dangers the consensus approach poses to substance and clarity.

In light of problems such as these, it may have been better if CIOMS had been more modest in the rhetoric selling its guidelines. The Preamble of the documents claims no less than that, "the ethical principles are regarded as universal." (1: p xii). Given the demonstrably problematic production process, we have good reason to reject this claim.

Despite all that was said

Having said all this, the new set of guidelines makes for an impressive addition to the research ethics literature. I know many of the members on the CIOMS authoring committee well. I worked with some of them over many years on journal

editorial boards or research projects, and I respect them deeply as colleagues and professionals working in our field. I have no wish to question their integrity or claim bad faith on their part. They have produced a document that is far superior to the documents it replaces, and that might be a justification of sorts for the effort that went into the production of these guidelines.

However, I remain sceptical that small organisations such as CIOMS should try this hard to influence the research ethics policies that countries of the global South give themselves, because it is this that is attempted here.

Acknowledgment

I gratefully acknowledge this journal's external reviewers' comments, some of which led to changes in the manuscript, and, hopefully, to improvements.

Conflict of interest

The author knows several members of the CIOMS authoring committee well, and has worked with some of them on journal editorial boards or research projects

Note

¹See eg the research ethics guidelines produced by the Canadian public research funding agencies. http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

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