Ethics Guidelines for Environmental Epidemiologists

Introduction


Elsevier has kindly granted permission to post the ethics guidelines portion (Section 4) of this paper to the ISEE web site (see below). The abstract to the full paper is posted below the guidelines. An introduction, the preamble to the guidelines, and the concluding remarks can be found only in the print version of the full paper. Reprints in hard copy may be requested from Colin Soskolne at colin.soskolne@ualberta.ca. Visit the home page of *The Science of the Total Environment* (http://www.sciencedirect.com/science/journal/00489697).

Substantial portions of the ethics guidelines were drawn heavily from "Ethics Guidelines for Epidemiologists," which appears as reference [3]. Wherever an asterisk (*) appears in the guidelines, this refers to material not included in reference [3], but more to material derived from the Proceedings of a World Health Organization (WHO)/International Society for Environmental Epidemiology (ISEE) International Workshop, "Ethical and Philosophical Issues in Environmental Epidemiology," 16-18 September 1994, Research Triangle Park, North Carolina, USA. All papers from this workshop are contained in the Special Issue of *The Science of the Total Environment*, Vol. 184 (Nos. 1,2) 17 May 1996 (148 pages).

The ethics guidelines are structured into four subsections:
1. Obligations to subjects of research
   (for 'subjects,' please read also/instead: 'participants/people');
2. Obligations to society;
3. Obligations to funders/sponsors and employers; and
4. Obligations to colleagues.

Through these guidelines the ISEE seeks to ensure the highest possible standard of transparent and accountable ethical practice. Please send any comments on the guidelines to Colin Soskolne for consideration in possible updates.

4. Ethics Guidelines for Environmental Epidemiologists

4.1. Obligations to Subjects of Research

4.1.1. Protecting the welfare of subjects
The environmental epidemiologist should treat subjects respectfully and should strive to minimize discomfort, disturbances, inconveniences, and risks caused to subjects. Environmental epidemiologists should be aware of any intrusive or harmful potential present in their investigations. There is a fundamental obligation to abstain from intentionally injuring subjects and, insofar as conditions permit, an obligation to further the interests of subjects by preventing or removing possible harms.

If a research study discovers information about the health and safety of particular individuals or populations, this information should not be withheld from a subject in the study who might be significantly (*i.e. adversely) affected. If reasonable in the circumstances, the information should be communicated to the appropriate parties. Wherever possible, all significant (*i.e. adversel...
important) risks should be disclosed before the research commences. A good faith effort should be made to communicate study information to study subjects and to the population of whom they are a representative sample.

4.1.2. *Consultation with stakeholders*
Possible mechanisms of consultation with members of affected groups or their representatives should be sought wherever appropriate. Study protocols should address potential concerns of affected groups and should articulate any potential negative consequences of the study to any individuals or groups. Environmental epidemiologists should inform the public about risks and benefits for individuals and communities resulting from environmental epidemiological research and practice.

4.1.3. Obtaining informed consent
If epidemiologic inquiry involves the active participation of human subjects, explicit informed consent should be obtained. Disclosures should be made regarding the aims, methods, anticipated benefits and risks of the research, any inconvenience or discomfort that may be involved, and the right to withdraw from the research. Additional disclosures and special precautions to ensure that subjects understand the disclosures may also be necessary.

If participation in the research is voluntary, subjects should understand that they are not required to participate and may refuse participation initially or at any stage in the research. Even if participation as a subject is legally required, proper information and an opportunity for discussion should be provided.

4.1.4. Loosening requirements of informed consent
With certain types of research it is neither feasible nor necessary to obtain informed consent, although subjects need and deserve protection in other ways, such as through security for confidential information. Decisions to loosen or bypass informed consent requirements should be approved through an appropriate review process, rather than approved by individual investigators.

Much research in epidemiology could not be conducted if consent were needed in order to obtain access to records. Use of records without consent is not necessarily an ethical violation. Research of this type may be the first stage of an investigation that determines whether there is a need to trace and contact particular individuals and obtain their permission for further participation in a study. However, there must be careful protection of the confidentiality of the information and the privacy of subjects. (See the following two sub-sections below.)

4.1.5. Protecting privacy
Privacy, the condition of limited access to a person, should be aggressively protected. Infringements of privacy are at times justified, but only if there is an overriding moral concern such as a health emergency.

The law sometimes requires invasions of privacy, especially under conditions of a threat to public health and safety. When under a legal obligation to make disclosures that invade privacy, the epidemiologist should carefully weigh an obligation to the law against the moral importance of preserving the privacy of subjects. If the epidemiologist must infringe privacy, those involved should be informed of the reasons and of their rights in the circumstances.

*A person's individual results should not be reported to anyone other than the person concerned. Indeed, results that could enable a person to be identified should not be published (e.g. statistical breakdowns/stratifications resulting in cell sizes of five persons or fewer should
not be published if there is any way that these individuals could be identified). (See sub-section 4.2.12 'Communication of results' below.)

4.1.6. Maintaining confidentiality
Information obtained about research participants prior to or during a research investigation is confidential. Identities and records of subjects should remain confidential whether or not confidentiality has been explicitly pledged. Epidemiologists should take appropriate measures to prevent their data from publication or release in a form that would allow previously undisclosed identifications to occur.

The obligation to protect confidential information does not preclude obtaining confidential information. The obligation is neither an obligation never to obtain confidential information, nor an obligation never to share the information with appropriate parties (assuming adequate safeguards).

Confidential medical and other vital records that identify individuals are essential to epidemiologic research, and identification of persons whose records have been obtained is often needed to prevent those individuals or others associated with them from developing disease or to identify the disease at an early stage.

4.1.7. Reviewing research protocols
All research involving human subjects should be reviewed by a proper review process, for both scientific design and for ethical adequacy. This review should operate pursuant to authoritative regulations that establish the composition of and principles for such review. Moral requirements in these regulations should always be considered in the review process. In circumstances in which informed consent is not required (see sub-section 4.1.4. 'Loosening requirements of informed consent' above), special scrutiny of the research and alternatives to the protocol should be considered. If a subject does or could be expected to object to involvement as a subject, the research should not be performed using that subject.

Review committees and (if appropriate) administrative review should be structured so that officials (e.g. Institutional Review Board members or members of its secretariat) work closely with investigators in improving the ethical quality of the research. However, investigators have a personal responsibility to evaluate the ethics of a study and to ensure its ethical adequacy throughout its term. Responsibility for ethical evaluation cannot be justifiably transferred to the review committee or to administrative review.

4.1.8. Sample storage
The storage of biological samples should not be carried out without the prior agreement of the subject. Future use of biological specimens for purposes other than those foreseen at the time of sample collection, may be allowable (subject to Institutional Review Board review) as long as the subject is not identified outside of the research team. In longer-term, prospective cohort studies where most participants already may have died, testing of biological specimens again may be allowable under the same conditions noted in the preceding example.

4.2. Obligations to Society

4.2.1. Avoiding conflicting interests
A conflict of interests occurs whenever a personal interest or a role obligation of an investigator conflicts with an obligation to uphold another party's interest, thereby compromising normal expectations of reasonable objectivity and impartiality in regard to the other party. Such circumstances are almost always to be scrupulously avoided in conducting
environmental epidemiologic investigations (*because the health consequences of deliberate or inadvertent bias in environmental epidemiologic research can be great).

Every environmental epidemiologist has the potential for such a conflict. An epidemiologist on the payroll of a corporation, a university, or a government does not encounter a conflict of interest merely by the condition of employment, but a conflict exists whenever the epidemiologist's role obligation or personal interest in accommodating the institution, in job security, or in personal goals compromises obligations to others who have a right to expect objectivity and fairness.

4.2.2. Avoiding partiality
Problems of partiality are closely related to problems of conflicting interests. Partiality occurs when there is a value-directed departure from accuracy, objectivity, and balance, not merely an inadvertent distortion of facts. *Since value-directed departures can be unconscious, a careful selection of peer reviewers can improve the design, analysis and reporting of study results. The intrusion of personal or institutional values that distort an environmental epidemiologic study is as scrupulously to be avoided as a conflict of interests. Under no circumstance should environmental epidemiologists engage in selecting methods that are designed to produce misleading results or act to misrepresent environmental epidemiologic findings.

Environmental epidemiologic inquiry is predicated on the belief that sound research is beneficial to society. Although risks that environmental epidemiologic information will be misconstrued or misused are sometimes present, such a risk does not disqualify either the research or the investigator. The environmental epidemiologist should anticipate predictable consequences of collecting and disseminating certain information and should shield the information against misinterpretation or abuse that would result from the partiality of others. *Bias in scientific communication is a serious threat to the understanding of the role of environmental exposures in health.

4.2.3. *Political responsibilities of epidemiologists
Environmental epidemiologists provide the science used to inform the policy-making process at local, national and international levels. In addition, environmental epidemiologists may of course serve as advocates for particular issues. In principle, nothing is wrong with an epidemiologist using his or her skills to advocate some particular environmental health position. However, great care must be taken to distinguish between scientific and non-scientific considerations when embracing a role as an advocate as much as these issues may be separated. Epidemiologists, as scientists, have an obligation to try to clearly demarcate what part of their advocacy work is motivated purely by personal political/social concerns, rather than that part which stems less subjectively out of the requisites of their science. Appeals to 'objective science' should not be made as an attempt to mask personal convictions.

4.2.4. Widening the scope of environmental epidemiology
There are general obligations in environmental epidemiology to carry out research, to advance knowledge, and to protect the public health. Environmental epidemiologists should employ the means available to them to enlarge the reach of sound epidemiologic inquiry and to disseminate their findings so that the widest possible community benefits from the research. Whenever information has been obtained that would be valuable to the larger epidemiologic or public health community, the information should be shared and should remain free of distortions that might be introduced by preconceptions or organized policies - irrespective of whether the research is conducted with private or public funds.
The environmental epidemiologist should uphold his or her personal and professional integrity as well as communal responsibility whenever there exists a danger that others might be in a position to control the dissemination of information.

*Data protection advocates and social and health researchers should be brought together to address the implications of data protection on social and health research.

4.2.5. **Community involvement**
Discussions should be initiated at international, national and regional levels to facilitate community involvement and resolution of issues in environmental epidemiology practice. Such issues include, for example, genetic monitoring, markers of exposure, physiological changes of uncertain biological significance, potential for conflicting interests in the framing of research questions through dissemination of results, and the use of biological banks and historical datasets, issues so fundamental to much of environmental epidemiology. A project steering committee made up of representatives of all stakeholder groups is suggested as one mechanism for addressing these kinds of issues.

Research involving a community ought to include from the inception, or certainly prior to the formal design stage, through to completion of the study, community representatives (a) knowledgeable about the science (e.g. union and health representatives) and (b) affected by the problem being investigated (e.g. community stakeholders and also the unempowered). The Institutional Review Board, or its equivalent in different countries (e.g. in the European Union: Research Ethics Committee; in Canada: Research Ethics Board) likely will include lay community representatives. However, the researcher's task is to ensure that community input through the entire research process, from conception of the question to hypothesis formulation, methods selection, analysis, interpretation and dissemination is included in a partnership capacity with the principal investigator.

4.2.6. **Obligations to environmental health**
Environmental epidemiologists, through the performance of their professional duties, should work to advance the interests of the discipline, ensuring that the broader public interest is maintained. To assist in this process, interaction with environmental disciplines that go beyond human health is encouraged because discussion of ecological integrity has a direct bearing on human health.

4.2.7. **Obligations toward psychosocial health**
With psychological stress recognized as a significant determinant of morbidity, the consequences of negative risk information about the health impacts of environmental contaminants should be balanced against the psychological impact that such information could have on the affected community. Concerns about the consequences of negative news should include economic hardship which, in turn, could have further negative health impacts. The environmental epidemiologist has an obligation not to add undue stress to a population whenever possible. While this may present some tension with a desire to respect the autonomy of individuals, adding stress to a community should be avoided. However, this concern should not be invoked as a pretext for withholding information from appropriate stakeholders. Project steering committees comprising community representatives provide one mechanism for handling such concerns (see sub-section 4.2.5.'Community involvement' above).

4.2.8. **Ethical issues in risk analysis**
There are many important issues deriving from those sciences engaging in risk analysis. Perhaps most important is the issue of what conclusions can be correctly drawn from a premise of uncertainty. Environmental epidemiologists, and other professionals involved in risk analysis, including risk assessment, risk management and risk communication, are finding that
the more sophisticated techniques of analysis are revealing more about what we do not know, rather than about what we do know. If, as a result of our analysis, we are unsure about what constitutes a safe dose of a substance, then we must look to non-scientific criteria, such as social context, for deciding approaches for communicating risk information. Minimally, we have the obligation to make transparent the assumptions used in the models for our risk calculations.

Researchers have tried to draw more definitive conclusions from uncertainty; yet the premise of uncertainty can serve equally validly as a reason for a conclusion of risk taking or risk aversion. Environmental epidemiologists, because of the breadth of their discipline, should be prepared to caution other researchers who attempt to draw conclusions from uncertain premises. The environmental epidemiologist should try to remind his or her colleagues in the health sciences of the importance of taking moral considerations into account when faced with the dilemma of how to act in the presence of uncertainty about health risks.

4.2.9. Pursuing responsibilities with due diligence
The environmental epidemiologist has a general obligation to enhance, protect, and restore public health. On this basis, there must be sound reasons for commencing an epidemiologic investigation. It must employ a scientific method appropriate for the research, and adequate analysis must be performed to justify interpretations.

The more an individual or institution is involved in sponsoring or conducting the research, the more responsibility and care are due to ensure that the venture does not involve a compromise of the rights of others. Monitoring and watchfulness are therefore requisite for responsible investigations. The degree of diligence required depends on the position of responsibility occupied by the environmental epidemiologist and on the degree of the epidemiologist's involvement in the research.

4.2.10. *Research area bias
Environmental epidemiologists must strive to redress the imbalance of research attention to understudied populations. Disenfranchised groups have traditionally not had a voice loud enough to be heard by health research policy makers. Because of this, special attention should be directed at such groups. (This concern has become known as 'environmental justice' in the United States.)

4.2.11. Maintaining public confidence
Public confidence is vital for environmental epidemiologic research. Environmental epidemiologists should attempt to promote and preserve public confidence and not misrepresent (for example, by understating or overstating) the methods, results, or public health significance of environmental epidemiologic inquiry. All information vital to public health should be communicated in a timely, comprehensive, understandable, and responsible manner. *However, studies in progress should not report results to the media unless prior approval by a properly constituted Institutional Review Board, or its equivalent, has so sanctioned.

4.2.12. *Communication of results
Researchers ought to include in their proposals/grant applications a section identifying their 'communications plan.' This would describe (a) strategy for the (prior to publication) presentation of methods and results at any scientific gathering of peers (though if media are in attendance they specifically must be reminded to recognize the interim/preliminary nature of the report); (b) how the methods and results are to be subjected to peer-review for publication (see sub-section 4.4.2.'Publishing methods and results' below); and (c) the degree of care that will be exercised to ensure comprehensibility when communicating results to non-scientific groups (e.g. the community and/or other professions). Special attention should be paid to
prevent the distortion of results that could arise from any interest group pressure. Institutional Review Boards, or its equivalent, ought to evaluate this component (as well as being evaluated by other scientists in the grant review process).

4.3. Obligations to Funders/Sponsors and Employers

4.3.1. Specifying obligations
Environmental epidemiologists should inform employers and funders/sponsors, preferably in contractual form, how research is to be conducted and how it might involve moral and legal responsibilities. The obligations of employer, funder/sponsor, and environmental epidemiologist should be clearly specified in documents such as program manuals or protocols. The employer or funder/sponsor should be referred to the relevant part of these guidelines and other professional codes to which the environmental epidemiologist adheres.

Environmental epidemiologists should not accept contractual obligations that are contingent upon reaching particular conclusions from a proposed environmental epidemiologic inquiry.

4.3.2. Protecting privileged information
Environmental epidemiologists may use privileged information furnished by a funder/sponsor or employer under conditions that the information remains confidential. The privileged information may include intellectual property, including trade secrets. Epidemiologic methods, procedures, and results should not be retained as confidential and should be included in the final report.

4.4. Obligations to Colleagues

4.4.1. Reporting methods and results
Upon completion of their studies, environmental epidemiologists should provide adequate information to colleagues in order to permit the methods, procedures, techniques, and findings of their research to be critically assessed.

*There is a tension between the timely conduct of studies, reporting of scientific findings and the need for thorough analysis and peer review. The need for researchers to have the freedom to pursue a study to conclusion with due diligence and in a timely fashion must be discussed, especially in anticipation of interim findings that may not be pleasing to a sponsoring agency; the researchers must be protected from any attempts to discourage the orderly completion of a study. Neutrality in science is an imperative.

4.4.2. *Publishing methods and results
Researchers must submit their methods and findings (whether 'positive,' 'negative,' or 'no effect') to peer-review (e.g. editorial review for publication). If a research report does not withstand peer-review on scientific grounds, the work should, in all likelihood, not be communicated to the public, other than as a failed piece of scientific work. (See sub-section 4.2.12. 'Communication of results' above.) Selecting peer reviewers with a range of opinions on a given issue is one way to avoid inadvertent bias. Where findings have some urgency, mechanisms for accelerating the peer-review process ought to exist. Journal editors are obligated to consider both 'positive' and 'negative' studies with equal favor in their decision to publish.

4.4.3. Confronting unacceptable behavior and conditions
Environmental epidemiologists are at times faced with stresses that may result in misrepresentation, fraud, unethical behavior, illegal behavior, or incompetence (*shoddy science). When such behavior is encountered in colleagues or in other associates, the
environmental epidemiologist has an obligation to confront the problem and to encourage the repudiation of improper activities. In some cases there may be an obligation to take specific action to correct inappropriate behavior. However, difference of opinion does not necessarily equate to unacceptable behavior.

*The topic of 'Ethics and Law in Environmental Epidemiology' was addressed in 1992 at a symposium of the International Society for Environmental Epidemiology, held in Mexico. Issues of scientific misconduct and scientific dishonesty were discussed with several case studies. The proceedings of that symposium were published and can serve as additional material for discussions about guidelines [13].

4.4.4. Communicating ethical requirements
In circumstances of collaborative inquiry, environmental epidemiologists have a responsibility to ensure that their colleagues understand the ethical requirements applicable to the research. Collaborators, staff, assistants, student workers, and other involved parties should also be informed of the requirements.

References

Acknowledgment

Abstract of the full paper
Over the past 5 years, several epidemiology organizations have published draft ethics guidelines for epidemiologists in general, without regard to sub-specialty. In this paper, we have reviewed these various guidelines. We have extracted the most salient of the principles from these guidelines and consolidated them into a unified set of ethics guidelines for environmental epidemiologists. Those guidelines found most relevant to environmental epidemiology are those from the Industrial Epidemiology Forum and those from the 1994 Ethics Workshop jointly organized by the International Society for Environmental Epidemiology (ISEE) and the World Health Organization (WHO). From these, core values for those specializing in the field of environmental epidemiology are presented. It is to these core values that the guidelines relate. Additional areas of concern to environmental epidemiologists are noted that guidelines have yet to address. It is emphasized that guidelines require ongoing input from members of the profession and hence are expected to be revised periodically. A discussion of the role and importance of ethics guidelines to environmental epidemiologists within their individual practices, as they relate to one another as colleagues, and as they relate to society at large is included as a preface to the guidelines themselves.