Concerns Regarding the ISPOR Code of Ethics for Researchers

To the Editor—We read with interest the article by Palumbo et al. proposing an ISPOR Code of Ethics for Researchers. We have a number of questions and concerns about these guidelines that we would like to raise.

1. The article did not give information concerning the purpose for drawing up a code of ethics. What problems or issues have led to a code of ethics being desirable?

2. It was unclear what central principles guide the ISPOR Code of Ethics. Presumably the Code's statements are related to some broader set of principles. It would be helpful for these to be set out. One result of this absence of clear principles is that what is stated in the Code and what issues are covered in the Code seem somewhat arbitrary. What guided the task force in identifying the issues and in the position taken on those issues?

3. Most codes of practice, e.g., professional codes, have disciplinary processes or other procedures in place to respond to members who breach the code. Such processes would also normally have an appeal procedure, which could be used for those who believed that they had been unfairly treated by such a disciplinary process.

4. There is no review of other codes of ethics adopted by international societies. We imagine that the task force undertook some review of codes of ethics. It would be helpful if such background were provided in the “background paper” that was published. What features of other codes were adopted, what rejected and for what reasons?

5. There is no description of the process that led to the ISPOR Code being drawn up. The only information provided is that a task force was set up and the Code has been adopted by the ISPOR Board of Directors. It would be helpful to know what process was adopted for convening the task force, and what principles were used for selecting its members. There is no description of the process that the task force, or Directors, undertook to ensure wide and international input into the Code, or how any responses received were dealt with in forming the final Code. Of particular concern is that all the authors to the code are US based (see point 9 below), and that an Ethicist was not included as part of the authorship team.

6. There are no clear statements about the relationship of this Code to other relevant codes of ethics. One example is that there are many international and national guidelines for proper ethical conduct in the setting of medical research and other research involving human participants, or “human subjects” to use the phrase in the background paper. Are the statements made in this ISPOR Code supposed to replace, supplement, or provide a commentary on these other guidelines? Most of what is written in the ISPOR Code deals much less thoroughly than these many other guidelines with the issues covered, and also raises only a small number of the ethical issues dealt with in the major international and national guidelines.

Another example relates to the guidance on listing who should be an author on a publication. The background paper correctly states that some journals provide criteria for authorship. Nevertheless, many do not. It is unclear, however, what the ISPOR Code is advising. One way of reading the guidance is that ISPOR members should observe the rules on authorship provided by JAMA regardless of which journal is involved. It is not clear why rules set by one journal should be followed by authors submitting to another journal. Neither is it clear that the principles set out for JAMA are necessarily the correct principles.

This last point brings us to what seems to us a major limitation of the ISPOR Code: the guidance is generally rather vague. Here are a few examples.

In the preamble, the statement is made that “it should be generally agreed that patients are ultimately going to experience the greatest impact of the research conducted by ISPOR members.” The Code goes on to give the example that the results of research may lead to patients being denied coverage for certain drugs. Nevertheless, no guidance is given as to what the responsibilities of ISPOR members...
are with regard to this issue. Is there an implication that ISPOR members should prevent, in some way, such denial of coverage as a result of their work?

Later on in the preamble it is stated that research conducted by ISPOR members can directly affect price and coverage negotiations. What is unclear is what follows from this.

In the section on publication and dissemination, the ISPOR Code appears to say that there is an ethical requirement for members to publicly disseminate all their work. The guidance states: “It has been suggested that withholding publication is unethical.” It is unclear whether this Code endorses the view that it is unethical or takes the contrary view and is mentioning this suggestion because this Code takes a different view. If this is to be a code of ethics then it must state clearly what the code is, not simply draw attention to the suggestions of others.

Assuming the ISPOR Code endorses the view that it is unethical to withhold publication, we were then surprised to read that contractual rights restricting publication must be respected. This raises the question of whether a contract should ever be entered into by ISPOR members that limits the publication of data. The Society’s journal Value in Health requires authors to sign a statement that publication rights were not restricted for any article submitted to the journal, but this is not mentioned in the Code. The Code does state that some universities refuse to sign a contract where publication rights are restricted, but again, the Code fails to take a view. So what is the guidance to ISPOR members?

7. There are a number of statements that seem to us out of place in a code of ethics. One example is the first sentence of the preamble which states that “As an overriding precept, it would be prudent to say that an ISPOR researcher’s first relationship is. . . .” The word “prudent” here seems strange. It suggests that these guidelines may not be based on ethical principles at all but are simply advice as to what is in the best interests of ISPOR researchers.

8. The article as a whole seems to us to be written entirely from a US perspective, reflecting perhaps the wholly US authorship. Our own perspective—that of the UK—must be closer to the US perspective than that of many of the countries that an international society must include. And yet, even from a UK perspective the whole Code appears highly parochial. This is evident in the vocabulary, e.g., referring to what in the UK are called research ethics committees by using only the US phrase (institutional research review boards); the reference list is (almost) entirely US papers; the only reference to any relevant report of a set of principles guiding medical researchers is to the Belmont Report; and in talking about employment law, or in the presumptions of the organization of medical services, it is exclusively a US perspective that is provided.

9. Finally, the Code itself is somewhat contradictory in calling for ISPOR to assure that its journal, Value in Health, only publishes papers that have gone through a rigorous peer-review process. As an ISPOR-sponsored Task Force report, the article was not subjected to the usual rigorous peer-review process that the Editorial Board of Value in Health demands. Although the (unreported) process of producing these Task Force reports includes inviting comment on the draft report from a large proportion of the ISPOR membership, it would appear to be all too easy to be seduced into thinking that this is an appropriate substitute for anonymous peer review.

We are concerned that if the Code of Ethics for ISPOR is adopted as currently written, and without a more thorough account being given of the process by which it has been developed, it will damage the reputation of the Society and will alienate many of its members, particularly those who are not from the United States.—Tony Hope, Professor of Medical Ethics, University of Oxford, Andrew Briggs, BA, MSc, DPhil, Public Health Career Scientist, University of Oxford and Coeditor, Value in Health.