## 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)

**2022-23 Principles of Pediatric Clinical Pharmacology – Learning Objectives**

**10/12/2022: Developing your Elevator Speeches and Negotiation Tips and Insights**

**Lecture Speaker:** Lauren Celano

**Learning Objectives:**

* Understand the purpose of an elevator pitch.
* Learn how to develop an elevator pitch.
* Learn how to tailor an elevator pitch.
* Understand what is negotiable in a job offer.
* Understand how to determine what is most important for each individual to negotiate.
* Learn different strategies to negotiate an offer.

**10/19/2022: Inside NIH Study Sections – Navigating Grant Submission & Review**

**Lecture Speaker:** Dianne Hardy

**Learning Objectives:**

* Understand review criteria
* Understand what happens when you submit your grant application

**10/26/2022: Ontogeny of Transporters**

**Lecture Speaker:** Saskia deWildt

**Learning Objectives:**

* Explain the clinical relevance of membrane transporters in pediatric drug therapy and discuss several examples
* Describe transporter specific developmental patterns
* List research approaches for studying pediatric drug transporters
* Identify major challenges in elucidating the human ontogeny of drug transporters

**11/2/2022: Drug Exposure and Response in Pregnancy**

**Lecture Speaker:** Raman Venkataramanan

**Learning Objectives:**

* Describe important physiologic factors that impact drug exposure in pregnancy
* Design studies to evaluate pregnancy mediated changes in drug exposure
* Predict potential dosing changes for drugs with specific PK properties
* Interpret literature on PK in pregnancy

**11/9/2022: Physiologically-Based Pharmacokinetic Modeling**

**Lecture Speaker:** Sara Quinney

**Learning Objectives:**

* Recognize PBPK modeling structure and components, including drug- and system-specific parameters, and the difference between PBPK and empirical PK models.
* Understand how PBPK can support pediatric drug development and precision therapy.
* Discuss best practices for developing a pediatric PBPK model

**11/16/2022: Pharmacokinetic and Pharmacodynamic Studies for Inhaled Asthma Drugs**

**Lecture Speaker:** Leslie Hendeles

**Learning Objectives:**

* Explain how fluticasone propionate blood levels can be used to determine the relative amount of inhaled corticosteroid delivered to the airways.
* Describe how the static charge on a valved holding chamber affects the relative amount of albuterol delivered to the airways.
* Understand how a methacholine challenge can be used to determine the bioequivalence of a generic albuterol metered dose inhaler.

**11/30/2022: Pharmacogenomics and Bioinformatics in Drug Discovery**

**Lecture Speaker:** Anil Jegga

**Learning Objectives:**

* Introduce and give an overview of some of the state-of-art databases and servers that can be used for pharmacogenomics research and drug discovery
* Explain how existing data can be harnessed to “guide” or “inform” translational medicine
* Provide examples of the application of data repurposing for drug discovery

**12/7/2022: Quantitative Pharmacologic Systems Models**

**Lecture Speaker:** Jeff Barrett

**Learning Objectives:**

* Understand the mechanics of QSP modeling as applied to pediatric drug development and extrapolation strategies
* Examine the potential for QSP to examine adult and pediatric disease similarity
* Understand uses cases and how these examples have been incorporated into recent ICH guidance on pediatric extrapolation

**12/14/2022: Path Towards Authorization of a COVID-19 Vaccine for Children**

**Lecture Speaker:** Emmanuel Walter

**Learning Objectives:**

* Describe the rationale and benefits for vaccinating children to prevent COVID-19 disease
* Outline the steps to development of a COVID-19 vaccine for children
* Describe effectiveness of the COVID-19 vaccine in children
* Describe the safety considerations regarding the use of mRNA COVID-19 vaccines in children

**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.