



Ethical, Legal, and Social Implications (ELSI) of Gene-Environment Interaction (GxE) Research

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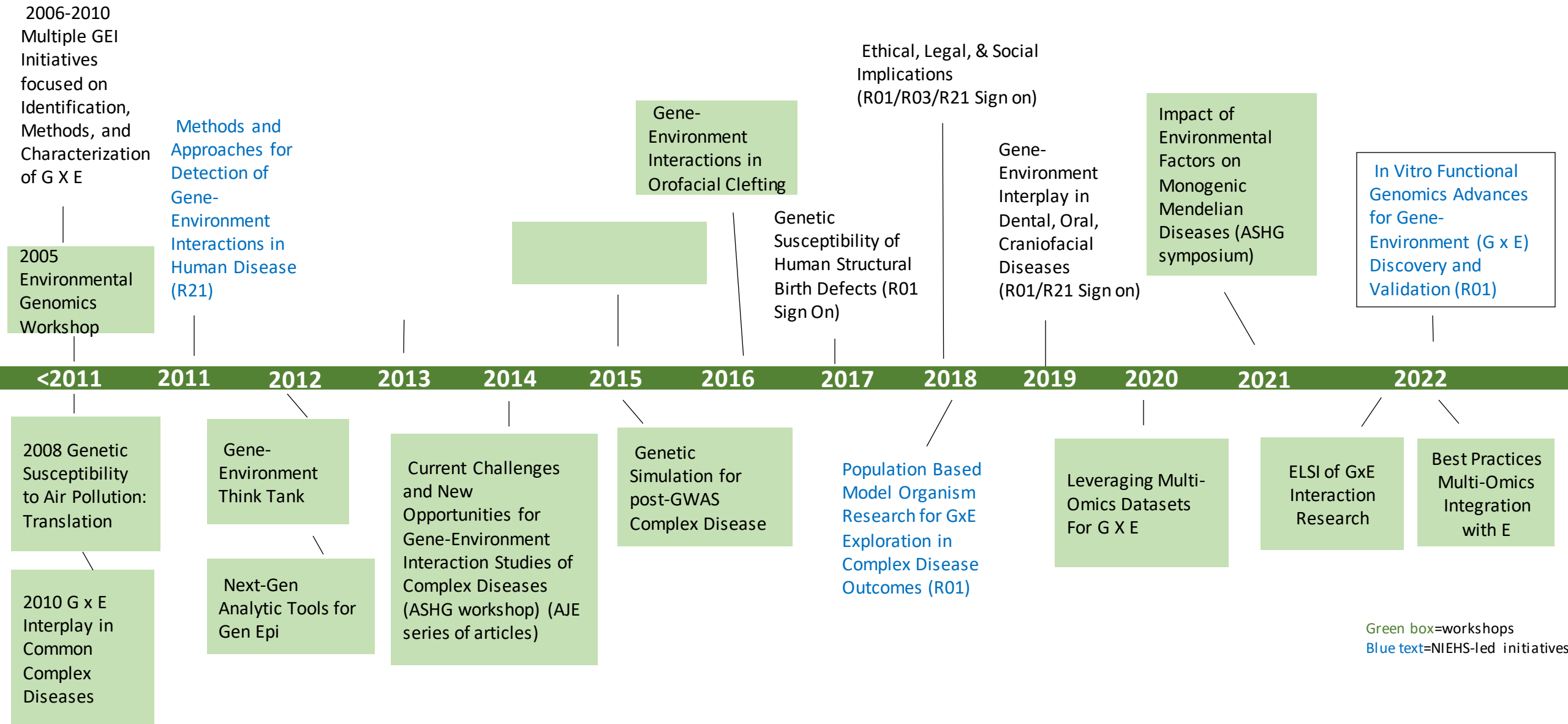
Your Environment. Your Health.

Gene- Environment Interaction (GxE)

Definition:

A varying effect of an environmental exposure(s) depending on genetic background of an individual.

NIEHS INVESTMENTS in G X E RESEARCH in Partnership with NHGRI, NCI, and Other NIH Institutes



- NHGRI and NIEHS have shared a small portfolio related to G x E ELSI issues:

NHGRI PAR-20-254, PAR-20-255, and PAR-20-257 *Ethical, Legal, and Social Implications* (ELSI) (R01, R21, and R03)

NIEHS has explored through workshops and initiatives:

- Confidentiality and privacy for sharing of environmental data
- Unique concerns of vulnerable populations who are disproportionately impacted by environmental exposures
- Potential harms from individuals being linked to exposure data

- NHGRI has extensive history and expertise in ELSI (genomics legacy)
- NIEHS has extensive history and expertise in community-based participatory research and environmental justice
- Very little has been written or explored in the GxE ELSI research space!





Hypothetical Simplistic Example: People with certain *GSTP1* (glutathione S-transferase P1) gene variants are more likely to have asthma when exposed to ozone:

- Should this affect how one prioritizes action on this pollutant?
- Should EPA standards always be revised to address risk to most vulnerable population (at cost)?
- How could one use genetic testing to protect the most at-risk groups and how do you communicate these results to affected populations?
- What if the genetic risk and/or the environmental exposure is correlated with disadvantaged populations?

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If a gene variant(s) make you more susceptible to a disease if you are exposed to a particular chemical (perhaps during a particular time in development):

*How do you explain this?

*How is that reported back in studies?

*Is 'increased knowledge' about susceptibility to an exposure helpful if we don't know the source of the exposure, what it does to you, or how to reduce it?

Issues Relevant to:

-Genomic and Environmental Literacy

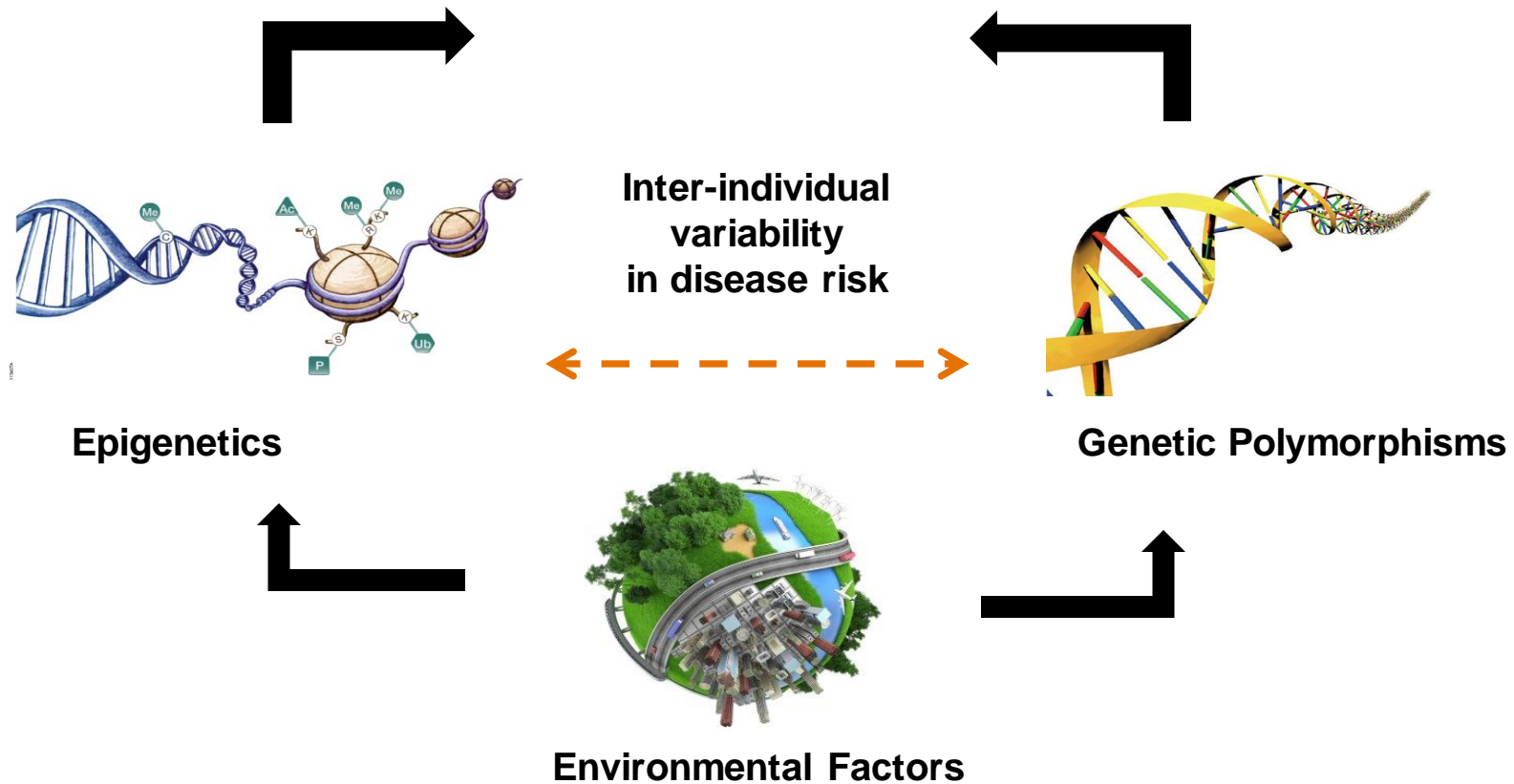
-Environmental Justice and Environmental Health Disparities and Privacy/Discrimination (Stigmas and discrimination related to identification of subpopulations at disease risk due to GxE)

**Report-back and
Communication/Privacy and
Discrimination for GxE
findings:**



ELSI issues associated with epigenomics (interface of genetics and environment)??

Epigenomic marks may be modifiable-allowing preventions/interventions
Potential human transgenerational inheritance effects



The Genetic Information Nondiscrimination Act (GINA) Passed the American Senate in 2003

- GINA prevents insurers and employers from discriminating based on genetic information. An insurance company cannot deny you insurance or charge you more because you have a particular genotype; an employer cannot fire you or pay you less because you have a particular genotype.
- **What about legal protection for GxE findings or environmental or epigenetics findings??**





Four Topic Areas Identified for Exploration

Tuesday:

- Communicating Risks and Findings from GxE Research:** How do we communicate both individual and community level risks?
- Community Research:** How to build GxE research portfolios that are most relevant to community concerns? What lessons from research with indigenous communities and other community-engaged GxE research can NIH build upon?

Wednesday:

- Social and Environmental Justice:** How to incorporate social determinants of health, structural racism, and the uneven distribution of healthcare resources and environmental hazards into the GxE research framework?
- Privacy Issues and Discrimination:** What risks to individuals/communities should be foreseen and addressed as researchers combine many types of genomic and environmental data with broad research consent?

Goals of Workshop

Bring a wide range of disciplines and expertise to inform NIH on ELSI topics relevant to GxE studies:

What current ELSI findings and practices might be ready for use in GxE research-what have we learned in both the G and E space?

What are the novel, critical GxE ELSI research gaps that NIH should support?

In future NIH funding announcements of large-scale genomics/environmental research, what frameworks should NIH use to ensure ethical, socially responsible work?

NIH is the Audience!

- What are the highest priority downstream implications of GxE research that NIH and our researchers must consider and address upstream?
- What models for research on the ELSI of GxE do you see?
- What policy issues or changes related to GxE ELSI research should NIH promote?
- What disciplines and methods need emphasis for GxE ELSI research?

Possible
Questions

Outcomes of Workshop:

Workshop report

Identify future opportunities to build on existing NIH efforts related to GxE ELSI research

Develop more extensive G x E ELSI guidelines for larger NIEHS or NHGRI consortium efforts related to G x E in future



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