

ISPOR Code of Ethics 2017 (4th Edition) SUMMARY POINTS

Chapter 1: Introduction to the ISPOR Code of Ethics

1. The ISPOR Code of Ethics was developed as guidance for the health economics and outcomes research community as a whole.
2. ISPOR strives for representativeness, transparency, and objectivity in its activities.
3. ISPOR has a Board of Directors that is representative of the various constituencies that the Society serves.
4. The ISPOR program planning and selection committees should have membership representative of its major constituencies.
5. ISPOR strives for a balance in sponsorship of its activities by providing decision criteria for acceptance and disbursement of funds to ensure full transparency and minimize the possibility of bias or conflict of interest.
6. Like other professional societies, ISPOR is conscious of broader ethical issues that impact global and regional medical resource allocation, public health policies, and the global health care environment or are relevant to research topics such as patient autonomy, patient outcomes, and research conduct. These issues include, but are not limited to, prejudice, equity in health care delivery, and access.

Chapter 2: Application of Ethical Principles to the ISPOR Code of Ethics

7. Members should maintain current knowledge of research practices, of general principles, and of local and regional relevant practices.
8. Members must conduct activities honestly, with integrity and good judgment, and in the best interests of the patients, health care professionals, decision makers, outcomes researchers, pharmaceutical manufacturers, and other public health communities we serve.
9. Privacy and confidentiality: It is essential that protected health information (PHI) and other personal data of patients are handled with the utmost care so that patient confidentiality is maintained at all times and that no breaches to patient privacy occur.
10. Transparency and Integrity: Members must disclose research methods in sufficient detail to permit replication. Funding sources should be clearly acknowledged, and any conflicts of interest declared.

11. Designing, conducting, and especially reporting of the study should be an objective (unbiased) reflection of the full range of findings generated.
12. Civility: Members' research and discussion should respect the dignity of all participants. Respecting the dignity of patients and providers of care is clearly a top responsibility. It is also a responsibility to treat fellow researchers with respect.

Chapter 3: Scope of the ISPOR Code of Ethics

13. Members should adhere to the standards of practice for their respective fields of research; hence they should identify and acknowledge any applicable official guidelines and standards used.

Chapter 4: Research Design Considerations

14. From the point of "first contact," researchers should provide potential subjects information about study intentions and how the research is funded, as well as all information mandated in their proposals to institutional review boards (IRBs) / independent ethics committees (IECs)¹ according to the primary objective with patient consent.
15. Members should describe the analytic study population in terms of its relevant demographic and medical characteristics, geography, time period, and selection criteria.
16. Members should justify the chosen target population and choose a suitable research setting for this population. In addition, existing data or literature should be included to provide information about the specific population to which the study results will be applied.
17. The number of patients and sites selected for a study should be appropriate to meet the research objectives without being greater than statistically necessary.
18. The balance of risk or harm to benefit for patients must be considered in HEOR studies and must be communicated to patients via informed consent.
19. Safety and adverse event reporting (AER) is an important aspect of all primary research involving patients and medical interventions. It is applicable to many HEOR activities and must follow the most up-to-date international and local guidelines.
20. Any incentive, honorarium or payment is subject to receivers' and providers' internal compliance guidelines. IRB/IEC approval and must be detailed in the proposal submitted for review.

¹ Also known as ethical review boards (ERBs), research ethics boards (REBs), or ethics committees (ECs).

21. Researchers should be diligent in ensuring that the incentive would not induce research participants to accept risks they would not be willing to accept if they were offered a smaller or no incentive.
22. When using secondary data sources initially collected for another purpose, HEOR researchers should ensure that intellectual property rights are respected and referenced and that all the appropriate permissions have been secured.
23. Given the potential for bias in the analysis of secondary data, the most important general ethical principles are those of reasonableness and transparency.
24. Any known or potential source of bias in the data that can affect the results must be disclosed whenever secondary data are used.
25. In those instances in which study methods include analysis of a database, members should describe approaches, methods, technologies used to ensure data completeness and validity, as well as the software package(s) used for data analysis. Members should have the education, training, and experience to perform the assigned tasks or provide evidence of collaboration with individuals who are qualified.
26. Members are encouraged to register clinical and observational studies prospectively on ClinicalTrials.gov, patient registries (e.g., patientregistry.ahrq.gov), EU electronic Register of Post-Authorisation Studies (EUPAS Register) or equivalent database in their own country. Where an HEOR study is being conducted alongside a clinical study gathering data prospectively (e.g., a clinical trial or observational study), joint registration of a clinical study and its accompanying economic analysis is recommended as an important element toward ensuring research transparency.
27. Members should be transparent about the estimates they use for key parameters, provide the logic they used in selecting particular estimates, and explore the impact of their choices through sensitivity analysis.

Chapter 5: Data Considerations

28. When a database (from primary data collection and/or secondary data use) is analyzed, members should provide a description of approaches, tools, and technologies used to store the data and maintain patient privacy/confidentiality and de-identification.
29. Personal data should be maintained securely, and adequate backup should be maintained. Data access should be limited to authorized individuals. Control systems should be put in place to ensure authenticity, integrity, and confidentiality of data records when transmitted electronically.
30. Researchers should offer the right to access the anonymized, group-level data used in their research. If data access is restricted by proprietary or contractual considerations,

those considerations should be disclosed. If journal reviewers deem it important that statistical review of proprietary data be conducted, authors should work with both the data owners and the reviewers to find appropriate confidential arrangements for such review, whenever feasible.

31. Members' hypotheses and research designs should be defined a priori, reported transparently, defended relative to alternatives, and planned to recognize and minimize all types of bias.
32. Members should fully disclose the identity of sponsors of their research.
33. 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.
34. 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 potential conflicts of interest described by major peer-reviewed journals and their own institutions.
35. Members should maintain their professional autonomy and objectivity in conducting research and in writing or verbally reporting research findings.
36. Methods sections of papers should identify and justify all departures from the a priori analysis plan.
37. Members should maintain and protect the integrity of data used in their studies, and any other aspect of their research (e.g., respect for patient autonomy, such as informed consent and data privacy).
38. Members should not draw conclusions beyond what their data would support and should discuss any limitations in a transparent manner.

Chapter 6: Relationship of Sponsor with Researcher and Others

39. Members should respect the reputations and rights of colleagues when engaged in collaborative projects.
40. Members should collaborate with team members, provide competent work, and protect proprietary information.
41. Members should treat their research employees and all non-research subordinates with respect and should compensate them fairly for their work.
42. Members should treat students with respect and refrain from taking advantage of them under any circumstances.
43. At all times, members acting as sponsors should allow researchers to maintain their scientific integrity and adhere to relevant standards in conducting and reporting research.

44. Members should respect contractual rights when they agree to perform work for hire and should refrain from disseminating information that might be proprietary.
45. When acting as KOLs or advisory board members, ISPOR members should be transparent about payments and any other benefits that they receive for acting in this capacity.
46. When acting as KOLs or advisory board members, ISPOR members should ensure that the information they are presenting is an accurate representation of the facts available. They should respond to questions and queries honestly and to the best of their abilities.
47. When relying on KOLs or advisory board members, ISPOR members should critically triangulate the claims being made. Where appropriate, they should seek independent corroboration of any factual claims and consider the full range of alternatives for themselves.
48. When acting as KOLs or advisory board members, ISPOR members should maintain their independence and professional autonomy and act transparently (e.g., declare conflicts of interest).
49. Members should respect the autonomy of research participants when designing and conducting studies, specifically including, but not limited to, informed consent and data privacy.
50. Members should, where appropriate, seek input from individuals or organizations that are able to represent the perspective of patients.
51. Members should, where appropriate, communicate their research findings to participants.

Chapter 7: Patient Centricity and Patient Engagement in Research

52. Patient input should be included throughout the medical product lifecycle from early development to dissemination and post-marketing surveillance.
53. Researchers should endeavor to involve patients and their representatives as partners before, during, and after conducting research.
54. To prevent or address ethical issues arising in the patient engagement process, follow published guidelines. Consultation with experienced stakeholders is useful as well.

Chapter 8: Publication and Dissemination

55. Members should not engage in any act of plagiarism, including self-plagiarism. If publishing work similar to anything jointly authored with others, members should ensure that no replication of the prior work was unintentionally done.

56. It is extremely important to give comprehensive citations to avoid unintentional plagiarism.
57. Members should not publish any material relating to the activities of an ISPOR Task Force, Special Interest Group, or other ISPOR group at any stage, without first consulting fellow group members/co-authors for permission.
58. In the case of sponsored research, members should agree to a contract that clearly sets out their rights, scope of work, and rights of the sponsor (e.g., intellectual property rights and rights to publish) in the conduct and reporting of the study. A summary of this agreement should be provided in the published paper.
59. Transparency in reporting is also essential to reduce the possibility of bias in research. Follow established reporting guidelines and endeavor to respond as fully as possible to requests for additional information on data or methods.
60. Where an HEOR study is being conducted alongside a clinical study gathering data prospectively (e.g., a clinical trial or observational study), members should report whether the clinical study has been registered and, if so, where.
61. Members should endeavor to publicly disseminate their work and to publish it in peer-reviewed journals, when possible.
62. Members should work, where appropriate, to encourage the establishment and/or maintenance of an appropriate peer review process that examines the quality of the methodologic rigor independently of the organization for which the individual works.
63. Members serving as peer reviewers for journals should respect the confidentiality of the material under review and understand that their access to it is solely for the purposes of performing the review.
64. The description of study methods (design, study setting, data sources and input values, sampling, and analyses) should be complete and transparent enough for a suitably trained researcher to replicate the study.
65. Methods sections of papers should give thorough, transparent attention to all measures taken to minimize bias.
66. Where allowable by law and IRB/IEC approval, members should respond favorably to requests from journal editors and reviewers for access to original data and electronic copies of models where this access is required to ensure a rigorous peer review process and where commercial in confidence arrangements can be maintained.
67. In those instances, in which study methods include analysis of a database (retrospective or prospective), members should describe approaches, methods, technologies used to ensure data completeness, and validity, as well as the software package(s) used for data analysis. Members should have the education, training, and experience to perform the assigned tasks.

68. In those instances, in which sharing of model(s) and/or data source(s) is not feasible, members should be encouraged to provide supporting material demonstrating model and/or data validity, such as range and logic checks and assessment of data completeness.
69. If submitting to a journal or publication that does not have peer review, or disseminating a report via electronic media, members should avoid the inclusion of material that cannot be supported by basic article references or make it clear that the article represents the author's own opinion. If research is being reported, then access to the underlying data and/or analyses should be offered in the same manner as would be done under a peer-review process.
70. It is important to disclose financial and/or other relationships that could be perceived as a conflict of interest, especially present or past relationships with manufacturers referred to in the research or any competitor products.

Chapter 9: Conclusion and Limitations

71. ISPOR expects its members to adhere to the highest ethical standards. By following these practices, stakeholders will be more likely to participate in health care research, as well as trust and benefit from it.
72. HEOR is improved by following the highest possible ethical practices in terms of improved research, decision-making, and, overall health and health care

