



## Towards ethics guidelines for environmental epidemiologists

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### Abstract

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.

**Keywords:** Professional ethics; Ethics guidelines; Professional development; Professional accountability; Moral philosophy

### 1. Introduction

The environment envelops all of humanity. Hence, environmental epidemiology, not restricted by either location of interest (such as industrial epidemiology) or population (such as paediatric epidemiology), has the greatest potential to impact human life from among all of the epidemiology sub-specialties. It is placed as a professional field in a unique position to contribute to more overall

good, or importantly bad, than most other professions. Furthermore, environmental exposures often derive from situations in which a group has gained a or profit from allowing pollution to occur while another group has been harmed. Environmental epidemiology is therefore often more politicized and ethically complex than other branches of epidemiology. These distinguishing features of the field provide the beginnings of an argument for why environmental epidemiologists should be *at least as concerned* with ethics as other epidemiologists, if not more so.

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Since 1984, there has been a growing movement among epidemiologists to construct ethics guidelines to provide a moral framework (i.e. a framework for distinguishing 'right' from 'wrong' actions) for the profession as a whole [1-4]. Our intent here is to produce a set of guidelines uniquely for use by *environmental* epidemiologists. Further, rather than adding yet another voice to the proliferating ethics guidelines for epidemiologists in general, we make specific recommendations and endorsements of some of the existing guidelines [3] as a foundation for ethical practice before addressing the unique ethical framework for specialists in environmental epidemiology. It is our hope that by collecting all of this material in a single document, we will provide practising environmental epidemiologists with a tool, useful and convenient in their daily activities.

### *1.1. The rationale behind a statement of core values*

First, we provide a summary statement of core values for environmental epidemiologists as a basis for the ethics guidelines which follow. Introducing ethics guidelines with a statement of core values is important because core values reflect what the profession stands for; what it intends to promote through its work, and what its members aspire towards. These are the values that infuse professional life with meaning and provide the foundation for its articulated ethics of conduct. Such values give foundation and purpose to expectations of character and to specific ethical duties. The commitment of professionals to the values central to their profession is what leads society to grant the profession collectively, and its members individually, authority and resources to pursue those values in the service of others [5].

Through the formation and documentation of core values, the members' moral commitment can be anchored, thereby enhancing not only the likelihood of ethical behaviors that promote the welfare of the public we serve, but also provide the basis for accountability; namely, society's evaluation and performance based on its expectations derived from a statement of values. Part of the essence of being a profession, and not just a collection of individuals who call themselves a

profession, is having an understanding of the core values and a commitment to them that is shared throughout the profession. A statement of core values, though much briefer than an outline of ethics guidelines, is vitally important in not only framing the guidelines, but also in providing an explicit link between the profession as a profession and the public.

### *1.2. Background on the role and function of ethics guidelines*

While environmental epidemiologists have clearly called for ethics guidelines [6], there is some disagreement among philosophers and practitioners over the use and function of stipulated guidelines in moral discourse. We believe that such guidelines are useful regardless of one's metatheoretical stance concerning the real contribution of guidelines to normative practices.

We also believe that ethics guidelines are organic, originating from within the profession, and hence will continually evolve. Ethics guidelines are tools for use which by no means are intended as ends of discussion on ethical concerns. Just as epidemiologists find more and improved ways to conduct research, over time ethics guidelines will become more and more refined. Thus, ongoing periodic review and revision of guidelines *should* be accepted as a necessary part of their production. Without such revision, ethics guidelines could become stagnant and fail to reflect the extent to which they should respond dynamically to the changing challenges of the profession while simultaneously adhering to a core set of primary principles.

The distinct relations we wish to affect through the formation of guidelines are: (a) the relation between a practitioner and her/his practices, (b) the ethical and professional relations among colleagues within the profession, and (c) the ethical basis of the relation between the profession and society.

#### *1.2.1. The ethical basis for standards of practice*

While it is true that the existence of action-guiding principles does not guarantee ethical practice, ethics guidelines provide guidance concerning

moral dilemmas faced by environmental epidemiologists. At least, ethics guidelines serve as advice for practitioners for guiding their practices with some sensitivity to normative concerns. At most, ethics guidelines serve as moral rules prohibiting some behaviors and permitting others. The final force of guidelines on practices, however, ought not to determine their formation. (See Section 1.2.3. below.)

### 1.2.2. Relationships among colleagues within the profession

A second and almost as important purpose for developing guidelines is to provide a teaching tool that will help orient/socialize students to the profession. As with core values which identify the profession's mission, ethics guidelines form the basis for a moral identification of the profession. Good training is essential to good practice. Ethics guidelines which are unique to the practice help to form part of the justification for the individuality of the profession, and the specific character of its training. As noted in the introduction, environmental epidemiology is distinct from other sub-specialties of epidemiology. Hence, the ethical responsibilities of this sub-specialty could be expected to differ from those of other branches of epidemiological activity. The responsibilities are, at least in part, defined by the unique burdens placed on practitioners. Some of these burdens are moral in scope.

### 1.2.3. Relationship between the profession and society

A third and final purpose for developing ethics guidelines is to provide practical guidance that can help practitioners, employers, and stakeholders make more informed moral decisions. Here we mean to bring out the sense in which ethics guidelines help to form the relationship between the practitioner and the stakeholder. Ethics guidelines are in some very strong sense the foundation of the trust relationship that is needed by a profession that is oriented to the service of the *public* good. While it is certainly the case that this relationship with the public can exist without stipulated principles or even organically evolved guidelines, their existence provides the concrete

point of reference needed to engender trust between both sides.

It is unclear whether ethics guidelines can serve as a document against which individual professionals in environmental epidemiology could be held accountable. This consideration falls into the area of 'guideline implementation' (or, 'guideline enforcement') which is beyond the scope of this paper. Certainly though, we would anticipate that the following guidelines can assist the public in its need to hold the profession collectively to account for its practices.

## 2. Foundations for an ethics of environmental epidemiology

As a foundation for ethics in epidemiology in general we endorse the Industrial Epidemiology Forums' (IEFs) 'Ethical Guidelines for Epidemiologists,' which appeared in the *Journal of Clinical Epidemiology* [3]. This document is sufficient as a foundation for ethical practice for the broad field of epidemiology. Philosophically, when compared with other attempts at general guidelines [4,7-10], the document is much clearer and theoretically elegant. Its components are written in very straightforward prose and phrased as direct, normative, action-guiding principles which are unambiguous in their scope. The IEF guidelines cover the four major areas of *obligation* of the epidemiologists to: subjects of research, society, funders/sponsors and employers, and colleagues. Though by no means exhaustive in their scope with reference to the possible areas in which epidemiologists could be morally concerned or in which they may find an ethical conflict, the guidelines provide a sound basis for ethical reflection for all sub-fields of epidemiology. Practically, they are succinct and lend themselves to easy understanding and use. These guidelines are reproduced here (see the original, however, for the commentary and elaboration of the principles [3]).

The most recent attempt to contribute to the development of ethics guidelines *specifically* for environmental epidemiologists was at a Workshop jointly organized by the World Health Organization and the International Society for Environmental Epidemiology (WHO-ISEE) at Research

Triangle Park, North Carolina, in September 1994. The Workshop title was 'Ethical and Philosophical Issues in Environmental Epidemiology [11].' Additional guidelines that we have integrated into the IEF guidelines are based on discussions from that Workshop. Their publication here is intended to ensure the wider dissemination of the consensus achieved and the concerns expressed at the Workshop, and to maximize the opportunity for grassroots input for the future revision of the guidelines which follow in section 4 below.

In forming the guidelines in section 4, we have essentially merged major components from primarily two documents [3,11] and cited them appropriately. While it may seem unusual to cite substantial amounts of material from other sources in this paper, our intention is to produce a consolidated document that can be more easily used by practitioners. Rather than asking the reader to seek out other sources which, together with our work, provides a comprehensive picture of ethics guidelines for environmental epidemiologists, we thought it best to package together our guidelines with those of others which we endorse.

We have *slightly* changed some of the language of the original IEF guidelines in order to specify their applicability to environmental epidemiology. No change has been made, however, in the content of those guidelines. Additional guidelines and statements from the Ethics Workshop Report (and any added language to the IEF guidelines) are prefaced with an asterisk. Section 4 of this paper thus presents a consolidated set of draft guidelines that epidemiologists engaging in environmental epidemiology may find useful as a basis for further discussion of the issues and for further guideline development.

### 3. Preamble to the guidelines

#### 3.1. Definition of environmental epidemiology

Environmental epidemiology is a sub-specialty of epidemiology that focuses on the identification and prevention of environmental health hazards in communities. It has been more formally defined as

follows: study of the effect on human health of physical, chemical, and biological factors in the external environment [12].

#### 3.2. Statement of core values

The mission of environmental epidemiology is to maintain, enhance, and promote health in communities worldwide by identifying or evaluating environmental hazards. This is done by investigating, interpreting, and disseminating information about environmental causes of disease and exposures in human populations. Environmental epidemiologists contribute to scientific knowledge about environmental risks and environmentally induced diseases, and protect public health at the local, regional, national and global levels. They also inform the public and health policy makers about potential health risks and help them to interpret and understand this information.

#### 3.3. Scope of the guidelines

The guidelines address environmental epidemiology per se, focusing most specifically on human health. It is recognized, however, that human health is directly determined by environmental health in its broadest sense. This necessitates that concerns about environmental integrity, including sustainability of all regional, national, and global life-support systems, be recognized as predicated any of the following guidelines.

### 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 con-

ditions 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. 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 ac-

curacy, 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 from 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 methodology 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 subsection 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 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 parts 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.

## 5. Conclusions

It has not been possible to address all areas of possible ethical enquiry faced by environmental epidemiologists. For example, the following concerns, among others, may warrant attention in the further development and revision of these guidelines:

- Ethical Review Committees [4].
- Relevance of perception of communities in assessing priorities [4].
- Forums for conflicts [4].
- Sensitivity for value differentiation of communities and professionals [4].
- Ethical issues involving the linking of data bases for research [11].
- Research involving children, persons with mental or behavioral disorders, or prisoners [8].
- Research involving subjects in underdeveloped countries [8].
- Obligations of sponsoring and host countries [8].

This document is intended as a resource for the community of environmental epidemiologists. It is open for suggestion, amendment, and further expansion. To our knowledge, this attempt is the profession's initial foray into this area of professional development. As such, we would hope that this document will serve as the basis of future workshop discussions. It ultimately should evolve into an improved statement of core values, ethics guidelines, and relevant commentary for environmental epidemiologists, for those pursuing a career in environmental epidemiology, as well as for all stakeholder groups. Supporting case study

material to facilitate discussion around the principles articulated in these guidelines is in preparation.

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