Specifically...

- The National Children’s Study
- NICHD’s Scientific Visioning process
The National Children’s Study
Overall Goal of the NCS

- To improve the health and well-being of children and to identify antecedents of healthy adulthood
  - By examining the multiple effects of environmental influences and biological factors on the health and development of ~100,000 children across the U.S., following them from before birth until age 21 years
Mandated by Children’s Health Act of 2000; largest and most ambitious long-term study of child health and development ever in U.S.

“Environment” as broadly defined: factors such as air, water, soil, dust, noise, diet, social and cultural setting, access to health care, socio-economic status, and learning

A data and biosample resource, not a conventional “study”
### Examples of Exposures and Health Outcomes

<table>
<thead>
<tr>
<th>Exposures</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Environment</td>
<td>Housing quality, neighborhood</td>
</tr>
<tr>
<td>Chemical Exposures</td>
<td>Pesticides, phthalates, heavy metals, BPA</td>
</tr>
<tr>
<td>Biologic Environment</td>
<td>Infectious agents, endotoxins, diet</td>
</tr>
<tr>
<td>Genetics</td>
<td>Interaction between genes and environment</td>
</tr>
<tr>
<td>Psychosocial milieu</td>
<td>Family structure, socio-economic status, parenting style, social networks, exposure to media and violence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Outcomes</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy Outcomes</td>
<td>Preterm, Birth defects</td>
</tr>
<tr>
<td>Neurodevelopment &amp; Behavior</td>
<td>Autism, learning disabilities, schizophrenia, conduct and behavior problems</td>
</tr>
<tr>
<td>Injury</td>
<td>Head trauma, Injuries requiring hospitalizations</td>
</tr>
<tr>
<td>Asthma</td>
<td>Asthma incidence and exacerbation</td>
</tr>
<tr>
<td>Obesity &amp; Physical Development</td>
<td>Obesity, diabetes, altered puberty</td>
</tr>
</tbody>
</table>
Sample Size

- Vanguard Study: ~4,000 children
- Main Study: ~100,000 children
- Of 100,000 children, an estimated:
  - 30,000 will be overweight; 17,000 with obesity
  - 5,000 with learning disorders
  - 5,000 with asthma
  - 1,000 with autism spectrum disorders
  - 320 with childhood cancers
  - 125 with Down syndrome
  - 50 with Fragile X syndrome
NCS Components

- **Major components:**
  - **NCS Vanguard Study:** 21-year pilot phase for methods; started in 2009 with seven centers; added 30 more centers in 2010.
  - **NCS Main Study:** 21-year exposure response phase; runs ~three years behind Vanguard Study; planned start in 2012.
  - **Formative Research:** short-term studies, often methods development, to inform the Vanguard and Main Studies.
Changes in Past Two Years

- Original recruitment and enrollment assumptions proved faulty, so new approaches now being field-tested at Vanguard sites
- Moved from assumption-based to evidence-based planning
- NCS timeline modified, with ~1 year delay (to early 2012) in Main Study implementation
- Later this year, will have recommendations and cost estimates for the Main Study
NCS Projected Timeline

Pilot/Feasibility Study
- 2 Vanguard Centers (Begin Jan. 2009)
- 5 Vanguard Centers (Begin Apr. 2009)

Analyze Pilot Data and Plan

External Scientific Review

Main Study
- Proposed Main Study
- External Review
- Main Study
New Recruitment Strategies

- The original ten Vanguard sites used household-based recruitment
- Three alternate strategies now being field-tested:
  - Enhanced household recruitment
  - Provider-based recruitment
  - Two-stage recruitment
## NCS Recruitment as of April 2011

<table>
<thead>
<tr>
<th>Category</th>
<th>Alternate Recruitment</th>
<th>Initial Household</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locations</td>
<td>30</td>
<td>7</td>
<td>37</td>
</tr>
<tr>
<td>Locations currently in the field</td>
<td>29</td>
<td>7</td>
<td>36</td>
</tr>
<tr>
<td>Recruitment Duration, months</td>
<td>5</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Women Identified for contact</td>
<td>21550</td>
<td>33000</td>
<td>54550</td>
</tr>
<tr>
<td>Women contacted</td>
<td>13800</td>
<td>30000</td>
<td>43800</td>
</tr>
<tr>
<td>Women Eligible</td>
<td>2100</td>
<td>2450</td>
<td>4550</td>
</tr>
<tr>
<td>Women consented</td>
<td>1350</td>
<td>1400</td>
<td>2750</td>
</tr>
<tr>
<td>Babies</td>
<td>100</td>
<td>600</td>
<td>700</td>
</tr>
</tbody>
</table>

(Recruitment numbers rounded to the nearest 50.)
# NCS Budget: History of Congressional Funding

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>$ 69 million</td>
</tr>
<tr>
<td>2008</td>
<td>$ 111</td>
</tr>
<tr>
<td>2009</td>
<td>$ 180</td>
</tr>
<tr>
<td>2010</td>
<td>$ 194</td>
</tr>
<tr>
<td>2011</td>
<td>$ 191</td>
</tr>
<tr>
<td>2012</td>
<td>$ 194 (President’s budget request)</td>
</tr>
</tbody>
</table>
The NICHD Mission is to Ensure...

- That every person is born healthy and wanted
- That women suffer no harmful effects from reproductive processes
- That all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability
- The health, productivity, independence, and well-being of all people through optimal rehabilitation
Why a Scientific Visioning Process

- To identify the most promising scientific opportunities of the next ten years across that mission
- To set an ambitious agenda that inspires the research community to achieve critical scientific goals and meet important public health needs
Goals of the Process

- Give external communities ample opportunity to participate
- Foster cross-collaboration among NICHD, other ICs, and external partners
- Add early-stage investigators and other new stakeholders to the conversation
- Produce a publication worthy of a leading scientific journal
It Is About...

- The future, not the past
- Science, not strategic planning
- What the entire research community might do together, not NICHD-centric
Key Steps

- **Workshops (January-March)**
  - Nine workshops, organized by external scientists

- **White Papers (March-June)**
  - Posted online for public input

- **Large Meeting (June 23-24)**
  - Diverse group of external experts and NIHers refine white papers
Key Steps

- **NICHD Council Review** (September)
  - In-depth discussion of proposed vision

- **NICHD Scientific Vision** (December)
  - Vision published in leading journal and posted online

- **Further Dissemination** (2012)
  - Scientific presentations, newsletters, etc.
Then, Based upon the Science...

- **NICHD Strategic Planning (2011-2012)**
  - NICHD staff and our advisory councils determine how NICHD can best help achieve this Scientific Vision
Workshop Scientific Themes

- Plasticity
- Reproduction
- Development
- Developmental Origins of Health & Disease
- Behavior
- Pregnancy & Pregnancy Outcomes
- Diagnostics & Therapeutics
- Environment
- Cognition
Key Questions for the Workshops

- What should the future look like in key scientific areas? Where should we be in ten years?
- What would we like to look back at in ten years and be proud to have accomplished?
- What science is needed to address critical knowledge gaps and health needs?
And, Also…

- What basic, clinical, and translational research questions must we answer?
- What research tools, methods, or approaches should we develop?
- What are the innovative training and workforce development needs and opportunities particular to this area?
Cross-Cutting Elements

- Analytic and measurement tools and methods
- Animal and computational models
- Bioethics
- Bioinformatics
- Biotechnology/bioengineering, including high-throughput and assistive technologies
- Developmental lens
- Differences/disparities across populations
Cross-Cutting Elements

- Epigenetics
- Functional status
- Global health
- Implementation science and health economics
- Nutrition
- Prevention/personalized medicine
- Stem cells
- Systems biology
- Training and mentoring
A Smattering of Preliminary Thoughts from the Workshops ...  

A very early, partial, pre-pro version of what is to come...
Scientific Data

- Require a data-sharing plan in all relevant applications
- More effective ways to gather data, including those the private sector employs
- Better ways to process, store, and analyze masses of data
- Make data available to the entire scientific community
Conduct of Studies

- Enhance research capacity in low resource settings
- Use of social media and new technologies; e.g., to measure diet or movement
- Studies that can be linked in systematic ways and methods to merge data sets
Conduct of Studies

- Better IRB harmonization across multiple sites
- Methods to reduce bias when RCTs are inappropriate
- A centralized archive of data on interventions and evaluations of them
- Every patient a potential research participant
How We Think

- Replace dichotomies (e.g., healthy/unhealthy; ADHD/non-ADHD; obese/non-obese) with dimensional systems, which have advantages – greater power to detect effects, etc.
- Research that anticipates changing morbidity/mortality
- More orientation toward biological processes, rather than disease
How We Think

- What are the positive impacts of disabilities on individuals, families, and society?
- Getting beyond “SES”: disadvantage, disability, stress (toxic vs. beneficial), adversity
- Need to distinguish between social and scientific definitions of function (frequently used to qualify for economic benefits)
Doing Transdisciplinary Science

- Study sections that deal more effectively with transdisciplinary research
- Funding opportunities that favor/require co-PIs across disciplines
- Group sabbaticals
Transdisciplinary Science: Training

- Train people with expertise in one area and fluency in other area(s)
- Effective training programs across multiple departments and institutions
- Academic recognition for team science, including junior members of the team
Benefit: Community Involvement

May 31, 2011

Society members are encouraged to provide feedback to the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) as it develops a scientific vision to guide the coming decade of research the Institute will support. NICHD has requested the input of the scientific community, and the Society urges its members to provide their perspectives so that endocrinology continues to thrive at NICHD.

White papers have been produced from nine workshops centered on individual scientific themes. The white papers will form the basis of the 10-year vision and are available for comment on the NICHD Vision website. The Society has submitted formal comments in response to four topics with broad relevance to endocrinology: Reproduction, Development, Pregnancy and Pregnancy Outcomes, and Developmental Origins of Health and Disease. The opportunity for public comment ends June 10. Don’t miss this chance to help shape the future of science at NICHD.
For More

- Enter “nichd vision” in your search engine
- Or, visit:

www.nichd.nih.gov/vision
Thoughts and Questions?