DEPARTMENT OF HEALTH AND HUMAN SERVICES

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2016-2018 TRIENNIAL ADVISORY COUNCIL REPORT

CERTIFYING COMPLIANCE WITH THE

NIH POLICY ON INCLUSION GUIDELINES

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I. Background/Overview

Mission Statement

The NICHD was established by President John F. Kennedy, with the support of Congress, in 1962 to study the "complex process of human development from conception to old age." 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.

Description of NICHD Portfolio

The NICHD was established as the first NIH institute to focus on the entire life process rather than a specific disease or body system. In pursuit of its broad mission, the NICHD conducts and supports initiatives and projects that study physical and intellectual developmental disabilities, fertility, pregnancy, and childhood diseases; supports laboratory research, clinical trials, and epidemiological studies that explore health processes; examines the impact of disabilities, diseases, and variations on the lives of individuals; and sponsors training programs for scientists, health care providers, and researchers to ensure that NICHD research can continue. Some notable examples include:

- **Understanding Zika Virus.** The emergence of Zika virus has led to a surge in cases of microcephaly and other severe birth defects. The virus spreads primarily through the bite of an infected *Aedes aegypti* mosquito, but it also can be transmitted through sexual contact with an infected person and from a woman to her fetus during pregnancy. NICHD supports research priorities to understand how Zika virus infection affects reproduction, pregnancy, and the developing fetus. NICHD will leverage existing collaborations in Zika-endemic areas to plan observational studies of pregnant women.

- **Leading Research on Women's Health.** Women experience unique health issues and conditions, from pregnancy and menopause to gynecological conditions, such as endometriosis, polycystic ovary syndrome (PCOS), and urinary incontinency. NICHD-supported researchers have linked endometriosis to an increased risk for heart disease. Other researchers supported by NICHD reported that some women with PCOS might have an adrenal gland disorder that contributes to the hormonal imbalance. Treatment options for urgency urinary incontinence were identified by examining 6-month outcomes of a clinical trial that evaluated treatment with botulinum toxin or a sort of "pacemaker" that send electrical signals to control the bladder.

- **Studying Infertility and Pregnancy Loss.** Millions of people in the United States have experienced fertility problems. NICHD-supported researchers have identified a cellular switch that boosts the activity of sperm cells. The findings may lead to new options for male contraception, as well as treatments for infertility caused by problems with sperm mobility. NICHD also conducted research on fertility and body composition. Research on miscarriage included a study on the effects of daily low-dose of aspirin and behaviors linked to miscarriage risk.

- **Promoting Healthy Pregnancies.** A healthy pregnancy optimizes future health outcomes for both mom and baby. Unfortunately, more than 600 women die each year in the United States as a result of pregnancy or delivery complications, such as preeclampsia, maternal hemorrhage, and post-operative infections. NICHD-funded researchers estimated that the maternal mortality rate in 48 U.S. states and Washington, DC, had increased by more than 26 percent, from approximately 19 deaths per 100,000 live births in 2000 to nearly 24 deaths per 100,000 live births in 2014. To address this troubling trend, NICHD-supported studies have explored ways to prevent post-operative infections and study effects of healthy behaviors before and during pregnancy for promoting healthy outcomes.

- **Improving the Health of Infants.** Preterm birth, defined as birth before 37 weeks of pregnancy, is a leading cause of infant death and long-term disability. Steroids are a standard treatment for women likely to deliver before 34 weeks of pregnancy because these drugs can reduce respiratory and other complications. However, late preterm infants who are born between 34 and 36 weeks also have a risk of respiratory complications, but there is no standard treatment for them.

- **Preventing HIV Transmission.** Nearly 37 million people worldwide are living with HIV, including 2 million people who became infected in 2015. Improvements in HIV screening, prevention, and treatments promise to help reduce new cases and increase the quality of life for people with HIV. NICHD supports research to protect against HIV transmission between partners as well as mother-to-child. NICHD also funds research devoted to the health and well-being of U.S. teenagers and young adults with HIV or at risk for HIV infection.

- **Enriching Early Learning.** What children learn in their first few years of life—and how they learn it—can have long-lasting effects on their health and on their later success in school and in work. NICHD supports research that helps low-income mothers interact more effectively with their infants and toddlers, and other research that demonstrates the advantage of exposing infants to more than one language.

- **Understanding and Treating Autism.** Autism spectrum disorder (ASD) is a complex developmental condition that affects how a person behaves, interacts with others, communicates, and learns. Males are affected four times more often than females. Different people experience different symptoms, and the exact causes of autism are unknown. NICHD-supported researchers reported a better way to use magnetic resonance imaging (MRI) to study autism in children. A common symptom of autism is being oversensitive to sensory signals. In May, NICHD-funded researchers who use MRI to study autism identified brain activity patterns, notably during rest, that are linked to this type of hypersensitivity. These findings can help clinicians better understand how the brain overreacts to mild stimuli, possibly leading to therapies for overstimulation among people with autism.

- **Advancing Knowledge of Pediatric Diseases.** Newborn screening programs help identify infants who are at risk for certain diseases, allowing for early intervention and treatments. NICHD-funded researchers reported a faster and cheaper screening test for cystic fibrosis, and a newborn screening test for Niemann-Pick type C. NICHD also supports research that evaluates the safety, dosage, and efficacy of medications in children.

- **Enhancing Rehabilitation Research.** Approximately one in five adults in the United States has a disability. NICHD led the effort to develop and release the NIH Research

Plan on Rehabilitation, which provides a five-year framework for advancing the rehabilitation research field and helping people with disabilities reach their full potential.

- **Combating the Opioid Crisis.** More than 90 people die every day from an opioid overdose in the United States, according to the Centers for Disease Control and Prevention. Opioid prescriptions in the United States have quadrupled since 1999, meaning large numbers of reproductive-age women are at risk of developing opioid use disorder and of giving birth to infants who are opioid-dependent. In response to this crisis, NICHD brought experts together at a workshop to identify research gaps and opportunities to improve outcomes for families. NICHD announced a new study that aims to inform clinical care of newborns experiencing withdrawal. The study is a collaboration between NICHD's Neonatal Research Network, which has more than 30 years of experience designing and implementing clinical studies involving infants, and the Institutional Development Award (IDeA) States Pediatric Clinical Trials Network, part of NIH's Environmental Influences on Child Health Outcomes program. The IDeA network focuses on rural and medically underserved communities, and many of the states within the network are reporting a high incidence of opioid withdrawal syndrome among newborns.

- **Improving Rehabilitation from Injury and Stroke.** Brain injuries can have serious, long-term effects on a person's cognition and health. Some injuries are caused by external forces, such as head trauma, and others are caused by internal problems, such as a stroke. NICHD has supported studies on concussion recovery options, brain imaging techniques, and rehabilitation methods.

- **Developing New Technologies.** NICHD research resulted in several technologies that directly benefits patients, as well as the research community. A newborn screening device was developed with early-stage NICHD funding for the detection of lysosomal storage disorders. From a single blood spot obtained via newborn screening, the device detects four types of lysosomal storage disorders, which injure the brain and nervous system and can affect learning, development, and movement. A calibration device for medical imaging was invented by NICHD researchers to calibrate magnetic resonance imaging (MRI) scanners to perform diffusion MRI methods. Two NICHD-funded rehabilitation technologies received medical device clearance; one gives an amputee greater control and movement of his/her prosthetic limb, uses pattern-recognition technology to strengthen and improve the analysis of electric signals in the remaining muscles; the second technology, a virtual occupational therapy assistant, helps stroke

survivors and others with neurological impairments manage daily tasks. Finally, NICHD-funded researchers reported a new method that uses sound waves to isolate exosomes from blood.

II. Strategies for Ensuring Compliance

Peer Review

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race, and ethnicity. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex/gender, racial, and ethnic groups. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the summary statement. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If concerns are raised in review, program staff contact principal investigators to resolve such concerns prior to funding. Applications with unacceptable inclusion plans receive a bar to funding, an award cannot be made until there is an acceptable resolution.

NICHD's Scientific Review Branch (SRB) is responsible for a broad range of functions related to the review of grant applications for research and training and contract proposals for research. SRB typically reviews applications submitted in response to NICHD Requests for Applications (RFAs), and non-RFA applications in the following activity codes: R03 small research grants, R13 conference grants, K-series career development awards, and T32 institutional training awards. Other grant mechanisms are reviewed by the NIH Center for Scientific Review.

Program Monitoring and Grants Management Oversight

Prior to an award, program officials are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide

consultation when necessary. For NIH-defined Phase III clinical trials, program officials monitor the requirement for sex/gender and race/ethnicity analyses in applications and annual progress reports. Grants management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file.

Intramural

All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural IRBs review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the investigator documents the number, sex/gender, and race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by the pertinent IRB. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data.

Training approaches

NICHD program, review, grants management, and contracts management staff participate in NIH training opportunities relevant to the policies on inclusion; newly hired staff are required to have such training as soon as possible after assuming their position. Training opportunities are available live, via videocast, archived video, or computer-based programs. The NICHD Office of Extramural Policy (OEP) monitors participation and provides information about upcoming training opportunities.

In addition to training opportunities offered by NIH, the institute is involved in continuous training and outreach efforts with staff and the research community. These efforts are developed, overseen, and monitored by OEP, which also serves as a resource for staff and the extramural community. OEP staff also provide individualized one-on-one tutorials on the Human Subjects System for tracking enrollment for active grants.

Most recently, staff attended the May 11, 2018 training, *"Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts."* This training session was video-archived on the NIH staff intranet and available to new staff or for refresher training as needed.

III. Analysis and Interpretation of Data

Overview

The actual implementation of the NIH Inclusion Policy has undergone a number of major changes in recent years, particularly in the area of data collection. The earlier Population Tracking system used to compile enrollment data for the previous report (in 2015) was transitioned into the improved Inclusion Management System, which allowed the grantee to directly input enrollment data into an interactive database. Subsequently, the data collection approach was further refined last year by implementation of the present Human Subjects System, which compiles enrollment data on the basis of individual research projects and thus better facilitates data collection when grants or contracts support multiple projects.

The triennial reports prepared this year by all of the NIH will employ a uniform format following directions from the NIH Office of Extramural Research (OER). Following this approach, aggregate enrollment data are being presented in standardized tables developed by OER to depict overall compliance with the NIH policy. From the data provided by OER, we have selected the following tables for this Triennial Report as those that best depict enrollment data for research projects and clinical trials supported by NICHD. (Please note that we are not able to change either the formatting or the table number.)

Table 2-1	Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018
Table 2-2	Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between FY2016 and FY2018
Table 3-1-A	Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018
Table 3-1-B	Total Enrollment for All NIH-Defined Extramural Clinical Research Between FY2016 and FY2018
Table 3-1-C	Total Enrollment for All NIH-Defined Intramural Clinical Research Between FY2016 and FY2018
Table 5-1-2-C	US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex/Gender by Race and Ethnicity

Table 2-1 and 2-2 provide overviews of the scope of NICHD's clinical research and Phase III clinical trials portfolio, respectively, to show the number of inclusion data records (IERs) for clinical research projects and Phase III clinical trials over the three years of this reporting period. These tables show 1,070 inclusion data records for NICHD grants, contracts and intramural projects in 2016, of which 40 were identified as Phase III clinical trials. Similar numbers were reported for 2017 and 2018. The column marked "IERs without enrollment" represent projects where recruitment has not

begun or where enrollment has not yet been reported. The tables also show the number of U.S. vs non-U.S. projects, as well as those involving female-only or male-only projects.

Inclusion of Women

Table 3-1-A addresses the inclusion of women in all NICHD-supported projects in 2016-2018. Tables 3-1-B and 3-1-C, break this down for extramural and intramural projects, respectively. Looking at the aggregate enrollment data for all NICHD projects in 2016 (Table 3-1-A) we can see that the majority of participants enrolled were female (67.6%) and only 1.7% were unidentified with respect to sex/gender. In 2017 and 2018, females remained the majority (62.4% and 60.2%, respectively). Comparison of extramural and intramural aggregate enrollment (Tables 3-1-B and 3-1-C) shows a much higher percentage of female in intramural projects in all 3 years, which reflects a larger proportion of female-only studies in the intramural portfolio.

Inclusion of Minorities

Table 5-1-2-C addresses the inclusion of minorities in NICHD-supported projects for US sites during the reporting period. Aggregate enrollment data are presented in terms of race and then ethnicity (Hispanic vs non-Hispanic).

The very first portion of this table summarizes the total numbers and percentages of minority participants enrolled each year. This total includes each of the minority categories (American Indian/Alaska Native; Asian; Black/African American; Native Hawaiian/Pacific Islander), plus “More Than One Race”, plus White Hispanics.

The second portion of this table breaks down the numbers and percentages for each of the racial categories. In 2016 for example, 0.6% of the all the females enrolled were American Indian/Alaska Native. Asian females represented 12.1%; Black/African American 22.3%; Native Hawaiian/Pacific Islander 0.3%; and More Than One Race 3.6%.

The third portion of this table shows enrollment by ethnicity. In 2016 for example, 12.5% of females and 14.2% of males identified themselves as Hispanic.

When assessing these data, enrollment figures should not be directly compared to the national census figures. The goal of the NIH inclusion policy is not to satisfy any quotas for proportional representation, but instead to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will be generalizable to the entire population of the United States. Since these are aggregate enrollment data any conclusions must be

guarded. Determining whether inclusion is appropriate will depend upon the scientific question addressed in a particular study and the prevalence of the disease, disorder or condition under investigation. These are assessed on a case-by-case basis by NICHD program staff when they review the progress reports for individual research projects and clinical trials. Finally, it's important to remember that data on the inclusion of both women and minorities are based on self-identification by the participants, which accounts for many of the unknowns reported in these data tables.

Future Analyses

- NIH has developed a system to display enrollment data according to the NIH Research, Condition and Disease Categorization (RCDC) code. This will enable filtering the database by RCDC to pull up enrollment data for clinical research projects and clinical trials on a particular condition, like Down Syndrome for example. RCDC category reports are available for general public use at: https://report.nih.gov/RISR/.
- Recent changes to the NIH policy on inclusion of children (now called Inclusion of Individuals Across the Lifespan) will in the future allow NIH to gather more detailed data collection and analysis of children of different ages in clinical research projects and clinical trials.

IV. Additional information

Inclusion policy changes related to the 21st Century Cures Act.

The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities as Subjects in Clinical Research on November 28, 2017, to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and intramural studies initiated after this date. At present, NICHD has one project in 2018 that meets the criteria for reporting applicable analysis in ClinicalTrials.gov. This project is supported by a Small Business Innovation Research (SBIR) grant, 2R44HD092967-02A1, and has a planned enrollment of 630 participants; 312 males and 318 females, respectively. Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised policy, now called the NIH Policy and

Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, applies to individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated after this date. The 21st Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Thus, this first triennial report provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018. Section IV of the Report of the Advisory Committee on Research on Women's Health includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2015 and 2016.

Highlighted Research Area: Intellectual and Developmental Disabilities

NICHD's Intellectual and Development Disabilities Branch (IDDB) sponsors research and research training aimed at preventing and ameliorating intellectual and related developmental disabilities. When the institute was created in 1962, one of its primary charges was to encourage investigations of human development throughout the lifespan, with an emphasis on understanding intellectual and developmental disabilities (IDDs).

The mission of IDDB is to support a program of research in IDDs, including common and rare neuromuscular and neurodevelopmental disorders, such as Down, Fragile X, and Rett Syndromes; inborn errors of metabolism; autism spectrum disorders; and conditions currently and soon-to-be detectable through newborn screening. Many IDD conditions have a male preponderance, including Autism Spectrum Disorder (ASD) and X-linked recessive disorders such as Fragile X Syndrome, although some rare disorders such as Rett Syndrome are seen almost always in females. IDDB has a long and respected history of providing support for a diverse portfolio of research projects, contracts, training programs, and research centers dedicated to promoting the well-being of individuals with IDDs at all stages of development.

IDDB supports cutting edge research through individual research project grants and contracts, through training and career development awards, and through the activities of its network of IDD Research Centers (IDDRCs). Some highlights of notable research supported by IDDB that examine sex/gender differences in IDD populations are summarized as follows:

1. Urea Cycle Disorders Consortium: Brain Nitrogen Metabolism in Partial OTCD Using Imaging. 5U54HD061221-15. PI: Gropman, Andrea.
   Asymptomatic ornithine transcarbamylase deficiency (OTCD) patients undertook a battery of neurocognitive tests and MRI scans to determine whether any differences could be identified from controls. Only deficits in fine motor skills and executive function were demonstrated in non-symptomatic carriers. Since this is an X-linked condition with more severe effects in males, the majority of those with particle OTCD are women who are carriers for variants in the genetic mutation.

   Pacheco-Colón I[1], Washington SD[1], Sprouse C[2], Helman G[3], Gropman AL[4], VanMeter JW[1]
   Functional Connectivity of Default Mode and Set-Maintenance Networks in Ornithine Transcarbamylase Deficiency. PLoS One. 2015 Jun 11;10(6):e0129595. doi: 10.1371/journal.pone.0129595. eCollection 2015.

2. Exploration of the genetic basis and molecular mechanism for paternal mitochondrial DNA inheritance. 1R01HD092989-01A1. PI: Huang, Taosheng.
   Examining the genetic mechanism by which the paternal mitochondrial DNA was transmitted to the zygote, which challenges the current dogma that mitochondrial inheritance is only transmitted through the mother. In this recently-funded study, no papers have yet been published.

3. Sex-specific modulation of ASD liability: Compensatory mechanisms and recurrence. Project within the Washington University IDDRC, U54HD087011-02. PI: John Constantino.
   This is a highlighted research project of the Washington University IDDRC, which is examining the outcomes of female relatives of males diagnosed with ASD, and looking at the prevalence of autism in the offspring of these female relatives (next generation).

   Constantino, JN. Early behavioral indices of inherited liability to autism. Pediatr Res. 2018 Oct 24. doi: 10.1038/s41390-018-0217-3. [Epub ahead of print] Review. PMID: 30356093

4. 5R01HD079533-03, Role of Pre-natal Vitamin D and Gene Interactions in Autism Spectrum Disorders; Leveraging an Existing Case-Control Study. PI: Windham, Gayle, Sequoia Foundation.
   The aims of this study include an analysis to examine gender specificity and susceptibility of the vitamin D-ASD association.

5. Cognitive Outcome Measures in School Age Children with Down Syndrome. R01 HD093754 01A1. PI: Esbensen, Anna J, Cincinnati Children's Hosp Med Ctr.
   This grant will include an analysis of gender differences in psychometric properties of cognitive outcome measures for use in Down Syndrome.

6. Electrophysiological Response to Executive Control Training in Autism. 5R00HD071966-05. PI: Faja, SUSAN, BOSTON CHILDREN'S HOSPITAL.
   Gender differences will be examined in this study of the neural basis of executive control in children with ASD and typically developing children using well-established electrophysiological measures.

7. Temporal Connectomics for Infant Brain: Neurodevelopment Modulated by Pathology. 5R01HD089390-02. PI: Verma, Ragini, University of Pennsylvania.
   This grant will examine the developmental trajectories of whole brain longitudinal fiber tracts and longitudinal network structures in High-Risk (HR) and Low-Risk (LR) infants for ASD. The

research team plans to compare sex differences in connectivity in LR- and HR-infants to explore how they are attenuated or enhanced in each of the risk groups.

8. Co-occurring ADHD in Young Children with ASD: Precursors, Detection, Neural Signatures, and Early Treatment. 5P50HD093074-02. PI: Dawson, Geraldine, Duke University.
   Attention Deficit Hyperactivity Disorder (ADHD) occurs in 40-60% of individuals with ASD and contributes significantly to poorer clinical outcomes. One of the aims of Project 1 of this Autism Center of Excellence grant will examine early risk variables associated with later diagnosis of ASD versus co-morbid diagnosis of ADHD in ASD. The proposed analysis includes the following risk variables: ethnicity/race, maternal education, medical history, and socioeconomic status.

9. Early Detection of Autism Spectrum Disorder. 5R01HD039961-15. PI: Robins, Diana l, Drexel University.
   African American children are typically diagnosed with ASD later than children of other races. Findings from this grant have shown that race was a factor in parents' reports of concerns about their child's development and ASD symptoms to health care providers.

   Donohue, M.R., Childs, A.W., Richards, M., & Robins, D.L. (2017, online). Race influences parent report of concerns about symptoms of autism spectrum disorder. Autism: International Journal of Research and Practice. Online first, November 3, 2017. NIHMS926275 doi: 10.1177/1362361317722030

10. SMART EARLY SCREENING FOR AUTISM AND COMMUNICATION DISORDERS IN PRIMARY CARE. 5R01HD078410-05. PI: WETHERBY, AMY M , FLORIDA STATE UNIVERSITY.
    The publication listed below did not find significant differences in diagnosis and race/ethnicity interaction effects when controlling for maternal education.

    Stronach, S.T. & Wetherby, A.M. (2017). Observed and parent-report measures of social communication in toddlers with and without autism spectrum disorder across race/ethnicity. American Journal of Speech-Language Pathology, 26, 355-368. 10.1044/2016_AJSLP-15-0089.

11. Evaluation of a Novel Intervention for Infants at Risk for Neurodevelopmental Disorders. 5 R21 HD091547-02. PI: Watson.
    This is a is a clinical trial specifically stratifying by sex to be able to identify sex differences in outcomes for infants at risk for neurodevelopmental disorders.

12. The directors of the Rodent Cores from most of the funded IDDRCs came together to describe rigor and reproducibility in rodent behavioral research to ensure that sex as a biological variable and rodent strain variation were considered when designing robust studies in rodents to help understand complex human behavior and development. There is a section in the article cited below that specifically discusses the importance of considering and accounting for sex in rodent research focusing on neurodevelopmental/behavioral disorders.

    Gulinello M[1], Mitchell HA[2], Chang Q[2], Timothy O'Brien W[3], Zhou Z[3], Abel T[4], Wang L[5], Corbin JG[5], Veeraragavan S[6], Samaco RC[6], Andrews NA[7], Fagiolini M[7], Cole TB[8], Burbacher TM[8], Crawley JN[9] . Rigor and reproducibility in rodent behavioral research. Neurobiol Learn Mem. 2018 Jan 4. pii: S1074-7427(18)30001-7. doi: 10.1016/j.nlm.2018.01.001. [Epub ahead of print]. PMID: 29307548.

13. Markers of Disease Progression in MECP2 Duplication Syndrome. 5R01HD084500-05. PI: Peters, Sarika.
    MECP2 duplication syndrome, an X-linked genomic disorder that accounts for 1-2% of all cases of X-linked intellectual disability (ID), has been recently revealed as the most common subtelomeric duplication in a clinical population. Duplications of MECP2 result in overexpression of the protein product (MeCP2). The phenotype is characterized by infantile hypotonia, ID, autism, progressive neurological declines, choreiform movements, and recurrent respiratory infections, and is most devastating in males (who are not protected by having an extra “normal” copy of the gene as females are). In this study, the investigators are evaluating the clinical, genetic, immunological, endocrine, and developmental markers or regression and outcomes, and comparing females and males with the disorder.

14. Impact of CGG Repeats on FMR1 Gene Function and Human Health. Project within the University of Wisconsin IDDRC. U54 HD090256. PI: Mailick and Zhao. IDDRC PI: Qiang Chang.
    This IDDRC-related project is testing the hypotheses that Low or Gray Zone CGG repeats in the X-linked *FMR1* gene are associated with compromised health and an increased risk of having a child with a disability. In a population-based sample of participants in the Marshfield Clinic, the investigators are examining whether individuals with Low Zone or Gray Zone CGG repeats are at increased risk of neurocognitive, motor, and physical and mental health problems, and having a child with an IDD based on data mining of electronic medical records and population-wide genetic testing. They are evaluating the results in a sex-specific manner and comparing males to females.

    Mailick M, Hong J, Greenberg J, Dawalt LS, Baker MW, Rathouz PJ. FMR1 genotype

interacts with parenting stress to shape health and functional abilities in older age. Am J Med Genet. Part B, Neuropsychiatric genetics : the official publication of the International Society of Psychiatric Genetics. 2017 June;174(4):399-412. PubMed PMID: 28407408; PubMed Central PMCID: PMC5435525.

15. Genotype-Phenotype Relationships in Fragile X Families. 5R01HD036071-21. PI; Hagerman, Randi.
    This project is a prospective, longitudinal study to quantify the progression of Fragile X Tremor-Ataxia syndrome (FXTAS) through the repetitive assessment of specific clinical measures: neurological/motor, psychiatric, cognitive, event related potentials (ERP), eye-tracking studies, and MRI/DTI measures. Since this is an X-linked disorder, and females have 2 copies of the X chromosome, their hypotheses are based on evaluating sex-specific differences in outcomes on these parameters.

    Wheeler A, Raspa M, Hagerman R, Mailick M, Riley C. Implications of the FMR1 Premutation for Children, Adolescents, Adults, and Their Families. Pediatrics. 2017 Jun;139(Suppl 3):S172-S182. doi: 10.1542/peds.2016-1159D. PMID: 28814538

16. Rett syndrome, MECP2 Duplications, and Rett-related Disorders Natural History. 5U54HD061222-14. PI: Percy, Alan.
    This Rare Diseases Clinical Research Consortium is engaged in an integrated clinical research program investigating the three disorders: 1) Rett syndrome (RTT), 2) MECP2 Duplication Disorder, and 3) Rett-related Disorders including FOXG1 and CDKL5. The three Aims are: Aim 1) Perform longitudinal and neurobehavioral assessments regarding the core clinical features of each disorder; Aim 2) Perform robust biomarker and clinical outcome measures to identify additional biological factors that contribute to disease severity in each disorder; and Aim 3) Identify and characterize neurophysiological and neuroimaging correlates of disease severity in each disorder. Since RTT is X-linked dominant, most of the affected individuals are female, and most males affected either die or are severely impaired. By definition, the investigators must explore these conditions in a sex-specific manner.

    Olson HE, Tambunan D, LaCoursiere C, Goldenberg M, Pinsky R, Martin E, Ho E, Khwaja O, Kaufmann WE, Poduri A. Mutations in epilepsy and intellectual disability genes in patients with features of Rett syndrome. Am J Med Genet Part A. 2015 September;167A(9):2017-25. PubMed PMID: 25914188; PubMed Central PMCID: PMC5722031.

17. The eXtraordinarY Babies Study: Natural History of Health and Neurodevelopment in Infants and Young Children with Sex Chromosome Trisomy. 5R01HD091251-02. PI: Nicole Tartaglia.
The goal of this project is to describe the natural history of neurodevelopment, medical problems and early testicular/ovarian function in infants with sex chromosome trisomies by gathering prospective data through a national partnership with newborn screening-related resources. It is well known that those with 47,XXX are females, those with 47,XXY and 47,XYY are males but fertility is variable; historically, many have not come to medical attention until adulthood, if ever. However, with the advent of non-invasive prenatal screening, infants with these conditions are being diagnosed in utero.. The basis of comparisons of neurodevelopmental and gonadal/fertility outcomes will be predicated by the sex chromosomes underlying the disorders.

Highlighted Research Area: Health Disparities

The NICHD Office of Health Equity (OHE) serves as a catalyst to strengthen the institute's commitment to ensuring the health and well-being of all children, adults, families, and communities. This is accomplished by fostering the assimilation of health disparities and health equity research across the institute's research and training portfolios; identifying priorities and developing metrics to assess progress toward NICHD's diversity, inclusion, and equity goals; coordinating the development of innovative approaches to diversifying the biomedical and biobehavioral workforce; and coordinating NICHD's diversity outreach efforts.

Some highlights of notable research addressing health disparities are summarized, as follows:

1. ***Rural-urban differences in prescription opioid misuse among adolescents***: NICHD-supported researchers used data from a 2011-2012 nationally representative survey of over 30,000 adolescents to assess prescription opioid misuse in adolescents age 12-17. Rural adolescents perceived substance use to be less risky. Regardless of whether they lived in a rural or urban area, teens that misused opioids most commonly reported the source of the drug as friends and family. However, rural teens were more likely than urban teens to report having received opioids from a physician or dealer. PMID 26344571 (PDB/Pop Centers)

2. ***Searching for explanations for disparities in uterine fibroids:*** Researchers recently conducted a mutation analysis of *MED12*, a gene that is mutated in approximately 70% of fibroids, in 75 Black women undergoing surgery for fibroids. While *MED12* was associated with tumorigenesis, mutation analyses did not provide conclusive evidence that genetic anomalies found by the researchers are responsible for racial differences in the onset and/or severity of uterine fibroids in Black women. PMID 29666002 *(GHDB/PFDN)*

3. ***Extremely low use of folic acid supplements before pregnancy in a predominantly urban, low-income, minority population of women*** led to approximately 1/3 of women not having optimal plasma folate concentrations. Folic acid supplementation before conception and during early pregnancy has shown to prevent 50 to 70 percent of neural tube defects. (PMID 29672150)

4. ***Patient characteristics (demographic, health, and other factors) accounted for nearly a quarter of the difference among hospitals' rates of cesarean deliveries for low-risk patients.*** Nearly a third (31.9 percent) of U.S. births are by cesarean delivery, and the frequency of low-risk

cesarean deliveries varies considerably across hospitals. To help identify how patient, provider and hospital characteristics might contribute to different rates of cesarean deliveries, researchers analyzed data from 38,275 cesarean deliveries at 37 weeks or later among "nulliparous" women (those having their first child), who were pregnant with one fetus (no twins or triplets) that was well-positioned for vaginal delivery ("vertex" presentation). (PMID 29742665)

5. ***Experiences of racism and postpartum depression among African-American women:*** Researchers interviewed over 1,300 African-American mothers about their childhood and adult encounters with racism, and whether these experiences could enhance the risk of postpartum depression. They found that women directly subjected to racism during their childhood and early adulthood tended to have more symptoms of postpartum depression. The same pattern emerged when women observed racial discrimination against another person. *doi:* 10.1521/jscp.2016.35.10.840 *(PPB/Community Child Health Network)*

6. ***Brain-derived neurotrophic factor tied to depression in pregnancy:*** Prior research has shown that low blood levels of the growth factor brain-derived neurotrophic factor (BDNF) is associated with depression in non-pregnant women. Scientists assessed samples from 139 racially diverse women, during and after pregnancy, to determine their blood BDNF levels. They found that BDNF dropped considerably in all women from the first through the third trimesters, but increased at postpartum. Overall, Black women exhibited significantly higher BDNF than white women during and after pregnancy. Lower BDNF levels at both the second and third trimesters predicted greater depressive symptoms in the third trimester for all women. PMID 27588702 *(PPB)*

7. ***Using data from 37 U.S. states, researchers found that homicide risk was 1.8 times higher among pregnant/postpartum women compared to non-pregnant women in the population.*** In contrast, the risk of suicide was 38% lower among pregnant/postpartum women than the general population. The analysis found that young women, non-Hispanic black women and undereducated women were at greatest risk of pregnancy-associated homicide and homicide appeared to occur more frequently during pregnancy, while pregnancy-associated suicide was more likely to occur in older and non-Hispanic white women and was most common during the late postpartum period. Suicide and homicide are the fourth and fifth leading causes of death among reproductive-aged women and these data suggest that pregnancy may be a time of heightened homicide risk, particularly for younger Black women. The authors suggest that pregnancy may be an important opportunity to identify women – who would not otherwise have contact with health providers – who are at risk of violent death. (PMID 27026475)

8. ***Data from diagnostic codes underestimate cases of postpartum hemorrhage.*** Using a large dataset of electronic medical records from an insurer in Northern California, researchers compared physicians' diagnoses of postpartum hemorrhage using the International Classification of Disease Coding (ICD-9) with data on the estimated amount of blood lost among women who had cesarean deliveries. The medical record data identified more women with significant blood loss (1.0 liters or more) than women who were formally diagnosed with postpartum hemorrhage using the ICD diagnosis codes. This indicates that data from diagnostic codes can substantially underestimate the number of cases of postpartum hemorrhage. Under-diagnosis of postpartum hemorrhage was also more common when the patients were older women, black women, obese women, and women with other types of serious pregnancy complications. (PMID 29377131)

9. ***Pretreatment with azithromycin lowers infection rate after C-section.*** To learn more about factors that affect women's risk for infection after a cesarean, researchers compared the rates of maternal infection following cesarean delivery in 1,019 women who received standard antibiotic pretreatment along with a dose of an antibiotic called azithromycin and 994 women who received standard pretreatment only. The additional treatment with azithromycin reduced the risk of infection by about half. However, in both groups, risk was higher for black women, those with membrane rupture more than 6 hours before surgery, and those whose surgery lasted more than 49 minutes. The scientists suggest that alternative timing of antibiotics or different dosing might help reduce risk for these women. (PMID 28178058, PMID 27682034

Highlighted Research Area: Intramural Research

The NICHD Division of Intramural Research (DIR) conducts laboratory and clinical research programs to seek fundamental knowledge about the nature and behavior of living systems through basic, clinical, and population-based research. DIR uses this knowledge to illuminate developmental origins of health and disease and to help ensure that women and men have good reproductive health, that children are born healthy, and that people develop to live productive lives.

The DIR research program is a multidisciplinary environment that investigates the physics, chemistry, and biology of cells; the processes that govern and regulate cellular function; and the effects when these processes fail. The Division includes more than 60 tenured and tenure-track investigators, organized into 13 affinity groups, and approximately 250 postbaccalaureate, clinical, and postdoctoral fellows and graduate students.

DIR research addresses several fundamental questions:

- How do cells transmit signals from the outside environment to the nucleus, initiate gene expression and replication, and then translate molecular responses into changes in function, differentiation, and communication with the cells' neighbors and environment?
- How do cells talk to one another, identifying their properties and location to give rise to tissues and organs?
- How are these processes integrated during embryonic, fetal, and postnatal development?
- When these processes go awry and disease ensues, how may we intervene and treat the disease?

Most DIR laboratories are located on the NIH campus in Bethesda, Maryland, or in nearby Rockville. DIR also has a lab focused on perinatal research and obstetrics in Detroit, Michigan.

V. CONCLUSIONS

NICHD has strived to promote the objectives of the NIH inclusion policy, by implementing procedures to monitor and assure compliance with the legislative mandate and by providing appropriate training to staff. The NICHD research mission is quite broad and scientifically diverse; much of our research portfolio focuses on topics relevant to women's health, and a number of our clinical trials are targeted specifically towards women. The aggregate enrollment data provide an overview of our research portfolio and clearly show substantial inclusion of women and minorities as subject in clinical research projects and clinical trials supported by NICHD. Not shown in these tables is the ongoing oversight of each individual project by NICHD staff to monitor the progress made in recruitment of research participants to reach the planned enrollment goals set forth in the original application and to provide guidance to investigators as needed. Even more important than the numerical data are the numerous contributions to scientific knowledge that will be generalizable to different populations, as shown by the representative grants and publications listed at the end of this report.

From its outset over 20 years ago, implementation of the NIH inclusion policy has been science driven. The primary focus of this policy has been to identify and remedy gaps in scientific knowledge as they relate to the health of all populations in the United States. The inclusion policy is based on the ethical principles of justice and beneficence, as it strives to assure that all groups share in both the risks and potential benefits of participating in clinical research. Finally, the policy represents a partnership between researchers, NIH staff, and most importantly the millions of individuals who have agreed to participate in clinical research projects and clinical trials.

Section 2: Metrics Based on Inclusion Data Records (IERs)

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male-only and Female-only*
2016	1,070	66	1,004	896	108	254	40	710
2017	1,129	104	1,025	929	96	277	37	711
2018	1,121	150	971	862	109	232	43	696

*Inclusion Data Records (IERs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).

Total Inclusion Data Records (IERs): All NIH-Defined Phase III Trials

Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between FY2016 and FY2018

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male-only and Female-only*
2016	40	1	39	19	20	7	2	30
2017	45	2	43	31	12	16	2	25
2018	30	6	24	18	6	16	0	8

*Inclusion Data Records (IERs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).
The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Section 3: Metrics Based on Aggregate Enrollment: Sex/Gender

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	2,784,689	1,882,262	67.6	856,033	30.7	46,394	1.7	206,730	7.4	9,936	0.4	1,675,532	60.2	846,097	30.4
2017	1,212,881	757,047	62.4	447,090	36.9	8,744	0.7	213,151	17.6	10,557	0.9	543,896	44.8	436,533	36.0
2018	1,293,100	778,357	60.2	503,448	38.9	11,295	0.9	144,882	11.2	9,027	0.7	633,475	49.0	494,421	38.2

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 3-1-B. Total Enrollment for All NIH-Defined Extramural Clinical Research Between FY2016 and FY2018

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	2,611,242	1,728,938	66.2	838,045	32.1	44,259	1.7	136,081	5.2	9,822	0.4	1,592,857	61.0	828,223	31.7
2017	1,050,337	610,138	58.1	432,542	41.2	7,657	0.7	139,820	13.3	10,444	1.0	470,318	44.8	422,098	40.2
2018	1,197,768	692,616	57.8	494,518	41.3	10,634	0.9	125,399	10.5	8,963	0.7	567,217	47.4	485,555	40.5

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 3-1-C. Total Enrollment for All NIH-Defined Intramural Clinical Research Between FY2016 and FY2018

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	173,447	153,324	88.4	17,988	10.4	2,135	1.2	70,649	40.7	114	0.1	82,675	47.7	17,874	10.3
2017	162,544	146,909	90.4	14,548	9.0	1,087	0.7	73,331	45.1	113	0.1	73,578	45.3	14,435	8.9
2018	95,332	85,741	89.9	8,930	9.4	661	0.7	19,483	20.4	64	0.1	66,258	69.5	8,866	9.3

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

US Site Enrollment: All NIH-Defined Clinical Research

Table 5-1-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex/Gender	Minority	% Minority
2016	Female	284,572	49.2
2016	Male	193,417	54.3
2016	Unknown	13,978	68.0
2017	Female	218,227	42.1
2017	Male	130,072	43.5
2017	Unknown	802	11.8
2018	Female	197,983	41.5
2018	Male	136,595	43.4
2018	Unknown	669	13.8

Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	Female	3,258	0.6	69,957	12.1	128,899	22.3	1,998	0.3	294,229	50.9	20,982	3.6	58,957	10.2
2016	Male	2,229	0.6	67,700	19.0	64,948	18.2	416	0.1	160,637	45.1	18,610	5.2	41,427	11.6
2016	Unknown	42	0.2	200	1.0	2,300	11.2	13	0.1	12,823	62.3	195	0.9	4,995	24.3
2017	Female	6,585	1.3	17,136	3.3	119,107	23.0	3,329	0.6	277,590	53.6	21,147	4.1	73,131	14.1
2017	Male	5,231	1.7	9,858	3.3	63,528	21.2	956	0.3	165,473	55.3	18,011	6.0	36,269	12.1
2017	Unknown	20	0.3	59	0.9	402	5.9	8	0.1	1,105	16.3	85	1.3	5,121	75.3
2018	Female	6,002	1.3	19,182	4.0	96,276	20.2	6,922	1.5	265,271	55.6	22,438	4.7	60,670	12.7
2018	Male	4,731	1.5	11,767	3.7	64,469	20.5	2,538	0.8	166,322	52.9	19,297	6.1	45,312	14.4
2018	Unknown	44	0.9	44	0.9	258	5.3	16	0.3	758	15.7	63	1.3	3,654	75.5

Year	Sex Gender	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	414,498	71.7	72,225	12.5	91,557	15.8
2016	Male	280,618	78.8	50,467	14.2	24,882	7.0
2016	Unknown	4,919	23.9	12,959	63.0	2,690	13.1
2017	Female	354,878	68.5	66,258	12.8	96,889	18.7
2017	Male	234,114	78.2	45,639	15.2	19,573	6.5
2017	Unknown	3,508	51.6	270	4.0	3,022	44.4
2018	Female	360,290	75.6	62,837	13.2	53,634	11.2
2018	Male	238,226	75.8	47,327	15.1	28,883	9.2
2018	Unknown	1,140	23.6	344	7.1	3,353	69.3

Additional Information

Highlighted projects that address differences in sex/gender, race, and/or ethnicity

Title	Grant Number
A Client-Based Outcome System for Individuals with Lower Limb Amputation	R01 HD065340
A multilevel comprehensive response on uptake and adherence to HIV Prevention among adolescent girls and young women	R01 HD094629
A Prospective Study of Biochemical and Genetic Predictors of PCOS in High Risk Early Postmenarchal Girls	K23 HD090274
A prospective study of cervical dysplasia, cervical surgery, and fertility	R03 HD094117
A RCT of preconception weight loss vs. OCP in overweight infertile PCOS women	U10 HD038992
Adolescent Medicine Trials Network for HIV/AIDS Interventions Study (ATN 139 Get Connected): Linking YMSM to Adequate Care	U19 HD089881
Adolescent Medicine Trials Network for HIV/AIDS Interventions Study (ATN 145 YMHP): Comparative Effectiveness Trials of clinic-based delivery of an HIV risk reduction intervention for YMSM	U19 HD089875
Adolescent Medicine Trials Network for HIV/AIDS Interventions Study (ATN 148 Stepped Care for Youth living with HIV): Optimizing the HIV Treatment Continuum with a stepped care model for Youth living with HIV	U19 HD089886
Adolescent Medicine Trials Network for HIV/AIDS Interventions Study (ATN 151 Work to Prevent): Employment as HIV prevention for YMSM and Young Transgender Women	U24 HD089881

Title	Grant Number
Adolescent Medicine Trials Network for HIV/AIDS Interventions Study (ATN 156 We Test): Enhancing sexual safety – Couples' communication and HIV testing among YMSM	U19 HD089875
Adolescent Medicine Trials Network for HIV/AIDS Interventions Study (ATN 157 We Prevent): Relationship skills intervention to improve HIV prevention uptake among young, gay, bisexual and other MSM and their primary partners	U19 HD089880
Adolescent Trials Network 15-site National Study Evaluating Human Papilloma Virus Vaccine in HIV-Infected Females	U01 HD40533 U01 HD40474
Alternative Cleavage and Polyadenylation in Trophoblast Differentiation	R21 HD081682
Ambulatory Care Access and Quality	R01 HD074756
Antiretroviral periconception HIV prevention for HIV discordant couples	R00 HD076679
Antiviral prophylaxis and infant vaccination to prevent perinatal hepatitis B infection	R01 HD092527
ART Adherence and Secondary Prevention of HIV	R01 HD075630
Assessing the preliminary effects of a multisectoral agricultural intervention on the sexual and reproductive health of HIV-affected adolescent girls	R21 HD095739
Assisted Reproduction and Child Health: Risk of Birth Defects, Mortality, and Effect on Grade School Performance	R01 HD084377
Bedside prediction of opioid-induced respiratory depression in children with pupillometry	HD094311-01
Biologic Roles of Novel Axonal Guidance Genes in Isolated GnRH Deficiency	K23 HD077043

Title	Grant Number
Breast Milk Microbiota Influence on Infant Immunity and Growth (BEAMING)	U01 HD094658
Caregiver Age- and HIV-associated Neurocognitive Decline in relationship to impaired cognitive development and long-term functional deficits in HIV-infected and Uninfected Dependent Children	R21 HD088169
Causes and consequences of mitochondrial dysfunction in oocytes and cumulus cells	R01 HD092550
Center for Reproductive Health After Disease	P50 HD076188
Center for Reproductive Science and Medicine	P50 HD012303
Clinical and Basic Studies in Polycystic Ovarian Syndrome	P50 HD028934
CMV viremia and mortality in hospitalized HIV-infected children	R21 HD089821
Cognitive Outcome Measures in School Age Children with Down Syndrome	R01 HD093754
Community Intervention for HIV Testing & Care Linkage Among Young Roma and Bulgarian MSM	R01 HD085833
Control of the Neonatal Septisome and Hydrocephalus in sub-Saharan Africa	DP1 HD086071
Co-occurring ADHD in Young Children with ASD: Precursors, Detection, Neural Signatures, and Early Treatment	P50 HD093074
Cooperative Multicenter Reproductive Medicine Network	U10 HD027049
Cooperative Multicenter Reproductive Medicine Network (U10)	U10 HD077841
Cooperative Multicenter Reproductive Medicine Network UNC Clinical Site	U10 HD077844

Title	Grant Number
CVCTPlus: A Couples-Based Approach to Linkage to Care and ARV Adherence	R01 HD075655
Data Coordination Center for the RMN	U10 HD055925
Decreasing Adverse Birth Outcomes among HIV-infected Women on Antiretroviral Therapy	K23 HD088230
Determining the contribution of zinc deficiency to perinatal Group B Streptococcus infections	R01 HD090061
Developing an Instrument to Assess Adolescent Risk for Disengagement from HIV Care	K23 HD095778
Developmental Epidemiological Study of Children born through Reproductive Technology (DESCRT)	R01 HD084380
Direct quantitation of the circulating Mtb-peptidome for pediatric TB management	HD090927
Disorders/differences of Sex development- Translational Research Network	R01 HD93450
Disparities in Disability after Traumatic Brain Injury for Hispanic Children	K23 HD078453
Dysregulation of FSH in Obesity: Functional and Statistical Analysis	R01 HD081162
Early Detection of Autism Spectrum Disorder	R01 HD039961
Early Intervention Outcomes Research using Innovative Patient-Reported Outcome (PRO) Measures	R03 HD084909
Early neonatal treatment and immune quiescence	U01 HD080441

Title	Grant Number
Effects of continued Progestin-based contraceptive usage in the adolescent genital tract: implications for HIV acquisition	R21 HD89836
Effects of Hormonal Contraceptives on Genital Immunity and HIV Susceptibility	R01 HD089831
Electrophysiological Response to Executive Control Training in Autism	5R00HD071966
Epigenetic Markers for Neonatal Abstinence Syndrome: Mechanistic Insights from an Established Birth Cohort	HD090733
Evaluating a youth focused economic empowerment approach to HIV treatment	R01 HD074949
Evaluation of a Novel Intervention for Infants at Risk for Neurodevelopmental Disorders	R21 HD091547
Evaluation of mHealth strategies to optimize adherence and efficacy of PMTCT/ART	R01 HD080460
Evaluation of the HITSystem to Improve Early Infant Diagnosis Outcomes in Kenya	R01 HD076673
Exploration of the genetic basis and molecular mechanism for paternal mitochondrial DNA inheritance	R01 HD092989
FANMI: Community Cohort Care for HIV-Infected Adolescent Girls in Haiti	R01 HD091935
Food Environment Measurement with People with Mobility Impairments	R21 HD095380 R01 HD074756 R21 HD095380
Genotype-Phenotype Relationships in Fragile X Families	R01HD036071
GHSU/WSU Cooperative Reproductive Medicine Network	U10 HD039005

Title	Grant Number
Harvard Reproductive Endocrine Sciences Center	P50 HD028138
HIV Exposed Uninfected Infant Cohort Study	R01 HD094650
Host Factors Influencing HIV Viral Load and Infectivity in Semen	R01 HD074511
Human Trophoblast Stem Cells: The In Vivo Niche and Relationship to Pluripotent Stem Cells	R01 HD089537
Hyperandrogenemia, Diet and Female Reproductive Health	P50 HD071836
Identifying sources of HIV infection in adolescent girls in rural South Africa	R01 HD083343
Impact of CGG Repeats on FMR1 Gene Function and Human Health	U54 HD090256
Impact of Concurrent Initiation of DMPA Contraception and Tenofovir PrEP on Bone Loss in Young Women	R01 HD89843
Impact of Gestational Serotonin Availability on Brain Function & Social Behavior	HD081261
Impact of periconceptual vaginal microbiota on women's risk of preterm birth	R01 HD087346
Impact of progestin contraception on risk of HIV acquisition and transmission	K23 HD078153
Improving infant hydrocephalus outcomes in Uganda: Predicting developmental outcomes and identifying patients at risk for early treatment failure after ETV/CPC	R01 HD096693
Improving the Detection of STIs in the Pediatric Emergency Department: A Pragmatic Trial	R01 HD094213
In our own words: Peer-to-peer messaging to increase uptake of HIV prevention strategies among adolescents in Kenya	R01 HD094683
Innovations in HIV testing to enhance care for young women and their partners	R01 HD083033

Title	Grant Number
Integrative Approaches to Decipher Genetic Determinants of Disease Penetrance in Prokineticin 2 Pathway Related Human Reproductive Disorders	R01 HD096324
Integrative metabolism of oocyte development and its modulation by maternal diet	R21 HD097601
Kidney Tubular Dysfunction in Hepatitis B Mono-Infected Women Receiving a Short Tenofovir Disoproxil Fumarate Course in Pregnancy and Postpartum Period to Prevent Mother to Child Transmission	R03 HD096131
Kisspeptin and Neurokinin B: Physiology in Monkey to Pathophysiology in Human	R01 HD043341
Laboratory of Developmental Neurobiology	R24 HD000836
International Epidemiology Databases to Evaluate AID (IEDEA)	U01 AI096299;
Population Dynamics Centers Research Infrastructure	P2C HD050924
Implementation Science in Prevention of Maternal-Child HIV Transmission	R01 HD075171
PEPFAR Collaboration on Implementation Science for HIV	R01 HD087993
Long-term Impact of Fertility Treatment Study	R01 HD088393
Luteal Progesterone Supplementation in Clomiphene Citrate-IUI Cycles	U10 HD077680
Markers of Disease Progression in MECP2 Duplication Syndrome	R01HD084500

Title	Grant Number
Mechanisms of post-discharge morbidity and mortality in HIV-infected and HIV-exposed uninfected children	R01 HD079695
A Novel Regimen to Prevent Malaria and STIs in Pregnant Women with HIV	K23 HD090993
Mobile-phone integrated diagnostic tests for measurements of fertility hormones	R43 HD095351
Morphine Pharmacogenomics to Predict Risk of Respiratory Depression in Children	K23 HD082782
Multiethnic Fine-Mapping of Polycystic Ovary Syndrome Susceptibility Loci	R01 HD85227
Neonatal imaging as an early marker of neurodevelopment and predictor of cognitive performance in infants exposed to HIV and ART in utero and perinatally	R01 HD085813
Neurocognitive outcomes and changes in brain and CSF volume after treatment of post-infectious hydrocephalus in Ugandan infants by shunting or ETV/CPC: a randomized prospective trial	R01 HD085853
Nicotine Replacement for Smoking Cessation During Pregnancy	HD069314
Anti-malarial Pharmacology in HIV Co-infected Children and Pregnant Women in Uganda	R01 HD068174
Optimal Physical and Cognitive Rest after Sports-Related Concussions among Youth	R21 HD086451
Optimizing routine HIV viral load monitoring in pregnant and postpartum women	R21 HD093463
Origins and Biological Consequences of Human Infertility	P50 HD055764
Ovarian ultrasonography for the clinical evaluation of polycystic ovary syndrome	R56 HD089962
Pediatric HIV/AIDS Cohort Study (PHACS), Pediatric AIDS Clinical Trials Group 219/219C/International Maternal Pediatric Adolescent AIDS Clinical Trials Group, and the Reaching for Excellence in Adolescent Care and Health (REACH)	U01 HD052102 U01 HD052104

Title	Grant Number
collaborative cohort analysis: Prevalence of and progression to abnormal noninvasive markers of liver disease (aspartate aminotransferase-to-platelet ratio index and Fibrosis-4) among US HIV-infected youth	
Pediatric TBI Treatments: Optimal Timing, Targets, and Patient Characteristics.	R21 HD089076 R01 HD065340 R21 HD089076
Penn Center for Study of Epigenetics in Reproduction	P50 HD068157
Pharmacokinetic and pharmacogenomic approach to indomethacin therapy in pregnancy	HD083003
Pharmacokinetics and modeling of betamethasone therapy in threatened preterm birth	HD088014
Phase II PK/PD driven dose finding trial of Praziquantel in children under four	HD095562
Pluripotent human stem cells as models for normal and abnormal trophoblast at implantation	R01 HD094937
Pluripotent Stem Cells: Modeling syncytiotrophoblast development and pathogenesis	R01 HD077108
Predicting PrEP Uptake and adherence among adolescent girls and young women in Sub-Saharan Africa: Leveraging programmatic and clinical trials data	R01 HD094682
PrEP Adherence among AGYW: A Multidimensional evaluation	R01 HH094630
Providing online counseling for home-based HIV testing.	R01 HD078131
RCT of an Implementation Science Tool to Integrate HIV testing into Family Planning Services	K24 HD088229
Reproductive Hormones and their impact on HIV-1 acquisition	R01 HD072693

Title	Grant Number
Reprometabolic Syndrome Mediates Subfertility in Obesity	R01 HD087314
Rett syndrome, MECP2 Duplications, and Rett-related Disorders Natural History	U54 HD061222
Role of novel SphK1 inhibitor, PF543 in therapy of Bronchopulmonary dysplasia and Airway remodeling	HD090887
Role of Pre-natal Vitamin D and Gene Interactions in Autism Spectrum Disorders; Leveraging an Existing Case-Control Study	R01 HD079533
Safety and Effectiveness of Triple Antiviral Drug Strategies for Prevention of Mother to Child HIV Transition	R01 HD080485 R01 HD080477
Selective Glucocorticoid Action in the Developing Brain	HD087288
Sex-specific modulation of ASD liability: Compensatory mechanisms and recurrence.	U54 HD087011
Simulated Patient Encounters to Promote Early Detection and Engagement in HIV Care for Adolescents	R01 HD085807
Smart Early Screening for Autism and Communication Disorders in Primary Care	R01 HD078410
STI and Implications for HIV Transmission and Prevention	R01 HD092033
Surveying Physicians to Understand Health Care Disparities Affecting Persons with Disability and Identify Approaches to Improve Their Care	R03 HD084909
Surveying Physicians to Understand Health Care Disparities Affecting Persons with Disability and Identify Approaches to Improve Their Care	R01 HD091211
Temporal Connectomics for Infant Brain: Neurodevelopment Modulated by Pathology	R01HD089390
The eXtraordinarY Babies Study: Natural History of Health and Neurodevelopment in Infants and Young Children with Sex Chromosome Trisomy	R01 HD091251

Title	Grant Number
The impact of in utero HIV exposure on infant T and B cell responses in Malawi	U01 HD092308
Translating Oral-HIV Testing to Low Income, Low Literacy Youth in Tanzania	R01 HD085780
Unemployment in Multiple Sclerosis : The Role of Personality, Coping and Health	K23 HD069494
Urea Cycle Disorders Consortium: Brain Nitrogen Metabolism in Partial OTCD Using Imaging	U54 HD061221
Using technology to match young Black MSM to HIV testing options	R01 HD078595
Uterine bitter taste receptors in pregnancy and preterm labor management	HD095539
Women's Life Events & HIV Transmission Potential: A Multidisciplinary Study	R01 HD072617

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