



# HESI Subcommittee on Risk Assessment for Sensitive Populations

## Co-Chairs:

***Ronald Hines, PhD***

(Medical College of Wisconsin)

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(Bayer CropScience)

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HESI Annual Meeting

Tucson, AZ



# HESI Subcommittee on Risk Assessment for Sensitive Populations

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- **Spring 2006:** Topic selected by HESI Emerging Issues Steering Committee
- **Fall 2006:** Subcommittee kick-off meeting
- **Work product:** Manuscript to be submitted for publication in peer-reviewed journal



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# Mission

- **Broaden and increase knowledge about the characterization of sensitive populations.**
  - **Understand efforts to apply current and proposed methods for assessing risks to sensitive populations.**
  - **Integrate results from applications and lessons learned to improve risk assessment for diverse sensitive populations in the future.**
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# 2008 Subcommittee Participation

## INDUSTRY

3M Pharmaceuticals  
Bayer CropScience  
Dow AgroSciences  
Monsanto Company

## PUBLIC

Alfred I. duPont Hospital for Children  
European Food Safety Authority  
Medical College of Wisconsin  
Federal Institute for Drugs and Medical Devices (BfArM)  
National Institutes of Health  
    National Cancer Institute  
    National Institute of Environmental Health Sciences  
University of Washington  
University of Aarhus, Denmark  
US Environmental Protection Agency  
    National Center for Computational Toxicology  
    National Health and Environmental Effects Research  
    Laboratory  
US Food and Drug Administration  
    Center for Drug Evaluation and Research  
    National Center for Toxicological Research



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# Manuscript

## APPROACHES FOR ASSESSING RISKS TO SENSITIVE POPULATIONS: LESSONS LEARNED FROM EVALUATING RISKS IN THE PEDIATRIC POPULATION

Ronald N. Hines<sup>1</sup>, Dana Sargent<sup>2</sup>, Herman Autrup<sup>3</sup>, Linda S. Birnbaum<sup>4</sup>,  
Robert L. Brent<sup>5</sup>, Nancy G. Doerrler<sup>6\*</sup>, Elaine Cohen Hubal<sup>4</sup>,  
Daland R. Juberg<sup>7</sup>, Christian Laurent<sup>8</sup>, Robert Luebke<sup>4</sup>, Klaus  
Olejniczak<sup>9</sup>, Christopher J. Portier<sup>10</sup>, William Slikker<sup>11</sup>

(targeted journal: *Environmental Health Perspectives*)



# Scientific Manuscript: Four Fundamental Issues

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- 1. Identification of critical biological, toxicological, and exposure-related factors that should be examined when evaluating vulnerability (in this case, in the pediatric population).**
  - 2. Identification of methods, models, and experimental designs for evaluating pediatric populations which may be useful in evaluating other populations.**
  - 3. Identification of parameters unique to the pediatric population and that are not useful for extrapolating to other groups.**
  - 4. Identification of key gaps in the pediatric/vulnerability literature that should be addressed for pediatric and other potentially vulnerable groups.**
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# Major Topics in Manuscript

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- **Consideration of pediatric subjects as a sensitive population model when evaluating other potentially vulnerable groups**
  - **Defining a sensitive population**
  - **Relevant factors in the identification and assessment of sensitive populations (e.g., pharmacokinetics, pharmacodynamics, genetics, environmental exposure)**
  - **Biomarkers of susceptibility**
  - **Implementation of population-specific factors in risk assessment / modeling**
  - **Discussion**
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# Approach and Timeline

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- **July 2007** - Subcommittee selected published literature for review.
- **September 2007**- Subcontractor was retained to review literature and produce summaries and commentaries regarding utility.
- **December 2007** - Subcommittee developed a manuscript outline.
- **January 2009** - Manuscript completed and submitted for HESI peer review.
- **February 2009** - Manuscript submitted for publication in a scientific peer-reviewed journal (*EHP*).





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# Next Steps

- **Sunset the Subcommittee after submission of manuscript to peer-reviewed journal (early 2009).**
  - **The HESI Emerging Issues Steering Committee (EISC) could consider convening a more focused group on this topic when and if a proposal is submitted in future years through the annual emerging issues survey.**
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