

# **NIEHS-EPA Collaborative Project to Improve Characterization of Personal Care Product and Home Exposures**

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## Outline

- Significance: Research Needs
- Background
- Collaboration
- Objectives
- Proposed Approach

## Significance: Research Needs

- **NIEHS Strategic Plan 2013**
  - Theme 2: Goal 3: Exposure research to advance characterization of environmental exposures through improved exposure assessment, at both the individual and population levels.
- **NIEHS Mixtures Workshop 2011**
  - Evaluate the effectiveness of existing survey instruments for classifying or quantifying exposures
  - Develop better tools to improve exposure assessment
  - Better understand the nature of combined exposures or mixtures



## Background

- NIEHS Sister Study's personal care product questionnaire
- Characterize as exposure assessment tool
  - Aid interpretation of analyses that use this questionnaire
  - Utility of the questionnaire, or subset of questionnaire items (Objective 1)



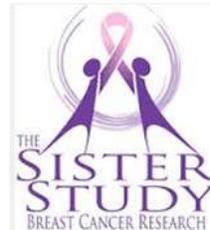
PC45 45. In the past 12 months, how frequently have you used hand lotions or creams? (Mark one.)

- 1  Did not use
- 2  Less than once a month
- 3  1-3 times per month
- 4  1-5 times per week
- 5  More than 5 times per week

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## NIEHS Sister Study

- Prospective cohort study of 50,000 women in the U.S.
- Participants have at least one sister diagnosed with breast cancer and breast cancer-free themselves at time of enrollment
- Enrollment ended in 2009
- Analyses are currently underway to look at associations between personal care product usage and breast cancer and other health outcomes
- <http://sisterstudy.niehs.nih.gov>



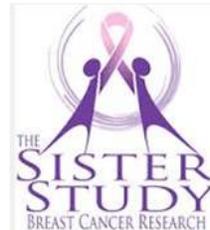
## NIEHS Sister Study

- Health outcomes
  - Breast, lung, ovarian and skin cancers
  - Cardiovascular disease
  - Autoimmune disease
  - Thyroid disease
  - Fibroids
  - Diabetes and obesity
  - Reproductive



## NIEHS Sister Study

- Environmental exposure
  - Personal care questionnaire
  - Residential history and exposures
  - Occupational history and exposures
  - Reproductive history
  - Medical history
  - Lifestyle factors
  - Socio-economic characteristics
  - Diet questionnaire
  - Family history questionnaire
- Biological samples
  - Household dust
  - First morning void urine
  - Blood
  - Toenail clippings
  - Household dust



## Questionnaire Exposure Assessment Tools

- Sister Study personal care product questionnaire
- Sister Study household/residential questionnaire
  - Captures exposure to products that may also contain potential endocrine disrupting and other chemicals (e.g., household pesticides)
  - Will be also be used to assess and categorize exposures
- Food packaging and food processing (Rudel et al., 2011)
  - Exposures to the same chemicals as personal care and household/residential products come from food packaging and processed food

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## Collaboration with EPA

- Expand scope of the project - extensive and repeated collection of exposure information
- Include additional exposure information
  - E.g., air, dust samples, household inventories of consumer products
- Evaluate and improve EPA's exposure prediction models
  - ExpoCast
  - High Throughput Stochastic Human Exposure and Dose Simulation (SHEDS-HT) initiatives (Objective 2)

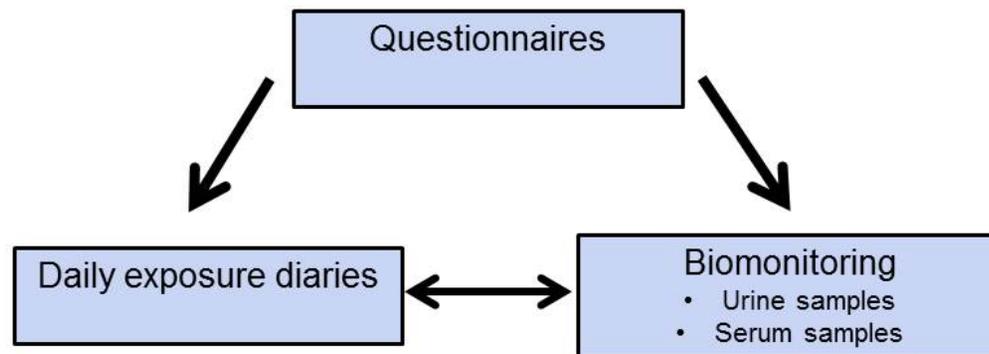


## **Collaboration with EPA**

- Co-funding – chemical analysis
- Sharing of equipment
- Sharing of expertise and data analysis
- EPA field team
- Adds second Objective to project

## Objective 1: Evaluate Questionnaires

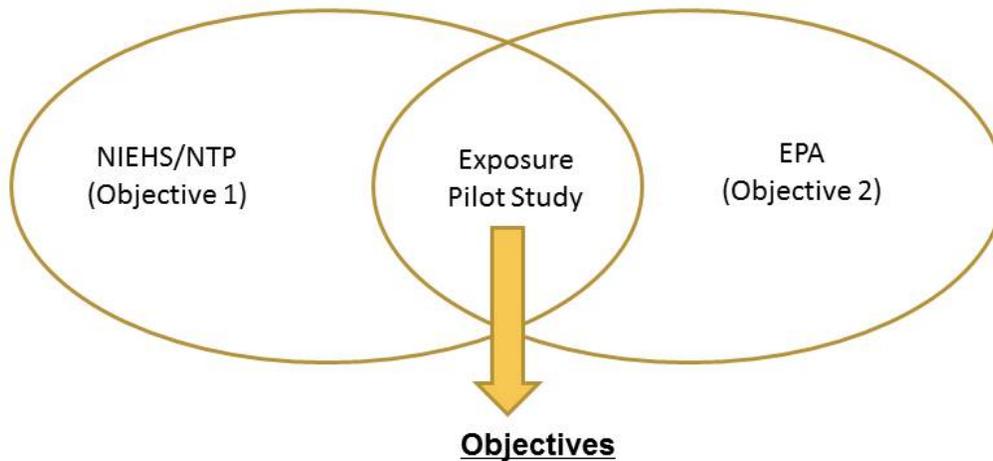
- Evaluate the utility of questionnaire instruments to assess exposure from the following to inform the design and interpretation of epidemiologic studies
  - Personal care products (Sister Study)
  - Household chemicals (Sister Study)
  - Packaged and processed food (Rudel 2011)



## Objective 2: Model Development and Validation

- Inform and evaluate models designed to predict exposure to chemicals in the environment; demonstrate and evaluate novel methods for chemical exposure measurement
  - Test a variety of modeling approaches designed to predict chemical exposures from consumer products
  - Test and demonstrate measurement methods to more fully and accurately characterize consumer product chemical exposure
  - Based on models and measurements described above, (1) evaluate patterns of co-exposure and, (2) consider approaches for mass balance analysis

## Inter-Agency Leveraging & Bridging of Research



- **NIEHS:** Evaluate the utility of questionnaire instruments to assess personal care and consumer product exposures.
- **EPA:** Evaluate predictive models of chemical exposure; demonstrate and evaluate novel methods for chemical exposure measurement

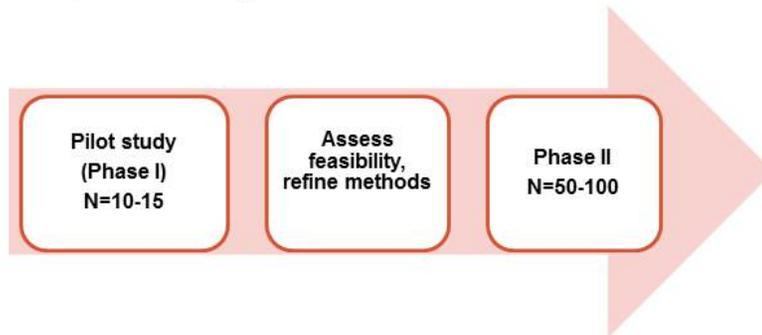


## Proposed Approach

- Pilot study
  - Feasibility
  - Practicality
  - Recruitment and screening
  - Compliance

## Pilot Study is Valuable

- Refine procedures for a larger exposure study
- Highlight areas of uncertainty
  - e.g., discordance between questionnaire, daily diary, and biomonitoring data for specific types of chemicals
- EPA can evaluate and refine current predictive exposure models
- Certain aspects may not be feasible



## Proposed approach: Major Elements

- 10-day pilot study
- Enroll 10-15 eligible women of reproductive age (25-40 years) using Clinical Research Unit's (CRU's) sample registry
- High personal care product users: participants who use 15 or more products per day
- Low personal care product users: participants that use 5 or less products per day
- Participants will be women who work from home or stay at home the majority of the day
- Non-smokers

## Proposed approach: Major Elements Cont.,

- At enrollment, participants will take the three questionnaires
  - Personal care product questionnaire
  - Household and environmental exposure questionnaire
  - Food packaging and processing questionnaire
- Participants will have their blood drawn at the CRU the first day and last day
- Participants will collect urine samples at home

## Proposed Approach: EPA Contribution

- EPA field team member will visit the participants the morning of each sampling day
  - Collect urine samples, review the activity diary, and the daily exposure diary to ensure that everything has been recorded correctly
  - House dust collection
    - Using same method as Sister Study
  - Experience from previous exposure reconstruction pilot study (Ex-R Study) (Morgan et al., 2013)

## Proposed Approach: EPA Contribution Cont.,

- Personal sensors to inform exposure: GPS, t-VOC, accelerometer
- Nielsen HomeScan™ and Life360™ technology
  - Consumer product purchases and use
- Food intake via Meal Snap™
- House dust analysis using high-throughput methods
- Modeling: Bayesian-empirical, SHEDS-Lite, ExPriori

## Analysis and Interpretation

- CDC will conduct analysis of biomonitoring data (NHANES chemicals)
  - Excluding metals, PCBs, dioxins, and persistent pesticides (e.g., DDT)
- Consider developing methods for analyzing emerging chemicals of interest (e.g., phosphorylated flame retardants)
- Use results from pilot to inform a larger exposure study (derive power, estimate Ns)

Chemical Panels Measured in NHANES	
phytoestrogens	urine
creatinine	urine
OH-PAH	urine
phthalates	urine
phenols & parabens	urine
perchlorate	urine
organophosphate insecticides (DAPs; non-specific metabolites)	urine
pyrethroid insecticides & OP specific metabolites	urine
PBDEs	serum
PFCs	serum
cotinine	serum



## Thanks to Collaborators

- NIEHS
  - OHAT (Kristina Thayer, Abee Boyles, Katie Pelch, Kembra Howedeshell, Andy Rooney, Vickie Walker)
  - NTP (Chad Blystone, Mike Devito, Dori Germolec, Grace Kissling, Scott Masten, Cynthia Rider, Suramya Waidyanatha)
  - DIR (Donna Baird)
  - CRU (Stavros Garantziotis, Shepherd Shurman)
- Inter-agency
  - EPA (Tim Buckley, Tina Bahadori, Michael Breen, Peter Egeghy, Elaine Hubal, Kristin Isaacs, Haluk Ozkaynak, Jon Sobus, Dan Stout, John Wambaugh)
  - CDC (Antonia Calafat)
- External (Ruthann Rudel et al. - Silent Spring Institute)

## References

- Morgan M, MacMillian D, Zehr D, Alston L. 2013. Pyrethroids and their environmentally-degraded metabolites in duplicate diet samples from the ex-r study [abstract]. Pyrethroids and their environmentally-degraded metabolites in duplicate diet samples from the Ex-R study" at the ISES, ISEE, and ISIAG conference in Basel, Switzerland August 2013 Available: <http://ehp.niehs.nih.gov/ehbasel13/p-3-23-21/>
- NIEHS, 2012. NIEHS Strategic Plan. Available: <http://niehs.nih.gov/about/strategicplan/index.cfm>
- Rudel RA, Gray JM, Engel CL, Rawsthorne TW, Dodson RE, Ackerman JM, et al. 2011. Food packaging and bisphenol a and bis(2-ethyhexyl) phthalate exposure: Findings from a dietary intervention. Environmental health perspectives 119:914-920

## Charge Questions

- 1) Comment on the merit of the proposed project relative to the mission and goals of the NTP.  
*The NTP's stated goals are to: Provide information on potentially hazardous substances to all stakeholders; Develop and validate improved testing methods; Strengthen the science base in toxicology; Coordinate toxicology testing programs across DHHS*  
(<http://ntp.niehs.nih.gov/go/about>).
- 2) Comment on the clarity and validity of the rationale for the proposed project. Has the scope of the problem been adequately defined? Are the relevant knowledge gaps identified and clearly articulated?
- 3) Comment on the strategy and approach proposed to meet the stated objectives of the project. Are specific aims reasonable and clearly articulated? Is the scope of work proposed appropriate relative to the public health importance of the issue(s) under consideration? If not, what modifications do you recommend? Where steps to further refine the strategy and/or approach are proposed, are they appropriate?
- 4) There are challenges inherent to achieving the aims of any proposed project. Are the relevant challenges and/or key scientific issues identified and clearly articulated? Where approaches to overcome challenges are proposed, are they appropriate? Are you aware of other scientific issues that need to be considered?
- 5) Rate the overall significance and public health impact of this project as low, moderate, or high. Identify any elements of the proposed project that you feel are more important than others, and/or that have a higher likelihood of success at meeting pre-defined specific aims.
- 6) Provide any other comments you feel NTP staff should consider in developing this project.