ISPOR NEW CODE OF ETHICS

BACKGROUND INFORMATION

This report was prepared by the ISPOR New Code of Ethics Task Force
May 2007

ISPOR NEW CODE OF ETHICS TASK FORCE:

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Introduction

The following provides supportive information and justification for the ISPOR Code of Ethics for Researchers and includes a discussion of the stakeholders as well as ethical considerations for the researcher on research practices, research sponsorship, research publication and dissemination, and relationships with others. This section also includes a discussion of the ethical considerations for the Society.

ISPOR is an organization that represents research professionals from a variety of disciplines. These include but are certainly not limited to economists, epidemiologists, social and behavioral scientists, health services researchers, researchers in managed care organizations, physicians, pharmacists, and many others. As an organization, ISPOR expects itself and its members to adhere to the highest ethical standards. In attempting to meet these expectations, ISPOR recognizes that its activities and those of its members affect a number of constituencies and these include:
Patients. It should be generally agreed that patients are ultimately going to experience the greatest impact of the research conducted by ISPOR members. As the results of the research digested by others are incorporated into their programs of pharmacy and medicine, the decisions that are made are going to impact patients most. For example, will patients be denied coverage for certain drugs? Will they be forced to pay additional cost sharing for a particular drug? Will they be shifted from one drug to the next while they are attempting to control a chronic condition? And, will they receive the most appropriate therapy for their conditions at the most reasonable price?

Practitioners. Physicians, pharmacists and others will be treating patients with interventions made available because of particular research. The research presented to the various practitioners must meet the relevant standards of practice for research so that the practitioners will be able to have available to them the best tools to help their patients.

Decision-Makers and Payers

a. Government Groups. Governments still represent the largest payers of health care. The policies and practices adopted for government programs tend to establish a standard that others follow.

b. Employers. Employers are often responsible for providing a substantial amount of health care coverage to employees and their dependants as well as retirees. Employers are pressured to provide reasonable health care coverage at an affordable cost. Given that the cost of medical care increases substantially every year, this becomes more and more of a challenge. Notwithstanding other medical care items, the expenditures for prescription drugs are increasing at approximately 15% per year. So employers are challenged to provide a comprehensive drug benefit while attempting to minimize employee out of pocket costs. Therefore, the research that is conducted by ISPOR members and their
colleagues can directly affect U.S. price and coverage negotiations and the employers’ decision as to which benefits to provide.

c. **Administrators and Others.** While patients are certainly the ultimate focus of medical care, being able to provide comprehensive care to patients for an affordable cost is a challenge. Deciding what would be covered and the extent of that coverage while attempting to ensure that the health of the patient is optimized requires credible information. The individuals who must make decisions about coverage and cost require results of studies that are both practical and useful, reflecting the fact that the information presented must be in such a form that individuals who may not be trained in research can understand and apply the information.

**Professional Outcomes Researchers.** This is a rather broad-based profession in that outcomes researchers represent a variety of research disciplines which include epidemiologists, economists, health services researchers, clinical scientists, pharmacists, and others. Each of these categories represents a research profession and each essentially has its own standards, practices and conventions. An economist and an epidemiologist may approach the same issue from two slightly different perspectives. Perhaps neither approach is better than the other even if both are designed to answer the question. For example, an economist may develop a behavioral model that requires parameter estimates from a variety of sources, while an epidemiologist may make greater use of statistical analyses of large databases.

➢ **Colleagues, Research Employees and Students who work for researchers.** In dealing with colleagues one must be cognizant of the professional relationships and the rights and responsibilities of colleagues when conducting collaborative research. Colleagues are generally independent researchers with their own reputations. Research employees are also colleagues in the sense that they are often doctoral level individuals with their own careers. They must be accorded respect and given appropriate credit for the work they perform on research projects.
➢ **Clients.** Researchers develop relationships with clients over time and the researcher-client relationship is vital to the continuation of the researchers’ business whether private or non-profit. In pursuing research and maintaining this relationship, it is important that both parties understand and accept ethical principles surrounding that relationship.

**Design and research practices**

ISPOR members must maintain a current knowledge of research practices. In dealing with relationships among any of the constituencies, especially clients, payers and decision-makers, members have an ethical obligation to remain current in the field. In addition, members should adhere to standards of outcomes research practice for their respective fields as well as identify any official guidelines or standards that they may have used.

Members’ research designs should be defined a priori, reported transparently, defended relative to alternatives, and planned to minimize all types of bias. Transparency is absolutely critical. At no time should a reader or user of the research be expected to act on findings where there may be questions as to how the research was conducted or the data were interpreted.

Journals must be encouraged to allow sufficient space to publish detailed information on the research designs. For randomized controlled trials (RCTs), the Consolidated Standards of Reporting Trials (CONSORT) statement provides an excellent example of detailing the quality of reporting. It is specific to RCTs but offers some excellent models for reporting in general.

Members should respect the rights of human subjects at all times. Human subjects issues arise in a variety of ways. Human subjects may represent ID numbers in a paid claims database, may be survey respondents, may be clinical trial subjects or may be patients whose medical records are being reviewed. Regardless of the setting in which the research is conducted or the nature of the human subject definition, respect for the rights of the human subjects must be paramount. In recent times, stringent restrictions have been placed on research involving human subjects and institutional research boards (IRBs) oversee much of the research conducted. But even so, occasionally problems occur.
For example, several years ago a major university in the U.S. was involved in an incident where a young woman died as a result of ingesting a substance during a trial. That substance was thought by the researchers to have been harmless, yet it was found to have been a substance with a history of toxicity.

Privacy and confidentiality must be respected and guarded. The information in databases, medical records and survey files must be protected and individual patients or other human subjects, such as prescribers, must not be identified.

Members should respect the reputations and rights of colleagues when engaged in collaborative projects. From a design and research practices perspective, it is important to recognize that each individual’s actions can positively or negatively affect the reputation of his or her colleagues. It is thus important to work closely with colleagues, obtain agreement on the approach to the research design and obtain agreement on the data analysis and interpretation of the results.

Members should maintain and protect the integrity of the data used in their studies. Often data are in the form of claims, either pharmacy or medical, and these data are by definition not designed for research. The researchers must assure that the database is clean and that there is no patient duplication, that identifiers are unique, and that medical and pharmacy claims are merged appropriately. In other types of research, such as survey research or medical records review, coding is very important. And, with regard to medical records review, the records are rarely copied in their entirety and decisions need to be made as to exactly which data to abstract from a chart.

Members should not draw conclusions beyond those which their data would support. The data will be used to test the hypotheses that were generated a priori and will be used to support any subsequent analyses. However, the researchers in their design and research practices must continue to adhere to standards of practice and ethical precepts for their disciplines and be certain to form only those conclusions that their data will support. For example, if there is insufficient power to conclude that there is a significant difference between two groups, this should be reported as such.
Sponsorship

Sponsorship relates to initial decisions on whether to conduct the research and the relationships between the researchers and the sponsors. At all times, the source of sponsorship for research should be fully disclosed. It allows the recipient of the research, whether a reader or an entity that is going to implement the research into their daily practices or policies, to judge the level of confidence they might place in that research based on that source. Members (of ISPOR) should strive to avoid bias and the appearance of bias in conducting research. The disclosure of the identity of the sponsor should serve to place sufficient pressure on researchers to be sure that their research and subsequent publication is well balanced and as unbiased as is possible. As a routine matter, most journals require that authors disclose the source of support for the research and publish this information as a footnote in most cases.

In reporting and conducting research, members must be able to maintain their professional autonomy at all times. In the long run, the information reported might be better received with a higher level of confidence than if the researcher’s professional autonomy were in question. Ultimately, the professional is responsible for the conduct of the research and his or her reputation will certainly be affected by perceptions that the research is biased or that professional autonomy has been compromised.

Members should also avoid conflicts of interest, and the mere appearance of conflicts of interest. In this area, members need to be most vigilant. It is beyond the scope of this paper to attempt to detail every possible situation where a conflict of interest might exist. However, there are few areas where members would need to be concerned. These include but are not limited to: working for competing clients in a product line that both clients produce without full knowledge on the part of both clients that you are working for the other; having substantial ownership in a client’s company without divulging that information; or using confidential data from one client to perform work for another.
**Publication and dissemination**

Research is often undertaken for a client where the resulting product is a report to that client which then becomes the property of that client. This is often the case in the private consulting arena. Often, universities will refuse to sign a contract where publication rights are restricted. A more common practice is to include in that contract a provision that publication may be withheld for a period of three to six months after which the investigators are free to publish. Usually this is designed to address intellectual property issues but can be used for virtually any reason at all.

ISPOR members should endeavor to publicly disseminate all of their work and to publish it in peer reviewed journals when possible. ISPOR members should have a philosophy of advancing knowledge in a particular area and should therefore publicly disseminate their work, holding it up to peer review. However, members should respect contractual rights when they agree to perform work for hire and should refrain from disseminating information which they agreed in advance at the time the contract was signed would remain proprietary.

Methods sections of papers should give thorough, transparent attention to all measures taken to minimize bias and should identify and defend all departures from the a priori analysis plan. This basically implies that the methods section of the paper should be thorough and detailed enough so that the reader has a good understanding of exactly how the research was conducted. For example, sampling measures should be presented in sufficient detail to enable the reader to determine whether the sampling plan presents a particular bias. Analyses should be those which are best suited to examining the data generated from the study and testing the hypotheses that were proposed in the study. Research often leads an investigator down roads that he or she may not have contemplated when drawing up the original research plan. When this occurs it should be reported truthfully, thus allowing the reader to draw his/her own conclusions.

Members should not allow listing of an author on any publication where that individual has not performed substantial work. Members should also not exclude from listing as an author any individual
who has performed substantial work. Authorship is frequently a difficult problem within an organization. The question often arises as to whether a particular individual has performed work that is substantial enough to merit listing as a co-author. One alternative which can be considered by researchers is to acknowledge the contribution of an individual who has not performed enough work to qualify as a co-author but has greatly assisted the effort in a footnote. Members should utilize checklists, such as those found in major peer reviewed journals, to determine whether an individual should be included as an author based on his or her contribution to the intellectual content of the paper. While this does not address all author-related issues, it is very helpful.

Finally, as a general rule members should work with editors of journals and other publications to encourage an appropriate peer review process that examines the quality of the methodological rigor rather than the institution for which the individual works. Contributors should disclose relationships with a company or competitor of any product discussed in the work so that the reader can draw his or her own conclusions.

**Role of ISPOR as a Professional Society**

ISPOR is an organization representing members from a variety of disciplines. As the organization producing this Code, ISPOR is not particularly interested in serving as arbiter of complaints or as a licensure board. The Society is merely interested in putting forth a Code of Ethics that its various members can subscribe to as part of belonging to this organization. However, there are certain roles and responsibilities that ISPOR, as a professional society, should undertake.

First, ISPOR should publicize this Code of Ethics to both members and non-members. This could be done through dissemination of information on the ISPOR website as well as publication in hard copy as a stand alone document or a publication in a peer reviewed journal. Second, ISPOR should strive for a balance in sponsorship of its conferences and other activities thereby avoiding the opportunity for, as well as the appearance of, bias or conflict of interest. While, as with other organizations, much of the funding for activities may come from one particular sector of the health
care industry, the organization should seek to obtain support from other quarters. Because as a practical matter there is funding from commercial interests, ISPOR should issue its own statement of objectivity and autonomy from sponsors. Third, ISPOR should continue to assure that its journal only publishes papers that have gone through a rigorous peer review process. Fourth, ISPOR should maintain a board of directors that is representative of the various constituencies that the society serves. Fifth, ISPOR program planning and selection committees should have membership representative of the major constituencies. Finally, the task force took note of the fact that the Toronto Resolution addresses many issues related to the activities of professional societies. As other societies are beginning to do, ISPOR should plan and conduct its wide ranging activities in a socially responsible and environmentally sustainable manner, particularly with regard to global health and equity.

References


The Toronto Resolution.
