

Eunice Kennedy Shriver
National Institute of Child Health
and Human Development

**Patient Safety at the NIH Clinical Center-
The Right Path**

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Eunice Kennedy Shriver National Institute
of Child Health and Human Development

Mission Statement



- That all children are born healthy and wanted
- That women suffer no harm from reproductive processes
- That all people have the opportunity to achieve their full potential, free from disease or disability
- The health, productivity, independence, and well-being of all people through optimal rehabilitation research

NICHD DIR Overview

NICHD Division of Intramural Research Goal

Promote high-risk, high-impact laboratory and clinical investigations that can not be readily supported by extramural NIH

NICHD DIR Overview

Basic Science

Developmental Biology
Neurosciences
Biophysics and Imaging

Clinical Science

Endocrinology
 Pediatric
 Adult
 Reproductive
Genetics
Perinatal Medicine

By the Numbers

55 Tenured Investigators
6 Tenure-Track Investigators

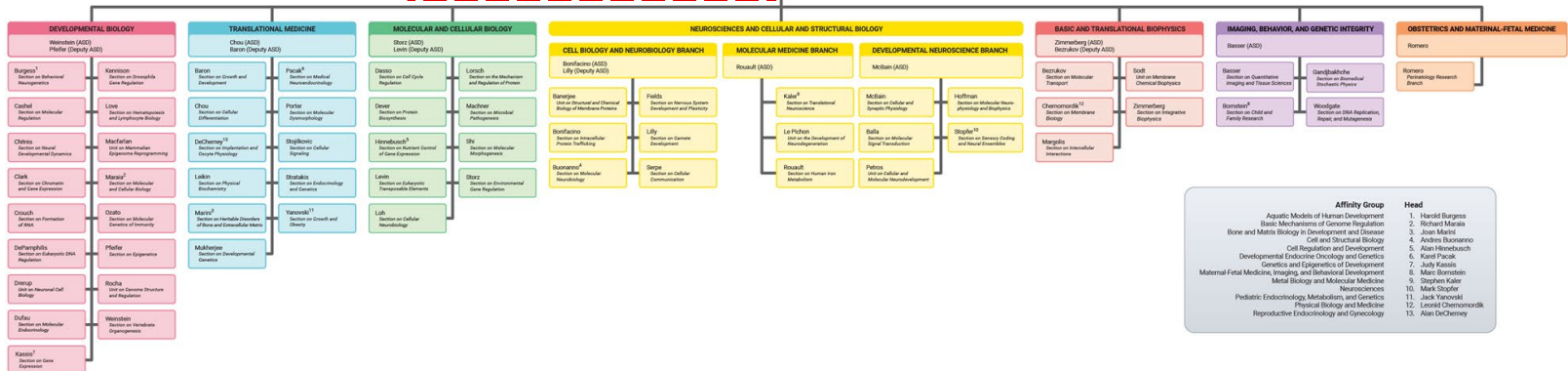
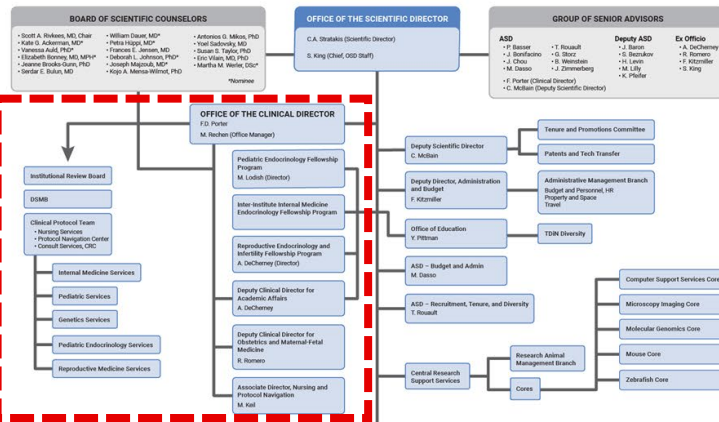
~900 Total Staff
~270 Trainees

FY18 Budget: ~\$186 million

NICHD DIR Overview

- NICHD Division of Intramural Research Organization
- “Flat structure” organized around research affinity groups

NICHD
Office of the
Clinical Director



NICHD Clinical Program

- 89 Clinical Protocols
- 31 Principal Investigators
- 154 Associate Investigators
- NICHD Institutional Review Board
- NICHD Data Safety and Monitoring Committee
- NICHD Biorepository
- Clinical Trials Database
 - 15 Institutes

NICHD Clinical Program

- Pediatric Endocrinology

- Obesity
- Bone development and growth
- Regulation of puberty

- Endocrinological Tumors

- Adrenal and pituitary tumors
- Pheochromocytoma

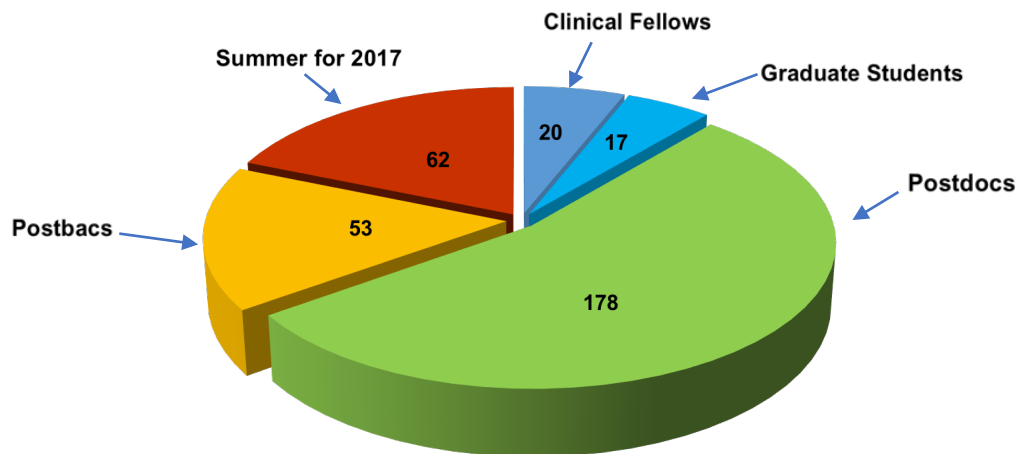
- Reproductive Endocrinology

- Rare Genetic Disorders

- Osteogenesis imperfecta
- Lysosomal storage disorders
 - NPC1, CLN3
- Smith-Lemli-Opitz syndrome
- Menkes Disease
- Creatine Transport Deficiency
- Limb-Girdle Muscular Dystrophy

NICHD Clinical Program

- NICHD Supported Medical Training Programs
 - Pediatric Endocrinology
 - Adult Endocrinology (with NIDDK and NIDCR)
 - Reproductive Endocrinology and Infertility
 - Medical Genetics (with NHGRI)
 - Maternal-Fetal Medicine (Wayne State Univ.)



NICHD Clinical Program

- NICHD Supported Consult Services

- Pediatric Endocrinology

- Leadership: Miranda Broadney (NICHD)
- Consults per year: ~500

- Adult Endocrinology

- Leadership: Ranganath Muniyappa (NIDDK), Lynnette Nieman (NICHD/NIDDK), Michael Collins (NIDCR) and Fady Hannah-Shmouni (NICHD)
- Consults per year: ~650

- Gynecology/Reproductive Endocrinology

- Leadership: Alan DeCherney (NICHD)
- Consults per year: ~480
- Surgeries per year: ~35

NICHD Clinical Program

- Reorganization of NICHD Clinical Research
 - Consolidation of clinical support resources in the NICHD Office of the Clinical Director
 - Initiated 2014/2015
 - Increase efficiency
 - Team concept
 - Cross coverage
 - Hiring of Staff Clinicians

NICHD Clinical Program

- May 2015: FDA inspection of the Pharmacy Development Service
 - August 2015: Carotid body paraganglioma resection complicated by postoperative bleeding and subsequent death of the research participant
 - NICHD Research Team
 - NIDDK Fellow
 - NCI Surgical Team
 - CC Nursing Staff
- Sentinel event reported to Joint Commission

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The Ward Chief Safety Net

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Safety at the Clinical Center



- Clinical Center Working Group (“Red Team”) Report to the Advisory Committee to the NIH Director, April 2016
- Conclusions:
 - Safety was treated as secondary to research needs
 - Failure to report/address concerns related to safety/compliance in many cases
 - Inadequate research and clinical support systems in place



Red Team Report

1. Improve the safety and quality of clinical patient care
2. Reduce risks of clinical research
3. Identify and eliminate potential gaps among clinical services

NICHD Ward Chief



- Oversee and enhance the safety and quality of clinical care provided to all NICHD inpatients
- Clinical support for research protocols

NICHD Ward Chiefs

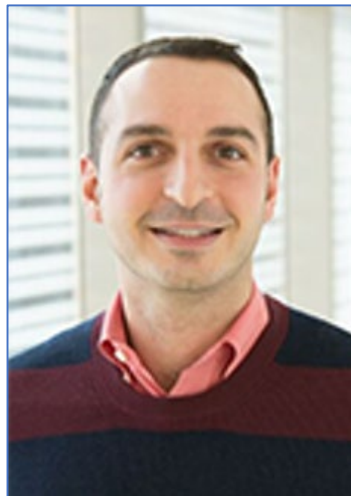
Deena Zeltser, MD
Pediatric Hospitalist



Simona Bianconi, MD
Pediatric Geneticist



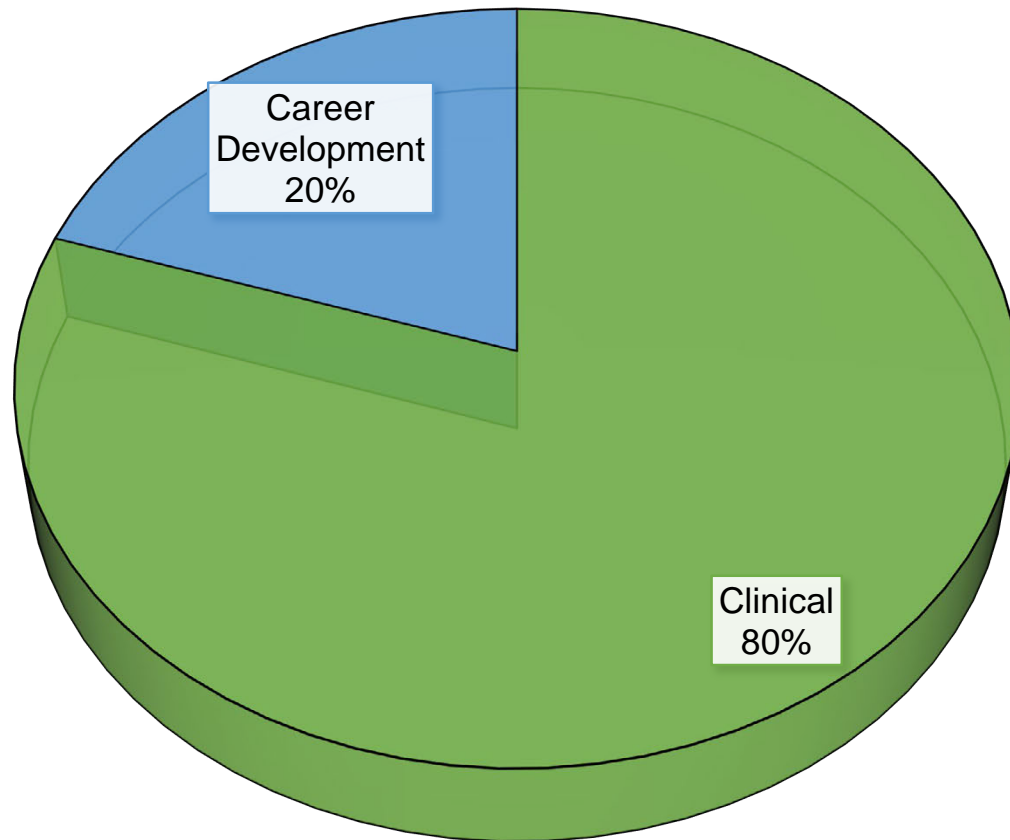
Fady Hannah-Shmouni, MD
Adult Endocrinologist
and Geneticist



An Dang Do, MD, PhD
Adult and Pediatric
Geneticist



Ward Chief Duty Allocation



Clinical Duties



- Rounds daily with the NICHD protocol teams
 - **Clinical support** for general pediatric issues (post-op analgesia, arrhythmias, anemia, tachycardia, hypertension, etc.)
 - **Liaison** between the patients, families, protocol team, and other NIH caregivers
 - Establish rounding times for multiple protocol teams to enhance each team's overall **workflow efficiency**
 - General **point of contact** and provide backup clinical support if the primary team cannot be reached

Clinical Duties: The 3 C's



- **Catches: A Safety Net**
 - Comprehensive review of medical charts of all NICHD pediatric inpatients
 - Safety catches: medication errors, intravenous fluid rate/composition errors, documentation errors
- **Consultation**
 - General Pediatric consultation for non-pediatric Principal Investigators (PI's), and Internal Medicine (IM) consults for non-IM PI's
 - Medical clearance for surgical candidates
- **Communication**
 - Improve and facilitate communication between research teams, clinical providers, and patients/families

Professional Development



- **Education**

- Associate Director of Adult Endocrinology Inter-Institute Fellowship Program
- Enrolled in the Masters in Clinical Research Program (Duke University)
- Developing a NICHD Medical Genetics Elective for clinical trainees
- Daily clinical support and supervision for Endocrinology clinical trainees

- **Committees**

- CRIS Provider Group Committee (Chairperson)
- Pediatric Care Committee
- Pharmacy and Therapeutics Committee
- Clinical Informatics Management Committee
- NICHD Scientific Review Committee
- Pediatric Anesthesia and Critical Care (PACC) Hospitalist Selection Committee

- **Clinical Research**

- Principal Investigators and/or Associate Investigators with research protocols related to multiple endocrinologic and genetic disorders

NICHD Clinical Program

Impact of the Red-Team Report on NICHD

Impact of the Red-Team Findings on NICHD

- Closure of Pharmacy Development Service
 - Studies cancelled and delayed
 - Increased costs
 - Lack of placebos
- Increased concern with respect to medical care available for pediatric research participants
 - Decreased admissions and increased referrals
 - Modified protocol admissions
- Impact on clinical research?
 - Study of rare disorders with childhood onset
 - Development of novel therapies
 - Therapeutic interventions prior to significant disease burden
 - Developmental origins of health and disease

Impact of the Red-Team Findings on NICHD

- Forward Steps

- Increased patient safety by implementation of a Ward Chief system for NICHD patients
- Oral agent compounding being considered
 - Placebo and active agent
- Intermediate Care Unit (IMC)
 - Sedation of pediatric research participants
 - Sedation of cognitively impaired research participants
- Pediatric Anesthesia and Critical Care Unit (PACC)
 - Monitored beds
 - 24/7 in house pediatric coverage
- Collaboration with extramural institutions

NICHD Clinical Program

High quality and safe clinical care
and
Unique, high-risk and high impact clinical science

