

**Request for Approval under the “Generic Clearance for the Collection of Qualitative
Feedback on Agency Service Delivery (NICHD)”
(OMB#: 0925-0648 ExpDate: 6/30/2024)**

2023 Principles of Pediatric Clinical Pharmacology – Learning Objectives

1/11/2023: Stages and Phases - the Importance of Mentorship Throughout Your Career

Lecture Speaker: Susan Abdel-Rahman and Stephani Stancil

Learning Objectives:

- Build and strengthen constructive, productive relationships between mentors and mentees
- Define and distinguish various levels of engagement
- Expand your toolbox for fostering professional growth

1/18/2023: Application of Metabolomics in Pediatric Type 2 Diabetes

Lecture Speaker: Jennifer Meijer

Learning Objectives:

- Receive an overview of metabolomics sample collection, instrumental analysis, and data analysis.
- Understand the application of metabolomics in acute macronutrient challenges, including a high-fat challenge for prediction of type 2 diabetes risk.
- Receive an overview of metabolic changes in response to glucagon-like peptide-1 receptor agonist treatments.

1/25/2023: In Vivo Bioimaging in Pediatric Infections

Lecture Speaker: Sanjay Kumar Jain

Learning Objectives:

- Identify the differences between conventional and molecular imaging approaches to measure antimicrobial drug distribution.
- Recognize the spatiotemporal kinetics of antimicrobial drug distribution.

2/1/2023: Pharmacotherapy of Diabetes in Pediatrics

Lecture Speaker: Kristen Nadeau

Learning Objectives:

- Identify differences in demographic and physiological differences in youth vs. adults with type 2 diabetes and how this impacts therapeutic choices.
- Identify current recommended treatment approaches to youth with type 2 diabetes.
- Review similarities and differences between type 1 and type 2 diabetes in youth, especially in the setting of obesity.
- Identify pediatric data available on adjuvant pharmaceutical therapies in type 1 diabetes that address insulin resistance and obesity.

2/8/2023: Pharmacotherapy to Treat Pediatric Obesity

Lecture Speaker: Jack Yanovski

Learning Objectives:

- Describe the data supporting the use of anorexiants to treat childhood obesity
- Describe the supporting the use of malabsorptive agents to treat childhood obesity
- Describe the data evidence supporting the use of therapies that diminish insulin secretion to treat childhood obesity
- Understand the mechanisms of action of new agents approved for use in adults over the past year but not yet studied in pediatric samples

2/15/2023: Neonatal Pharmacology**Lecture Speaker:** Jack Aranda**Learning Objectives:**

- Become familiar with the various developmental changes in ADME and their impact on drug dosing in the various populations of newborn babies
- Have knowledge on the dynamic changes in drug disposition and drug action
- Become familiar with the ongoing challenges in drug development and in pharmacotherapies for newborn infants

2/22/2023: Remotely Targeted and Triggered Drug Delivery Systems**Lecture Speaker:** Daniel Kohane**Learning Objective:**

- Develop an understanding of the rationales behind targeted and triggered drug delivery systems, the types of clinical problems they can be adapted to, and the types of drug delivery systems and remote triggers that can be employed

3/1/2023: Pediatric Formulations - Past, Present, and Future**Lecture Speaker:** Karen Thompson**Learning Objectives:**

- Understand how gaps in PBPK modeling still lead to uncertainties in dosing level or frequency
- Understand how new guidance to seek to minimize dosing errors leads to additional testing in usability / human factors
- Learn about evolving approaches to taste assessment
- Gain understanding of the need for paths of shared learning to move knowledge forward in pediatric development

3/8/2023: Recent Developments in Nanomedicine for Pediatric Therapy, Diagnosis, and Imaging**Lecture Speaker:** Srinivas Sridhar**Learning Objectives:**

- Understand the role of nanotechnology in medicine
- Learn about nano formulations for drug delivery: synthesis, characterization, manufacturing
- Learn about the use of nanotechnology for diagnostics
- Discuss applications in pediatric imaging
- Appreciate the promise and challenges of translating nanomedicines to the clinic

3/15/2023: Maternal Medications and Breastfeeding**Lecture Speaker:** Philip Anderson**Learning Objectives:**

- Understand what affects the transfer of maternal drugs into breastmilk
- Understand infant absorption of medications in breastmilk
- Know at least 2 reliable resources that can help determine the safety of medications in breastmilk

3/29/2023: Preparing for Science-Based Non-Traditional Careers**Lecture Speakers:** Priya Jayachandran, Eric Wohlford, Suruchi Batra**Learning Objectives:**

- Learn about different science-based career opportunities outside of academia.

4/12/2023: Challenges and Opportunities in Pediatric Drug Development**Lecture Speaker:** Jonathan Davis**Learning Objectives:**

- Better understand difficulties in studying new and existing drugs for children
- Learn about legislative efforts to accelerate drug approvals
- Learn about precision medicine efforts to develop therapies for rare diseases

- Learn about cooperative networks and public private partnerships to accelerate these efforts

4/19/2023: Neonatal Drug Disposition and Renal Maturation

Lecture Speaker: Jian Wang

Learning Objectives:

- Explore the utilization of equations used to define pediatric renal function and how this relates to individualized drug exposure.
- Demonstrate several examples related to optimization of those models that incorporate renal function and utility of individual predictions using population pharmacokinetic models.
- Explore the impact of when estimating varying renal function and the impact on pharmacokinetic parameters such as drug clearance in neonates.

4/26/2023: Ethical Considerations for Maternal and Pediatric Pharmacology Research

Lecture Speaker: Annie Lyerly

Learning Objectives:

- Understand historical reasons for the exclusion of pregnant persons from research, and the harms that have resulted
- Identify ethical principles that support increased pharmaceutical research in pregnant populations
- Describe key opportunities to advance responsible research in pregnancy within the current regulatory environment

5/3/2023: Pharmacotherapy for Transgender Children and Adolescents

Lecture Speaker: Johanna Olson-Kennedy

Learning Objectives:

- Recognize the indications for and the benefits of GnRH analogs in youth with gender dysphoria
- Understand the goals of gender affirming hormone use in transgender youth care
- Describe the permanent changes that result from the use of estrogen and testosterone and those that require ongoing use of hormones

5/10/2023: Parade of Fellow Graduates

Lecture Speaker: Pending.

Learning Objectives:

- Learn about peer research from different fellowship sites.
- Identify areas for collaborations across sites.