

A SCIENTIFIC VISION FOR THE NEXT TEN YEARS: THE PROCESS



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September 22, 2011



What's Ahead



- Before lunch: the Process
 - Review of why and how we got to where we are and where we go from here
- After lunch: the Science
 - What has the process produced
 - A chance for Council to weigh in and help perfect the product

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

NICHD Scientific Visioning: Purpose



- To identify the most promising scientific opportunities of the next **ten years across NICHD's mission**
- To set an ambitious agenda that inspires the NICHD, its partners, and the research community to achieve critical scientific goals and improve health

NICHD Scientific Visioning: Goals



- **Involve the NICHD's external communities**
- Foster communication and collaboration
- Add early-stage investigators and other new stakeholders to the conversation
- Produce a publication worthy of a leading scientific journal
- Catalyze creative and ambitious thinking and discussions

NICHD Scientific Visioning: Approach



The Vision is about:

- Scientific opportunity, not organizational issues or funding mechanisms
- The future, not the past
- Ways that NICHD and its partners, not NICHD alone, can advance science and health



NICHD Scientific Visioning: Key Steps



- Workshops (January-March)
 - Nine workshops, organized by external scientists
 - Input from participants of diverse backgrounds
- White Papers (February-May)
 - Drafted by workshop co-chairs
 - Posted online for public input
- Large Meeting (June)
 - Diverse group of external experts and NIH leaders refined ideas for draft vision statement

NICHD Scientific Visioning: Key Steps



- Draft Vision Statement (July-August)
 - Informed by meetings, white papers, comments
- NICHD Council Review **(Today)**
 - In-depth discussion to inform final revisions
- NICHD Scientific Vision (~December)
 - Published in leading journal and posted online
- Further Dissemination (2012)
 - Via 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



A Few Observations About the Process



- Helpful both at intensifying involvement with NICHD of many of our old friends and involving some new ones

NICHD Scientific Visioning: Involvement



Many people, from a wide range of disciplines and professional backgrounds, have taken part:

- **~1,670** people nominated to participate in at least one of the ten Vision meetings
- **~700** people attended Vision meetings, from **39** states and **6** foreign countries
- Attendees represented a total of **229** institutions and organizations

Benefit: Community Involvement



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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 <http://www.endo-society.org/advocacy/legislative/letters/index.cfm>.

The nine themes are:

- Reproduction
- Plasticity
- Development
- Cognition
- Behavior
- Pregnancy and Pregnancy Outcomes
- Developmental Origins of Health and Disease
- Environment
- Diagnostics and Therapeutics

The opportunity for public comment ends June 10. Don't miss this chance to help shape the future of science at NICHD.

Scientific Visioning: Public Comments

- NICHD received **>200** comments in response to Vision documents, from many individuals and organizations, including:



Population Association of America



A Few Observations About the Process



- Qualitative data from exit polling...

[Video link](#)

A Few Observations About the Process



- Helpful both at intensifying involvement with NICHD of many of our old friends and involving some new ones
- Helpful at introducing our communities **(including NICHD staff) to NICHD's new director**, and vice versa
- I think it energized much of our staff and many members of our community
- It also created some anxieties

A Few Observations About the Product



- Granularity varies
- Some overlap of areas and ideas
- Many will take >10 years, but we should be able to make important starts in that period
- In the end, we want to advance the science, but cultural change is an important part of accomplishing that, and the scientific visioning process was a good start at that...

A Review of the Key Questions



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?

Evolution of Scientific Theme Areas

Original 9 areas:

- Behavior
- Cognition
- Developmental biology
- Developmental origins of health & disease
- Diagnostics/therapeutics
- Environment
- Plasticity
- Pregnancy & pregnancy outcomes
- Reproduction



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

Evolution of Scientific Theme Areas

From:

- Behavior
- Cognition
- Developmental biology
- Developmental origins of health & disease
- Diagnostics/therapeutics
- Environment
- Plasticity
- Pregnancy & pregnancy outcomes
- Reproduction



Evolution of Scientific Theme Areas

Via:

- Behavior
- Cognition
- Developmental biology
- Developmental origins of health & disease
- Diagnostics/therapeutics
- Environment
- Plasticity
- Pregnancy & pregnancy outcomes
- Reproduction
- Transdisciplinary Science & Career Development



To: Final Scientific Theme Areas



- Reproduction
- Pregnancy
- Developmental Biology
- Early Origins of Health, Disease, Growth, and Development
- Behavior and Cognition
- Plasticity and Rehabilitation
- Population Dynamics
- The Conduct of Science

Some Specific Disorders of NICHD Interest...



Rett syndrome Microsomia HIV/AIDS Krabbe disease Dyslexia Retinopathy of prematurity
Postpartum hemorrhage Asthma Down syndrome
21-hydroxylase deficiency Attention deficit disorders Leiomyomas Macrosomia
Batten disease Cystic fibrosis Hypoxic-ischemic encephalopathy Prader-Wili syndrome
Angelman syndrome Spinal muscular atrophy Hyperbilirubinemia
Ehrler-Danlos syndrome Cerebral palsy Diabetes Vulvodynia Turner syndrome
Cerebellar ataxia Metabolic syndrome Fetal alcohol syndrome Smith-Lemli-Opitz syndrome
Obstetric fistula Carney-Stratakis syndrome Niemann-Pick disease Menkes disease
Stroke Neural tube defects Goltz syndrome Invasive candidiasis Turner syndrome Incontinence
Idiopathic congenital heart disease Urea cycle disorders Cytomegalovirus Urea cycle disorders
Postpartum hemorrhage Bilateral adrenocortical hyperplasias Necrotizing enterocolitis
Placental abruption Congenital diaphragmatic hernia Infantile neuronal ceroid lipofuscinosis
Invasive candidiasis Osteoporosis Cornelia de Lange syndrome Osteogenesis imperfecta
Intrauterine growth restriction Congenital hydrocephalus
Sudden infant death syndrome Ectopic pregnancy Galactosemia Uterine rupture
Bronchopulmonary dysplasia Respiratory distress syndrome Congenital adrenal hyperplasia
Primary pigmented nodular adrenocortical disease Parkinson's disease Endometriosis
Polycystic ovary syndrome WAGR syndrome Freidreich's ataxia Primary ovarian insufficiency
Spinal cord injury Fragile X syndrome Cushing syndrome Sleep disorders Infertility Kallman syndrome
Phenylketonuria Pelvic floor disorders Human hereditary folate malabsorption syndrome
Prolapse Muscular dystrophies Pompe disease Primary ovarian insufficiency Traumatic brain injury Preeclampsia

A Final Thought



“Make no little plans; they have no magic to stir men’s [and women’s] blood and probably will themselves not be realized. Make big plans; aim high in hope and work, remembering that a noble, logical diagram once **recorded will not die...**” - Daniel H. Burnham



The Process Does NOT End Today



- We want the conversations with staff, Council, and our many communities of researchers and advocates to continue as **long as the scientific opportunities do...**
- **And so to lunch...**

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What's Ahead



- Before lunch: the Process
- After lunch: the Science
 - Organized into 8 areas (3 to 14 slides each)
 - **“Bold ideas” included at end of each of area**
 - Will present each area separately for Council input and discussion
 - **Will also ask you: “What have we missed?”**
 - **If time allows, we will revisit all of the “bold ideas” as a group at the end**

Reminder: Scientific Theme Areas



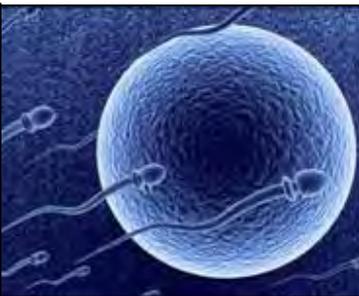
- Reproduction
- Pregnancy
- Developmental Biology
- Early Origins of Health, Disease, Growth, and Development
- Behavior and Cognition
- Plasticity and Rehabilitation
- Population Dynamics
- The Conduct of Science

Remember...



- This is just the draft, we want Council's input...
- This is not about what NICHD per se should do, but about identifying the scientific opportunities of the next decade that the entire research community should tackle

REPRODUCTION



1. Basic Biology of Mammalian Germline



- Delineate problems of gametogenesis, preimplantation, implantation
- Link to fundamental questions of early lineage specification in mammalian development
- Make greater use of genetically tractable model organisms

2. Infertility/Subfecundity



- Conduct molecular genetic, genomic, and epidemiological studies to discern and define heritable and non-heritable components
- Understand the mechanisms by which chronic conditions, disabilities, and reproductive tract disorders play roles
- Use animal models to compare long-term health and development of individuals conceived via assisted reproductive technologies (ART) with individuals conceived via unassisted conception

3. Contraception



- Identify novel molecular targets to develop new contraceptive methods, specifically including
 - Male contraceptives
 - Contraceptive agents targeted to different phases of the life cycle
- Use implementation science to improve understanding of contraceptive behavior, e.g., what factors influence use of agents, safe sex practices, male and female interactions, and relevant cultural factors

4. Reproductive Health & Life Transitions



- Understand the biology, special vulnerabilities, and life implications of reproductive transitions, e.g., puberty, menopause, and andropause
- Develop reproductive normative data for periods of life transitions, e.g., adolescence
- De-stigmatize typical reproductive processes and life transitions

Bold Ideas



- Develop means to characterize both female and male single germline cells at specific stages of development
- Understand how microbial flora change in periods of reproductive transition, and the health effects of these changes

PREGNANCY



1a. Fetal Development



- To improve understanding of normal and abnormal placental function, develop new:
 - Hemodynamic measurement techniques
 - Imaging technologies
 - Diagnostics for placental disease
- Develop biomarkers of early adverse pregnancy outcomes
- Develop a molecular anatomy and epigenetic map/atlas of human development from gamete through birth

1b. Fetal Development



- Identify the roles of regulators (such as progesterone) in early fetal development, placental function, and parturition
- Determine the importance of commensal microbiota, immunity, and infectious diseases in fetal development and define the mechanisms underlying these effects
- Determine standards for maternal circulating cytokines, markers, etc.

2. Fetal Health



- **Leverage the National Children's Study and other** international databases, biorepositories, and observational cohorts, to understand implications of events in pregnancy
- Better define the biology of intrauterine growth
- Develop and validate diagnostic/imaging tools to assess maternal and fetal well being, e.g., fetal magnetic resonance
- Develop approaches and protocols for more effective management of multiple gestations
- Improve outcomes of preterm births by understanding late fetal brain development and how to replicate it in the extrauterine environment

3a. Prevention of Preterm Birth and Stillbirth



- Delineate gene-environment and epigenetic factors in preterm birth and stillbirth
- Determine mechanisms by which biological, behavioral, and social risk factors lead to preterm labor and stillbirth
- Develop and evaluate new models of preterm birth and stillbirth prediction and risk assessment

3b. Prevention of Preterm Birth and Stillbirth



- Conduct randomized controlled trials of interventions to prevent preterm birth and stillbirth
- Identify patient and health professional factors that lead to decisions that increase risk of preterm birth
- Use new technologies for data gathering and education to decrease preterm birth and stillbirth

4a. Pregnancy and Women's Health



- Explore pregnancy as a marker for later disease; e.g., metabolic syndrome of pregnancy as a cardiometabolic risk indicator; preeclampsia as indicator of risk for later stroke, hypertension, cardiovascular disease
- Explore pregnancy and pregnancy complications as causes of later disease and develop interventions in pregnancy to lessen these effects

4b. Pregnancy and Women's Health



- Delineate the effects of pregnancy on women with chronic medical conditions and/or disabilities
- **Understand the consequences for women's** health and well-being of number of pregnancies, multiple births, Cesarean sections, and pregnancy loss

5. Drugs and Therapeutics



- Evaluate interactions in pregnancy and lactation of therapeutics with drugs of abuse, chronic illness, and environmental toxin exposures
- Evaluate drug safety in pregnancy and lactation
- New tools for drug development
 - Develop safe harbor research and encourage animal/non-human primate preclinical studies
 - Develop screening tools for drug libraries pertaining to pregnancy
 - Longitudinal database and atlas of adverse drug effects in pregnancy and lactation

6. Management and Care



- Delineate the effects of micronutrients on pregnancy and pregnancy outcome
- Evaluate the impacts - on both woman and child - of various models of pregnancy care and delivery

7. Repositories and Databases



- Create placental, blood, and other national tissue banks of normal and abnormal pregnancies, to gain understanding of preterm birth and other morbidities
- Develop a map/atlas of human development
 - Develop linked maternal and infant databases and longitudinal cohorts to understand health outcomes and decrease health disparities
 - Develop standardized phenotype measures for pregnancy and pregnancy outcomes
 - Make datasets available to all investigators/public

Bold Ideas I



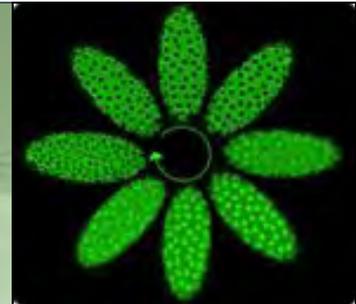
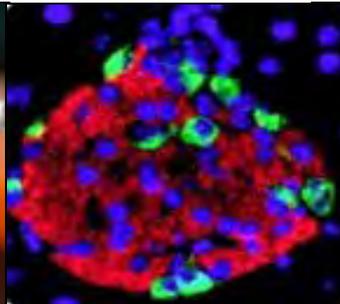
- Create a comprehensive 4D atlas of in utero development: cellular resolution; gene expression; epigenetic information
- Develop tools for real-time, non-invasive assessments of placental function throughout pregnancy
- Create an atlas of placental physiology and pathophysiology linked to phenotypes

Bold Ideas II



- Delineate all the causes - environmental, sociocultural, genetic - of preterm birth and of stillbirth
- Develop the use of personalized medicine to guide maternal and fetal care in pregnancy
- Demonstrate and communicate effectively the economic and societal benefits of healthy pregnancy and birth

DEVELOPMENTAL BIOLOGY



1. Mechanisms across the Life Span that Affect Development



- Develop virtual tool sets for integrative biology
- Use humans and model organisms to understand genomic, epigenomic, and environmental variability
 - Develop typical and atypical model systems
 - Understand conserved and divergent mechanisms
 - Examine gender specificity and variability
 - Define diurnal/seasonal effects
 - Delineate environmental (e.g., teratogens, radiation) interactions with the genome
 - Understand macro- and micro-nutritional and metabolomic influences
 - Study population-specific effects

2. Use the Human Model System to Inform Developmental Biology



- Engage unique populations (e.g., isolated populations) as model systems
- Perform quantitative phenotyping (magnetic resonance imaging, MR spectroscopy, near-infrared spectroscopy, and other modalities)
- Focus on physiological changes that occur in critical periods of human development

3. Employ Regenerative Medicine and Reprogramming of Stem Cells



- Develop novel *in vitro* and *in vivo* methodologies to study early human development
- Determine contributory roles of intrinsic (genetic) and extrinsic (environmental) influences on cell and tissue biology
- Understand cues for germ cell differentiation and sustenance

Bold Ideas



- Develop a complete genetic map of common and rare structural and functional birth defects
- Create sexually dimorphic atlases of molecular anatomy over the life course
- Translate linear genomic data into four-dimensional information
- Develop a complete library of organ- and tissue-specific information for every pluripotent cell

EARLY ORIGINS OF HEALTH, DISEASE, GROWTH, AND DEVELOPMENT



1. From Associations to Mechanisms



- Identify mechanisms in the pre- and peri-conception, fetal, and childhood periods that lead to the most pressing child and adult health concerns, such as obesity, cancer, diabetes, cardiovascular disease, asthma, and neurobehavioral disorders
 - Focus on critical windows of vulnerability, specific exposures, and evolving phenotypes
 - Make creative use of basic science tools to model the human experience in vitro

2. Unique Biologic Opportunities and Exposures



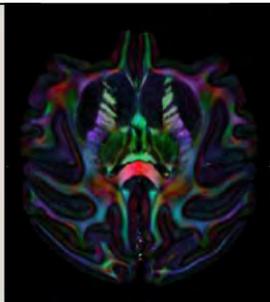
- Engage specific populations representing unique biologic opportunities and exposures, such as:
 - Preterm infants
 - Offspring of women with specific profiles, such as mothers: with diabetes mellitus, cardiovascular disease, preeclampsia, or HIV; who employed assistive reproductive technologies; at both ends of the reproductive age spectrum; or who used specific dietary interventions
 - Children of parents with depression, mental illness, social stressors
 - Children from endogamous populations with greater genetic homogeneity
 - Children who are uniquely resilient or particularly vulnerable

Bold Ideas



- Exploit the placenta as a record of intrauterine gene-environment interactions
- Define the mechanisms of multi-generational effects on health, growth, and development

BEHAVIOR AND COGNITION



1a. Behavior



- Delineate how genetic factors interact with environmental factors to influence behavior
- Detail how the epigenome and gene expression change in response to behavior-changing events
- Develop robust biomarkers (e.g., DNA, proteins, metabolites) of later behavior
- Identify/develop better animal models of human behavior
- Identify the effects of new technologies on child and adolescent behavior

1b. Behavior



- Understand the effects of interventions in critical periods of development; e.g., the influence on later behaviors of use of neonatal incubators or of incarceration of adolescents
- Determine how interventions (e.g., atypical antipsychotics, methylphenidate) change neuronal structure and function
- Identify predictors of resiliency, in both individuals and communities
- Better integrate behavioral research into the work of other disciplines

2. Cognition



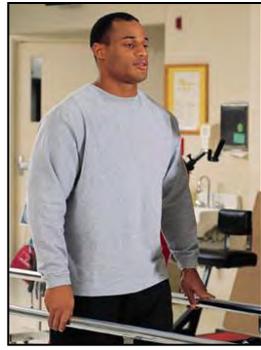
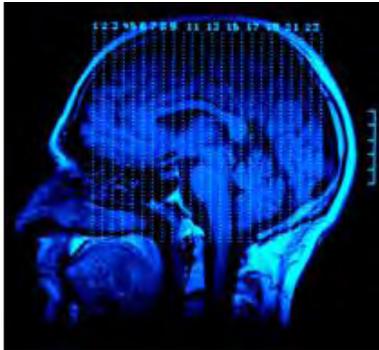
- Elucidate mechanisms of cognition at the molecular, cellular, and brain systems levels
- Ascertain the mechanisms underlying the development of learning and cognitive disorders
- Characterize normal cognitive trajectories across the lifespan
 - Determine how new technologies affect cognition and could be used as therapeutic interventions
 - Identify sex differences, if any, in cognition and delineate the mechanisms underlying them

Bold Ideas



- Fully understand the neurobiological basis for five behavioral or cognitive disorders
- Identify 5,000 genetic variants that influence specific behaviors or cognitive traits
- Identify the causes of autism spectrum disorders, and use that knowledge to develop effective interventions
- Explore the value to the individual, family, and society of differing abilities

PLASTICITY AND REHABILITATION



1. Mechanisms of Plasticity



- Identify mechanisms of plasticity by:
 - Using comparative biology and non-traditional model organisms
 - Studying distinct human populations
 - Exploring individual and tissue-specific differences in plasticity
 - Defining the critical and sensitive periods that determine the extent of plasticity

2. Developmental Plasticity and Reprogramming



Explore the roles of:

- Tissue- and organ-specific repair, healing, and recovery across the lifespan
 - Sex and endocrine effects
 - Genetic and epigenetic mechanisms
 - The role of the immune system
- Transdifferentiation and de-differentiation
- Induced plasticity

3. Influence of the Environment on Plasticity



- Determine the role and impact of nutrition, toxic agents (exposome), and social elements
- Identify and learn how to manipulate environmental factors that alter plasticity

Bold Ideas



- Identify distinct biological processes that translate the exposome to neuroplasticity and biomarkers of these processes
- Develop effective and inexpensive upper and lower extremity prostheses that can be manufactured and used in the developing world
- Determine the magnitude of risk and long-term impact of the full range of concussive injuries and design effective preventive, protective, and treatment measures for them

POPULATION DYNAMICS



1. The Modern Family



- Understand the implications for the life and health of the mother, father, child, family, and society of such factors as:
 - Extremes in maternal and paternal age
 - Family formation and structure
 - Urbanization
 - Migration
 - New technologies
 - Changing societal demographics

2. Special Populations



- Explore populations with distinctive genetic backgrounds
- Explore populations with distinctive environmental experiences

Bold Ideas



- Develop more effective health care, housing, employment, and social options that plan for the increasing longevity of those with intellectual, developmental, and/or physical differences

THE CONDUCT OF SCIENCE



1. Compelling Science



- **NICHD's areas of research have witnessed historic accomplishments over many decades**
- In recent years, however, some areas have not taken full advantage of dramatic advances in biomedical science
- We now have great opportunities to accelerate progress in our mission areas and to foster collaboration across our many scientific and public communities
- Our science must be so compelling as to attract the best and brightest researchers

2. Transdisciplinary Science



- Standardize ontology, nomenclature, and data standards across disciplines
- Use transdisciplinary “**incubators**” to **identify scientific opportunities**
- Adopt IT-based strategies to link researchers in different disciplines
- Publish and publicize success stories and **dos and don'ts for** transdisciplinary research
- Expand open access data sets and analysis methods
- Improve reward and de-risk transdisciplinary research at commitment, execution, and career impact stages

3. Culture of Science



- Incorporate qualitative and quantitative assessment of quality of life (specifically including sexual and reproductive function) in a wider range of biomedical studies
- Reevaluate existing diagnostic tools with an evidenced based approach
- Develop social networking approaches for collaborative research efforts
- Involve tech-savvy individuals in brainstorming about use of information technology to advance science

4. Data Acquisition



- Conduct longitudinal analyses of anticipated healthy subjects and at-risk cohorts to correlate markers of health to specific exposures and both to later health, including:
 - Leverage existing data sets; also, re-examine them to include additional outcomes
 - Link fetal and early childhood phenotypes back to paternal/maternal exposures and genetic factors, and forward to phenotypes evolving across the lifespan
- Develop toolkits and multidisciplinary rapid-response teams to allow researchers to collect exposure and outcome **data in the event of “natural experiments”**
- Exploit technologies developed in other fields (e.g., global information systems) to measure environmental exposures

5. Biorepositories



- Develop broad, diverse repositories with expanded sample types and careful phenotyping, starting in pregnancy, including healthy individuals
- Identify/create biological tissue repositories for studying bio-accumulating compounds with long half-lives
- Appropriately utilize available long-standing newborn screening samples in research

6a. Data Analysis and Sharing



- Decrease barriers to accessing data from prior studies
- Develop population and data-based methodologies applicable to specialized populations and to diverse populations
- Create epidemiologic tools to evaluate connections of genetics, biology, and environmental exposures (toxins); e.g., gestome and exposome

6b. Data Analysis and Sharing



- Focus on bioinformatics and computational biology
 - Develop user-friendly, integrative tools
 - Make information across multiple disciplines and biological scales easily and widely available
 - Create and employ technologies for information storage and dissemination
 - Develop multi-institution bioinformatics cores

7. Other Tools



- Further develop molecular imaging, microscopy, biosensors, biomanipulators, nucleic acid sequencing
- **Make widely available “-omic” (genome, epigenome, transcriptome, metabolome, microbiome, exposome, etc.) libraries that go across the lifecycle**
- Use mathematical modeling to predict life-course changes
- Develop and use broader range of model organisms

8. Clinical Trials



- Consolidate currently available information from clinical trials and make it easily accessible to researchers, clinicians, and the public
- Identify clinical strategies for low-resource settings
- Fully analyze existing and preclinical research before entering into clinical trials

9. Implementation Science



- Incorporate analyses of economic impacts on health care in implementation science
- Evaluate why interventions fail
- Promote and develop effective research strategies to translate research into evidence-based health care practices

10. Public Involvement



- Redesign privacy and confidentiality rules and regulations to address the real needs of both participants and researchers, so that research maximally advances the public good
- Diffuse more effectively to the entire population that which is already known
- Engage communities in the search/surveillance of emerging exposures

11. Training



- **Increase graduate students' exposure to physiology, pathophysiology, and behavioral sciences**
- **Increase inter-disciplinary fluency, specifically including in biocomputation**

12. Workforce



- Build global infrastructure of mentored partnerships to increase research capacity
- Utilize research on diseases affecting underrepresented communities to help recruit and retain a more diverse biomedical workforce
- Recruit and support a diverse workforce across all stages of career development

Bold Ideas



- Develop biorepositories that capture the diversity of the U.S. population
- Utilize research participants as a pool of diverse individuals from which to recruit future scientists
- Make our areas of science so compelling that they attract the best and brightest researchers