



Ethics Guidelines for Environmental Epidemiologists

April 25, 2012

The Governing Council of the International Society for Environmental Epidemiology adopted these Guidelines on April 25, 2012. From time to time, the Society reviews its Guidelines. We welcome comments, which should be sent to the designated member of the Society's Ethics and Philosophy Committee for consideration in possible updates at waldelaimy@ucsd.edu and with a copy to the ISEE secretariat at carol_rougvie@jsi.com.

This 2010-2012 revision and update of the ISEE Ethics Guidelines was carried out under the primary authorship of Shira Kramer, Colin L. Soskolne, Wael Al-Delaimy and Adetoun Mustapha.

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1. INTRODUCTION

1.1 Definition of Environmental Epidemiology

Environmental epidemiology is the sub-specialty of epidemiology that focuses on the description and analysis of physical, chemical and biological factors in the external environment that may affect the occurrence and distribution of disease, functionality and well-being of people¹. A more [comprehensive definition](#), developed by the ISEE, is available online².

1.2 Moral and Ethical Norms

This document is primarily informed by Western norms for thinking about what environmental epidemiologists “ought to do” when serving the public good. The term “morality” is often used when discussing what individuals “ought to do” to other sentient beings and even ecological systems, as well as what they “ought to do” in regard to purely intrapersonal issues. The term “Ethics”, on the other hand (and in the context of applied professional ethics), is often used to convey how we ought to behave as professionals³.

1.3 Salient Ethical Issues in Environmental Epidemiology

Because environmental epidemiologists focus on health and the environment, they deal not only with representative samples of diseased and healthy individuals, but sometimes with geographically defined communities composed of stakeholders with different ethical world views and different economic interests. Often, those impacted by hazards represent a minority of these communities and often are groups who are disadvantaged in other and unfair ways. In many cases, the community itself argues as to what constitutes “the public good”. Each step of the research process is thus fraught with ethical issues. Powerful economic or ideological stakeholders sometimes fund environmental epidemiological research; the epidemiologist needs to deal with pressure from these funders who might want to influence various research steps with the aim of distorting the research process and its conclusions to advance their interests. Hence, these Guidelines deal with the obligations that environmental epidemiologists have to communities, society, sponsors and colleagues.

1.4 Statement of Core Values

A core value of science in general, and environmental epidemiology in particular, is to strive towards being objective about its subject matter. However, this process is not straightforward, and may be influenced by myriad personal, cultural and socio-political factors. Both in describing the distribution of exposure and the distribution and occurrence of environmentally-caused disease, as well as analysing causal relations, there are ideological and economic stakeholders who have preferences for what such facts should be and how they are presented. The epidemiologist is tasked with resisting those pressures. Epidemiologists must strive to conduct the highest quality, unbiased research, and to recognise influences that may impair objectivity.

Another core value is to assist environmental health practitioners and policy makers in advancing the health and welfare of the general public and of groups of unusually exposed, susceptible or traditionally marginalised⁴ sub-groups, particularly when they are disadvantaged in other ways as well. These include vulnerable groups such as the foetus and young children. They have little voice and no vote, and it is important to consider the long-term implications of today's policy decisions on their future health.

There is no consensus among ISEE members as to whether environmental epidemiologists have a duty to go beyond objectively communicating facts or to become policy advocates.

There is also no consensus as to what funding sources environmental epidemiologists should find acceptable when there are allegations that an environmental factor of interest to an economic or ideological stakeholder has been falsely incriminated or exonerated. Our duty as scientists is to do the best science possible with a view to reducing uncertainties. However, the presence of uncertainty is no justification for inaction in the face of environmental harms⁵.

1.5 Scope of the Ethics Guidelines

The importance of ethical deliberation and public health values to the science of environmental epidemiology has led to the establishment of ethics guidelines by consensus of the ISEE Ethics and Philosophy Committee. The ISEE Ethics Guidelines are structured into four sections:

- a) Obligations to Individuals and Communities Subjected to Research (see [section 2 below](#))
- b) Obligations to Society (see [section 3 below](#))
- c) Obligations Regarding Funders/Sponsors and Employers (see [section 4 below](#))
- d) Obligations to Colleagues (see [section 5 below](#))

Through these Guidelines, the ISEE seeks to ensure the highest possible standard of transparent and accountable ethical practice, not only for those environmental epidemiologists in research, but also for those in public health practice. Therefore, we consider these recommendations consistent with and extending the original ISEE ethics guidelines⁶ as well as the extant ethics guidelines of the over-arching discipline of epidemiology⁷ with respect to the study of environmental exposures.

2. OBLIGATIONS TO INDIVIDUALS AND COMMUNITIES SUBJECTED TO RESEARCH

2.1 Research Should Avoid Harm to the Individuals and Communities Studied. Knowledge Gained Should Be Disseminated Widely, and Benefits Gleaned Should Be Accessible to the Community Studied

- 2.1.1 **Beneficence:** The primary goal of environmental epidemiology research and practice is beneficence; i.e., improving the health and welfare of the population by identifying and assessing the magnitude of environmental exposures that are

suspected of being harmful to health, and by identifying and evaluating the factors or interventions that enhance health and well-being.

- 2.1.2 **Accessible Language:** Environmental epidemiologists should present their results in accessible language, identifying the strengths of the study, its limitations, and the authors' recommendations to allow stakeholders to understand the report and, where appropriate, to act to promote environmental health, even in the face of uncertainty⁸ (see also [sub-section 3.5 "Communication and Action Plan"](#) and [sub-section 5.2 "Reporting Methods and Results"](#)).
- 2.1.3 **Precautionary Principle:** Research and practice in environmental epidemiology are both driven by respect for life and human dignity as attainable through health and well-being. These underlying principles are guided by the precautionary principle⁹, placing an emphasis on actions and standards in favour of safeguarding public health, particularly in the presence of uncertainty. Specifically, application of the precautionary principle results in lines of enquiry that serve to narrow scientific uncertainties. The absence of certainty does not justify inaction⁵.
- 2.1.4 **Non-maleficence:** Research and practice in environmental epidemiology shall be designed to minimise risk, disruption and harm to both study participants and their source populations (upholding the biomedical ethical principle of non-maleficence; i.e., do no harm).
- 2.1.5 **Respect for Autonomy:** The design and conduct of environmental epidemiology research should demonstrate respect for study participants and communities, for their lifestyle(s), their socio-political environment(s) and their cultural values compatible with respect for life, human dignity, health and well-being.
- 2.1.6 **Community Input:** In community-based research settings, early consultation and input should be sought from members and/or (elected) representatives of affected populations (see [sub-section 3.4.2 "Community Partnerships"](#)).
- 2.1.7 **Full Disclosure:** Research protocols shall clearly identify the benefits, the risks or negative consequences to any individual or group; concerns articulated by stakeholders; potential for positive public health impact, and/or barriers to the research; and the potential for implementation of its findings in public health practice.
- 2.1.8 **Prompt Disclosure:** If, in a research study, information is discovered about the health and safety of particular individuals or populations, this information should not be withheld. Guidelines on the harms and benefits of possible early reporting of results to individuals or groups should be developed in advance of ethics approval and certainly before the study or practice intervention is initiated.

2.2 Informed Consent in Environmental Epidemiology Research: Before Research is Initiated

- 2.2.1 **Informed Consent:** If environmental epidemiology research involves the active participation of, or contribution of bio-specimens from (individual) people (i.e.

human subjects), explicit prior, documented, informed consent should be obtained. Resources for guidance on the need for and securing of informed consent in research involving human subjects in the broad category of biomedical research¹⁰⁻¹³ and specifically epidemiologic research⁷ are readily available. These resources should be accessed on a regular basis to ensure that the most current guidelines/practices are implemented. Consultation with one's host institution is needed to ensure that one is in compliance with local standards for obtaining consent. The distinction between linked and unlinked data for research as opposed to public health surveillance must be recognised, because surveillance work is often governed by legislation.

- 2.2.2 **Individual Rights:** There should be clearly-communicated disclosure of the aims; methods; anticipated benefits, risks, inconvenience and discomfort associated with the research; the right to refuse participation at any time; the right to withdraw from the research without retribution of any kind; and confidentiality safeguards. Research participants shall have the right to request data pertaining to themselves through the entire time period of data storage and for which clinical interpretation has been established. There shall be no implicit or explicit pressure from any party placed directly or indirectly on a person to participate in a research project.
- 2.2.3 **Public Communication:** The public/affected populations should be informed by appropriate mechanisms (e.g., mayor, chief, newspapers, town hall meetings) about potential benefits, risks, or other known impacts of the environmental epidemiology research project, both at the individual and group level.
- 2.2.4 **Consent for Bio-specimens:** If bio-specimens are to be collected from study participants, the benefits, risks and discomfort associated with bio-specimen collection should be fully explained. Details should be provided as to the procedures that will be performed in order to collect, analyse and store the specimens. The purpose for collection of bio-specimens must be disclosed, stating the specific tests and/or diseases that are to be investigated. The ultimate fate of the bio-specimens, after study completion, should be disclosed, including potential future use in follow-up or other studies. Future use of bio-specimens proposed for purposes other than those foreseen at the time of sample collection would be subject to renewed Informed Consent, whenever possible, and Institutional Review Board (IRB)/Research Ethics Board (REB) approval (see [sub-section 2.4.1 "IRB/REB Roles and Responsibilities"](#)). Guidelines on these issues from the European Union were published in 2010¹⁴.
- 2.2.5 **Cultural Sensitivity of Consent:** Culturally-appropriate, additional means of communication and special precautions may be necessary in order to ensure that study participants fully understand the disclosures. This tenet is based upon the universal ethical principle of respect for autonomy (i.e., the person's right to self-determination).
- 2.2.6 **Financial Disclosure:** There should be full disclosure to study participants and to Institutional Review Boards/Research Ethics Boards (or an equivalent oversight committee) of all sources of financial support, sponsorships, or financial relationships of study directors and other research personnel that may be related to the research or analysis of research outcomes. Disclosure should be provided

not only at the application stage to the IRB/REB and the sponsoring entity, but also in all forums in which the project is discussed and presented.

- 2.2.7 **Financial Conflict Verification:** IRBs/REBs or an equivalent oversight committee (when an IRB/REB does not exist) should take special steps to verify that full and voluntary prior, documented informed consent, participant safety, study design and methods, and communications plan have not been compromised when financial sponsorship of study personnel may favour a particular outcome.
- 2.2.8 **Confidentiality of Public Data/Records:** Research based upon records or data contained in special databases is of critical importance in environmental epidemiology research, and does not always require prior informed consent. This type of research does, however, require review by an appropriate IRB/REB or an equivalent oversight committee, and a plan for the protection of the confidentiality of the data and privacy of both the people and their records.

2.3 Confidentiality

- 2.3.1 **Essential Need for Information:** Obtaining and analysing potentially confidential information about individuals is essential to environmental epidemiology research.
- 2.3.2 **Assuring Confidentiality:** In all types of environmental epidemiology research, there should be a comprehensive and detailed plan to assure confidentiality of data and privacy of individual study participants. Any information obtained about research participants prior to or during a research project is subject to this confidentiality requirement, regardless of whether confidentiality has been explicitly pledged.
- 2.3.3 **Data Security:** Important elements of the confidentiality plan include security of data to be collected; control of access to data; chain of custody of data, including bio-specimens; strict control or removal of individually identifiable data; and follow-back or follow-up intentions (and protocol).
- 2.3.4 **Avoiding Identification of Participants:** Individually identifiable results or data should not be published. Results should be published in tabular or graphical form, as grouped data. The groups should be large enough to prevent any individual from being identified.
- 2.3.5 **Sharing Confidential Information:** Sharing of confidential information between investigators should follow the guidelines of the confidentiality plan and conform to procedures approved by an IRB/REB or an equivalent oversight committee.
- 2.3.6 **Allowed Breach of Confidentiality:** Infringement of privacy or breach of confidentiality should occur only in extraordinary circumstances (e.g., health emergency; threat to public health and safety; child abuse; illegal activities), and be subject to prior review by an IRB/REB or an equivalent oversight committee.

2.4 Review of Research Protocols by Institutional Review Boards/Research Ethics Boards

- 2.4.1 **IRB/REB Roles and Responsibilities:** It should be acknowledged by researchers that research involving people should include institutional oversight. Thus, research that is planned needs to be reviewed by a properly constituted review panel for both scientific design and ethical adequacy. This review is expected to operate pursuant to transparent, authoritative regulations that establish the composition of review panels and the principles for such review, including ethical issues and requirements. In certain circumstances, the IRB/REB may cause needless obstruction or delay for timely and important research and therefore there should be an institutional oversight mechanism to adequately handle such exceptional situations. In parts of the world where IRBs/REBs do not exist, an *ad hoc* committee of community members/representatives, researchers and officials should be formed as an oversight committee to the investigative team (see [sub-section 2.4.4 "The Principal Investigator Has the Ultimate Ethical Responsibility"](#)).
- 2.4.2 **Ethics are Local:** The IRB/REB should represent and reflect local values and cultural norms that apply to the populations under study, but in accordance with core ethical values of public health. This role may be delegated to a more central IRB/REB where multi-centred studies are being proposed. In this case, the strategy for multi-country studies should pay special attention to vulnerable and traditionally marginalised communities and populations.
- 2.4.3 **Ethical Study Design:** Environmental epidemiology research plans and protocols should include a section on ethical considerations, and should demonstrate that the study design has the critical elements (e.g., inclusion of appropriate study populations, power, sufficient length of follow-up, latency) which will enable it to address the research question(s) and draw meaningful conclusions, noting both the strengths and limitations of the study's findings, whether positive, negative or of no effect.
- 2.4.4 **The Principal Investigator Has the Ultimate Ethical Responsibility:** The IRB/REB or an equivalent oversight committee should work closely with study investigators to improve the ethical quality/rigor of the research. However, ultimate responsibility for evaluating and ensuring ethical standards rests with the principal investigator.
- 2.4.5 **Conflicting Interests of Reviewers:** IRB/REB members should disclose any financial support or relationship that could create a conflict of interests in the review process, and recuse themselves if conflicting interests may influence decision-making.

3. OBLIGATIONS TO SOCIETY

3.1 Avoiding Partiality

- 3.1.1 **Partiality:** Partiality is said to occur when there is a value-directed departure from accuracy, objectivity and balance.

- 3.1.2 **Unconscious Partiality:** Unconscious partiality is a human tendency. There is sociological evidence to show that one's ethical and political worldview influences the many phases of the scientific process. In order to avoid this unconscious partiality, environmental epidemiologists have a moral duty to the profession and an ethical duty to society to seek a range of advice including from those who often disagree with us.
- 3.1.3 **Choice of Methods and Practices:** Under no circumstance should environmental epidemiologists engage in selecting methods or practices that are designed to produce misleading results, nor should they misrepresent findings. They should resist institutional pressures to do these things.
- 3.1.4 **Interference:** It is acknowledged that sponsoring institutions and funders have a positive and crucial oversight role in the research process. However, they should avoid inappropriate interference with the initiation, conduct and publication of research, unless unethical or scientifically unacceptable practices are being proposed or pursued by the researcher(s). They should help resist stakeholder pressure designed or intended to corrupt research to serve their own financial or other interests.
- 3.1.5 **Avoidance of Bias:** Environmental epidemiologists, reviewers, and journal editors should not engage in practices that may lead to biases in study design, data analysis, or publication of results, such as *post hoc* analyses or revisions aimed at supporting a sponsor's point of view or financial interests; cherry picking results for publication that do not represent the full spectrum of actual results generated in the analysis of the research; avoidance of publication of 'null' results; and rejection of research results that do not support a point of view.

3.2 Avoiding Conflicting Interests

- 3.2.1 **Avoiding Conflicting Interests:** A conflict of interests occurs whenever a political, bureaucratic, career, or economic incentive, real or perceived, has the potential for producing partiality or compromising objectivity. Every environmental epidemiologist has the potential for a conflict of interests. A conflict exists whenever an epidemiologist's role, obligation, or personal interest in accommodating an institution, sponsor, job/financial security, or personal goals compromises obligations to others who have a right to expect objectivity and fairness. Such circumstances are to be scrupulously avoided in conducting environmental epidemiology investigations because the attendant negative health consequences in environmental epidemiology research can be great.
- 3.2.2 **Full Disclosure:** Environmental epidemiology researchers, IRB/REB members, journal reviewers and editors, research grant reviewers, and other professionals who have a decision-making or primary role in the funding, conduct, or publication of research should provide full disclosure of financial and/or other advisory relationships that could influence their decision-making. Such disclosure should occur in all scenarios in which the research is presented, including oral presentations; written communications and publications; decision-making about research funding, methods, or approval; and research oversight. Individuals in a position of authority over research funding, publication, or data access should recuse themselves in circumstances where financial, personal, or other

relationships may interfere with objective evaluation.

- 3.2.3 **Guidelines Governing Disclosure:** Institutions, funding agencies, regulatory agencies, journals and other organisations that control the conduct, publication, or implementation of environmental epidemiology research should support the goal of transparency by establishing guidelines governing disclosure of relationships that may underlie all types of conflicting interests.

3.3 Epidemiological Conduct that Facilitates Good and Just Environmental Health Policy and Practice

- 3.3.1 **Recognising Different Ethical Worldviews and Interests:** Environmental health policy and practice is usually the result of a societal negotiation between stakeholders with different ethical worldviews and economic interests. The environmental epidemiologist should present any descriptions and causal analyses in such a way as to facilitate informed, evidence-based discussion among these stakeholders. For example, stakeholders concerned with duties and rights will be interested in epidemiological information about “unfair” distributions of exposure or the existence of subpopulations with special vulnerabilities. Those who argue from a cost-benefit perspective will have other informational needs.
- 3.3.2 **Causal Inference:** Stakeholders and political jurisdictions may implement environmental health policy using the precautionary principle, adopting an approach that specifies that where there is evidence of risk attributable to a certain agent, the presence of uncertainty shall not be used as a reason for postponing measures to prevent or minimise such exposure. When an epidemiologist is asked to summarise or comment on epidemiological and biological evidence with the purpose of providing professional judgment as to causality, the epidemiologist should present the nature and extent of available evidence in a clear and objective manner, and in such a way as to avoid interfering with, or obstructing a precautionary approach. In expressing opinions about causality, the epidemiologist should make explicit the assumptions and general rules of inference that form the basis for his/her opinions and that underlie the linkage of research evidence to conclusions relating to causality.
- 3.3.3 **Contextualisation:** The environmental epidemiologist should exercise caution when describing the quality, the amount of evidence and the degree of possible added risk conveyed by an environmental agent. For example, citing only the rate ratio for a rare disease may cause alarm, while citing only the lifetime probability of not contracting a rare disease among the exposed may falsely reassure. Putting a possible risk in context requires the citing of both.
- 3.3.4 **Re-analysis:** If an epidemiologist participates in a re-analysis of existing data by someone other than the original author, he/she should refer to the ISEE Guidelines for such re-analysis¹⁵.
- 3.3.5 **Advocacy Role:** Some environmental epidemiologists may choose to become advocates for abating some environmental risk or rebutting what they believe to be a false incrimination of some environmental factor. In either situation, they have a duty to avoid partiality in the conduct and interpretation of their research

or in the interpretation of others' research.

- 3.3.6 **Distributive Justice:** Historically, investments in health research have neglected vast portions of the population, both locally and globally, to rather focus on the needs of the more affluent. The principle of distributive justice calls for equity, and hence on the need to reduce disparities in health outcomes resulting from this imbalance; locally, nationally and globally. As such, environmental epidemiologists ought to focus more on traditionally under-served populations that tend also to be least protected from environmental harms⁴.
- 3.3.7 **Research Priorities:** Funding priorities for public health research should be reflective of public health burden; e.g., morbidity, mortality, disability, potential years of life lost, and cost to the individual and society of the risk factor(s) and/or health outcome(s). In addition, research resource allocation should take account of lifetime risks (e.g., risks to foetuses and children), and the need to consider especially susceptible populations.
- 3.3.8 **Data Access in the Public Interest:** Data protection advocates hold that the individual's right to privacy trumps the benefits of data access for research purposes, particularly for record linkage studies. Environmental epidemiologists generate important findings from research that is dependent upon the linkage of administrative datasets. This puts them at odds with data protectionists. It is thus important for environmental epidemiologists to engage with data protectionists, as well as with entities that control data access, to work together to address mutual concerns. The benefits to be gained from such research ought to be clearly articulated, as they are critical to the pursuit of knowledge about environmental health risk factors, and thus to the protection of the health of the public.

3.4 Community Involvement

- 3.4.1 **Engagement of Stakeholders:** Depending upon the primary study's aims and settings, and whenever feasible, environmental epidemiologists should budget for and meaningfully engage community stakeholders, public health agencies, industry and others with an interest in the design, conduct, analysis and dissemination of research. Their roles should be agreed upon ahead of time.
- 3.4.2 **Community Partnerships:** Research involving a community or any other defined group ought to include at all stages of research, from formal design stage through completion of the study, representatives of those groups who are (a) knowledgeable about the health, science, social, political and economic issues under investigation (e.g., union and health representatives) and (b) are affected by the issue being investigated (e.g., community stakeholders including, but not limited to, the traditionally marginalised/disenfranchised). The IRB/REB or its equivalent in different countries likely will include lay community representatives. Whatever the situation, the researcher's task is to ensure, whenever feasible, that community input throughout the research process is included in a partnership capacity with the principal investigator. This goal could be accomplished by including representatives of stakeholders on a project steering committee.

- 3.4.3 **Understanding Information of Uncertain Biological Significance:** It is important to ensure that members of the community understand that there may be uncertainty associated with the implications or interpretation of the measures being evaluated through the research process, including results of genetic monitoring, markers of exposure, and physiological changes of uncertain biological significance. In communications with community research participants, the environmental epidemiology research team should be clear that research is an on-going and cumulative process. Further, results from individual studies contribute to a greater understanding of the significance of that which has been measured.

3.5 Communication and Action Plan

- 3.5.1 **Reporting:** All research findings and information vital to public health should be communicated to stakeholders in a timely, clear, comprehensive, understandable and responsible manner, in a format appropriate to and understandable by the specific audiences.
- 3.5.2 **Media Communications:** Studies in progress should not report results to the media without prior authorisation by a properly constituted IRB/REB, or an equivalent oversight committee.
- 3.5.3 **Transparency:** Environmental epidemiologists must be transparent about the assumptions underlying their studies and share uncertainties with relevant stakeholders; any communication plan should acknowledge the limits and uncertainties of the study. Furthermore, they should explain and acknowledge proper interpretation of statistical analytical results; e.g., that the absence of data or failure to attain statistical significance does not prove the absence of risk, and that statistical significance does not establish biological significance.
- 3.5.4 **Communications and Action Plan:** Researchers should include in their proposals/grant applications a section identifying their 'communications and action plan'. This would describe (a) the strategy for the prior-to-publication presentation of methods and results at any scientific gathering of peers (if media are in attendance, they must be specifically reminded to recognise the interim/preliminary nature of the results); (b) how the methods and results are to be subjected to peer-review for publication (see [sub-section 5.2 "Reporting Methods and Results"](#) below); (c) the degree of care that will be exercised to ensure clarity when communicating results to non-scientific groups (e.g., the community and/or other professions); and (d) the types of actions or interventions that might be contemplated or recommended, based upon the outcome of the research.
- 3.5.5 **Avoid Misrepresentation and Improper Interference:** Environmental epidemiologists should work to promote and preserve public confidence and not misrepresent (for example, by understating or overstating) the methods, results, limitations or public health significance of environmental epidemiology inquiry. In stakeholder-funded research, contractual language should rule out the possibility of sponsors writing the reports without attribution or pre-empting the conclusions. Any influence from stakeholders to change an *a priori* hypothesis or research design in response to being privy to preliminary results is unacceptable. Obligations should rule out *post hoc* changes in protocols and analyses (i.e., after

study results are generated, analysed, or submitted for publication), and the specification of peer reviewers or editors with known conflicting interests.

- 3.5.6 **Psychological Impact:** With psychological stress recognised as a significant determinant of morbidity, the consequences of risk information about the adverse health impacts of environmental factors should balance the obligation to disclose results with the potential psychological and/or economic impact that such information could have on the affected community. The concern and respect for autonomy should not be invoked as a pretext for withholding information from appropriate stakeholders. Project steering committees comprising community representatives provide one mechanism for addressing such concerns (see [sub-section 3.4 "Community involvement"](#) above).

4. OBLIGATIONS REGARDING FUNDERS/SPONSORS AND EMPLOYERS

4.1 Specifying Obligations

- 4.1.1 **Protecting the Public Interest:** Environmental epidemiology research topics and designs are shaped by public and private institutions, as well as advocacy groups. Some institutions may benefit financially from practices that are less concerned with hazardous environmental exposures than with competitive and financial interests. Likewise, advocacy groups may apply pressure to decision-makers or funding sources to focus on research topics that they believe have an etiologic role in particular health outcomes. Similar to other applied and basic scientists, environmental epidemiologists have a duty to critically evaluate the interests and motivations of stakeholders, employers and funders. Indeed, environmental epidemiologists have a duty to advocate for research topics and designs that place the health of exposed or at-risk populations ahead of concern for the reputation and financial well-being of any institution or organisation. They work to protect the public interest over any other interest.
- 4.1.2 **Communicating Obligations:** Environmental epidemiologists should inform employers and funders/sponsors, preferably in contractual form, about how research is to be conducted, and how research results will be communicated to stakeholders, the public, the scientific community and to governmental agencies, in accordance with these guidelines. The moral and legal responsibilities of all parties should be acknowledged in this process. The obligations of employer, funder/sponsor and environmental epidemiologist should be clearly specified in documents such as program manuals, protocols and/or professional contracts. The employer or funder/sponsor should be referred to the relevant part of these guidelines and other professional codes to which environmental epidemiologists subscribe.
- 4.1.3 **Avoid Funding Influence:** Environmental epidemiologists should not accept funding from sponsors, accept contractual obligations, or engage in research that is contingent upon reaching particular conclusions from a proposed environmental epidemiology inquiry. Likewise, they should not accept funding if conditions are placed on their right and, indeed, on the obligation to publish the research findings. It is acknowledged, however, that there are certain work

settings (e.g., within the context of litigation) where confidentiality is normally required and publication of analyses is/may not be permitted, and also whenever professional opinions that extend beyond a specific project are discussed and presented.

- 4.1.4 **Undue Influence:** Environmental epidemiologists who develop research plans or protocols, or administer funding on behalf of a sponsor or employer should not attempt to influence study personnel, protocols, analyses, or publications in such a way as to favour a particular *a priori* conclusion or interpretation of results.

4.2 Protecting Privileged Information

- 4.2.1 **Privileged Information:** Environmental epidemiologists may use privileged information furnished by a funder/sponsor or employer provided that permission was granted to use the privileged information, and that confidentiality restrictions are respected/maintained. The privileged information may include intellectual property, including trade secrets.

5. OBLIGATIONS TO COLLEAGUES

5.1 Specifying Obligations

- 5.1.1 **Intellectual Property:** There should be respect for, and acknowledgement of ownership of intellectual property, research ideas, on-going research activities, leadership roles, research funding/resources and research attribution at all professional levels, including those of students.
- 5.1.2 **Avoid Conflicting Interests and Misappropriation:** Environmental epidemiologists who fund research protocols or influence the publication of results should avoid partiality and any conflict of interests in funding or publication decisions. They should avoid using their special access to the new ideas of others to appropriate these research ideas as if they were their own.

5.2 Reporting Methods and Results

- 5.2.1 **Assessment and Replication:** Upon completion of their studies, environmental epidemiologists should provide in their final reports/publications adequate information in order to permit the methods, procedures, techniques and findings of their research to be critically assessed and replicated.
- 5.2.2 **Independence and Neutrality:** There is a tension among the timely conduct of studies, reporting of scientific findings and the need for thorough analysis and peer review. Researchers should have the freedom to pursue a study to conclusion with due diligence and in a timely fashion, especially in anticipation of interim findings that may not be pleasing to a sponsoring organisation. Researchers should be protected from any attempts to interfere with the orderly completion and analysis of a study, demonstrating analytical rigor throughout. Neutrality/impartiality in science is an imperative.

- 5.2.3 **Peer Review:** Researchers should 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 objective peer-review on scientific grounds, the work should, in all likelihood, not be communicated to the public (see [sub-section 3.5 “Communication and Action Plan”](#)). Selecting peer reviewers with an appropriate range of expertise and points of view 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 ‘positive’, ‘no effect’, and ‘negative’ studies with equal favour in their decision to publish.
- 5.2.4 **Objectivity of Reviewers:** Environmental epidemiologists who are asked to suggest reviewers should avoid selecting reviewers whom they know would be likely to accept their submitted research article based upon the conclusions drawn rather than on the appropriateness of the methods employed.

5.3 Confronting Unacceptable Behaviour

- 5.3.1 **Confronting Improper Practices:** Environmental epidemiologists are at times faced with practices that may result in misrepresentation, fraud, unethical behaviour, illegal behaviour, or incompetence. When such behaviour is encountered in colleagues or in other associates, the environmental epidemiologist should attempt to confront the problem by discretely, but directly, communicating the concern to the colleague and to encourage the repudiation of improper activities. In some cases, there may be an obligation to take specific action to correct inappropriate behaviour.
- 5.3.2 **International Review Panels:** It is particularly difficult to challenge the actions of senior-level investigators or “thought leaders” within research teams, within institutions, and at various levels of hierarchy within the professional community. There is widespread aversion to openly challenging colleagues. Therefore, an independent review panel consisting of representatives from many countries should be created within major environmental epidemiology organisations for the purpose of considering cases of alleged misconduct or ethics violations, and issuing recommendations. It is important to note, however, that scientific difference of opinion does not necessarily equate to unacceptable conduct.
- 5.3.3 **Protecting Whistle-Blowers:** Environmental epidemiologists ought to consider supporting colleagues who are subjected to pressures and who might even be fired from employment when they are diligent in upholding these Guidelines. Such individuals are commonly labelled as “whistle blowers”. Support might take many forms, the least of which is the provision of moral support. Ideally, institutional protections should exist that guard against the practice of victimising the whistle blower.

5.4 Communicating Ethical Requirements

- 5.4.1 **Duty to Communicate Ethical Requirements:** In circumstances of collaborative inquiry, as well as in the usual practice of environmental epidemiology,

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; likewise in the practice field of environmental epidemiology.

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Note: clicking on the reference numbers will take you back to the main text.

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