The National Children’s Study Archive

Linda Andrews
Social & Scientific Systems, Inc.
Background of the National Children’s Study (NCS)

• With passage of the Children’s Health Act of 2000, NICHD was directed to conduct a longitudinal study on children’s health.
• The study was to be a nationally representative longitudinal cohort study of 100,000 children from before birth through age 21.
• The purpose was to investigate the effects of environmental exposures (chemical, biological, physical, and psychosocial) as well as gene-environment interactions on pregnancy outcomes, child health and development, and precursors of adult disease.
Background of the National Children’s Study (NCS)

- The NCS as initially planned consisted of two distinct but related studies:
  - NCS Vanguard (Pilot) Study
  - NCS Main Study
- All study procedures could be tested within the Vanguard Study prior to being considered for inclusion with the Main study.
- Both studies would run for 21 years.
- NCS Vanguard Study was active from 2009–2014 enrolling nearly 6,000 children and their parents (mostly mothers) from 40 locations throughout the US.
- In December 2014, NIH decided not to launch the Main Study and stopped data collection for the Vanguard Study.
The data was collected from 40 Study Center Locations through the U.S. Five different recruitment strategies were used throughout the Vanguard Study at various times, with each location assigned one strategy.
NCS Participant Demographics

5,420 mothers — over 2000 having biological and/or environmental samples

Race/ethnicity

- Unknown
- Hispanic
- Non-Hispanic White
- Non-Hispanic Black
- Non-Hispanic Other

Age at delivery

- Unknown
- Under 25
- 25-35
- 35 or older
• 5,608 children – over 1,800 with biological samples

• 1,009 fathers – over 400 with biological samples
Interview Data — Women

• Interviews
  – pre-conception, pregnancy, birth visit, and post natal visits

• Some topics covered:
  – reproductive and pregnancy history
  – medical conditions and history
  – health behaviors
  – mental health
  – occupation
  – hobbies
  – environmental exposures
  – social support
Interview Data — Children

- Interviews
  - Birth visit, 3, 6, 9, 12, 18, 24, 30, 36, and 42 months

- Some topics covered:
  - Infant feeding, crying patterns, and sleep
  - Well baby care, immunizations, medical conditions
  - Child care arrangements
  - Child development
  - Pets and in-home exposures
Assessments

Neuro-psychosocial and cognitive assessments.

- Kaufman Brief Intelligence Test, 2nd Edition (K-BIT2)
- Ages & Stages Questionnaires®, Third Edition (ASQ-3™)
- Brief Infant Toddler Social Emotional Assessment (BITSEA)
- Brief Symptom Inventory (BSI)
- Infant & Toddler Sensory Profile (ITSP)
- Modified Checklist for Autism in Toddlers (M-CHAT)
- Strengths and Weaknesses of Attention-Deficit/Hyperactivity-symptoms and Normal-behaviors (SWAN)
- Major Life Event
Samples Collected
### Sample Inventory — Biological

#### Samples in inventory (number of sampled participants) by sample type and visit

<table>
<thead>
<tr>
<th>Study Event Type and Participant</th>
<th>Pre-Pregnancy</th>
<th>Early Pregnancy</th>
<th>Late Pregnancy</th>
<th>Pregnancy (undefined)</th>
<th>Birth</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
<th>36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woman and Mother</td>
<td>8089 (238)</td>
<td>14038 (385)</td>
<td>35191 (833)</td>
<td>2892 (205)</td>
<td>6373  (342)</td>
<td>863 (495)</td>
<td>3687 (513)</td>
<td>268 (35)</td>
<td>1969 (154)</td>
</tr>
<tr>
<td>Blood</td>
<td>5551 (279)</td>
<td>8995 (478)</td>
<td>20192 (1015)</td>
<td>1448 (109)</td>
<td>8347 (426)</td>
<td>1143 (66)</td>
<td>978 (133)</td>
<td>1188 (149)</td>
<td>8259 (585)</td>
</tr>
<tr>
<td>Urine</td>
<td>750 (251)</td>
<td>874 (343)</td>
<td>1915 (544)</td>
<td>132 (43)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal Swabs</td>
<td>275 (275)</td>
<td>506 (506)</td>
<td>14 (14)</td>
<td>279 (279)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hair</td>
<td>1665 (293)</td>
<td>3303 (477)</td>
<td>254 (44)</td>
<td>149 (75)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nails</td>
<td>57 (29)</td>
<td>1665 (293)</td>
<td>3303 (477)</td>
<td>254 (44)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saliva</td>
<td>3186 (424)</td>
<td>774 (373)</td>
<td>49153 (918)</td>
<td>4152 (273)</td>
<td>509 (25)</td>
<td>454 (451)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Fewer than 10 samples available
# Sample Inventory — Environmental

Samples in inventory (number of sample collections) by sample type and visit

<table>
<thead>
<tr>
<th>Study Event Type and Participant</th>
<th>Pre-Pregnancy</th>
<th>Early Pregnancy</th>
<th>Late Pregnancy</th>
<th>Pregnancy (undefined)</th>
<th>Birth</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woman</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>251 (248)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formula - Infant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air</td>
<td>251 (248)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water - Pesticides</td>
<td>147 (62)</td>
<td>307 (135)</td>
<td>42 (19)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water - Pharmaceuticals</td>
<td>268 (73)</td>
<td>501 (139)</td>
<td>58 (18)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dust - Plates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dust - Vacuum</td>
<td>866 (414)</td>
<td>1082 (443)</td>
<td>131 (63)</td>
<td></td>
<td>94 (92)</td>
<td></td>
</tr>
<tr>
<td>Dust - Wipes</td>
<td>275 (274)</td>
<td>10 (*)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Fewer than 10 samples available
Sample Analytic Laboratory Results
Existing laboratory results are stored in several datasets classified into three groups:

**Biological specimens**
- consisting of blood, urine, saliva, breast milk, vaginal swabs
  - Pre-pregnancy, pregnancy, and birth
  - 6-, 12-, and 36-months

**Environmental specimens collected 2009–2010**
- consisting of air, surface dust wipes, and water
  - pre-pregnancy, pregnancy, and 6 months

**Environmental specimens collected 2011–2012**
- consisting of household vacuum bag dust samples
  - pregnancy
Sample Analytic Laboratory Results

- The documentation for each group includes a full description of the collection and storage, laboratory analysis methodology, and data set content.

- These datasets are structured at the result-level and one participant may have multiple results for multiple sample types.

- https://ncsarchive.s-3.net/bioshare/sample_datasets/
The NCS Archive

The NCS Archive is the data and sample repository of the Vanguard Study.

The NCS Archive is comprised of three components:

- **NCS Webpages** – Public Website
- **Registered Website** – Requires creating an account
- **Secure Researcher Portal** – Access available upon approval of a research request
The NCS Archive Overview

- **NCS Webpages** ([https://ncsarchive.s-3.net](https://ncsarchive.s-3.net))

- **Registered Website.** Registered users will be able to:
  - Access exploratory tools, downloadable, restricted-use datasets and supporting documentation, and other documents related to data collection.
  - Access reports generated by the NCS on topics specifically relevant to collecting data on children's health.
  - Communicate with NCS Archive staff.
  - Propose new research projects in which to use NCS data and samples.

- **Secure Researcher Portal**
  - Accessing requires submission of a research plan and other information to ensure that NCS data are protected and used in accordance with the terms of participant consent.
  - Researchers with approved projects will be able to analyze NCS data on secure virtual workstations within a supported Researcher Portal, and have access to operational data files, instrument data files, codebooks, and analyte files.
  - Contains analysis software and a virtual data enclave of detailed participant data.
Helpful Links

- **National Children's Study Archive: Study Description and Guide** contains a detailed summary of the scientific basis and operations of the NCS Vanguard Study —
  https://www.nichd.nih.gov/research/NCS/Documents/NCS_Archive_Study_Description.pdf

- For complete overview on using the NCS Archive refer to **The NCS Archive Quick Guide: Overview** —
NCS Archive Demonstration

Website: https://ncsarchive.s-3.net
Thank You

For more information, please contact:

Linda Andrews
E-mail: NCSarchive@s-3.com
Website: https://ncsarchive.s-3.net