

Collaborative Opportunities Between the CTSA Program and NICHD

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Presentation Outline

- Overview of NICHD
- Clinical Research and the NICHD
- Multidisciplinary Networks and Consortia supported by NICHD as Opportunities for CTSA Involvement
- Value of Partnerships and Collaborative Activities

NICHD- Snapshot

- Established in 1962
- The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.

NICHD-Snapshot

- Four centers plus intramural program
- Overall budget of about \$1.26 B of which about 90% is for extramural funding

Center for Population Research (CPR)

- **The CPR is the federal government's focal point for population research. Through grants and contracts, the Center supports: fundamental biomedical research on reproductive processes that influence human fertility and infertility; development of better methods for regulating fertility and for preventing the spread of sexually transmitted diseases, including HIV; evaluation of the safety and effectiveness of contraceptive methods now in use; and behavioral and social science research on the reproductive behavior of individuals, sexual transmission of HIV, and the causes and consequences of population change.**
- **The Center also supports an extensive training program for individuals interested in all aspects of reproduction and population research through its 3 branches:**
 - **Contraception and Reproductive Health Branch**
 - **Demographic and Behavioral Sciences Branch**
 - **Reproductive Sciences Branch**

Center for Developmental Biology and Perinatal Medicine (CDBPM)

- The CDBPM provides support for basic, clinical, and applied research and research training in maternal, fetal, and infant health, and disorders of human development. The Center seeks to advance fundamental and clinical knowledge about maternal health and problems of child development, such as preterm birth, intellectual and developmental disabilities, congenital and genetic disorders, fetal and infant morbidity and mortality (including fetal growth restriction, stillbirth, SIDS, fetal therapy, and disorders of the high risk neonate), and other conditions. The Center achieves its mission through the efforts of 3 branches:
 - Developmental Biology, Genetics, and Teratology Branch
 - Intellectual and Developmental Disabilities Branch
 - Pregnancy and Perinatology Branch

Center for Research for Mothers and Children (CRMC)

- The CRMC is a major source of research and research training in child health and in the health of mothers. The Center and its programs focus on maximizing growth and development, preventing transmission of HIV/AIDS in various populations, and improving knowledge about children's behavior and behavioral outcomes. Areas of emphasis include, but are not limited to: behavioral, social, and emotional adaptation from infancy through adolescence and early adulthood; learning disabilities; nutrition; endocrine disorders and growth retardation; and pre-conceptional, prenatal, and postnatal infectious diseases and HIV/AIDS. The Center achieves its mission through the efforts of its branches:
 - Endocrinology, Nutrition, and Growth Branch
 - Child Development and Behavior Branch
 - Pediatric, Adolescent, and Maternal AIDS Branch
 - Obstetric and Pediatric Pharmacology Branch



National Center for Medical Rehabilitation Research (NCMRR)

- The NCMRR funds research training and projects to develop the scientific knowledge needed to promote the health, productivity, independence, and quality of life for people with disabilities. A primary goal of the Center is to bring the health-related problems of people with disabilities to the attention of the nation's best scientists, to capitalize upon the myriad advances occurring in the biological, behavioral, and engineering sciences. The NCMRR supports a number of research programs:
 - Behavioral Sciences and Rehabilitation Engineering Technology Program
 - Biological Sciences and Career Development Program
 - Pediatric Critical Care and Rehabilitation Program
 - Traumatic Brain Injury and Stroke Rehabilitation Program
 - Spinal Cord and Musculoskeletal Disorders and Assistive Technology Program

Scope of Investment

- NICHD funds annually about 2000 clinical research projects with about 1700 Principal Investigators at about 500 institutions in 27 countries with a budget of about \$ 650 million
- The total annual NIH budget for pediatric research is about \$ 3 billion
- The National Children's Study has a separate budget that is administered through the NIH Director's Office

NICHD Multi-Institution Support

- NICHD either totally or partially supports about 60 clinical research consortia or networks annually
- Operationally a consortium is multiple sites that receive support to conduct research on different aspects of a common topic or theme, share information and coordinate projects
- Operationally a network is like a consortium with the additional dimension of sharing common multi-site protocols

Multi-Institution Projects

- Currently about 60 % of the NICHD supported multi site projects are formal networks with shared protocols and about 40% are consortia working on a common theme
- Most programs are on a 5 year cycle with the constituent institutions competitively reviewed every cycle, leading to a dynamic population
- Entire programs are periodically evaluated with an ever evolving portfolio based on public health needs, scientific opportunities, available resources and other factors

Examples of NICHD Extramurally Supported Clinical Research Networks

Adolescent Literacy Research Network

Adolescent Medicine Trials Network (ATN) for HIV/AIDS Interventions

Adult Literacy Research Network

Birth Defects Initiative and Research Network

Child Health Research Centers

Collaborative Pediatric Critical Care Research Network (CPCCRN)

Community Child Health Research Network (CCHN)

Contraceptive Clinical Trials Network (CCTN)

Cooperative Research Program on Male Fertility Regulation

Diabetes Research in Children Network (DirecNet)

Domestic and International Pediatric/Perinatal HIV Clinical Studies Network

Fragile X Syndrome Research Centers (FXRSC)

Genomic and Proteomic Network on Premature Birth Research

Global Network for Women's and Children's Health Research

Intellectual and Developmental Disabilities Research Centers (IDDRCs)

Examples of NICHD Extramurally Supported Clinical Research Networks

International Epidemiologic Database to Evaluate AIDS (IeDEA)

International Maternal-Pediatric-Adolescent AIDS Clinical Trials (IMPAACT)

Group

Learning Disabilities Research Centers

Maternal-Fetal Medicine Units Network

Maternal-Fetal Surgery Network

Mathematical Cognition and Math Disability Network

Medical Rehabilitation Research Infrastructure Network

Microbicide Trials Network (MTN)

National Children's Study

National Cooperative Program on Female Health and Egg Quality

Neonatal Research Network

NIAID/NICHD Primary Immunodeficiency Research Consortium

NIH-DC Initiative to Reduce Infant Mortality in Minority Populations

Obstetric-Fetal Pharmacology Research Unit (OPRU) Network

Pediatric HIV/AIDS Cohort Study (PHACS)

Pediatric Pharmacology Research Unit (PPRU) Network

Pediatric Research in the Office Setting (PROS)

Examples of NICHD Extramurally Supported Clinical Research Networks

Pelvic Floor Disorders Network

Prenatal Alcohol and SIDS and Stillbirth (PASS) Network

Reproductive Medicine Network (RMN)

Rare Disease Collaborative Research Centers

Specialized Centers of Research (SCOR): Sex and Gender Issues affecting Women's Health

Specialized Cooperative Centers Program in Reproduction and Infertility Research (SCCPIR)

Stillbirth Collaborative Research Network

Study of Early Child Care and Youth Development (SECCYD)

Traumatic Brain Injury (TBI) Clinical Trials Network

Trial to Reduce the Incidence of Type 1 Diabetes for those Genetically at Risk (TRIGR)

Urinary Incontinence Treatment Network (UITN)

Women Interagency HIV Study (WIHS)

Women and Infants Transmission Study (WITS)

Work, Family, Health, and Well-Being Initiative

Program Details and Listings

- Additional information is listed on the Clinical Research section of the NICHD public web page

<http://www.nichd.nih.gov/health/clinicalresearch/NICHD.cfm>

- NIH Wide Inventory of Clinical Research Networks

<https://www.clinicalresearchnetworks.org/>

Partnerships

- **NICHD clinical research programs can be productive partnerships on many levels**
- **Examples include partnerships with**
 - **NIH institutes (diabetes etiology and treatment, HIV infection, rare diseases, immunodeficiencies and other programs)**
 - **National Cancer Institute for pediatric specific terminology and research informatics**
 - **Food and Drug Administration for identification of therapeutic needs and product labeling**
 - **Gates Foundation for tropical diseases and nutrition**
 - **Robert Wood Johnson Foundation for childhood obesity**
 - **Foundation for the National Institutes of Health and the Biomarker Consortium for identification of opportunities for biomarker development**
 - **District of Columbia for epidemiology of infant mortality**
 - **Government of India for clinical research and biotechnology development**

Best Pharmaceuticals for Children Act and Pediatric Device Development

- NICHD is the NIH lead for coordinating and advancing the Best Pharmaceuticals for Children Act (BPCA) and medical device development for children
- Interagency activities between Agency for Healthcare Research and Quality (AHRQ), FDA, and NIH

Other NICHD Collaborative Activities

- **Genome Wide Association Studies policy development (NIH)**
- **Trans NIH Biomedical Informatics Committee (NLM and other ICs)**
- **Trans NIH Information Technology Standards Subcommittee (NLM and other ICs)**
- **Trans NIH Data Sharing Workgroup**
- **Clinicaltrials.gov (NLM and others)**
- **Neonatal examination terminology project (NCI and others)**
- **Newborn Screening Data Harmonization (DHHS and others)**
- **Bridging research standards and health care delivery standards (DHHS and others)**
- **Methods of integrated analysis for pediatric research (FDA and others)**
- **Clinical Data Acquisition Standards Harmonization Collaborative Group (NIH, FDA and others)**

NICHD Collaborations Seek to:

- Build partnerships to enhance and advance scientific discovery and clinical research
- Consolidate and harmonize infrastructure to facilitate clinical research
- Build trust in the medical research enterprise