

***Eunice Kennedy Shriver* National Institute of Child Health and Human Development**
Division of Intramural Research
BOARD OF SCIENTIFIC COUNSELORS
MINUTES
December 6, 2019
Building 31, Room 2A48

Members Present: Dr. Elizabeth Bonney (acting chair), Dr. Hugo Bellen (nominee), Dr. Serdar Bulun, Dr. William Dauer (nominee), Dr. P. Ellen Grant (nominee), Dr. Frances Jensen, Dr. Deborah Johnson, Dr. Ursula Kaiser (nominee), Dr. Kojo A. Mensa-Wilmot, Dr. Eric Vilain, and Dr. Martha Werler.

Federal Employees Present: Dr. Constantine A. Stratakis, Dr. Arlyn Garcia-Perez, Dr. Chris McBain, Mrs. Francie Kitzmiller, and at various times additional members of the NICHD staff participated in the meeting.

I. OPEN SESSION

The meeting convened at 8:30 a.m. Dr. Elizabeth Bonney started by welcoming everyone and introducing herself as the new acting chair of the Board of Scientific Counselors (BSC).

Dr. Bonney introduced Dr. Stratakis who noted that Dr. Bonney will be the interim chair until the appointment of the chair is confirmed. Dr. Stratakis also acknowledged Dr. Scott Rivkees for his years of service on the BSC and as chair of the BSC. Dr. Rivkees has moved on to his new role as the Surgeon General of the State of Florida.

Dr. Stratakis introduced Dr. Diana Bianchi, Director, NICHD, to provide the Director's Report.

Director's Report

Dr. Bianchi provided an outline of her talk which included budget updates, trans-NIH projects and NICHD initiatives, public-private partnerships, the NICHD Strategic Plan, NICHD research initiatives, and staff updates.

After a nearly two-year process, NICHD recently released its 2020 strategic plan that can be downloaded online, Dr. Alison Cernich, NICHD Deputy Director, will present the strategic plan in detail later in the meeting.

NIH is currently on a continuing resolution through December 20, 2020 to operate at fiscal year (FY) 2019 levels. Only those extramural grants that scored extremely high are being funded, until the final budget is known. NIH is now working on the congressional justification for the FY2021 budget. The President's budget request for FY2021 is expected to be released in February 2020.

Dr. Collins was recently featured in an article in *Science* marking his 10-year anniversary as Director of NIH, which noted his hallmark achievements. One noteworthy contribution is his recruitment of

the majority of the 27 Institute and Center (IC) Directors. Ten of the IC Directors are currently women and many of the recent recruits have been women. Dr. Patricia Brennan, Director of the National Library of Medicine wrote a blog called “The Power of 10” that describes the 10 different female Directors, what they bring to the table, and how things have changed at NIH in the last five years. Dr. Collins is also leading a number of large initiatives that challenge the status quo, including the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative (started in 2013), the Precision Medicine Initiative now known as “All of Us” (started in 2015), the Cancer Moonshot (started in 2016), and the Helping to End Addiction Long-term (HEAL) initiative (started in 2018). NICHD is actively involved in the All of Us and HEAL initiatives but is not really involved in Cancer Moonshot because pediatric cancer is handled at the National Cancer Institute (NCI).

HEAL is a trans-NIH initiative to address opioid addiction, a significant issue that affects many of NICHD’s core populations including children, pregnant and lactating women, and people with intellectual and physical disabilities. HEAL focuses on six core areas around enhancing pain management and improving treatments for the misuse and addiction of opioids. While NICHD is particularly focused on enhancing outcomes for infants and children exposed to opioids, the institute is also involved in addressing other core areas, including enhancing pain management, particularly pain related to reproductive disorders and how pain is managed following cesarean section deliveries. HEAL projects are currently supported with \$945 million in funding. As part of HEAL, NICHD leads the Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW) studies to optimize health for infants who have been exposed to opioids in utero, including determining to what extent clinicians can safely reduce or eliminate opioid treatment for neonates with opioid withdrawal symptoms. In partnership with the Environmental Child Health Outcomes (ECHO) program, there are currently four interlinked studies under ACT NOW. The Current Experience Study investigated how clinicians are treating babies now around the country and found that there is no current standard of care. The Eat, Sleep, Console (ESC) Trial is testing the hypothesis that babies do not need pharmacologic treatment at all and whether this is safe or if there are long-term consequences? The Weaning Randomized Trial is comparing outcomes of fast weaning versus slow weaning approaches for babies who need opioids. The fourth trial, a Longitudinal Cohort Observational Study, aims to address what happens long-term to babies exposed to opioids in utero in terms of their neurodevelopment. The ultimate goal of ACT NOW is to come up with an evidence base standard of care for infants and children exposed to opioids.

All of Us, the NIH’s precision medicine effort, is creating a research community of one million people who will share their unique health data, with an emphasis on recruiting people from underrepresented minorities. Participants will respond to surveys, share their electronic health records, and some will have genome sequencing or provide blood and urine samples. The study has been enrolling subjects for a couple of years. No children have been enrolled as of yet, but the program anticipates beginning enrollment of children in 2020. Due to the difficulty of recruiting pregnant women to All of Us and PregSource, the two efforts are partnering to encourage enrollment. PregSource is a crowdsourcing study to obtain information on typical pregnancy experiences and develop strategies for improving maternal care. Women who are enrolled in *All of Us* will be offered the opportunity to participate in PregSource to get real time information on how their experiences compare to those of other pregnant women. There is currently an English language website that is live, and mid-December a Spanish language website will be available. As part of the 21st Century Cures Act, NICHD is running a federal taskforce, PRGLAC, on research related to medications taken by pregnant women and lactating women. To support this effort, PregSource and

All of Us are being used to collect information on medications taken by either pregnant women or lactating women.

NICHD has a variety of public-private partnerships to advance science opportunities. One way to do this is through trans-NIH partnerships. An example is autism research in which NICHD partners with NIMH who leads the efforts. NICHD also partners with other federal agencies, for example on addressing maternal mortality. The institute has been less involved in partnerships with nonprofits or for-profit organizations compared with other ICs, but is beginning to explore some of those relationships. Many of these partnerships involve research efforts, but may also include committees and working groups, meetings, conferences, workshops, public education campaigns or training initiatives. Additional ways to partner, include technology transfer, co-sponsorship, and through an organization called the Foundation for NIH (FNIH) that helps facilitate these partnerships. One of the biggest and most successful of these partnerships is with the Mars Corporation and the Waltham Centre, which supports research on human-animal interactions, especially as they relate to child development, health, and the therapeutic use of animals and children and adolescents. Dr. Bianchi noted that NICHD was very grateful for their support, which has helped establish this field of research that would not have been able to grow otherwise. As part of PregSource, NICHD has partnerships with a number of different NIH institutes and centers, other federal partners, and professional societies to form the initiative. The FNIH was congressionally established as a 501(3)(c) organization in 1990 to support the mission of NIH through research programs, educational activities, and public-private partnerships, without being subject to government policies and regulations regarding funding. Other institutes have been very involved with FNIH to help fund partnerships to accelerate clinical trials or help to develop new therapies. A potential NICHD-FNIH partnership with the Bill and Melinda Gates Foundation is looking to leverage our Global Network for Women's and Children's Health, with eight sites around the world to look at potential administration of an antibiotic to reduce the chance of maternal sepsis or mortality and infant sepsis or mortality.

Dr. Bianchi discussed NICHD's strategy for clinical trials research. As part of the strategic planning portfolio analysis, clinical trials networks were found to be very successful and impactful. For example, some networks like the Maternal Fetal Medicine Units Network, have about 25 percent of their publications cited in professional society guidelines, showing their impact to the field. As much of the infrastructure for these networks is three decades old, NICHD wants to encourage new ways to envision clinical trial support as the networks come up for re-funding to enhance rigor and reproductivity, promote greater availability of infrastructure, facilitate data sharing and access to biospecimens, and facilitate greater involvement of diverse populations in multi-site clinical trials. Adhering to these principles will ensure proper stewardship of public funds, increases accountability, and help NICHD maintain the public trust. Review within these networks is different from external peer review, but in an effort to level the playing field an investigator who wants to do a clinical trial study will have to go through peer review just like everybody else does now. As part of its vision, NICHD is committed to providing critical infrastructure support for multisite trials that involve populations of key relevance to our research mission, completing all currently active protocols as they were designed. NICHD recognizes that there is no "one size fits all" approach to supporting the multi-site clinical trial infrastructure. A request for information (RFI) was issued to solicit input on NICHD's vision for supporting multisite clinical trial infrastructure and Dr. Bianchi asked anyone who has input to consider submitting a response on the NICHD website by December 20, 2019.

NICHD recently revised its mission and vision statements with the help of a working group of the Advisory Council in an effort to make them more concise and memorable. NICHD's revised mission statement is: *The NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.* Its new vision statement is: *Healthy pregnancies. Healthy children. Healthy and optimal lives.*

Dr. Bianchi concluded her presentation with a couple of staff updates. Dr. Alison Cernich was recently named as Deputy Director of NICHD. Dr. Cernich has been instrumental in the planning, development and implementation of the strategic plan and will present an outline of NICHD's 2020 Strategic Plan later in the agenda. Prior to her appointment as Deputy Director, she served as Director of NICHD's National Center for Medical Rehabilitation Research (NCMRR) where one of her major accomplishments was leading the development of the congressionally mandated NIH Rehabilitation Research Plan in 2018 with 17 ICs and several external stakeholders. Dr. Theresa Cruz, a Health Scientist Administrator in NCMRR, is serving as the center's Acting Director while a national search is conducted to identify the next NCMRR Director. Mr. Rodney Rivera was named NICHD's Associate Director for Administration and Executive Officer. He has served NICHD in multiple roles, including as the Acting Executive Officer since October 2017 and NICHD's Deputy Executive Officer since August 2015. In addition to the search for the NCMRR Director, NICHD has a number of other positions it is recruiting for including Director for the Division of Intramural Population Health Research (DIPHR); Branch Chief for the Pregnancy and Perinatology Branch; and several program officer positions in the Child Development and Behavior Branch, Intellectual and Developmental Disabilities Branch, Obstetric and Pediatric Pharmacology and Therapeutics Branch, Pediatric Trauma and Critical Illness Branch, and Pregnancy and Perinatology Branch. These are great opportunities for people who want to shape science and want to be on the cutting edge, but who don't want to be a PI in the lab.

Questions followed. A propos of the HEALthy Brain and Child Development (BCD), Dr. Bianchi indicated that study, which is led by NIDA, is not directly linked to PregSource, but NICHD is involved in the overall project particularly in determining what strategies are and are not working. Regarding the HEAL initiative overall, the BSC suggested that NIH consider looking at new moms who may be vulnerable for relapse and who are likely interacting with the medical establishment because of their child, providing an opportunity for interventions. Regarding changes to the clinical trials network, there is no one size fits all approach but the goal is to make these opportunities available to more investigators around the country and they are also building a consultation feature where investigators who aren't at a large center can get advice on clinical trial design. This restructuring should also help junior investigators and underrepresented minority investigators to get access and training.

Scientific Director's Presentation

Dr. Stratakis began his comments by thanking the BSC members who had recently rotated off the BSC of their five years of service. In addition, two more members will be rotating off in June 2020: Dr. Frances Jensen and Dr. Eric Vilain. Dr. Stratakis acknowledged and thanked new recruits: Dr. Ursula Kaiser, Chief of the Division of Endocrinology, Diabetes, & Hypertension and Co-Director of the Brigham Research Institute at Brigham and Women's Hospital; Dr. Hugo Bellen, Professor of Molecular and Human Genetics and Neuroscience at Baylor College of Medicine; Dr. Nancy Carrasco, CNH Long Professor of Cellular and Molecular Physiology at Yale School of Medicine; Dr. Ellen Grant, Director of the Fetal-Neonatal Neuroimaging and Developmental Science Center

at Boston Children's Hospital; and Dr. Errol Norwitz, Chair and Louis E. Phaneuf Professor of Obstetrics and Gynecology at Tufts University School of Medicine. Drs. Bellen, Carrasco, and Norwitz are expected to join in June 2020. Dr. Stratakis noted that Dr. Scott Rivkees rotated out of the BSC as both chair and a member and asked the BSC for their help in getting recommending a new member who will cover the scientific areas that Dr. Rivkees was covering: clinical trials, general pediatrics, pediatric endocrinology, and molecular endocrinology. Dr. Stratakis also asked for the BSC to help in suggesting successors for Dr. Jensen and Dr. Vilain. He thanked Dr. Elizabeth Bonney for taking on the role of acting chair of the BSC.

Dr. Stratakis reviewed the tasks of the BSC, including the main one which is to evaluate the research of all investigators, cores, and programs within the Division of the Intramural Research (DIR) and the Division of Intramural Population Health Research (DIPHR); advise on programmatic decisions, budget and space allocations; promote high-risk, high-impact laboratory and clinical investigation that could not be readily supported in the extramural environment. The BSC meets twice a year, each June and December to evaluate tenure-track investigator progress, review site visit reports and tenure considerations; and advise the NICHD Director and NICHD DIR Scientific Director. Since the reorganization of the intramural program, site visits are scheduled the day before BSC meetings. DIPHR is the only division that has their quadrennial review, off-cycle of the June and December meetings. The next site visit of DIPHR is scheduled for September 2020. It is up to the BSC and the next director of the division whether they want to change DIPHR's schedule going forward. The review policy is outlined in the NICHD DIR Guidelines for Site Visit Reviews which has been a dynamic policy since it was adopted in 2010. Dr. Stratakis noted that reviewers at the last site visit had recommended possible changes to the process which will be discussed during the closed session for possible inclusion into the guidelines.

Dr. Stratakis reviewed the NICHD DIR's organizational structure. With the October 2015 reorganization, NICHD adopted the Blue Ribbon Panel recommendations for a more flat structure to allow for increased diversity of leadership and more leadership opportunities, as well as allow recruitment of early stage investigators to our program. Scientists are divided into divisions each headed by an Associate Scientific Director (ASD) who may serve up to two consecutive four year terms. NICHD was the first intramural research program to adopt rotational leadership, something that is now being considered across the NIH intramural research program. Each of the ASDs serves one area of science: developmental biology, translational medicine, molecular and cellular biology, neurosciences, basic and translational biophysics, translation imaging, and OBGYN and maternal-fetal medicine. This structure also facilitated a process of relocating labs to consolidate NICHD's overall footprint to fewer buildings, with each division occupying a separate building hub. The effort, started in 2012, cost approximately \$20-24 million and resulted in 80-85% of staff moving to new buildings or into totally renovated laboratories.

An important group for how the NICHD DIR functions is the Group of Senior Advisors (GSA). This group consists of ASDs, most of whom head one of the building hubs. The GSA advises the Scientific Director on a number of issues including resource allocations. They also meet every spring to review the lab budgets for the coming fiscal year and make adjustments based on the advice and recommendations of the BSC. Notably, with the reorganization more than 50% of the DIR's leaders are female scientists and more than 60% of the membership of the BSC is now female. In addition to the ASDs who oversee building hubs, the GSA includes Dr. Mary Dasso, who serves as the ASD for Budget and Administration; Dr. Tracey Rouault, the ASD for Recruitment, Retention, and Diversity; Dr. Chris McBain, Deputy Scientific Director; Dr. Forbes Porter, Clinical Director of

NICHD; Ms. Francie Kitzmiller, Deputy Director for Administration & Budget; and Ms. Sara King, Chief of Staff of the Office of the Scientific Director. The ASDs all recently completed their first four-year terms leading to some turnover. Current memberships of the GSA and affinity groups were presented. A propos of the ASD terms, Dr. Stratakis noted that a small subcommittee of the GSA will be evaluating how to stagger the rotation going forward and also how to adopt a new policy on lab/branch chief (and equivalent) appointments in NICHD that is expected to be implemented across the NIH intramural program.

The Office of the Scientific Director (OSD) oversees the NICHD DIR with the support of a number of other offices. The OSD works very closely with the Office of the Clinical Director (OCD), which is responsible for clinical resources, IRB functions, and for the clinical protocols. NICHD's Clinical Director, Dr. Forbes Porter, now reports directly to Dr. Bianchi. The Office of Education is essential for serving trainees across all the sciences and across all levels of education from summer students to postdocs and senior fellows. They also oversee the five graduate medical education programs that are run at the Clinical Center and at the Perinatology Research Branch in Detroit: in pediatric endocrinology, adult endocrinology, medical genetics, reproductive endocrinology and infertility, and maternal-fetal medicine. The Administrative Management Branch (AMB), under the leadership of Ms. Francie Kitzmiller, ensures that public funds are being spent efficiently. All investigators are organized into 12 self-selected intellectual affinity groups. An investigator must choose a primary affiliation but may have additional secondary affiliations with other affinity groups. Each affinity group elects a head who serves for four years, but unlike the ASDs there are no term limits for affinity group heads. The affinity group head plays a role in recruitment efforts, representing the interests of the group to the ASDs in terms of what common equipment should be bought, supporting the resource and mentoring needs of tenure track investigators in their group, and in working with the OSD to identify recruitment priorities for the future. Based on recommendations from the affinity groups, the OSD is working with the Office of Education to establish a new invited speaker series for each affinity group, to foster research collaborations between our intramural researchers and scientist at various institutions outside NIH. Dr. Stratakis noted that since the strategic planning, affinity groups can have their affinity group head attend the site visit exit interview as their representative.

In FY19, NICHD's budget was approximately \$1.5B, of NIH's total budget of about \$39B. The intramural program represented 14% of NICHD's total budget, or approximately \$200M including the DIR and DIPHR. Of the approximately \$195M the DIR received for FY19, 23% was allocated for lab consumables, 34% toward personnel, 20% toward the NIH Office of Research Services to cover buildings, maintenance, etc., and 16% was paid in support of the NIH Clinical Center. There have been discussions about changing how the Clinical Center tap is calculated. Over the last 10 years or so NICHD has under-utilized the Clinical Center by about 5% compared to what it contributes. Smaller portions of the budget go to central support of animal care, capital equipment, IT support, renovations, and various contract agreements. The DIR was also able to dedicate approximately \$2.4M towards capital equipment in FY19. Each year the OSD collects capital equipment requests which are evaluated by the GSA. Approximately 1-2% of the total budget supports competitive awards, the Scientific Director's Awards, to support new projects and collaborations that could not be supported with existing lab budgets with two years of funding. Proposals are submitted using an R-21 like application, which are evaluated with help from staff in the Division of Extramural Research. The Perinatology Research Branch, headed by Dr. Roberto Romero, is supported through a \$15.5M contract currently awarded to Wayne State University in Detroit, MI. In addition to DIR's allocation, DIPHR has a budget of approximately \$9.5M. A

propos of the research portfolio, Dr. Bianchi indicated that the new strategic plan would serve as a guide to identify opportunities in the DIR to develop new programs as others phase out. The DIR has some resources to recruit now, but has to be mindful of its number of FTEs as well as the ability to balance the budget, should the funding level fluctuate.

The total number of DIR staff is 855, with 283 FTEs, and 572 non-FTEs which includes trainees and contractors.

Dr. Kristina Rother has been recruited from NIDDK as the interim Director for the Pediatric Endocrinology Inter-Institute Training Program. Dr. Rother is a former graduate of the program. Dr. Christina Tatsi, a staff clinician, was recruited in September 2019 to serve as the program's Deputy Director to assist Dr. Rother. Dr. Jeffrey Farrell was recruited as a Stadtman Investigator to head a new unit on the genetic basis of cellular differentiation. Dr. Farrell will start with NICHD in January 2020 and will have a secondary appointment with NHLBI. Dr. Ruth Woodward has been appointed as the Director of the Research Animal Management Branch. Dr. Joseph Schech, the former Director, stepped down in September 2019 to accept a position with Baylor University. Dr. Stephen Kaler retired on November 30, 2019 to take to a faculty position at Ohio State University. Dr. James Kennison will be retiring on December 31, 2019. Dr. Stratakis also noted that there is an intramural research-wide effort to recruit clinician scientists through the Lasker Program.

Recent honors were highlighted. Dr. Mary Dasso was elected to the American Society for Cell Biology. Dr. Jack Yanovski received the Obesity Society's Thomas A. Wadden Award for Distinguished Mentorship. Dr. R. Douglas Fields was just recently elected to the American Association for the Advancement of Science (AAAS).

Dr. Stratakis hosted Republican Representative Bill Flores for a visit to the NIH Clinical Center on September 17, 2019. Dr. Stratakis recently completed his term as President of the Society of Pediatric Research from 2018-2019.

NICHD DIR investigators continue to be successful in competing for funding. NICHD is the lead institute for the U-01 program, to support collaborative research projects allowing extramural investigators access to the NIH Clinical Research Center through collaborations with intramural investigators, currently in its fifth cycle. Support includes up to \$500,000 a year in direct costs for a period of up to five years. The pre-application (X02) deadline this year is December 11, 2019 and final applications are due in March 2020. The NICHD DIR Director's Awards are entering their fourth cycle. This competitive award was established following the recommendation from the 2013 Blue Ribbon Panel Report to foster new collaborations and support new research ideas. Applications are based on an R-21 and reviewed by a panel of NIH extramural reviewers, with successful awards receiving two years of funding. Approximately \$3.2 M in awards were made to investigators in FY18-19, and the 12 successful applications were funded.

Dr. Stratakis then reviewed the activities of the Office of Education under the direction of Dr. Yvette Pittman. The Office of Education continues to support trainees at all levels through a variety of activities, including a monthly newsletter and an Annual Fellows Retreat. NICHD's trainee population totals about 320 including 180 postdoctoral fellows, 101 postbaccalaureate fellows, 22 clinical fellows, 15 graduate students, with an additional 52 summer students hosted in 2019. Graduate students participate in the NIH Oxford-Cambridge program, Karolinska Neurosciences, and other postgraduate partnership programs. To enhance and promote physician-scientist training,

Dr. Fady Hannah-Shmouni, Associate Director for the Inter-Institute Endocrinology Training Program, was recently appointed as Director of Graduate Medical Education in the Office of Education. The Inter-Institute Endocrinology Training program successfully matched all four of its slots this year. Results of the match for the Inter-Institute Pediatric Endocrinology training program are expected in mid-December. The NICHD Annual Fellows Retreat was held May 31, 2019 and the keynote address was by Dr. Elaine Ostrander, NIH Distinguished Investigator, NHGRI. Clinical and basic science trainees who attend participate in poster sessions, fellows talks, and career panel sessions.

The Office of Education, along with the Scientific Director, supports a number of initiatives to increase diversity. As part of the summer program, 10 centrally funded students from groups traditionally underrepresented in science or from disadvantaged backgrounds were supported in 2019, representing 20% of the summer population in NICHD. The Developing Talent Scholars program supported four recruitments at the postbaccalaureate level in 2019. Two new alumni from the program started medical school in the fall. The Fellows Recruitment Incentive Award, which supports fellows at the postdoctoral level, recruited Velencia Witherspoon in the Basser lab. NICHD has a number of international collaborations for training including the NICHD-Inserm Exchange Program and the Future Researchers Program which supports medical students from the Santa Casa de São Paulo School of Medical Sciences (Brazil) to train with NICHD investigators. Postbaccalaureate fellow medical and graduate school acceptances were presented.

The Office of Education continues initiatives aimed at public speaking, teaching, and grantsmanship, and career counseling. The Intramural Research Fellowships provide an opportunity for postdoctoral and clinical fellows to get experience on how to write the various components of an NIH grant. Dr. Stratakis thanked the BSC members for agreeing to review these applications, which will be sent to them shortly. NICHD fellows have been successful in applying for a number of funding opportunities, including for K-99 awards. The annual Three-minute Talks (TmT), a competition that promotes the effective communication of science, with five institutes now competing.

Questions followed. A propos of how the institute encourages collaboration across the affinity groups, Dr. Stratakis noted that the SD Awards, the ability to invite seminar speakers together, and other opportunities to collaborate and compete for awards that are cross-discipline provide incentive for new collaborations.

Following a short break, Dr. Stratakis introduced Dr. Una Grewal, Deputy Director of DIPHR, to provide an update on division.

Presentation on DIPHR

Dr. Grewal reviewed the mission of DIPHR, to conduct research leading to the promotion of population health and wellbeing. The Division pursues this mission through (1) innovative etiologic and interventional research across the lifespan, (2) translating the findings into clinical practice and public policy, and (3) through building capacity. The vision of the division is to be a leader for population health research focusing on successful reproduction, the health and well-being of pregnant women and their infants, and the optimal growth and development of children and adolescents across the lifespan. They work to realize the elimination of health disparities. DIPHR includes 29 FTEs organized into three branches and one program: the Epidemiology Branch, the

Biostatistics and Bioinformatics Branch, the Social & Behavioral Sciences Branch, and the Contraceptive Development Program. The division is in the process of finalizing the recruitment of a Branch Chief for the Biostatistics and Bioinformatics Branch and anticipates a formal announcement early next year. DIPHR expanded in September 2017 to include the Contraceptive Development Program headed by Dr. Diana Blithe, which was previously a part of NICHD's extramural program.

DIPHR's operating budget represents approximately 5% of the NICHD intramural research budget. The increase for FY18 is the result of the incorporation of the Contraceptive Development Program. The division's R&D budget from 2013 to present was presented, which stood at about \$13.8M in FY19. It was noted that the R&D budget includes indirect costs to extramural partners.

Dr. Bruce Simons-Morton, a pioneer in the field of high-risk teen driving, retired after 30 years of dedicated service to NICHD. Dr. Simons-Morton is the DIPHR's first scientist emeritus. Several members of the division received major recognitions this year within NIH and by leading professional organizations, journals, and academic institutions. Papers led by Dr. Enrique Schisterman, Chief of the Epidemiology Branch, and Dr. Lindsey Sjaarda, Staff Scientist of the Epidemiology Branch, were recognized separately on the short list of 12 candidates for two Scientific Congress Prizes by the American Society for Reproductive Medicine. One of DIPHR's Earl Stadtman Investigators, Dr. Sunni Mumford, received multiple awards including a 2019 NIH Ruth L. Kirschstein Mentoring Award as well as the Star Award and the Star Reviewer Award from the American Society for Reproductive Medicine. In the Social & Behavioral Sciences Branch, an article led by Dr. Risë Goldstein was recognized with the Editor's Choice Award by the *Journal of Epidemiology and Community Health*. Dr. Denise Haynie received an Excellence Award for her paper presented at the Annual Meeting and Scientific Sessions of the Society of Behavioral Medicine. Dr. Marion Ouidir will be receiving one of the 2020 William G. Coleman Minority Health and Health Disparities Research Innovation Awards from the National Institute on Minority Health and Health Disparities. Dr. Ouidir joined the division two years ago as part of the NICHD-INSERM partnership program and now she is a postdoctoral fellow in the Epidemiology Branch. Dr. Mengying Li, a postdoctoral fellow in the Epidemiology Branch received two awards from the American Society for Nutrition, Postdoctoral Research Excellence Award and the Emerging Leaders in Nutritional Science Award. Dr. Ellen Francis, predoctoral Fellow with the Epidemiology Branch received the NIH Fellows Award for Research Excellence and was a finalist in the Emerging Leaders in Nutritional Sciences Poster Competition at the 2019 Annual Nutrition Conference of the American Society for Nutrition. Two Visiting Fellows in the division were awarded prizes for their doctoral theses. Dr. Carolina Schwedhelm-Ramirez was recognized with the Best Doctoral Thesis in Nutrition at the German Institute of Human Nutrition Potsdam-Rehbrücke. Dr. Pablo Vidal-Ribas Belil was recognized with the King's Outstanding PhD Thesis Prize at King's College London.

The division continues to advance its long-standing track record of productivity and innovation and makes contributions to the field of population health research. A number of scientific discoveries were highlighted in the slides provided to the BSC.

Questions followed. A propos of the division's thematic priorities will be for the next few years, Dr. Grewal noted that one of the top priorities over the next three years is to grow the Biostatistics and Bioinformatics Branch, which has lost four investigators over the last several years. DIPHR will also work to align its scientific priorities with those identified in NICHD's Strategic Plan. One priority in particular will be trying to harness its existing large cohorts and data to conduct research across the

entire lifespan. Once DIPHR recruits a new director, the division will undertake its next strategic planning to identify research priorities, informed by the institute's new strategic plan.

Dr. Stratakis introduced the next speaker, Dr. Alison Cernich, Deputy Director of NICHD, to provide and update on the NICHD Strategic Plan.

Deputy Director's Presentation on the NICHD Strategic Plan

Dr. Cernich starting by thanking everyone who was involved in the strategic planning process. She also summarized her background noting that she was trained as a neuropsychologist and her primary work was in traumatic brain injury and computerized assessment. Prior to NIH, Dr. Cernich worked for the Department of Veterans Affairs and was detailed to the Department of Defense as the Deputy Director for the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury. In that role, Dr. Cernich served as the Director of the Office of Strategy Management for a year and a half.

The goals of the strategic plan were to identify where NICHD should lead, where should NICHD partner and collaborate, and to inform future investments in research, training, and infrastructure. Essentially to identify where the gaps were and what needed to be prioritized. The core principles of the process were transparency, stakeholder participation, and decisions informed by evidence. The process included a complete portfolio analysis and review of NICHD and NIH strategic plans and other internal scientific plans to see what the evolving science was yielding. Decisions informed by evidence examined bibliometric analysis of our portfolio to show where NICHD is having large yields in terms of scientific impact and citations. In regards to transparency, videos, a website, and presentations were made to communicate the process with staff, external grantees, and other stakeholders. Input was sought from the NACHHD advisory council, Friends of NICHD, working groups of NICHD staff, and external experts. The Friends of NICHD is a coalition of advocacy groups and stakeholders that work to advance the mission of NICHD and NIH. Draft themes were released for public comment and the feedback was considered as the themes were revised and refined. The strategic plan was published in September of 2019 and presented to the Advisory Council the same month.

There are five research themes in the strategic plan. The first research theme is "Understanding the Molecular, Cellular, and Structural Basis of Development", which is the recognition of powerful new technologies and techniques that can help at looking at the discovery of new cell types, for looking at the way that development evolves, in terms of genetics, other omics, and epigenetics. This research theme will expand our ability to discover fundamental mechanisms related to development and also to address other issues in pregnancy, in child development, and in normal child development as well as in disability. The second is "Promoting Gynecologic, Andrologic, and Reproductive Health" including understanding the conditions that contribute to fertility and infertility; studies on puberty such as timing of puberty and its later effects; the developmental processes related to pregnancy and infertility and gynecologic conditions; and using more model systems, genomics, phenotypic expression, and other techniques to really understand gynecologic and andrologic conditions. The third theme is "Setting the Foundation for Healthy Pregnancies and Lifelong Wellness," which includes continued emphasis on preterm birth, currently represented both in the extramural and intramural programs. Dr. Cernich noted that maternal mortality has become an all hands-on deck activity and has been a priority within the administration, with multiple initiatives in the Department of Health and Human Services and other groups working on maternal

health conditions. NICHD also continues with its Human Placenta Project related to this priority. The fourth theme is “Improving Child and Adolescent Health and the Transition to Adulthood”. Originally adolescent health had been listed separately but many in the community felt we needed to have a continuum with respect to development, while also recognizing that development ends with the transition to adulthood and adult services especially for those with intellectual, developmental, or physical disabilities or those who have been exposed to injury and trauma. This also includes looking at risk reduction strategies for infant mortality, the multiple exposures that children are experiencing both environmentally, socially and behaviorally, and looking to improve the timing of interventions or sensitive periods where we can intervene and make a real difference in the development of children. The last theme is “Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities.” As noted through PRGLAC, and in multiple opportunities through our institute, many of the populations served by NICHD are often prescribed things that have not been developed with their specific needs in mind or recognizing that there are changes in metabolism. For example, when you lose a limb, it changes the pharmacodynamics of medications because there is not the same capacity to metabolize them, there are changes in blood flow, as well as other impacts to the system. Similarly, for people who are pregnant or are lactating, we do not know what the changes are or the impact to the fetus or child. There is a need for fundamental research on pharmacokinetics, pharmacodynamics, pharmacogenomics, as well as dosing and formulation, that are critical. The study of devices is also underappreciated in this community. The idea is to think of innovative ways to address that and have multiple programs focused there.

In addition to the five research themes, there are a number of cross-cutting themes across NICHD’s scientific and public health priorities. These include global health, health disparities, prevention, nutrition, and infectious disease. The institute also recognized a number of aspirational goals which transcended all of our work and looked at crosscutting places where we could leverage multiple areas of expertise in order to advance science without being tied to specific initiatives. Dr. Cernich highlighted a few of these including limb regrowth, ways to synthesize and personalize human milk, and training investigators in artificial intelligence.

In 2016, the 21st Century Cures Act outlined requirements for the NIH Strategic Plan as well as IC strategic plans. It specifically stated that NIH should have a common template for strategic plans which had to include an overview and introduction, scientific goals, objectives, priorities of the plan, as well as serving as an efficient and effective steward of public resources with respect to scientific stewardship and management and accountability, and a section on the strategic planning process. The scientific stewardship goals are about the programs and aspects of the institute that support the science. This includes things like what we should be doing from an infrastructure perspective and programmatic perspective. The scientific stewardship goals identified in the Strategic Plan include to: promote an inclusive scientific workforce that fosters research training; facilitate data sharing and access to biospecimens; partner to enhance science; setting research priorities; align resources to support science; improve clinical trial oversight and management; monitoring and evaluating programs; and facilitating transparency and communication. Management and accountability goals include promoting workforce development and balance, ensuring infrastructure innovation, improving administrative efficiency, and advancing enterprise risk management. These goals are just as critical as the scientific goals, particularly for an organization as large as NICHD.

An additional aspect of the strategic plan is implementation and metrics, to consider how to make progress towards each objective within these themes and goals and how to develop measures to

mark progress. This is especially important for long-term goals as the institute cannot focus on everything simultaneously. In addition, the implementation processes are going to remain flexible to accommodate advances in technology, pivots in a field of research, national health priorities, etc. NICHD will be working with NIH's Division of Program Coordination, Planning, and Strategic Initiative's Office of Evaluation, Performance, and Reporting to build a system to automatically pull information from our system on any specific metrics that may be requested to tie in the strategic plan.

Questions followed. Dr. Cernich noted that even though there may be some things that are not explicitly addressed in the strategic plan, it does not mean that NICHD is no longer going to do some of that work or that we are no longer funding it. Instead the document is meant to be a guide to determine where NICHD can focus and make the most impact over the next five years. The institute will continue to partner with other institutes and ensure its populations are represented in trans-NIH initiatives.

Dr. Stratakis introduced the next speaker, Dr. Veronica Gomez-Lobo, Senior Clinician and Director of the Pediatric and Adolescent Gynecology Program. Dr. Gomez-Lobo was recently recruited from National Children's, starting with NICHD in July 2019.

Pediatric and Adolescent Gynecology Program

Dr. Gomez-Lobo presented an update on the status of the Pediatric and Adolescent Gynecology (PAG) Program. Two new faculty started September 2019: Dr. Tazim Dowlut-McElroy, from the University of Kansas who is trained in PAG, and Dr. Jacqueline Maher, from Johns Hopkins whose training was in Reproductive Endocrinology and Infertility (REI). In addition, the program had two fellows start in July 2019. The second-year fellow had done her first year fellowship through MedStar. For the 2020 match, the program also got its first and second choices, showing its standing in the field. With the start of new fellows in July, the program immediately started performing gynecologic consults in the NIH Clinical Center. They have developed a teaching protocol for pediatric and adolescent gynecology that is being submitted for scientific review and IRB.

As a new program, Dr. Gomez-Lobo has identified research priorities in four general categories. These include fertility preservation, which match the 2020 NICHD Strategic Plan: to identify biologic, social, and environmental factors that can lead or contribute to idiopathic female or male infertility. The second priority is childhood and adolescent beginnings of gynecologic conditions, to address issues like PCOS and endometriosis. There is the opportunity to potentially partnership with DIPHR and look at the NICHD Data and Specimen Hub (DASH) to see what existing databases can help answer some of existing questions regarding the origins of these gynecologic conditions. The third category is rare conditions and the implications for human health, to plan how to better take care of patients with rare conditions, implications of the abnormality, and human health in general. The fourth category is gynecologic conditions in rare diseases, to study patients' gynecologic conditions later in adulthood.

Dr. Gomez-Lobo discussed in more detail fertility preservation and ovarian tissue cryopreservation efforts. Ovarian tissue cryopreservation (OTC) is the only option for fertility preservation for prepubertal girls receiving gonadotoxic therapy. Dr. Gomez-Lobo has been running an OTC protocol at Children's National since 2012. She sees an opportunity to evaluate OTC for girls at risk

for early gonadal failure, such as those with galactosemia, Turner Syndrome, and idiopathic primary ovarian insufficiency. This protocol was submitted to scientific review, after reviewing the protocol with bioethics. Dr. Maher will be the laboratory lead on this study, looking at the anatomy and physiology of normal prepubertal ovaries, mechanism of gonadal failure in several conditions, and the possible activation and inhibition of follicles in adolescent girls with primary ovarian insufficiency. Donor tissue is being sought through the Washington Regional Transplant Consortium (WRTC) to serve as control tissue. They will also be partnering with Dr. Woodruff's Oncofertility team for the project as well as in the creation of a digital image database of all their ovarian tissue HE slides. They plan to make this image database available to the public. The PAG program is also submitting a U-01 application through the NIH intramural-extramural collaboration to study premature ovarian insufficiency in adolescents with Dr. Catherine Gordon at Boston Children's. Dr. Gomez-Lobo noted that there are many opportunities and resources across NIH and they are concentrating on opportunities to perform excellent clinical research. Dr. Gomez-Lobo concluded her presentation by thanking the staff in her program.

Questions on the science followed. Dr. Gomez-Lobo has been meeting with Dr. Mary Lilly, a basic scientist in the DIR, to discuss possible areas where they could collaborate. The BSC also recommended that Dr. Gomez-Lobo consider including the transgender population in her research.

With that, the open session concluded.