

PedSAP 2017 Book 1 (Research and Study Design in Pediatrics)

Total Available Hours: 8.5

BCPPS test deadline: 11:59 p.m. (Central) on May 15, 2017.

ACPE test deadline: 11:59 p.m. (Central) on January 14, 2020.

Research and Study Design in Pediatrics I (Module 1) – Credit Hours: 5.0

Chapter: Ethical Considerations in Pediatric Research

Learning Objectives

1. Apply the ethical principles described in the Belmont Report.
2. Demonstrate the concepts of beneficence, justice, and respect for persons as they relate to pediatric research.
3. Discover study design issues that are implicated by the inclusion of pediatric subjects.
4. Evaluate challenges to conducting research in pediatric populations.

Chapter: Study Design in Pediatrics

Learning Objectives

1. Justify when a pediatric study is scientifically necessary and when extrapolation from adult data is valid.
2. Evaluate design issues unique to pediatric drug studies for each age category (neonates, infants, children, and adolescents).
3. Design a clinical study for a child of any age.
4. Apply the principles of developmental pharmacology in the design, conduct, and interpretation of pediatric studies.
5. Develop and apply strategies for overcoming the challenges of conducting clinical trials in children.
6. Judge whether a research protocol is appropriate for conduct in a child of a given age.

Chapter: Database Research in Pediatrics

Learning Objectives

1. Analyze the different types of database resources available for database research.
2. Evaluate the advantages and disadvantages of database research.
3. Estimate the impact that confounding has in the practice of database research.
4. Evaluate common study designs used in database research and assess their impact on interpretation of study results.
5. Design a plan that will assist the researcher in preparing to conduct pediatric database research.
6. Justify the use of popular pediatric databases and the information they contain for research.

Clinical and Practice Updates (Module 2) – Credit Hours: 3.5

Chapter: Recorded Webcast: Pediatric Study Design

Learning Objectives

1. Demonstrate knowledge of the clinical research process, including the process for developing a study concept.
2. Analyze the most important elements in preparing a study protocol.
3. Identify the different types of study costs, and estimate these costs when preparing a budget.
4. Classify the various strategies used in recruitment and enrollment of pediatric subjects.

Chapter: Interactive Case: Developing and Adopting Novel Therapies in the NICU

Learning Objectives

1. Demonstrate an understanding of clinical practice guidelines and their intent.
2. Account for the frequency with which practice guidelines and expert opinions are reversed in medical practice and the areas of vulnerability for neonatal practice guidelines.
3. Evaluate when early adoption of new therapeutic practices may be indicated.
4. Argue the potential negative impact of early adoption of expert panel practice guidelines founded primarily on systematic reviews of studies with several limitations, without sufficient consideration for future outcomes.
5. Account for the inherent flaws of many expert guidelines and recommendations, and place in perspective the pharmacologic considerations for when guidelines and dosing handbooks may be ill informed.

Chapter: Recorded Webcast: Medical Records Research

Learning Objectives

1. Classify the elements and functions of the medical record.
2. Apply real-world data to clinical research methods.
3. Analyze the strengths and weaknesses associated with medical records research.
4. Assess examples of pediatric-specific medical records research.