REPORT OF THE ISPOR TASK FORCE ON CODE OF ETHICS

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ISPOR NEW CODE OF ETHICS TASK FORCE

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INTRODUCTION

In 1997, ISPOR set up a number of issues panels, and one of them was asked to study questions about bias, credibility, and quality of health economic evaluations. This panel presented its conclusions during a general session of the May, 1998 Society conference, and subsequently published them in Value in Health [Barnes R, Heaton A, Magoffin C, McMillan J, Taylor T, Wertheimer A.] One of their recommendations was that ISPOR should establish a code of ethics. The panel felt that such a code would help the still developing science of pharmacoconomics and outcomes research deal with credibility challenges stemming from concerns about methods or bias.

After studying the issues, and codes from other societies, a second group completed a December, 2002 report laying out ISPOR’s first formal Code of Ethics for Researchers. It was subsequently published in Value in Health in 2004 [Palumbo FB, Barnes R, Deverka P, McGhan W, Wertheimer A, Mullany L.] Their objective was to clearly establish procedures for insuring that this research is designed, conducted, and reported in the most proper and ethical way possible so the various affected constituencies can trust and benefit from the findings as much as possible.

ISPOR received some criticism of its first Code in a letter to the editor [Hope & Briggs] and in an editorial piece [Milne] both published in Value in Health in 2004. The ISPOR Board considered those comments and initiated a review of the initial Code to address the legitimate concerns that were raised. This report proposes a modified Code adjusted to address the criticisms.

The seven current authors include individuals from New Zealand, Canada, and the U.K. to address the “too U.S.” criticism. Additionally, note that Dr. Milne who is a co-author on this revision of the Code authored a critique of the 2004 version published in Value in Health. Moreover, Dr. Briggs, another critic of the 2004 version, was invited but unable to participate substantially as a revising author.
ISPOR CODE OF ETHICS
Approved by Board of Directors, March 2008

PREAMBLE

ISPOR expects itself and its members to adhere to the highest ethical standards because the Society recognizes that its activities and those of its members affect a number of constituencies. These include but are not limited to:

- **Patients** who are ultimately going to experience the greatest impact of the research.
- **Health care professionals** who will be treating or not treating patients with therapies, medications and procedures made available or not made available because of the research.
- **Decision-Makers and Payers** who must decide what is covered so as to optimize the health of the patient and resource utilization. This includes:
  - **Government Groups** who require the results of research to set policy and prices.
  - **Insurers** who base health care coverage and/or payment decisions on the research.
  - **Employers** where the research affects their decisions on providing health benefits.
  - **Administrators and Others** such as U.S. managed care personnel who need results that are both practical and useful.
- **Professional Outcomes Researchers.**
- **Pharmaceutical Manufacturers** whose products are often the subject or focus of the research.
- **Colleagues**, where relationships in conducting research and related activities are particularly critical.
- **Research Employees** concerned about how they are regarded, compensated and treated by the researchers for whom they work
- **Students** who work for researchers, where respect and lack of exploitation are important. They are the future of the profession.
- **Clients** for whom the research is conducted and the researchers’ relationships with them.

The main objective of the Code is to help the science of pharmacoconomics and outcomes research avoid or otherwise deal with credibility challenges based on methods or bias concerns, through behaviors and practices intended to insure that this research is designed, conducted, and reported in the most proper and ethical way possible. By accomplishing this, the various affected constituencies will be able to trust and benefit from research findings as much as possible. The Code also includes some general ethical considerations for the Society.

The Code is something to which we believe all ISPOR members should aspire. However, we recognize that members’ own organizations may also have ethical codes that should be followed. We also recognize legal considerations may sometimes be important, for example in relation to employment law. Moreover, ISPOR and its Board have no official jurisdiction over those who voluntarily choose to join the Society. Thus, there are no disciplinary or enforcement processes, no system for reporting violations, and no non-compliance consequences in the Code. The Code is advisory rather than mandatory, and ISPOR welcomes an ongoing debate about ethical standards in the field of pharmacoconomics and outcomes research.

However, from this date forward the Board will make the Code available to all new and renewing members, and seek their pledge to abide by it. Additionally, ISPOR will make this Code available on its website and in regular issues of Value in Health to encourage compliance. For all papers published in Value in Health, all authors are asked whether they adhered to the ISPOR Code of Ethics when conducting their research that was used to inform this manuscript. Further, ISPOR will make the Code available to all university programs teaching pharmacoconomics and outcomes research, and encourage them to instruct students on the Code.
THE ISPOR CODE OF ETHICS

DESIGN AND RESEARCH PRACTICES

1. Members should maintain a current knowledge of research practices, with due consideration of those practices most relevant to the research that is being done in their own countries.
2. Members should adhere to the standards of practice for their respective fields of research and identify any official Guidelines/Standards used.
3. Members’ research designs should be defined a priori, reported transparently, defended relative to alternatives, and planned to recognize and minimize all types of bias.
4. Members should respect the rights of research subjects in designing and conducting studies.
5. Members should respect the reputations and rights of colleagues when engaged in collaborative projects.
6. Members should maintain and protect the integrity of the data used in their studies.
7. Members should not draw conclusions beyond or inconsistent with what their data would support.

SPONSORSHIP

8. Members should fully disclose the identity of sponsors of their research.
9. Members should strive to avoid bias and the appearance of bias in conducting research, such as in the choice of methods and data inputs, or in the selective reporting of results.
10. Members should be aware of conflicts of interest and the appearance of conflicts of interest. As a point of reference, members should look to the rules on disclosure of interest laid down by major peer reviewed journals.
11. Members should maintain their professional autonomy and objectivity in conducting and reporting, in writing or verbally, research findings.

PUBLICATION AND DISSEMINATION

12. Members should endeavor to publicly disseminate their work, and to publish it in peer reviewed journals when possible.
13. Members should discourage, where possible, listing of an author on any publication where the individual has not performed substantial work. As a point of reference, members should look to the checklists provided by major peer reviewed journals to assist them in deciding inclusion of authors.
14. Members should seek to establish, in advance, a clear agreement on whether the results of a given piece of work could be published. This could include statements on whether the sponsor has a right to review or approve any manuscript prior to publication. Considerations could include revelations of safety issues.
15. Members should respect contractual rights when they agree to perform work for hire and should refrain from disseminating information which they agreed in advance to keep proprietary.
16. Methods sections of papers should give thorough, transparent attention to all measures taken to minimize bias.
17. Methods sections of papers should identify and justify all departures from the a priori analysis plan.
18. Members should work with editors of journals and other publications to encourage the establishment and/or maintenance of an appropriate peer review process that examines the quality of the methodological rigor independently of the institution for which the individual works.
19. Any contributor to a report or publication should disclose any current or past relationships with a company or competitor of any product discussed in the work.
RELATIONSHIPS WITH OTHERS

20. Members should treat their research employees with respect and should compensate them fairly for their work.
21. Members should protect and promote the interests of their employers, provide competent work, adhering to these broader guidelines, and protect proprietary information.
22. Members should treat students with respect and refrain from exploiting them under any circumstances.
23. Members should provide competent, honest and objective work for clients, adhering at all times to relevant standards of conduct for conducting and reporting research.

ROLE OF ISPOR

24. ISPOR should publicize this Code of Ethics to members and non-members involved in pharmacoconomics and outcomes research.
25. ISPOR should strive for a balance in sponsorship of its conferences and other activities, thereby avoiding the appearance of bias or conflict of interest.
26. Because, as a practical matter, most funding will come from commercial interests, ISPOR should continue to maintain its own statement of objectivity and autonomy from sponsors.
27. ISPOR should strive to assure that its journal, Value in Health, only publishes papers that have gone through a rigorous peer-review process.
28. As much as is possible, ISPOR should have a Board of Directors that is representative of the various constituencies the Society serves.
29. Similarly, to the extent that it is feasible, the ISPOR program planning and selection committees should have membership representative of all of its major constituencies.
30. Like other professional societies, ISPOR should be conscious of broader ethical issues impacting on global and regional medical resource allocation, public health policies and the global healthcare environment. These issues include but are not limited to: prejudice, equity in healthcare delivery and access. ISPOR should encourage researchers to utilize opportunities in their activities and work to address these issues.