



Ethical and Philosophical Dimensions of Applying Biomarkers (O-04)

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- All authors of this presentation have read the definition of Financial Conflict of Interest and certify:

There are no financial conflicts of interests to declare

OR

- One or more of the authors <specify the names> have the following financial conflict-of-interest to declare relevant to activities with industry and related to the topic of this presentation:

Research Contracts or Employment

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Aims of this discussion

- To facilitate dialogue about the ethical dimensions relevant to the presentations in this session with regard to, for instance, hypothesis formulation, methods, analysis, dissemination of results, data archival/sharing, and community engagement.
- To promote greater ethical transparency and accountability.

Before we move on, let's quickly remind ourselves about Ethics Principles:

From Bioethics	From Public Health & Environmental Epidemiology
<ul style="list-style-type: none">● Respect for autonomy: respecting the right of participants to self-determine the extent of their participation● Beneficence: doing good through our research● Non-maleficence: doing no harm● Social/Distributive Justice/ Fairness: who is deriving benefits and who is taking risks?	<ul style="list-style-type: none">● Protect the Most Vulnerable● The Precautionary Principle● Environmental Justice● Scientific Integrity● Protect the Public Interest Over Any Other Interests● Others ...

Background

- In not every case of exposure do we know the clinical/health significance of a biomarker, raising questions about the state of science and of undue alarm to people (incl. pregnant women as an especially sensitive population)
- Some exposures are “voluntary” and others “involuntary”
- Some exposures arise as a result of natural processes (e.g., oxidative stress in pregnancy, alkaloids, disinfection by-products, etc.)

Questions (1 of 2)

- What are our obligations to the woman, the fetus, and to the new-born child when considering pre-natal testing?
- Are developmental windows known?
- Is there a distinction to be made between voluntary and involuntary exposures?
- Are vulnerable populations accessible for needed intervention?

Questions (2 of 2)

- Do first generation studies require both replication and corroboration of a body of evidence before we can apply them in a screening or commercial setting?
- When are we confident that a biomarker is both valid and reliable?
- Some exposures might cause harm without a threshold. Without a known threshold, how should that be interpreted & communicated?
- When is risk communication appropriate, and what form should it take?

About ISEE Ethics and Philosophy Committee

http://www.iseepi.org/About/ethics_cmte.htm

- Established in 1991; we address ethical and philosophical underpinnings at the nexus of environment and health
- We sponsor symposia; maintain and develop ethics guidelines; offer recommendations and definitions; provide moral support to victimized colleagues
- **Are you aware of the ISEE Ethics Guidelines for Environmental Epidemiologists - Revised April, 2012? Have you read them?**
(Kramer *et al* 2012 Revised Ethics Guidelines for Environmental Epidemiologists. *Environ Health Perspect* 120(8)
http://iseepi.org/About/Docs/ethics_guidelines_adopted_april_25_2012.pdf
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