Energy Research Program

March 2018

# SCOPING MEETING:

## REVIEW OF THE HUMAN HEALTH LITERATURE RELATED TO UNCONVENTIONAL OIL AND NATURAL GAS DEVELOPMENT

January 17, 2018
Meeting Summary

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# CONTENTS

# 1. INTRODUCTION

The Health Effects Institute (HEI) formally initiated its national Energy Research Program (the "Program") with a public Scoping Meeting on January 17, 2018, where a diverse group of stakeholders helped to inform HEI's strategy for the first year of the Program. This report provides a summary of discussions at the Scoping Meeting along with background information about the Program.

# 2. HEI'S ENERGY RESEARCH PROGRAM

The purpose of the Program is to identify and conduct highest priority research on the potential population exposures and health effects from the onshore development of oil and natural gas from shale and other unconventional resources across the United States (UOGD) [1]. With resource development projected to continue, alongside growing efforts to switch to renewables and conserve energy, a source of high-quality, impartial science is needed to support decisions about how best to ensure protection of public health.

To define and oversee the Program in collaboration with HEI staff, HEI has empaneled a multidisciplinary Energy Research Committee (the "Committee"):

- George Hornberger, Vanderbilt University, Director, Vanderbilt Institute for Energy & Environment, Nashville, Tennessee (Chair)
- Shari Dunn-Norman, Missouri University of Science and Technology, Rolla, Missouri
- Elaine M. Faustman, University of Washington–Seattle
- Howard Hu, University of Toronto, Ontario, Canada
- Judy S. LaKind, LaKind Associates, LLC, Catonsville, Maryland, and Adjunct Faculty, University of Maryland–Baltimore
- Armistead (Ted) G. Russell, Georgia Institute of Technology, Atlanta
- Stefanie Ebelt Sarnat, Emory University, Atlanta, Georgia

To ensure the highest scientific quality and integrity of the Program, the Committee consists of members who are internationally recognized experts in one or more subject areas relevant to the Committee's work, have demonstrated their ability to conduct and review scientific research impartially, are independent of sponsor organizations, and have been vetted for conflicts of interest.

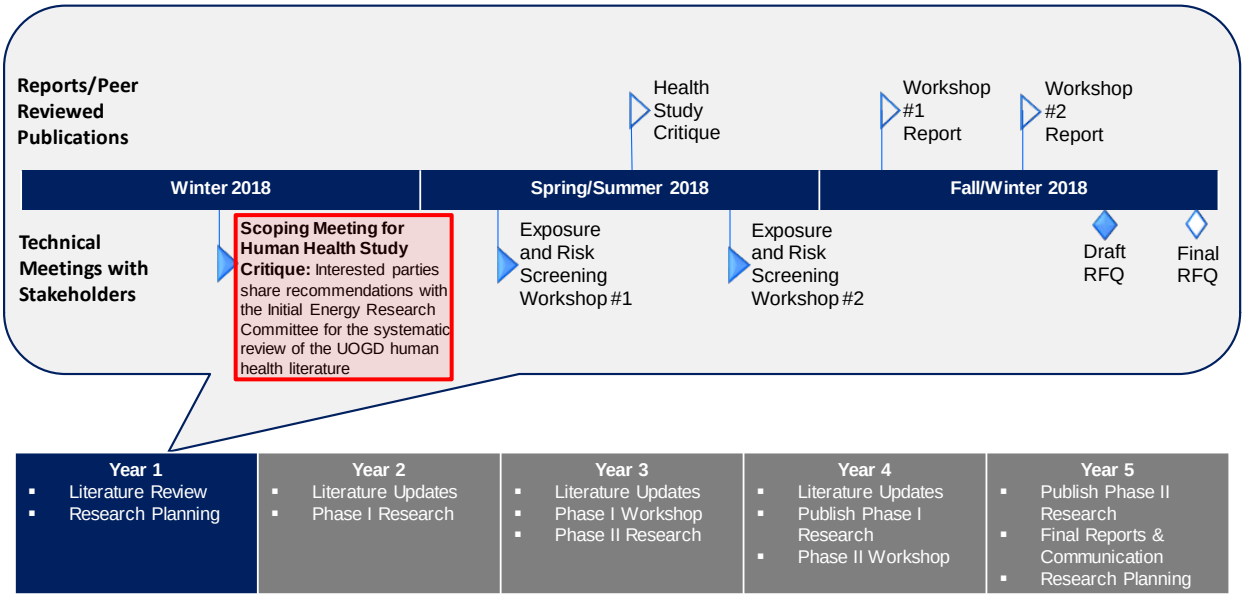
During Year 1 of the Program, the Committee is charged with reviewing the literature on potential human exposure and health effects of UOGD and research planning, culminating in the drafting and issuance of a competitive Request for Qualifications (RFQ) for research to fill important knowledge gaps (Figure 1). HEI would begin funding research in Year 2 of the Program. To ensure that only the highest quality studies receive funding for research, the Committee will carefully review proposals for technical quality and significance, vet investigators for potential bias and conflicts of interest that might interfere with the integrity of the scientific work and interpretation of results, and monitor research progress at key

[1] In its reports, HEI uses the phrase "unconventional oil and natural gas development," abbreviated UOGD, to refer to onshore development and production of oil and natural gas from shale and other unconventional geologic formations as practiced today, recognizing that industry practices continue to change in response to evolving technologies, regulations, and other factors. Current practice involves staged hydraulic fracturing (i.e., fracturing that occurs in sequential stages along a horizontal wellbore) combined with horizontal drilling. In the future, this practice could be used more widely with both conventional and unconventional geologic formations.

intervals. The Committee's oversight ends when investigators complete the research and submit their final report, which is then independently reviewed in detail by a separate HEI Energy Peer Review Committee.

HEI makes the results from all literature reviews and original research – both positive and negative – publicly available at no charge and provides summaries written for a general audience. HEI expects results from this research program to be used by government officials, communities, industry, environmental and public health organizations, and other stakeholders to inform policy development in this important area.

**Figure 1**. Major Milestones for the Energy Research Program, showing Year 1 in detail. This report summarizes the first milestone: discussions at a Scoping Meeting for the Committee's first task: a systematic review of human health literature related to onshore development of oil and natural gas from unconventional resources.




# 3. A Scoping Meeting to Inform HEI's Systematic Literature Review

HEI hosted the public Scoping Meeting to help inform the forthcoming HEI Energy Research Committee's (the Committee) critique of the scientific literature about potential human health effects related to UOGD. The Scoping Meeting provided an opportunity for a wide range of stakeholders to engage with one another and share their recommendations for the Committee's Critique.

The primary objectives for the review are to (1) highlight the strengths and limitations of the epidemiological[2] literature, reaching conclusions on what it does and does not tell us about potential adverse effects, and (2) define knowledge gaps about potential exposures and effects and identify the subset that might merit original research. The Committee's review will occur even as the regulatory environment, oil and natural gas markets, and industry standards-of-practice continue to evolve; therefore,

[2] Epidemiological studies examine the distribution and determinants of health conditions or events among populations and the application of that study to control health problems (CDC 2014).

the Committee will consider these changes when making its findings. The Committee will summarize its review and findings in an HEI report that will undergo peer review before public release later in 2018.

## 3.1 MEETING PARTICIPANTS

Hosted by HEI's new Energy Research Committee, the meeting brought together a wide range of stakeholders to discuss recommendations for the systematic review of human health literature, and to inform HEI's strategy for all Year 1 tasks.

Speakers and other meeting participants represented sponsor organizations, federal and state government, industry, academia, environmental and public health nongovernmental organizations, community organizations, and HEI's Committee and staff. HEI sought the participation of individuals with diverse expertise, experience, and perspectives about UOGD to ensure that the Committee is aware of all relevant research as well as the questions and concerns of various stakeholders. Meeting participants engaged in a productive exchange with the Committee and other meeting participants about HEI's plans for its systematic review of the health literature, its review of the exposure literature, and future research challenges and opportunities.

## 3.2 MEETING OVERVIEW

The Scoping Meeting consisted of three parts:

1. Introduction to the Energy Research Program and the Energy Research Committee,
2. Presentations by ten speakers, and
3. Open discussion among all meeting participants.

Part 1. The meeting opened with an introduction to the Program, the Committee, and the scope of work. The Committee presented its initial approach to the systematic review of human health literature, which is modeled after the protocol defined by the National Toxicology Program Office of Health Assessment Technology (OHAT) within the U.S. Department of Health and Human Services. The protocol includes five primary steps (1) define the study question, (2) define paper inclusion criteria based on study type, location, publication type, population of interest, exposure type and outcomes, (3) collect papers, (4) assess the quality of included studies, and (5) identify gaps in the literature to inform research needs.

Part 2. Ten speakers from federal and state government, non-governmental organizations, community groups, industry, and academia addressed the following questions:

- What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?
- What criteria should the committee use to evaluate study quality?
- Looking beyond the initial Human Health Study Critique task, what do you see as key contributions from the Committee's review of literature and research planning in Year 1 and beyond?
- What do you see as key contributions that the Committee can make to the science and the public dialogue around the development of oil and natural gas from shale and other unconventional resources?

Part 3. Dr. Hornberger moderated open discussion among meeting participants, guided by the same questions as those addressed by the formal speakers. During the open discussion, meeting participants engaged in an active and collegial exchange with the Committee and other participants about HEI's plans for its systematic review of the health literature and future research challenges and opportunities.

# 4. PROMINENT DISCUSSION TOPICS AND RECOMMENDATIONS

Meeting participants discussed a wide range of topics related to the Critique, but also to the Committee's later review of exposure, toxicity, and risk literature and planning for original research to fill important knowledge gaps.

This section briefly summarizes major themes that emerged from the speaker presentations, question and answer sessions, and the open discussion, all of which the Committee will take under consideration as it begins its work. The themes are intended to provide a summary of the meeting discussion and do not necessarily reflect the views of HEI, the Committee, our speakers, or any individual meeting participant.

## 4.1 INFORMATION RECOMMENDED FOR INCLUSION IN THE COMMITTEE'S REVIEW

This section summarizes recommendations that the Committee received about the information that it should review to inform its critique of the human health literature.

**UOGD operations and emission profiles**: The Committee's review should be based on an understanding of UOGD operations, their emission profiles, and how operations and emissions have changed over time, distinguishing between emissions that result from routine operations and accidental conditions.

**Paper inclusion**: The Committee should define a systematic and clear process for selecting papers that will be included in the Critique. The process should err on the side of including more rather than less papers to avoid missing important information.

**Gray literature**[3]: Meeting participants advised the Committee to include gray literature in the Critique. The Committee can apply inclusion criteria and assess the quality of gray literature just as they do peer-reviewed literature, use it for hypothesis-generating purposes, and use it to contextualize their main findings. The Committee also should consider review articles in the peer-reviewed and gray literature.

**Worker studies**: Exposure and epidemiological studies of worker populations (though not the focus of the Program) could be useful in understanding potential concerns for people living near UOGD. The Committee should consider recent research conducted by the National Institute of Occupational Safety and Health (NIOSH) on worker exposures to silica dust and volatile organic compounds. Epidemiological studies on oil and gas workers focus on refinery workers, a less mobile worker subpopulation than UOGD workers, because oil and gas companies have some ability to follow up with them.

**Non-chemical exposures**: The Committee should include studies of noise, psychosocial stress, and other potential non-chemical exposures. Multi-well pads with associated noise are increasingly a source of community concern.

**Social Disruption**: UOGD can lead to social disruption and community change. The Committee should not rule out studies of UOGD with such impacts as an outcome.

[3] Gray Literature is "the term for information that falls outside the mainstream of published journal and monograph literature, not controlled by commercial publishers" (National Institutes of Health Office of Management. "The Literature Search - Databases and Gray Literature," https://nihlibrary.nih.gov/resources/subject-guides/systematic-reviews/literature-search-databases-and-gray-literature; accessed March 7, 2018).

## 4.2 Recommendations for Assessing Study Quality

This section summarizes general recommendations for the Committee's systematic review process and specific guidance for assessing the quality of individual studies and the full body of evidence.

**Systematic review approach and assessment of study quality**: The Committee should conduct a systematic review, with a design that is based on strong protocols that have been defined in the literature, such as NTP's OHAT protocol. The systematic approach should include criteria for assessing quality with respect to many study features, such as the selection and representativeness of exposed and unexposed populations, methods used to identify and measure exposure to health stressors and health outcomes, plausibility of exposure pathways, control for bias[4] and confounding, sample size, data quality, robustness of statistical analyses, uncertainty analysis, level of peer review, and the soundness of interpretation and generalizability of study results.

**Problem statement**: The Committee should define a well-articulated problem statement, define decision-relevant questions, and break down its findings by specific UOGD phases or operations to the extent feasible. Some participants noted that, if an exposure of concern is identified, regulators would need to know the specific phase or operation that gave rise to the exposure before they could act to reduce it.

**Proximity studies**: Studies that employ proximity metrics to quantify exposure can be a useful starting place, serving as a proxy for multiple types of exposure. At the same time, they are not typically useful for understanding specific sources of exposure, especially in the absence of any effort to account for wind direction and other meteorological variables and the existence of other possible sources. Proximity metrics need to be improved upon in future studies, with exposure metrics that can be used to help with apportioning sources of exposure (e.g., a specific UOGD phase or operation or another source entirely) and quantifying exposure (e.g., biomonitoring). This information, in turn, will be useful for prioritizing exposure research or defining interventions.

**Confounding**[5]: Uncontrolled confounding (e.g., from other sources of exposure) can obscure the reality of whether or not a relationship exists between UOGD and adverse health outcomes. Participants mentioned conventional oil and gas operations as a possible confounding source of exposure. Are there demographic differences between people living near and far from wells, and might these differences confound study results?

**Consistency**: The Critique should include a discussion about the various factors leading to consistency and inconsistency across epidemiological study findings.

**Generalizability**: Many commented on the variability in UOGD operational practices and regional differences and how this variability affects the applicability, or generalizability, of individual studies to other populations, locations, and circumstances. Some example remarks: (1) If you understand conditions at one well pad, that doesn't mean you understand conditions at all well pads, (2) Emissions may be similar across studies, but industry practices may differ, (3) Population demographics differ across

[4] Bias refers to a systematic deviation of results or inferences from the truth or processes leading to such systematic deviation; any systematic tendency in the collection, analysis, interpretation, publication, or review of data that can lead to conclusions that are systematically different from the truth. In epidemiology, does not imply intentional deviation (CDC 2014).

[5] Confounding refers to the distortion of an association between an exposure and a health outcome by a third variable that is related to both (CDC 2014).

studies, and potential impacts may differ across these populations, and (4) Industry planning to protect communities might be appropriate, but that implementation at the local level is not always consistent or complete. Results of studies must be interpreted considering the fraction of UOGD operations or locations represented by the results.

## 4.3 Thoughts on the Committee's Year 1 Work and its Contribution to the Science and Broader Public Dialog about UOGD

This section summarizes thoughts about the utility of the Committee's work and important research planning considerations to ensure that future HEI-funded research contributes positively to the science and public dialog about UOGD.

**Collaborative Research Planning**: As the Program moves forward, there is value in continuing to have multiple perspectives in the room to inform discussions of research priorities so that study results have the broadest relevance, utility and acceptance.

**Communication**: HEI should communicate and disseminate the Committee's Critique quickly and widely. Community members want answers to their questions about potential health impacts without undue delay. Some general questions posed during the meeting: Is it okay to live near UOGD? What should we worry about and what don't we need to worry about?

All findings should be summarized for a general audience. Ideally, the Committee will provide a clear explanation of the strengths and weaknesses of studies, the conclusions that can and cannot be drawn from them, and will reach general conclusions about the strength of the collective evidence for possible health effects. It is as important to acknowledge what studies do not say and do not include as it is to acknowledge what they do say and do include. Also, be clear about the conditions to which various conclusions apply (e.g., not all wastewater has radiation in it).

**Data availability**: In the context of future research planning, open platforms are needed to facilitate sharing of knowledge and future research with full access to research protocols, data and findings. The Committee should take advantage of archived samples and other publicly available monitoring data. Several questions arose about options for gaining access to – and where necessary maintaining confidentiality of – chemical composition data, monitoring data, and de-identified health data that are not currently available to the public. The federal government can contribute data from a range of research sites. One example is the Department of Energy National Energy Technology Laboratory (DOE NETL) Marcellus Shale Energy and Environment Laboratory (MSEEL) at West Virginia University.

**Chemical characterization**: NGOs and governmental organizations have started to document the most commonly used chemicals in hydraulic fracturing fluids, with data provided by industry (e.g., the FracFocus chemical disclosure registry database, which is jointly managed by the Ground Water Protection Council and Interstate Oil and Gas Compact Commission). The Committee can be instrumental in expanding these efforts through its review of literature and public databases and collaboration with industry officials who can advise the Committee on the most commonly used chemicals nationwide. Some discussion focused on the need to understand trends in fracturing fluid composition over time and across regions as they relate to the timeframe of health studies. Less attention has been paid to the composition of waste, such as flowback water and produced water , but this information also will be important for understanding potential exposures (e.g., with use of produced water for irrigation or dust control). The Committee can help by defining toxicology studies that are needed to characterize the fluids, wastes, and even treated wastes. One speaker suggested that the Committee could ask NTP to study the toxicity of produced water.

**Longitudinal technological changes**: The technology and chemicals used in UOGD are evolving, for example, with industry phasing out chemicals over time. The Committee should consider these changes in their Critique, specifically in assessing the generalizability of individual studies. Though challenging, meeting participants expressed willingness to help define these changes.

**Distinguish between routine conditions and accidental conditions**: The Committee needs to understand typical emission profiles and how they differ from accidental conditions (e.g., spills) and attempt to distinguish between them in both its review of the literature and research planning.

**Background Conditions**: Ideally, one would like to know the contribution of UOGD to exposures, above and beyond natural sources and other anthropogenic sources. The collective contribution of these other sources is commonly referred to as background, or baseline, conditions. Meeting participants emphasized the need for monitoring before, during, and after UOGD operations to develop an understanding of background conditions. There was additional discussion around (1) industry's role in collecting background conditions before well pad development occurs, (2) options for industry to alert researchers to future UOGD activity so that baseline measurements can be obtained (with two company representatives indicating that they might be able to provide such notice), and (3) the extent to which existing health and exposure studies account for the existence and/or magnitude of background conditions.

**Baseline Health Status of Study Population**: Population change surrounding UOGD operations may confound epidemiological studies. For example, population mobility associated with UOGD can lead to changing rates of disease incidence or hospitalization, which could mistakenly be attributed to direct exposure to UOGD operations.

**Frame the literature review and research planning in the context of a *Conceptual Model of Exposure*[6]**: The Committee should consider all the air, water, and other pathways by which people might be exposed to UOGD and interpret the literature in light of this broader perspective, considering which exposure pathways have been studied, which have not, and which might warrant study. The Committee needs to consider the likelihood (e.g., frequency of impacts on drinking water), magnitude (e.g., does the exposure reach a level of concern for health), and temporal/spatial trends (e.g., the exposure has been mitigated over time or only exists in one region) of exposures and the sensitivity of those exposed (e.g., various life stages and baseline health status) over all relevant exposure periods (e.g., acute and chronic). Putting the literature review into the context of a conceptual model of exposure could provide a road map that can be used by HEI and others to fund original research.

**Other factors to consider in research planning**: (1) start with the highest possible exposures (e.g., workers and closest neighbors) to assess the relative utility of various methods to quantify exposure, (2) move from retrospective studies to prospective studies across multiple locations and populations, ideally with research located where it can profit from and build on earlier research and data collection, and (3) consider multiple types of available health outcome and exposure metrics, and be sure to assess background conditions in addition to identifying appropriate comparison locations and populations.

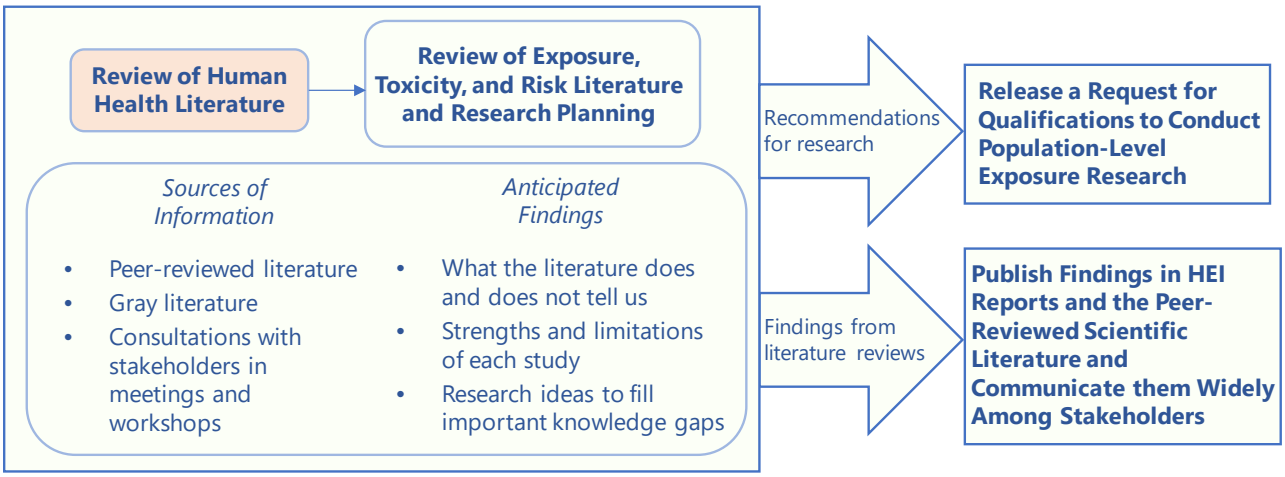
[6] A conceptual model includes a written description and visual representation of relationships between people (populations or population segments) and the chemicals or other stressors to which they may be exposed (USEPA 2014).

# 5. NEXT STEPS

HEI and the Committee found the scoping meeting to be informative to its review of the human health literature and are grateful to all those who participated. The Committee will carefully consider all discussion and recommendations from the meeting as it completes its Critique of the human health literature and moves ahead with other literature review tasks and research planning. HEI anticipates release of a final Critique in the Summer 2018.

After completing the health study Critique, the Committee will focus on its review of literature about potential UOGD exposures among people living in communities where such operations occur and whether any such exposures give rise to health concerns. This literature will be the topic of two *Exposure and Risk Screening Workshops* during Year 1 of the Program, during which the Committee will again seek comments and recommendations from a wide range of knowledgeable stakeholder groups. The workshops will culminate in preparation of an HEI Request for Qualifications to fund research beginning in Year 2. HEI anticipates that the research will involve a multi-center population-level exposure study in two or three major oil and gas-producing regions of the United States.

**Figure 2**. The review of human health literature in the broader context of subsequent Year 1 tasks and products.



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# APPENDIX A

**Scoping Meeting Agenda**

**HEI Energy Research Program**

## SCOPING MEETING FOR HUMAN HEALTH STUDY CRITIQUE

January 17, 2018

Metro Meeting Centers, 101 Federal Street, 4th Floor, Boston, MA

| | | |
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| *8:00 - 8:30 AM* | *Breakfast and Registration* | |
| **Introduction to HEI's Energy Research Program** | | |
| 8:30 - 8:45 AM | Introductions and Purpose of Session | George |
| 8:45 - 9:00 AM | Overview of the Energy Research Program and how today's meeting contributes to overall objectives for Year 1 and beyond | Donna |
| 9:00 – 9:30 AM | HEI Research Committee's general approach to conducting the Human Health Study Critique | George supported by one or more committee members |
| **Presentations** | | |
| *Speakers will address the following questions, in addition to any other comments that they choose to contribute:*<br>▪ *What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?*<br>▪ *What criteria should the committee use to evaluate study quality?*<br>▪ *What do you expect from the committee's review?*<br>▪ *Looking beyond the initial Human Health Study Critique task, what do you expect from the Committee's Year 1 review of literature and research planning?* | | |
| 9:30 - 10:00 AM | Nicole Deziel, Assistant Professor of Epidemiology, Yale University School of Public Health | |
| 9:40 – 9:50 AM | Dennis Devlin, Senior Environmental Health Advisor, Exxon Mobil Corporation | |
| 9:50 – 10:00 AM | Kevin Teichman, Senior Science Advisor, Office of Research and Development, United States Environmental Protection Agency | |
| *10:00 - 10:15 AM* | *Break* | |
| 10:15 AM – 10:25 AM | Elena Craft, Senior Health Scientist, Environmental Defense Fund | |
| 10:25 – 10:35 AM | Paul Hodgins, Chief Medical Officer, ConocoPhillips | |
| 10:35 – 10:45 AM | Martha Rudolph, Director of Environmental Programs, Colorado Department of Public Health and Environment | |
| 10:45 – 10:55 AM | Raina Rippel, Director, Southwest Pennsylvania Environmental Health Project | |
| 10:55 – 11:05 AM | Judy Hess, Epidemiologist, Shell Oil Company | |
| 11:05 – 11:15 AM | Michael Honeycutt, Toxicology Division Director, Texas Commission on Environmental Quality | |
| 11:15 – 11:25 AM | Aubrey Miller, Senior Medical Advisor, National Institute of Environmental Health Sciences | |
| 11:25 – 11: 30 AM | Morning wrap-up and plan for the afternoon | George |
| *11:30 AM - 12:15 PM* | *Lunch* | |
| **Comments from Meeting Participants** | | |
| 12:15 - 2:30 PM | Comments from meeting participants | All |
| 2:30-2:45 PM | *Break* | |
| 2:45 – 3:55 PM | Comments from meeting participants | All |
| 3:55 - 4:00 PM | Concluding Remarks | George |
| *4:00 PM* | *Scoping Meeting Adjourns* | |

# APPENDIX B

**Biographies for the Initial Energy Research Committee**

**George M. Hornberger (Chair)**

Dr. Hornberger is a University Distinguished Professor at Vanderbilt University, where he directs the Vanderbilt Institute for Energy and Environment and has a shared appointment as the Craig E. Philip Professor of Engineering and as Professor of Earth and Environmental Sciences. Previously he was a professor for many years at the University of Virginia where he held the Ernest H. Ern Chair of Environmental Sciences. He has been a visiting scholar at the Australian National University, Lancaster University, Stanford University, the United States Geological Survey, the University of Colorado, and the University of California at Berkeley. Dr. Hornberger's research centers on the coupling of field observations with mathematical modelling. Recognizing that water resources are under pressure from many human activities from climate change to urban development, he pursues broadly interdisciplinary research focused on coupled natural-human systems. The goal of the research is to understand how climate, groundwater, surface water, and human abstraction of water interact in complex ways. Current projects include work in Sri Lanka on adaptation to drought and in the United States on how cities evolve water conservation practices. He has published extensively, with numerous scientific papers, book chapters, and books.

Dr. Hornberger has served on numerous boards and committees of the National Academies, most recently as chair of the Committee on "Future Water Resource Needs for the Nation: Water Science and Research at the U.S. Geological Survey" and chair of the Water Science and Technology Board. He has also served other organizations, for example, he chairs the Geosciences Policy Committee of the American Geosciences Institute and serves on various committees of the Geological Society of America, the American Geophysical Union, and other organizations. In 2015, he recently completed service as the chair of the Health Effects Institute Special Scientific Committee on Unconventional Oil and Gas Development. Before that in 2013, he chaired a related National Research Council Committee on Development of Unconventional Hydrocarbon Resources in the Appalachian Basin. He previously served as an editor on several highly regarded journals. Dr. Hornberger won the Robert E. Horton Award (Hydrology Section) from the AGU in 1993. In 1995, he received the John Wesley Powell Award from the USGS. In 1999, he was presented with the Excellence in Geophysical Education Award by the AGU and in 2007 he was selected Virginia Outstanding Scientist. Professor Hornberger was elected to the U.S. National Academy of Engineering in 1996. He was also elected a Fellow of the American Geophysical Union in 1994, the Association for Women in Science in 1996, and the Geological Society of America in 2005, received the William Kaula Award from the American Geophysical Union in 2010, and the Harvie Branscomb Distinguished Professor Award from Vanderbilt University in 2017.

Dr. Hornberger holds a B.S.C.E. in Civil Engineering and an M.S.C.E. in Hydrology from Drexel University and a Ph.D. in Hydrology from Stanford University.

**Shari Dunn-Norman**

Dr. Dunn-Norman is Associate Professor and the former Program Head of Petroleum Engineering at the Missouri University of Science and Technology. Previously, she worked in both domestic and international assignments for the Atlantic Richfield Companies (ARCO), beginning her career as a summer field roustabout and advancing to Senior Operations Engineer at ARCO International. Dr. Dunn-Norman's research has focused on pipeline flow and leak detection, well construction for the protection of underground sources of drinking water, hydraulic fracturing, and well completions. She has over 25 years of combined academic, industrial and consulting experience in well design and well completion technology. She has published extensively, with numerous scientific papers and book chapters and co-authored a book on well construction.

Dr. Dunn-Norman is a member of the Society of Petroleum Engineers (SPE), where she has served on numerous committees. She was elected and currently serves as the National President of Pi Epsilon Tau, the Petroleum Engineering Honor Society. She is also a member and volunteer for the St. Louis Academy of Science and the Missouri Academy of Science. Dr. Dunn-Norman served on the U.S. Environmental Protection Agency Science Advisory Board 2011 Ad Hoc Hydraulic Fracturing Research Advisory Panel, which reviewed EPA's draft "Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources." For more than 20 years, Dr. Dunn-Norman has taught numerous industrial short courses about production engineering and well completions for various companies, such as Petroleum ETC, a private corporation that operates events worldwide on topics ranging from multiphase pumping and artificial lift, to hydraulic fracturing; and Petroskills, a leading world organization in all areas of oil and gas training. Dr. Dunn-Norman has received numerous awards, most recently the Society for Professional Engineers' Distinguished Member Award in 2015 and several excellence in teaching awards.

Dr. Dunn-Norman holds a B.S. in Petroleum Engineering from the University of Tulsa and a Ph.D. in Petroleum Engineering from Heriot-Watt University, Edinburgh, Scotland.

**Elaine M. Faustman**

Elaine M. Faustman is Professor in the Department of Environmental and Occupational Health Sciences and Director of the Institute for Risk Analysis and Risk Communication in the School of Public Health and Community Medicine at the University of Washington. Dr. Faustman's research includes quantitative risk assessment for non-cancer endpoints, molecular mechanisms of developmental and reproductive toxicity, and in vitro and molecular biological methodologies. She develops decision-analytic tools for communicating and translating new scientific findings into risk assessment and risk management decisions. Dr. Faustman directs the NIEHS/EPA-funded Center for Children's Health Research. She has served as Principal Investigator for the Pacific Northwest Center for the National Children's Study and has directed the Pacific Northwest Center for Human Health and Ocean Studies. The goals of Dr. Faustman's research are to discover the mechanisms that define susceptibility in at-risk populations and to provide linkages across disciplines. She has over 200 peer reviewed research publications and reports.

Dr. Faustman is an elected fellow of the American Association for the Advancement of Science and the Society for Risk Analysis. She has served on the USEPA Science Advisory Board. She previously chaired the National Academy of Sciences Committee on Developmental Toxicology and served as a member for the National Advisory Environmental Health Sciences Council, the National Institute of Environmental Health Sciences (NIEHS)-National Toxicology Program (NTP) Committee on Alternative Toxicology Methods, the NIEHS-NTP Board of Scientific Counselors, the National Academy of Sciences Committee on Toxicology, and the Institute of Medicine Upper Reference Levels Subcommittee of the Food and Nutrition Board. She has just completed two terms as Secretary General for the International Union of Toxicology. She is currently a member of the International Science Council World Data Systems Advisory Board. She served on the U.S. Environmental Protection Agency Science Advisory Board 2011 Ad Hoc Hydraulic Fracturing Research Advisory Panel, which reviewed EPA's draft Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources. Dr. Faustman also served on the executive boards of the Society of Toxicology, the Teratology Society, and the Society for Risk Analysis. She has served as an editor on several highly regarded journals. Dr. Faustman has been honored with numerous awards, most recently the 2016 Josef Warkany Lecturer Award from the Teratology Society, the Distinguished Achievement Award from the Society for Risk Analysis in 2014, and the University of Washington's Outstanding Teaching Award.

Dr. Faustman holds an A.B. in Chemistry and Zoology from Hope College and a Ph.D. in Pharmacology/Toxicology from Michigan State University.

**Howard Hu**

Dr. Hu is Professor of Environmental Health, Epidemiology, Global Health, and Medicine and the Founding Dean of the Dalla Lana School of Public Health, a Faculty of the University of Toronto. Previously, Dr. Hu had been Professor of Occupational & Environmental Medicine, Founding Director of the NIH/NIEHS Center for Children's Environmental Health, and Director of the Occupational Medicine Residency at the Harvard School of Public Health and the Channing Laboratory of the Brigham & Women's Hospital in Boston (1988-2006). Dr. Hu then served as the NSF International Chair of the Department of Environmental Health Sciences, Professor of Environmental Health, Epidemiology and Internal Medicine, and Founding Director of the NIH/NIEHS Environmental Health Core Sciences Center at the University of Michigan (2006-2012). Dr. Hu retains an appointment as Adjunct Professor at the University of Michigan. On July 1, 2017, Dr. Hu started a 1-year sabbatical/administrative leave from the University of Toronto, during which he is pursuing scholarly activities in Seattle, Washington, USA, in part, as a Visiting Scholar at the University of Washington School of Public Health.

Dr. Hu is a physician trained in internal medicine, occupational medicine, and epidemiology with a research career that has focused primarily on environmental epidemiology using novel biomarkers and other exposure assessment tools. In partnership with a network of collaborators and partners, he has created and continued to conduct cohort studies on the environmental (especially lead and other toxic pollutants), nutritional, social, genetic and epigenetic determinants of chronic disease and impaired child development in the U.S., Canada, Mexico, India (where he was a Senior Fulbright Scholar, 1999-2000), China, and elsewhere around the world. His team's work has generated over 300 publications and won several awards, such as the 2009 Linus Pauling Lifetime Achievement Award and the 2015 John Goldsmith Award for Outstanding Contributions from the International Society for Environmental Epidemiology. In 2016, Dean Hu was elected to Fellowship in the Canadian Academy of Health Sciences.

Dr. Hu has served on numerous professional boards and committees. His government service includes membership on the Board of Population and Public Health Practice of the Institute of Medicine of the National Academy of Sciences, the Board of Environmental Studies and Toxicology of the National Research Council; and the External Advisory Council of the U.S. National Institute for Environmental Health Sciences. His nongovernmental service includes service on the Board of Directors and as the principal epidemiologist on four fact-finding missions for Physicians for Human Rights (Nobel Peace Prize co-winner, 1997), and Chair of the Research Commission for the International Physicians for the Prevention of Nuclear War (Nobel Peace Prize, 1985).

Dr. Hu holds a B.Sc. in Biology from Brown University, an M.D. from the Albert Einstein College of Medicine, and an M.P.H. and Sc.D. in epidemiology from the Harvard School of Public Health. He trained in internal medicine at Boston City Hospital and in occupational and environmental medicine at Harvard.

**Judy S. LaKind**

Dr. LaKind is President of LaKind Associates, LLC, an Adjunct Associate Professor in the Department of Epidemiology and Public Health at the University of Maryland School of Medicine, and a Fellow-by-Courtesy in the Department of Applied Mathematics and Statistics at The Johns Hopkins University. Dr. LaKind has taught graduate level courses at The Johns Hopkins University and the University of Maryland in risk assessment and aquatic chemistry. Previously, Dr. LaKind was a geologist at the US EPA's Office of Federal Activities, where she was responsible for the evaluation of environmental impact statements and legislative reports. She is a health and environmental scientist with expertise in exposure science, assessment of human health risks, biomonitoring, scientific and technical analysis for regulatory support, and state-of-the-science reviews. Dr. LaKind has spoken and published extensively on children's exposures to environmental chemicals, the implications of uncertainty in the risk assessment process, weighing potential risks and benefits related to chemical use (for example, use of MTBE in gasoline, glycols in de-icing formulations, and chlorination of drinking water for zebra mussel control), the presence of environmental chemicals in human milk, and time-dependence and distributional analysis of exposure.

Dr. LaKind is President of the International Society of Exposure Science. She is a founding member of the International Society for Children's Health and the Environment and is a former member of Maryland's Children's Environmental Health and Protection Advisory Council, the Lead Poisoning Prevention Commission, and the Maryland Pesticide Reporting and Information Workgroup. She is a member of the World Health Organization Survey Coordinating Committee for the WHO Global Survey of Human Milk for Persistent Organic Pollutants (POPs), the HESI RISK21 Advisory Board, and the Maryland Department of Health and Mental Hygiene (DHMH) Cancer Cluster Advisory Committee. Dr. LaKind also served on the Institute of Medicine Committee on Blue Water Navy Vietnam Veterans and Agent Orange Exposure and the US Environmental Protection Agency Science Advisory Board Panel on Perchlorate - Approaches for Deriving Maximum Contaminant Level Goals for Drinking Water. Dr. LaKind has received awards, including the 2017 Society of Toxicology Regulatory and Safety Evaluation Specialty Section Award for Best Paper Contributing to the Field of Regulatory and Safety Evaluation in Toxicology and the 2015 EPA Scientific and Technological Achievement Award Level III for "Providing Critical Models and Information Needed for Exposure and Risk Assessments of Environmental Chemicals in Infants."

Dr. LaKind holds a BA in Earth and Planetary Sciences from Johns Hopkins University, an M.S. in Geology from the University of Wisconsin, and a Ph.D. in Geography and Environmental Engineering from Johns Hopkins University.

**Armistead (Ted) G. Russell**

Dr. Russell is the Howard T. Tellepsen Chair and Regents' Professor at the Georgia Institute of Technology School of Civil and Environmental Engineering. Dr. Russell's research is aimed at better understanding the dynamics of air pollutants at urban and regional scales and assessing their impacts on health and the environment to develop approaches to design strategies to effectively improve air quality. He currently co-directs the NSF Sustainability Research Network "Environmentally Sustainable, Healthy and Livable Cities" project and co-directed the Southeast Center for Air Pollution and Epidemiology. His research interests include air pollution modeling, aerosol dynamics, atmospheric chemistry, combustion emissions control. He has published over 300 peer-reviewed journal articles, book chapters and major reports.

Dr. Russell is a Fellow of the American Society of Mechanical Engineering and the American Association for the Advancement of Science and is a National Associate of the National Academies. Dr. Russell was a member of EPA's Clean Air Science Advisory Committee (CASAC) and a member of the National Research Council's Board on Environmental Studies and Toxicology, and he continues to serve on associated committees. He chaired the CASAC NOx-SOx, Secondary NAAQS review panel, the Ambient Air Monitoring Methods Subcommittee, and the Council on Clean Air Compliance Analysis' Air Quality Modeling Subcommittee, and was on the Health Effects Institute's Report Review Committee. Dr. Russell has been honored with numerous awards, including the 2015 Distinguished Alumni Award from Washington State University, the 2013 Regents' Professor Award, and he was the Most Influential Individual to 2013 semifinalist for the Intel Science Talent Search.

Dr. Russell holds a B.S. in Mechanical Engineering from Washington State University, and an M.S. and Ph.D. in Mechanical Engineering from the California Institute of Technology, conducting his research at Caltech's Environmental Quality Laboratory.

**Stefanie Ebelt Sarnat**

Dr. Sarnat is Associate Professor of Environmental Health at the Rollins School of Public Health of Emory University. Her epidemiological research focuses on examining health effects of ambient air quality using population- and panel-based approaches. She leads large-scale time-series studies of ambient air quality and acute morbidity, using emergency department visit data as an indicator of population health. Dr. Sarnat's work on these studies focuses on assessment of ambient air pollution mixtures and metrics of extreme heat, examination of the impacts of exposure measurement error on observed epidemiological findings, and assessing exposure and population factors that may modify health risk. Her studies also include prospective panel-based designs, using detailed field investigation methods to further understand environmental exposure factors and health effects among susceptible and vulnerable populations. She has published extensively in the peer-reviewed literature and has frequently been asked to speak on exposure and epidemiological topics.

Dr. Sarnat is a member of the International Society for Environmental Epidemiology, an editorial board member at Epidemiology, and an associate editor at the Journal of Exposure Science and Environmental Epidemiology. Dr. Sarnat participated on the National Research Council's Committee on Urban Meteorology: Scoping the Problem, Defining the Need and the Health Effects Institute's Review Panel on Ultrafine Particles. She has participated as an expert reviewer of drafts of the USEPA Integrated Science Assessments for particulate matter and nitrogen oxides. She serves as the Point of Contact for Emory University as an observer organization in the United Nations Framework Convention on Climate Change process. Dr. Sarnat has been honored with several awards, most recently the Department of Environmental Health Teaching Award at Emory University and a Supporting Paper for a Level III USEPA Scientific and Technological Achievement Award.

Dr. Sarnat holds a B.Sc. in Microbiology and Immunology and a M.Sc. in Occupational Hygiene from the University of British Columbia and a Sc.D. in Environmental Health from the Harvard School of Public Health.

# APPENDIX C

**Speaker Biographies**

**Elena Craft, PhD**

Dr. Craft's expertise is on air toxics issues, focusing specifically on reducing criteria and greenhouse gas emissions from the energy and transportation sectors. She has worked to reduce emissions especially around port areas and environmental justice communities. She has also worked to reduce toxics used in shale gas drilling practices such as hydraulic fracturing. Dr. Craft has been an integral strategist in designing and initiating comprehensive clean air measures, as well as in developing standards to measure environmental performance. Her efforts have led to the creation of clean truck programs in Houston and other ports around the Southeast. The University of Texas' School of Public Health recognized Dr. Craft as an adjunct assistant professor of Epidemiology, Human Genetics, and Environmental Sciences. She is also involved in innovative projects to increase efficiency from goods movement operations. Her strategy in securing emission reductions includes development of strategic partnerships with retailers and other stakeholders, with the ultimate goal of incorporating clean air and efficiency improvements into a sustainable business model. Dr. Craft advocates for policies that increase energy efficiency, reduce exposure to toxic compounds, and improve human health. Dr. Craft received her B.S. from UNC-Chapel Hill, M.S. in Toxicology from North Carolina State University, and Ph.D. in Toxicology from Duke University's Nicholas School of the Environment and Earth and Ocean Sciences.

**Dennis Devlin, PhD**

Dr. Devlin joined Exxon Biomedical Sciences in 1987. His early work focused on site remediations and product risk assessments. He transferred to the Brussels headquarters of Exxon Chemical International, Inc. in 1991 where he directed the toxicology program for European Exxon business groups and area offices. Following the merger of Exxon and Mobil, he became Director of Toxicology and Environmental Sciences, providing global affiliates and support organizations with consulting services, science development, and field support. In 2009, he assumed the role of Environmental Health Advisor for Exxon Mobil Corporation where he provides strategic guidance for environmental health policy and planning. Dennis has led several committees of the petroleum and chemical industries that addressed potential health risks of products and operations, is a past President of the ILSI Health and Environmental Sciences Institute, and a member of the National Academy of Medicine's Roundtable on Environmental Health Sciences, Research, and Medicine. Dr. Devlin received his B.A. in Biology from St. Louis University, M.S. in Environmental Engineering from Washington State University, and a Ph.D. in Toxicology from Dartmouth College.

**Nicole Deziel, MHS, PhD**

Dr. Nicole Deziel is an Assistant Professor in Environmental Health Sciences at the Yale School of Public Health and a member of the Yale Cancer Center and Yale Center for Perinatal, Pediatric and Environmental Epidemiology. She has expertise in exposure science and interdisciplinary training in epidemiology, biostatistics, and industrial hygiene. Her research involves developing and applying environmental exposure assessment methods to answer emerging research questions in environmental epidemiology. She combines existing and advanced statistical models, biomonitoring techniques, and environmental measurements to provide more comprehensive and quantitative assessments of exposure to multiple contaminants, with multiple sources, and varying spatiotemporal patterns. One of Dr. Deziel's main areas of interest is how environmental exposures are changing with new techniques for energy production (e.g., hydraulic fracturing) and climate change. She serves as Principal Investigator (PI) of a study funded by the American Cancer Society investigating co-exposures to multiple flame retardants, pesticides, and other persistent pollutants and thyroid cancer risk. She served as PI of the Ohio Water &

Air Quality Study, among the first hydraulic-fracturing-related, multi-media exposure and health studies, which measured multiple organic compounds in air and water, constructed geographic-information systems-based exposure metrics, and collected health surveys in communities with intense oil and gas development in the summer of 2016. Following on this work, she is PI of a project entitled "Drinking water vulnerability and neonatal health outcomes in relation to oil and gas production in the Appalachian Basin," funded by the Environmental Protection Agency. Dr. Deziel received her MHS and Ph.D. from the Johns Hopkins Bloomberg School of Public Health.

**Paul Hodgins, MD**

Dr. Paul Hodgins is the Chief Medical Officer for ConocoPhillips. Dr. Hodgins has 30 years of experience as a physician, and trained in Internal Medicine, Occupational and Environmental Medicine, and Public Health. Dr. Hodgins joined ConocoPhillips in 2010, and previously served in Senior Medical Director roles with GE Energy and Caterpillar. He has experience in private practice, and also served as a Visiting Scientist/Medical Officer for the Centers for Disease Control and Prevention. Dr. Hodgins received his MD from Trinity College/University of Dublin, Ireland and a MPH from Emory University.

**Michael Honeycutt, PhD**

Dr. Honeycutt is the director of the Toxicology Division of the Texas Commission on Environmental Quality (TCEQ). His career at TCEQ began in 1996, and he has managed the division of 14 toxicologists since 2003. His responsibilities include overseeing (1) health effects reviews of air permit applications, (2) review of the results of ambient air monitoring projects, and (3) reviews of human health risk assessments for hazardous waste sites. Dr. Honeycutt spearheaded the updating of TCEQ's Effects Screening Levels (ESLs), or toxicity factors for chemicals. The TCEQ ESL derivation procedure has undergone two independent external scientific peer reviews and multiple rounds of public comment (http://www.tceq.texas.gov/toxicology/esl/guidelines/about.html). Dr. Honeycutt serves as a technical resource for TCEQ management and staff on issues concerning air and water quality, drinking water contamination, and soil contamination. He also serves as an expert witness in public and state legislative hearings, participates in public meetings, and has conducted hundreds of media interviews. Dr. Honeycutt is an adjunct professor at Texas A&M University, has published numerous articles in the peer-reviewed literature, serves or has served on numerous external committees, and has provided invited testimony at Congressional hearings. He was recently appointed chairman of USEPA's Science Advisory Board. Dr. Honeycutt received his Bachelor's degree and Ph.D. in Toxicology from the University of Louisiana at Monroe.

**CAPT Aubrey K. Miller, MD, MPH**

Aubrey K. Miller, MD, MPH, is a Captain in the US Public Health Service, at the National Institutes of Health (NIH), and is board certified in Occupational and Environmental Medicine. He is currently the Senior Medical Advisor to the Director of the National Institute of Environmental Health Sciences (NIEHS), where he is responsible for strategic planning and coordination of environmental health issues and activities among U.S. federal agencies, academia, and other stakeholders, as well as supervisory oversight of the NIEHS Bethesda office. Additionally, his office oversees NIEHS efforts in global environmental health, disaster research, toxicology-related risk assessment, and congressional interactions. He has longstanding experience with public health investigations and studies, has numerous publications, and has contributed to a wide-range of occupational and environmental health issues and policies. He currently leads the NIH Disaster Research Response (DR2) Program and has been extensively involved in the NIH Gulf Oil Spill response providing congressional testimonies and

participating in a large-scale research study of cleanup workers. Over his career he has contributed to the leadership, coordination, and support for a number of disaster responses including the Libby Montana Public Health Emergency involving widespread asbestos contamination, Hurricanes Katrina and Sandy, the H1N1 pandemic influenza, the Ebola response, and the World Trade Center and anthrax attacks. His career includes notable public health and medical officer positions with the HHS Regional Office in Denver, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC). Dr. Miller received his M.D. from Rush Medical College in Chicago, Illinois and his M.P.H. in Environmental & Occupational Health Sciences from the University of Illinois, School of Public Health. He is board certified in Occupational and Environmental Medicine.

**Raina Rippel, BA**

Ms. Rippel serves as the Director of the Southwest Pennsylvania Environmental Health Project (EHP), an organization that she helped to found in response to growing concerns associated with gas drilling activity and health impacts in Washington County, PA. Rippel heads up a team of seventeen staff and consultants and various interns with expertise in healthcare, public health research, toxicology, air and water quality, strategic development and community organizing, in developing a targeted and timely public health response to unconventional natural gas development. EHP focuses their work on gathering data from residents of southwest PA and beyond on probable health impacts from oil and gas development and routes of exposure, providing best-practice air and water monitoring tools and guidance, and providing accessible and effective interventions for individuals and households. EHP receives no state or national funding and is entirely funded by private foundations. EHP partners with the Carnegie Mellon University CREATE Lab to distribute monitoring technologies to residents, and has worked on community-based participatory research projects with the Yale School of Medicine Occupational and Environmental Health Program, the University of Pittsburgh Department of Environmental and Occupational Health, Duquesne University, SUNY Albany's Institute for Health and the Environment, and various NGOs, including Earthworks, the Clean Air Council, and the Air Collaborative, among others. EHP is also a member of the Protect Our Children coalition and the Protect PA coalition. Ms. Rippel received her BA in Urban Studies from the University of Pittsburgh.

**Martha E. Rudolph, JD**

Martha E. Rudolph is the Director of Environmental Programs for the Colorado Department of Public Health and Environment where she oversees the Air Quality, Environmental Health and Sustainability, Hazardous Materials and Waste Management, and Water Quality Divisions. Ms. Rudolph has been with the Department since 2007, and served as the Executive Director of the Department in 2010. In 2015/2016, Ms. Rudolph was President of the Environmental Council of States, the national non-profit, non-partisan association of state and territorial environmental agency leaders. She currently serves on the Board of Directors for the Environmental Research Institute of the States and is a co-chair of the ECOS Shale Gas Caucus. Previously Ms. Rudolph was the Chair of the ECOS Air Committee and the Vice Chair of the ECOS Planning Committee. She is a member of the Division on Earth and Life Studies of The National Academies of Sciences, Engineering, and Medicine, a state advisor for the Georgetown Climate Center, and a member of the American College of Environmental Lawyers. A graduate of the Georgetown University Law Center, Ms. Rudolph is an environmental attorney, and served for 14 years in the Colorado Attorney General's Office. She has been in private practice in Denver, and was an assistant general counsel for Kinder Morgan Inc., a natural gas and energy transportation company. Ms. Rudolph received her BA in International Affairs from the University of Colorado-Boulder and Doctor of Law degree from the Georgetown University Law Center.

**Kevin Teichman, PhD**

Dr. Kevin Teichman is the Senior Science Advisor in the Office of Research and Development (ORD) at the U.S. Environmental Protection Agency. In addition to providing advice on all aspects of ORD's research programs, Dr. Teichman coordinates ORD's research efforts with other Federal agencies and organizations. Most recently, he has been working to coordinate interagency research devoted to unconventional oil and gas development, net zero environmental impact buildings, and sensors for air pollutants. Prior to assuming his current position, Dr. Teichman served as the ORD Deputy Assistant Administrator for Science, where he led the planning of ORD's research program and supervised the office's six National Program Directors. The ORD research program covers all aspects of environmental research, including research devoted to air and energy, safe and sustainable water resources, chemical safety for sustainability, sustainable and healthy communities, human health risk assessment, and homeland security. Dr. Teichman also previously served as the Director of the Office of Science Policy (OSP) within ORD. In this capacity, he coordinated ORD's participation in EPA's policymaking in all media (air, water, waste, pesticides and toxic substances) to ensure the Agency's policies reflected sound science. Before serving as Director of OSP, he managed EPA's indoor air quality research program, including research devoted to characterizing indoor pollutant sources, assessing indoor exposures, studying associated health effects, assessing potential risks, and developing prevention / mitigation approaches to indoor air pollution. Dr. Teichman received his B.S. and M.S. from the Massachusetts Institute of Technology and Ph.D. from the University of California at Berkeley, all in Mechanical Engineering.

**Judy Wendt Hess, PhD**

Dr. Hess joined Shell Oil Company as an Epidemiologist in 1999, and is currently a member of Shell Health's Risk Science Team, based in Houston. Her work focuses on both occupational and environmental health, and includes health surveillance related to chemical and non-chemical exposures, and providing advice on risk assurance processes within Shell. Specific areas of focus include health studies related to unconventional oil and gas development, air pollution epidemiology, and global ambient air quality standards. Dr. Hess also manages a large data warehouse system for Shell Health in the U.S., which includes employee exposure and health data dating back to the 1970s. Dr. Hess is a member of the Society for Epidemiologic Research and American College of Epidemiology and has an adjunct faculty appointment at the University of Texas School of Public Health in Houston. She received her B.S. in Community Health Education from the University of Texas, M.P.H. in epidemiology from the University of Michigan School of Public Health, and Ph.D. in epidemiology from the University of Texas School of Public Health.

# APPENDIX D

**Slide Presentations**

The Health Effects Institute

# Energy Research Program

## The Initial Energy Research Committee

Scoping Meeting for Human Health Study Critique
Boston, MA
January 17, 2018

1

## Selection Criteria for the Initial Energy Research Committee

- Internationally recognized expertise in one or more subject areas relevant to the Committee's work
- Demonstrated ability to conduct and review scientific research impartially
- Independent of sponsor organizations
- Free of significant conflicts of interest

2

## The Initial Energy Research Committee

- George Hornberger, Vanderbilt University *(Chair)*
- Shari Dunn-Norman, Missouri University of Science and Technology
- Elaine M. Faustman, University of Washington
- Howard Hu, University of Toronto
- Judy S. LaKind, LaKind Associates, LLC and University of Maryland
- Armistead (Ted) G. Russell, Georgia Institute of Technology
- Stefanie Ebelt Sarnat, Emory University

3

**Full size versions of all slides are posted at HEI's website:**
https://www.healtheffects.org/meeting/scoping-meeting-human-health-study-critique

The Health Effects Institute

# Energy Research Program

## A Brief Overview with Emphasis on Year 1

Scoping Meeting for Human Health Study Critique
Boston, MA
January 17, 2018



## Health Effects Institute's Energy Research Program

**Why a new research program?** To fill knowledge gaps left by past and ongoing research about potential population exposures and health effects from unconventional oil and natural gas development (UOGD) across the United States

**Approach?** A national multi-year research partnership between industry and government to leverage costs, gain access to UOGD sites, and foster a supportive environment to enable quality science

**Who will benefit?** Regulators, community groups, the oil and natural gas industry, environmental organizations, public health experts, and others who can use the research to inform policy development



*HEI's Energy Research Program*

## Origin of the Program




https://www.healtheffects.org/unconventional-oil-natural-gas/research-agenda

## Strategic Research Agenda

- Released in 2015 after extensive stakeholder consultation and expert review
- The Committee identified key research questions as a foundation for moving forward
- Building on this effort, the HEI Energy Research Program will fill knowledge gaps about potential population exposures and health effects across the US



*HEI's Energy Research Program*

## Governance Structure and Funding



## HEI: a Public-Private Partnership for Research since 1980

- An independent, nonprofit corporation
- Chartered to provide policy-relevant high-quality and impartial, science on the effects of air pollution on health (original research, including accountability studies, reanalyses of key studies, and critical reviews).
- Funded jointly by government and industry and, frequently, other public and private organizations in the United States and around the world



## Energy Research Program Governance

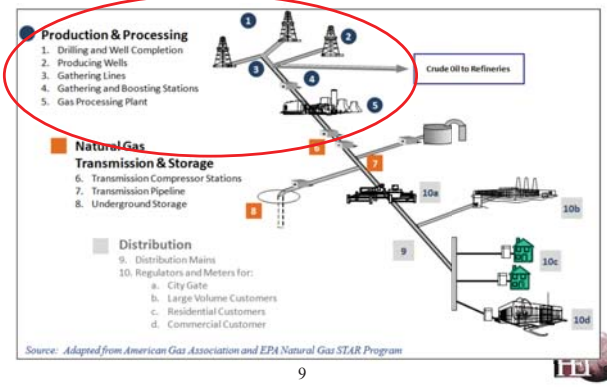
- Modeled directly after the one HEI has used for 35 years to answer questions about air quality and health
- Key elements:
  - Initial Energy Research Committee oversees impartial, policy-relevant literature reviews, research planning, and original research
  - An Energy Advisory Committee provides expert guidance to the Research Committee
  - All work is conceived, implemented, and peer-reviewed independently from sponsors of the research program
  - HEI effectively engages and shares data (all + and – results) with stakeholders



*HEI's Energy Research Program*

## Technical Scope with Emphasis on Year 1 Goals

## Overview of Oil and Gas Operations






## HEI's New Energy Research Program



**Goal**: Answer questions about *potential human exposure and health effects* from UOGD

**How:** Using the same model that HEI has used for 35 years to answer questions about air quality and health

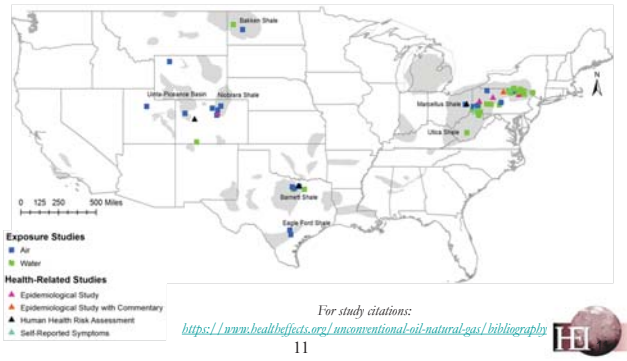
| Year 1: | Years 2 to 4: | Year 4 and Beyond: |
|---|---|---|
| Literature Review & Research Planning | Population-Level Multimedia (e.g., air and water) Exposure Studies in Multiple US Regions | ▪ Extensive Engagement and Communication<br>▪ Maybe further Exposure or Health Studies |

Throughout the research program, HEI engages with a broad range of stakeholders at key decision points



## As we begin the program, peer-reviewed literature about potential exposures and effects continues to be published

Unconventional Oil and Gas Peer-Reviewed Exposure and Health Study Locations




*For study citations:*
https://www.healtheffects.org/unconventional-oil-natural-gas/bibliography



## Also much work beyond the peer-reviewed scientific literature




## Year 1 Products

HEI's Initial Energy Research Committee will prepare:

- Report that summarizes (1) its review of the human health literature and what it does and does not tell us and (2) research recommendations
- Report that summarizes (1) its review of the exposure, toxicological, and risk literature and what it does and does not tell us and (2) research recommendations
- An HEI Solicitation based on research recommendations from the Committee, with research beginning in Year 2



*HEI's Energy Research Program*

## THE PATH FORWARD



## Next Steps

- Announce HEI's Energy Research Program and Introduce the Initial Energy Research Committee – TODAY
- Post brief summary of today's meeting at HEI's website (February 2018)
- Release the Initial Energy Research Committee's human health literature critique – following peer review (Summer 2018)
  - The Committee will consider comments received at this meeting as well as any sent to HEI by February 5, 2018
- First of two *Exposure and Risk Screening Workshops* (May-June 2018)



## Thank you for joining us today

## WE WELCOME YOUR QUESTIONS, COMMENTS, AND RECOMMENDATIONS

Health Effects Institute's Energy Research Program

# The *Initial Energy Research Committee's* General Approach to its Systematic Review of the Human Health Literature related to Unconventional Oil and Natural Gas Development

**Scoping Meeting**
**Metro Meeting Centers, 101 Federal St,**
**Boston, MA 02110**
**January 17, 2018**



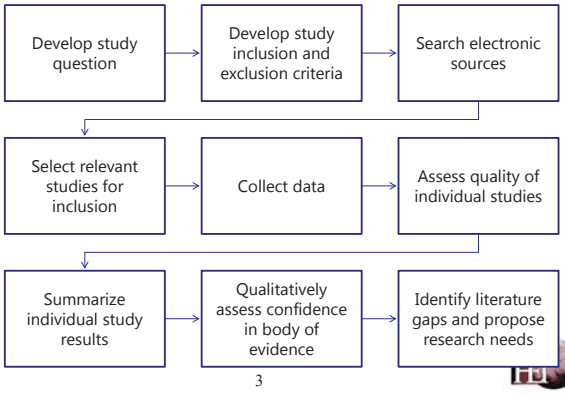
## Study Question

- What are the strengths and limitations of the UOGD* epidemiological literature regarding population exposure and health effects?
- What are the knowledge gaps and potential research needs?

*UOGD – unconventional oil and gas development



## Approach to the Systematic Literature Review






## Initial Literature Inclusion Criteria

| | |
|---|---|
| **Study Type** | Analytical epidemiologic |
| **Study Location** | Worldwide |
| **Publication** | Primary research, peer-reviewed |
| **Population** | Humans |
| **Exposure** | Direct measurements or surrogates of UOGD exposure |
| **Outcomes** | Human health outcomes, including health symptoms collected via surveys |

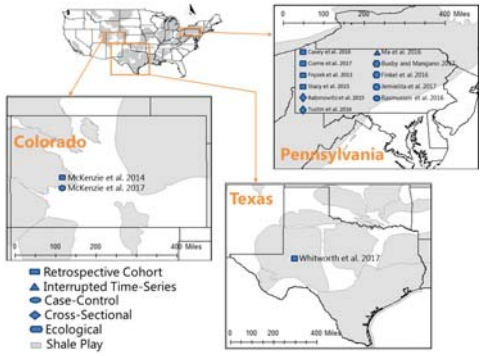


## Initial Criteria for Assessing Study Quality

| **Study Design** |
|---|
| Study Type |
| Study Population |
| Outcome Assessment |
| Exposure Assessment |
| Confounding |
| Effect Modification |
| Analytical Methods |
| **Results** |
| Results and Discussion |



## Initial List of Peer-Reviewed UOGD Epidemiological Studies






## Next steps for Health Critique and other Year 1 Tasks

- In preparing the critique, the Committee will consider comments and questions received at this meeting as well as any sent to HEI by February 5, 2018
- The Energy Research Committee will prepare a draft report, which will undergo peer review before public release of the final report in Summer 2018
- Findings and recommendations from the Health Critique will be considered (along with supporting literature) at the Committee's first of two *Exposure and Risk Screening Workshops* in May-June 2018

# Exposures and Health Impacts of Unconventional Oil & Gas Development

**Nicole C. Deziel, PhD, MHS**
**Assistant Professor, Yale School of Public Health**

**HEI Scoping Meeting**
**January 17, 2018**

Yale SCHOOL OF PUBLIC HEALTH

## Problem Scope

- 25-30,000 wells hydraulically fractured (HF) annually in the US (EPA 2016)
- ~4 million people live within 1 mile of a HF well (Czolowski 2017)
- Drinking water sources for 9 million people within a mile of an HF well (EPA 2016)
- UOG waste water contains toxic and radioactive compounds (Shih 2015, Elliott 2016)
- HF-related activities have affected drinking water resources (e.g., Jackson 2013, Llewellyn 2015)
- UOG sites release air pollutants (e.g., carcinogens) (Elliott 2017, McKenzie 2012)
- Water and air quality monitoring and human health data are insufficient

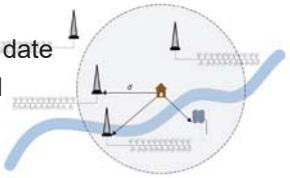
## Multiple Potential Exposures/Stressors


## Limited but Growing Epi Literature

- Perinatal outcomes (McKenzie 2014, Stacy 2015, Casey 2015, Whitworth 2017, Currie 2017)
- Childhood leukemia (McKenzie 2017, Fryzek 2013)
- Respiratory symptoms (Rabinowitz 2014, Rasmussen 2016, Tustin 2016)
- Self-reported dermal irritation (Rabinowitz 2014)
- Migraine, fatigue symptoms (Tustin 2016)
- Hospitalizations (Jemielita 2015)
- Risk Assessments (McKenzie 2012, Regli 2015)

## Challenges in Exposure Assessment in Epidemiologic Context

- Proximity/density metrics and models better suited for air emissions
- Models don't identify underlying etiologic agents
- Limited feasibility to conduct detailed monitoring on large-scale populations
- Only single-state studies to date
- Registry and records-based



## Increasing Detail in Exposure/Activity Modeling

Physically-based hydrogeological models

Activity model (incorporates proximity, density, well attributes, literature-based emission weights)

Inverse distance-weighted well count

Distance to Nearest Well

Zip code # UO&G wells

County-level # UO&G wells

Increasing precision

## Limited but Growing Water Literature*

| Author Year | State | # Samples | Primary Analytes | Geospatial Analysis |
|---|---|---|---|---|
| Elliott submitted | OH | 66 | VOCs, GRO, DRO linked to reprotox/carcinogenicity | Inverse distance well count, distance to nearest well |
| Drollette 2015 | PA | 64 | GRO, DRO | distance to nearest well, distance to nearest violation |
| Jackson 2013 | PA | 141 | methane, ethane | distance to nearest well |
| Osborn 2011 | PA | 68 | methane | distance to nearest well |
| Alawattegama 2015 | PA | 33 | methane, major ions | drilling activity over time |
| Fontenot 2013 | TX | 100 | major ions | distance to nearest well |
| Hildenbrand 2015 | TX | 550 | metals/ions, alcohols | distance to nearest well |
| Hildenbrand 2017 | TX | 77 | ions/bromides/chlorides | distance to nearest well |

*partial list

## Challenges & Opportunities for Water Exposure Studies

- Shift emphasis from methane to contaminants of greater public health concern
- Use hydrologic-based inferences to:
  - Reduce uncertainty in contaminant source attribution
  - Strengthen proximity-based metrics of exposure
- Leverage new analytical techniques to identify chemicals in frac fluids and UOG wastewater

## Limited but Growing Air Quality Studies*

| Author Year | State | Example Compounds |
|---|---|---|
| Ahmadi & John 2015 | TX | ozone |
| Brantley 2015 | CO | VOCs, HAPs |
| Brown 2014 | PA | PM2.5, VOCs |
| Bunch 2014 | TX | VOCs |
| Eapi 2014 | TX | methane, hydrogen sulfide |
| Elliott submitted | OH | VOCs |
| Goetz 2015 | PA | methane, VOCs, NOx |
| Halliday | CO | benzene |
| Karion 2015 | TX | methane |
| Lavoie 2015 | TX | methane |
| Macey 2014 | AK, CO, OH, PA, WY | VOCs |
| Walters 2015 | WI | PM |

*partial list

## Challenges & Opportunities of Air Exposure Studies

- Differences in:
  - Modeling vs measurements
  - Reported UO&G proximity information
  - Sampling location
  - Sampling methods
  - Sampling duration
  - Target analytes

## Study Quality

- Peer review
- Existing standards
  - STROBE (2007)
  - Journal guidelines
  - Navigation Guide (Woodruff 2014)

## References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## Why We are Sponsoring the HEI Energy Research Program

- Demonstrate our commitment to the health and safety of our onshore unconventional oil and gas operations.
- Address concerns and scrutiny of unconventional oil and gas operations
  - Communities are unfamiliar with industrial activity; get conflicting information;
  - Public health advocates promote delay; seek greater assurance of negligible risk;
  - Activists see it as a threat to the campaign to decarbonize the energy supply.
- Enhance the scientific literature with credible studies of actual human exposure, and health impacts as warranted.
  - Relevant, accepted protocols.
  - Peer reviewed and published.
  - Basis for evidence-based policy.
- Educate and inform: media et al. often fail to address robustness, uncertainties, identified limitations of studies.

## Media Interpretation of Health Studies




## Information to Consider in the Health Study Critique

Key Question: What conclusions on the potential for health effects from unconventional oil and gas operations can be drawn from existing literature, and what are the key uncertainties that research should address?

Begin with all the literature that relates to potential human health impacts from unconventional oil and gas development.

Include:

- health impacts related to exposures from all media; air, water, soil.
- all alleged stressors; e.g. chemicals, psychosocial stress.
- grey literature; e.g., primary sources, abstracts, non-peer reviewed reports, conference proceedings.

Exclude:

- Secondary sources, reviews.
- literature solely focused on air or water quality or monitoring, with no health-related findings.
- methodology papers unless they address hazard assessment or risk characterization of unconventional operations.
- literature on workers in the oil, gas, refinery industry unless it specifically addresses unconventional operations.



## Information to consider in the Health Study Critique

To facilitate appropriate use of the literature describe the strengths, limitations and important knowledge gaps?

- Make conclusions for categories of literature/studies or for individual studies

Hazard-based literature – no attempt to measure or predict exposure; e.g.

- Surveys of potential chemical stressors and related hazards;
- Toxicity studies of fracking fluids or components, produced water, environmental media;
- Endocrine modulation studies

Risk characterizations – includes measurement or consideration of actual exposure; e.g.

- Anecdotal reports;
- Community-based surveys;
- Local or regional public health evaluations;
- Health findings with no measurement of stressors (e.g. proximity as surrogate);
- Epidemiology studies that include exposure measurements



## Key Quality Criteria to Consider

- Protocol / methods: not defined; not relevant; widely accepted; GLP compliant.
- Stressor(s): absent; identified; measured.
- Sample size: inadequate to sufficient.
- Data produced: none; secondary sources; generated with relevant methods.
- Dose-response relationship: absent; described; supported by data.
- Statistical analysis: absent to robust.
- Uncertainty analysis: absent; identified; impact discussed.
- Peer review: absent; biased; weak; robust.

Epidemiology specific

- Properly selected exposed and unexposed groups (or cases and controls), with matching or stratification of potential confounders (e.g. age, socio-economic status).
- Clinical documentation of outcomes, or some verification other than self-reporting.
- Plausible exposure pathway scenario from source to receptor, proper exposure metrics.
- Control of potential selection bias, not self-selection.
- Proper interpretation of results with strengths and weaknesses described.



# Dr. Dennis Devlin Presentation

Health Effects Institute Energy Research Program

# Literature Review Scoping Meeting: Human Health Literature Related to UOG Development

Kevin Teichman, EPA
Office of Research and Development
January 17, 2018

## Disclaimer

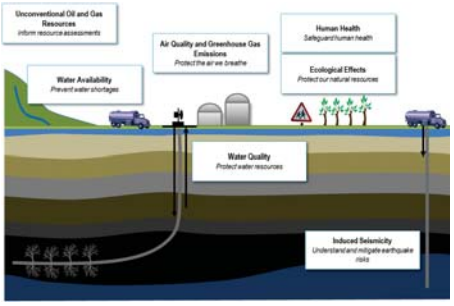
The views expressed in this presentation are those of the presenter and do not necessarily reflect those of the U.S. Environmental Protection Agency.

In addition, the mention of any trade names or products does not imply either endorsement or that the materials or products identified are necessarily the best available for the purpose.






## Research Strategy Topics






## Human Health
*Safeguard Human Health*

Research Questions
- What research is necessary to understand any potential impacts on the health of the nation's population?
- How can any potential negative impacts on human health be mitigated?

Priority Research Needs
- Occupational Studies
- Health Studies
- Toxicity Assessment



## Topic 5: Effects of Human Health

"The Steering Committee recognizes that most of the research needed to address potential impacts on human health … would most appropriately be led by federal health agencies."

NIOSH NIEHS NSF



## EPA Research Related to Potential Human Health Effects Associated with UOG Development

- Hydraulic Fracturing Study, including the Hydraulic Fracturing Drinking Water Assessment (HFDWA) (completed in December 2016)
- "Drinking Water Vulnerability and Neonatal Health Outcomes in Relation to Oil and Gas Production in the Appalachian Basin" (grant awarded in August 2017)



## HFDWA Main Conclusions

- Hydraulic fracturing can impact drinking water resources under some circumstances.
- Examples of impacts were identified for all five stages of the hydraulic fracturing water cycle.
- Impacts can range in frequency and severity, depending on the combination of hydraulic fracturing activities and local or regional-scale factors.
- Significant data gaps and uncertainties prevent quantifying the number or frequency of impacts nationwide.

## HFDWA Main Conclusions

- Circumstances that increase the frequency and severity of impacts include:
  - water withdrawals in times or areas of low water availability, or in areas with limited or declining groundwater resources;
  - spills of high concentrations of chemicals, or large volumes of HF fluids or produced water;
  - injection of HF fluids into wells with inadequate mechanical integrity, or directly into groundwater resources; and
  - discharge of inadequately treated wastewater to surface water, or disposal or storage of wastewater in unlined pits.
- EPA identified more than 1600 chemicals associated with HF activities. Some of the chemicals are known to be hazardous to human health, but most do not have human health, chronic oral, toxicity values.

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Multiagency Collaboration on Unconventional Oil and Gas Research

## Areas of Collaboration and Continued Research Needs

- At the January 2015 MAC Technical Summit, it was evident that there is a lot of current research in the human health research area
  - Baseline and real-time monitoring of air quality, water quality, and land impacts
  - Clinical outcomes, healthcare utilization, biomarkers of exposure and effects
  - Risk communication/perception
- But it was also apparent that there was a need to identify locales and communities where complementary research activities are taking place
  - This continues to be a both a short-term opportunity and a long-term research need
  - Such studies take time, especially since the HF chemicals injected and chemicals produced vary with geologic basin

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## Approach to Literature Review

- Analyze available literature and identify knowledge gaps guided by:
  - Understanding of changes in water quality, water availability, air quality, and other environmental media;
  - Knowledge of likely human exposures and exposure scenarios, including those associated with accidental events;
  - Toxicology (acute and chronic, oral and inhalation) related to likely exposures;
  - Populations and life stages susceptible to exposure and adverse physical and mental outcomes; and
  - Best practices for evaluating potential cumulative risks associated with multiple chemical and non-chemical stressors resulting from UOG development activities.

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## Consideration for the Task Ahead

- A major benefit of shale gas extraction to Pennsylvania has been the decision to site a multi-billion dollar ethane cracking plant.
- A major distinguishing feature between the cracker plant and the nearby Marcellus drilling activities is the long history of evaluating the emissions from such plants, including monitoring of ambient media.
- In contrast, UGD may lead to PA counties that within a few years may have over a thousand well sites, drilled by perhaps a dozen different drilling companies using different techniques, different hydraulic fracturing fluids, and different disposal practices.
- Studies that look at only one site, no matter how well done, cannot be generalized to all sites.

Based on Goldstein, BD, 2018. "The pertinence of Sutton's law to exposure science: Lessons from unconventional shale gas drilling." Journal of Exposure Science & Environmental Epidemiology. https://doi.org/10.1038/s41370-017-0015-8

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## Resources

https://www.epa.gov/hfstudy

https://energy.gov/fe/multi-agency-collaboration-unconventional-oil-and-gas-research

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# COMMENTS on HEI SCOPING MEETING FOR HUMAN HEALTH STUDY CRITIQUE

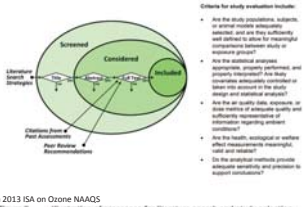
Elena Craft, PhD

HEI Research Committee Meeting, Boston

January 17, 2018

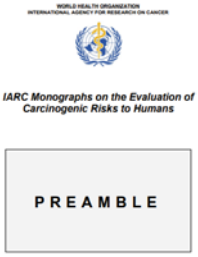
EDF ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

## Criteria for Study Evaluation




From 2013 ISA on Ozone NAAQS

**Figure II** Illustration of processes for literature search and study selection used for development of ISAs.




## Scoping Meeting

HEI

HEALTH EFFECTS INSTITUTE

October 2015

**Strategic Research Agenda on the Potential Impacts of 21st Century Oil and Natural Gas Development in the Appalachian Region and Beyond**

HEI Special Scientific Committee on Unconventional Oil and Gas Development in the Appalachian Basin

1. **Stressor & Exposure Characterization**
2. **Health & Well-being assessment**
3. **Evaluation of most-effective practices**

## Key Contributions Needed

**Science**

- Chemical toxicity
- Exposure Characterizations
- Impacts on Climate/Ecosystem
- Seismicity

**Health**

- Respiratory Issues
- Pregnancy Outcomes
- Psychosocial
- Worker Safety
- Health Analyses

**Law/Policy**

- Loss of Local Democracy
- Siting Policies/Best Practices
- Infrastructure
- Community services
- Monitoring
- Enforcement

**Unknowns**

- Handling/treatment of Produced Water
- "Beneficial" Reuse
- Risk Management
- Other gaps in the research
- Monitoring

## The Charge

- What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?
- What criteria should the committee use to evaluate study quality?
- What do you see as key contributions that the Committee can make to the science and the public dialogue around the development of oil and natural gas from shale and other unconventional resources?
- Looking beyond the initial Human Health Study Critique task, what do you see as key contributions from the Committee's review of literature and research planning in Year 1 and beyond?

## The Need


Re:Aliso Well Blow-out

Mr. Hamburg,

First I would like to thank you very much for the important work. Sometimes it's not until people personally that they begin to get it and I have at least about 6000 neighbors who get it now.

I am hoping you can help me with a question regarding any residual compounds from this blowout that we need to be concerned about. We are being returned to our homes by the gas company and other agencies who assured us that no further environmental testing needs to be done. We live in agriculturally zoned neighborhood that was affected. We have poultry, growing gardens, breeding horses etc. Los Angeles Department of Public health will not make a record of whether or not our gardens are safe to consume fruits and vegetables from or even the interior air quality of our homes. After a disaster of this magnitude and duration can you tell us what compounds that rained down left residuals behind? Trying to find out if our soil should be tested before we begin growing again and what method should be used and what lab is reliable...

Any help you can render would be greatly appreciated.

Best,

Eva

## Information-Data Acquisition


Peer reviewed literature


Industry

NGOs

Community -based participatory research

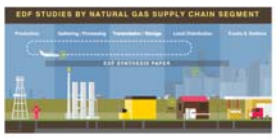
Insurance Providers

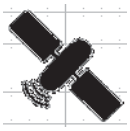

Other Special Councils


Government


Regulatory Agencies

## Other Comments



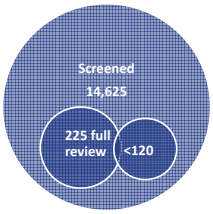
## Literature Review Objectives

- Identify chemicals detected in wastewater from on on-shore oil and gas operations
- Prioritize based on known/unknown toxicity hazards
- Search logic:


## Anticipated output (pending)

| CAS # | Name | FracFocus | Priority Pollutants | TRI | IRIS/IRIS | ToxValues | PPRTV | ATSDR | ToxCast | Tox21 | chlorines |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1002-43-3 | Undecane, 3-methyl- | | | | | | | | | ✓ | |
| 1002-84-2 | Pentadecanoic acid | | | | | | | | | ✓ | |
| 100-41-4 | Ethylbenzene | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | | ✓ | ✓ |
| 100-44-7 | Benzyl chloride | ✓ | | ✓ | ✓ | ✓ | ✓ | | | ✓ | |
| 10045-97-3 | Caesium-137 | | | | | | | ✓ | | | |
| 100-51-6 | Benzyl Alcohol | | | | | | ✓ | | ✓ | ✓ | |
| 100-52-7 | Benzaldehyde | ✓ | | | | | ✓ | | | ✓ | |
| 100666-89-5 | Tetrahydrofurfuryl acrylate | | | | | | | | | | |
| 1008-80-6 | 2,3-Dimethyldecahydronaphthalene | | | | | | | | | | |
| 101-81-5 | Diphenylmethane | | | | | | | | | ✓ | |
| 10222-01-2 | 2,2-Dibromo-3-nitrilopropionamide | ✓ | | ✓ | | | | | ✓ | ✓ | |
| 10222-95-4 | Benzene, 1,2,4-trimethyl-5-(1-methylethyl) | | | | | | | | | | |
| 1024-57-3 | Heptachlor epoxide | | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |
| 10317-17-6 | Oxetane, 3-(1-methylethyl)- | | | | | | | | | | |

## Current status




- Currently reviewing papers and pulling data
- Anticipate <120 paper to be included
- Data extraction: ~1200 unique chemicals identified so far

Photo: Jay Janner

**Elena Craft, PhD**
ecraft@edf.org
512-691-3452

# 1.17.18 Scoping Meeting for Human Health Study Critique

January 17, 2018

Raina Rippel, Director

## Southwest Pennsylvania Environmental Health Project (EHP) mission

***Our mission is to respond to individuals' and communities' need for access to accurate, timely and trusted public health information and health services associated with natural gas extraction.***

## UOGD Growth in PA 2002 - 2017

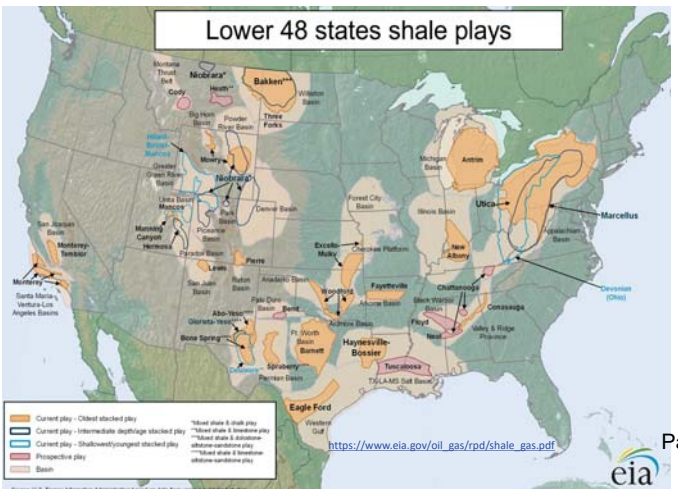

(Marcellus Air)

## Questions

1. What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?
2. What criteria should the committee use to evaluate study quality?
3. What do you see as key contributions that the Committee can make to the science and the public dialogue around the development of oil and natural gas from shale and other unconventional resources?
4. Looking beyond the initial Human Health Study Critique task, what do you see as key contributions from the Committee's review of literature and research planning in Year 1 and beyond?

## Summary of Recommendations

•Be aware that there is a widespread health problem (including stress, suicide, physical health, and impaired quality of life)
•Look at people, look at exposures, and look at the long-term implications of what's not known
•Localized exposures are crucial to define and prevent
•Ultimately, the court of public opinion will not accept these risks. Industry's only option is to get emissions under control.




## For More Information

www.environmentalhealthproject.org

724.260.5504

info@environmentalhealthproject.org

## HEI Energy Research Program Scoping Meeting

January 17, 2018

**Judy Wendt Hess, PhD**
Shell Health Risk Science Team




## Assessing study quality

- Study design
- Potential for measurement error (of exposure or outcome)
- Potential for confounding
- Analytic methods
- Appropriate interpretation of results




## Assessing study quality

- Study design
- Potential for measurement error (of exposure or outcome)
- Potential for confounding
- Analytic methods
- Appropriate interpretation of results



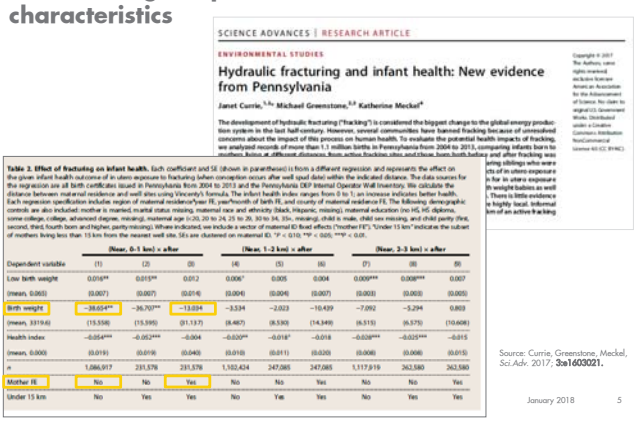

## Distance-based exposure metrics in URD* epidemiology studies

- Is an arbitrary distance between homes and wells useful for defining exposed and unexposed populations?
- Is the nature of unconventional oil and gas operations conducive to using distance-based calculations as a proxy for personal exposure to URD?
- Do we understand the degree of exposure misclassification in distance-based URD studies and the potential impact on risk estimates?

*Unconventional Resource Development




## Confounding - impact of unobserved maternal characteristics



SCIENCE ADVANCES | RESEARCH ARTICLE

ENVIRONMENTAL STUDIES

**Hydraulic fracturing and infant health: New evidence from Pennsylvania**

Janet Currie,[1,2]* Michael Greenstone,[3,4] Katherine Meckel*

The development of hydraulic fracturing ("fracking") is considered the biggest change to the global energy production system in the last half-century. However, several communities have banned fracking because of unresolved concerns about the impact of this process on human health. To evaluate the potential health impacts of fracking, we analyzed records of more than 1.1 million births in Pennsylvania from 2004 to 2013, comparing infants born to mothers living at different distances from active fracking sites and those born both before and after fracking was

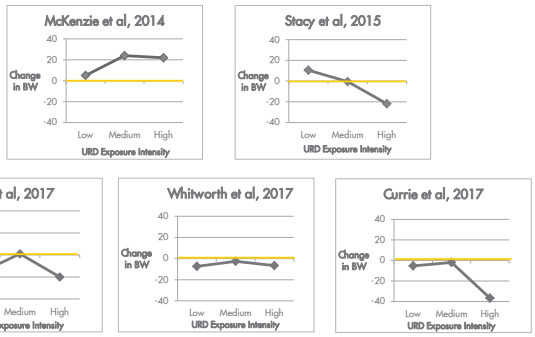
**Table 2. Effect of fracturing on infant health.** Each coefficient and SE (shown in parentheses) is from a different regression and represents the effect on the given infant health outcome of in utero exposure to fracturing (when conception occurs after well spud date) within the indicated distance. The data sources for the regression are all birth certificates issued in Pennsylvania from 2004 to 2013 and the Pennsylvania DEP Internal Operator Well Inventory. We calculate the distance between maternal residence and well sites using Vincenty's formula. The infant health index ranges from 0 to 1; an increase indicates better health. Each regression specification includes region of maternal residence*year FE, year/month of birth FE, and county of maternal residence FE. The following demographic controls are also included: mother is married, marital status missing, maternal race and ethnicity (black, Hispanic, missing), maternal education (no HS, HS diploma, some college, college, advanced degree, missing), maternal age (<20, 20 to 24, 25 to 29, 30 to 34, 35+, missing), child is male, child sex missing, and child parity (first, second, third, fourth born and higher, parity missing). Where indicated, we include a vector of maternal ID fixed effects ("mother FE"). "Under 15 km" indicates the subset of mothers living less than 15 km from the nearest well site. SEs are clustered on maternal ID. *P < 0.10, **P < 0.05, ***P < 0.01.

| | (Near, 0-1 km) × after | | | (Near, 1-2 km) × after | | | (Near, 2-3 km) × after | | |
|---|---|---|---|---|---|---|---|---|---|
| Dependent variable | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) |
| Low birth weight | 0.016** | 0.015** | 0.012 | 0.006* | 0.005 | 0.004 | 0.009*** | 0.008*** | 0.007 |
| (mean, 0.065) | (0.007) | (0.007) | (0.014) | (0.004) | (0.004) | (0.007) | (0.003) | (0.003) | (0.005) |
| Birth weight | −38.654** | −36.707** | −13.034 | −3.534 | −2.023 | −10.439 | −7.092 | −5.294 | 0.803 |
| (mean, 3319.6) | (15.558) | (15.595) | (31.137) | (8.487) | (8.530) | (14.349) | (6.515) | (6.575) | (10.608) |
| Health index | −0.054*** | −0.052*** | −0.004 | −0.020** | −0.018* | −0.018 | −0.028*** | −0.025*** | −0.015 |
| (mean, 0.000) | (0.019) | (0.019) | (0.040) | (0.010) | (0.011) | (0.020) | (0.008) | (0.008) | (0.015) |
| n | 1,586,917 | 231,578 | 231,578 | 1,102,424 | 247,085 | 247,085 | 1,117,919 | 262,580 | 262,580 |
| Mother FE | No | No | Yes | No | No | Yes | No | No | Yes |
| Under 15 km | No | Yes | Yes | No | Yes | Yes | No | Yes | Yes |

Source: Currie, Greenstone, Meckel, *Sci.Adv.* 2017; **3:e1603021.**




## URD birthweight studies – inconsistent results, lack of dose-response






*NOTE: Shell summary of data from the noted studies.*

# TCEQ Comments on HEI Literature Systematic Review

**Michael Honeycutt, Ph.D.**
**Director, Toxicology Division**

**What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?**

- Industrial process information. Exploration occurs in phases, beginning with site preparation (4-6 weeks typically), progressing to drilling (2-4 weeks), then fracturing (3-5 days per direction), and ending with production (years). Each phase has a different length of time and different potential emissions. Well depth, well density, presence of confining layers, regulatory requirements (emission controls, casing requirements, etc.) and many other factors affect the potential for exposure.
- Typical emissions profiles. In Texas, we've looked at several thousands of samples and nearly all cases involving elevated pollutants arose from human or mechanical failures. If this research is intended to be broadly applied to the industry, the operating conditions should be representative of the broad industry and the literature should ensure that ambient concentrations are not the result of individual operator errors. Alternatively, the consequences of operator error should be kept as a separate category
- Study design. Results from proximity studies are dubious. Similarly, ecological studies are not strong enough for definitive conclusions.
- Comparison values should be determined *a priori*. The committee should agree on what constitutes an adverse effect before the review begins, recognizing that the committee's determination and that of the study authors may differ.
- Bradford Hill considerations. (strength of association, consistency, specificity, temporality, dose-response or biological gradient, biological plausibility, coherence)

**What criteria should the committee use to evaluate study quality?**

- Study design.
  - Comparison group. Are the exposed and control groups appropriate?
  - Is the study design capable of determining effects of interest to the committee?
- Exposure. Ambient concentrations measured at a site several miles away are not always representative of personal exposure. The study authors should justify their choice of exposure data. This justification should include the following:
  - Sample averaging time.
  - Measurement technology. Ideally, studies will report on instrument reliability or reference a separate article that does.
  - Sample size.
  - Exposure duration. Is the length of expected exposure appropriate for the development of the health endpoint of interest?
  - Consideration of other sources (many chemicals associated with O&G activities can come from multiple sources).
- Effects or outcome measures.
  - Reliable measurements. Frank effects have a high degree of certainty, but hospital admissions data, for example, can be uncertain because it can be confounded by other health issues.
- Strength of association and adversity/clinical relevance of effect.
- Confounding/Modifying. Study authors should attempt to control for known confounders and modifiers, such as socioeconomic status, co-pollutants, spatio-temporal variation, etc.
- Appropriate statistical analyses.
- Discussion of limitations.

**What do you see as key contributions that the Committee can make to the science and the public dialogue around the development of oil and natural gas from shale and other unconventional resources?**

In Year 1, I expect that there will be a productive discussion of the review approach and inclusion/exclusion criteria. Ideally, a systematic review that follows published and generally accepted guidelines would be used to develop a review suitable for publication by sometime the following year. I would expect that the committee would provide useful suggestions and a thorough scientific peer review. I would suggest comprehensive inclusion criteria and limited exclusion criteria to include as many studies as possible.

**Looking beyond the initial Human Health Study Critique task, what do you see as key contributions from the Committee's review of literature and research planning in Year 1 and beyond?**

A well-articulated problem statement. The current project discussion is quite broad. For example, will the research consider all forms of unconventional exploration (tight gas, shale gas, coalbed methane)? All steps in the process (site preparation, production)? Will the research focus on air, water, soil, or all media? Any particular health endpoints?

- An understanding of the weight-of-evidence for selected health endpoints, as well as limitations in the current knowledge base.

## Health Effects Institute's Energy Research Program

### *Scoping Meeting for Human Health Study Critique*

**Aubrey K. Miller, M.D., M.P.H.**
Senior Medical Advisor
National Institute of Environmental Health Sciences

**January 2018**

**Boston, MA**



## Determining the Health Risks?

**Workers** **Community**

**The 4-Step Risk Assessment Process**

- **Hazard Identification** — What health problems are caused by the pollutant ?
- **Epidemiology** / Toxicology / Animal Effects
- **Exposure Assessment** — How much of the pollutant do people inhale during a specific time period? How many people are exposed?
- **Dose-Response Assessment** — What are the health problems at different exposures?
- **Risk Characterization** — What is the extra risk of health problems in the exposed population? ?

Air
Water: Surface / Ground
Ingestion
Dermal

www.epa.gov/ttn/atw/3_90_024.html





## NIEHS National Toxicology Program (NTP)

u **PAC Research Project**

- Evaluation of toxicity of a wide range of PACs & defined PAH mixtures
- Short-term in-vitro panels and in-vivo models for diverse health endpoints
- Increase availability of compounds for analytical chemistry and toxicity testing
- Develop better exposure and effect biomarkers
- Evaluate genetic and epigenetic effects of various PACs
- Develop and evaluate relevant pharmacokinetic models
- Develop experimental models to evaluate effects of low level exposures

u **Hydrogen Sulfide (H2S) Research**

- Individual and species toxicity research
- Better understanding of long-term effects associated with short-term high level exposures and chronic low-level exposures





## Available Literature re: Health Effects & Concerns

**Individual Health Impacts** (both workers & residents)

- **Acute**: asthma/*respiratory function, eye/nose/ throat/skin irritation, constitutional symptoms (headaches, fatigue, etc.); deaths from VOC exposures*
- **Longer-term**: *pregnancy, fetal development, cardiovascular, lung disease (silicosis?), cancers (leukemia)?, neurobehavioral, hearing loss, stress reactions….*

**Community Health Stressors**

- *Concerns: resource availability, traffic, noise, light, crime, social disruption, seismicity, waste & water disposal*

**Key Exposures to Consider**: **Air:** VOC's; ozone, PM2.5, silica, diesel exhaust, road dust/particulate, gas release outdoor/indoor
**Water**: contaminated ground & surface waters (exposure food, drinking, bathing); **Soils/Dust**: spills, surface contamination



**What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?**

**Systematic review of community health impacts of mountaintop removal mining.** Environ Int. 2017 Oct;107:163-172. Boyles et. al.

**Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration**

**What are the 7 steps in the NTP systematic review process?**

1. Formulate problem and develop protocol.
2. Search for and select studies for inclusion.
3. Extract data from studies.
4. Assess internal validity of individual studies.
5. Synthesize evidence and rate confidence in the body of evidence.
6. Translate confidence ratings into level of evidence for health effect.
7. Integrate evidence to develop hazard identification conclusions.

**https://ntp.niehs.nih.gov/pubhealth/hat/review/index-2.html**




**What criteria should the committee use to evaluate study quality?**

**Metrics of Study Design & Exposure Characterization**

- **Study representativeness and generalizability** (locations, exposures, populations)
- **Population**: who, workers/community, demographics
- **Size /robustness**: needed to identify health endpoints of concern
- **Assessment of health effect**: self-reported, objective measures, medical records
- **Baselines or Comparison Groups**: how are changes identified, strength of effect
- **Clarity of relationship:** bias, confounders accounted for, pre-existing conditions

**Exposure**

- **Characterization / What's being measured:** baselines, pathways, surrogates (distance) vs measured exposures, sensitivity/limits of detection, etc.
- **Concentration & duration**: when, where, how long, change in background
- **Intensity and Frequency:** peaks & averages
- **Confounders**: other sources, changes in production, environmental factors





**Looking beyond the initial Human Health Study Critique task, what do you see as key contributions from the Committee's review of literature and research planning in Year 1 and beyond?**

Limited epidemiologic studies (ecological, X-sectional, case-control) often using surrogates of exposure (distance) or estimates based on area air sampling of only a few target analytes. "Hypothesis Generation"

**What Critical Data is Missing and Why?**

What do studies of disease / adverse health impacts in populations tell us?

Who has been studied specifically, where, demographics, population sizes, etc.?

What kinds of health effects have been found (acute, chronic, cancer/non-cancer, heritable, etc.) and what do the findings indicate?

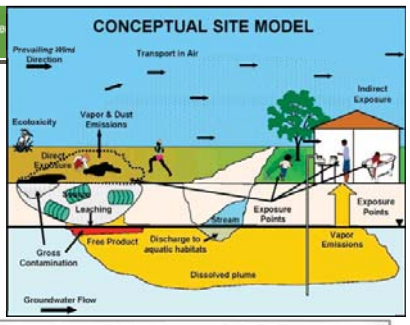
What do we understand about the pathways of exposure, the specific exposures themselves, the magnitude, duration, etc.?

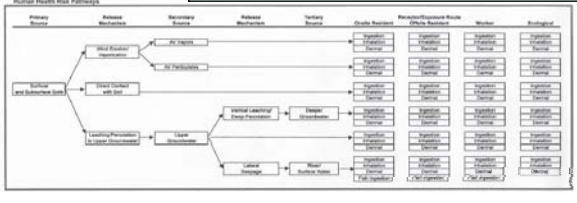
What do we understand about the health hazard / toxicity of each exposure individually, at what levels, and cumulatively? Mixed exposures?



## SYSTEMATIC DATA COLLECTION by Design

Routes of Exposure
Measured Exposures
Fate & Transport Considerations
Receptor Populations
Health Endpoints of Concern



National Institute of Environmental Health Sciences
Your Environment. Your Health.

**What do you see as key contributions that the Committee can make to the science and the public dialogue around the development of oil and natural gas from shale and other unconventional resources?**

***Roadmap for the science needed to inform understanding of health risks & exposures including types of data to be collected, metadata, quality assurance, data management, risk communications, community engagement, etc.***

- Human health prioritized research plan
- Identification of risk factors of injury & illness
- Identification of "best practices" to reduce health risks
- Identification of priority toxicology and risk assessments
- Open Platform: access to protocols, data, findings, lessons-learned, other issues to help facilitate future research

National Institutes of Health
U.S. Department of Health and Human Services

National Institute of Environmental Health Sciences
Your Environment. Your Health.

## Suggested Approach Priorities for Future Research

- Initially focus on worst case: workers & close proximity residences to pilot best methods for capturing exposures and health effects!!
- Prospective systematic design across multiple sites and populations
- Build off of well characterized areas with available data where possible
- Combined health data: medical records, surveys, medical testing, biomarkers of exposure and effect.
- Combined exposure assessments: extant data EPA, USGS, area monitors, personal sampling (e.g. wrist bands), home dust, water, air
  - **GIS coding & continuous samples for peak & average exposures**
  - **Archiving samples** (air, water, soil, ozone, dust PM 2.5)
  - **Sensitivity/ limit of detection** set for health effect research, not regulations
  - **Baseline testing** vital as well as comparison areas & groups

National Institute of Environmental Health Sciences
Your Environment. Your Health.

## Thank you!

National Institute of Environmental Health Sciences

National Toxicology Program
U.S. Department of Health and Human Services

# APPENDIX E

**Meeting Participants**

SCOPING MEETING FOR THE HUMAN HEALTH STUDY CRITIQUE

# PARTICIPANTS

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^ Speakers
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