

**UT Southwestern Medical Center
Department of Pediatrics
Division of Neonatal-Perinatal Medicine**

Clinical Studies – As of August 1, 2008

Faculty	Funding Agency & Number	Total Time of Support	Project Title	Annual Direct Costs
Brion, LP	IRB Approved Study		Use of Neonatal Intensive Care Nursery Registry to Evaluate the Process, and to Determine Clinical Events and/or Conditions that may Modulate Practice and Outcomes – NICU PHHS	No external funding
Brion, LP	IRB Approved Study		Use of neonatal intensive care nursery registry to evaluate the process, and to determine clinical events and/or conditions that may modulate practice and outcomes – NICU at Children’s Medical Center	No external funding
Brion LP, Wyckoff MH, Jaleel M, Sánchez P, Burchfield J, Christie L.	IRB Approved Study		Delivery room practice change following the initiation of the NICHD support trial	No external funding
Chalak L	NIH/NCRR 5 KL2 RR024983-02 (Packer - PI)	9/17/07- 5/31/12	North and Central Texas Clinical and Translational Science Initiative	\$50,000/year
Engle, W	IRB Approved Study		Effect of Phototherapy on Auditory Brainstem Response in Term and Near-term Neonates	No external funding
Engle, W	IRB Approved Study		Evaluation of Transcutaneous Bilirubinometry in the Preterm Neonate	No external funding
Engle, W	IRB Approved Study		Is Lumbar Puncture Indicated in Preterm Neonates with Early Apnea?	No external funding
Engle, W	IRB Approved Study		Altered Calcium Homeostasis in Term Neonates: Possible Association with Gentamicin Dose and/or Dosing Interval	(see below)
Engle, W	IRB Approved Study		Pulse Oximetry Screening at Four Hours of Age to Detect Critical Congenital Heart Defects	No external funding
Engle, W	IRB Approved Study		An Hour-specific Nomogram for Transcutaneous Bilirubin Values in Term and Late Preterm Hispanic Neonates	No external funding
Engle, W	IRB Approved Study		Meta-analysis of Skin Bilirubin Kinetics in Nomograms Describing the Natural Course of Neonatal Hyperbilirubinemia	No external funding

Engle, W	IRB Approved Study		Circulating Blasts and Associated Hematologic Disorders in Down Syndrome Neonates	No external funding
Engle, W	IRB Approved Study		Measurement of the Anterior Fontanel in Term and Late Preterm Hispanic Neonates: Description of Normal Measurements and Proposal of an Alternate Measurement Method	No external funding
Engle, W	Clinical Trial		Altered Calcium Homeostasis in Term Neonates: Possible Association with Gentamicin Dose and/or Dosing Interval	(see below)
Engle, W: local PI (PI is Dr. Aranda)	Government Funded	12/1/07 – 11/30/09	Multicenter open label, pharmacokinetic study of a single oral dose of codeine in mechanically ventilated newborn infants (NIH; PPRU) not listed above since this study has not been IRB-approved	\$4580, plus support from PPRU
Engle, W	Non-Profit Funded	5/28/02 - study	Altered Calcium Homeostasis in Term Neonates: Possible Association with Gentamicin Dose and/or Dosing Interval	GCRC, laboratory support; CMC Foundation, \$4495
Engle, W	For Profit Funded	10/01/07 – 09/30/08	Evaluation of a Transcutaneous Bilirubinometer in an Outpatient Setting	(Dräger Air-Shields, \$4300)
Heyne, R Follow-up PI (Sanchez-principal PI)	NIH (NICHD) 5-U10-HD40689-05	2006-2011 (5%)	Research Network – multiple follow-up studies, including Follow up ELBW, Support, Hypothermia (6-7yo)	~50,000
Heyne, R (Sanchez-principal PI)	Thrasher Foundation; IRB 102006-061	2007-2008	Influenza Vaccine Immunogenicity in Extremely Premature Infants – Clinical Study	Non-profit
Duncan, A (Mentor, Heyne, R)	AAP, Section on Perinatal Pediatrics, Klaus Award	07/01/07 – 06/30/09	Effects of VLBW, Prematurity and Postnatal Growth on Blood Pressure During the First 3yrs of Life	\$5,000
Sanchez, P PI	NIAID (CASG)	(1999 – present)	Collaborative Study Performed by the Collaborative Antiviral Study Group (CASG), “A Double-Blind, Placebo-Controlled, Virologic Efficacy Trial of Pleconaril (VP63843) in the Treatment of Neonates with Enteroviral Sepsis Syndrome	\$2000/patient

Sanchez,P PI	(GCRC Protocol #P806-10-05 USPHS Grant #M01- RR00633); Pediatric Infectious Disease Society Fellowship Award	2005 – present	“Nomogram for Gentamicin Dosing in Early Infancy,”	
Sanchez,P PI	RFP 260-03-19,	2005- 2012; 7 years	“The Natural History of CMV-related Hearing Loss and the Feasibility of CMV Screening as Adjunct to Hearing Screening in the Newborn, National Institutes of Health, National Institute on Deafness and Other Communication Disorders,	\$1,200,794 (25%).
Sanchez, P (PI)	MedImmune, Inc.,	2007-2008	“A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of MEDI-524, a Humanized Enhanced Potency Monoclonal Antibody Against RSV in Children with Hemodynamically Significant Congenital Heart Disease	\$9360/patient.
Sanchez,P PI	(CASG 114, DMID #06- 0059),”	2006-2008	Pharmacokinetic/Pharmacodynamic and Safety Evaluation of Oseltamivir (Tamiflu for the Treatment of Children Less than 24 Months of Age with Confirmed Influenza Infection.	\$8500/patient (1%).
Sanchez,P PI	NICHD: Grant Number: 2 U10 HD040689-06,	2006-2011 (10%)	NICHD Cooperative Multicenter Neonatal Research Network (NRN)	\$180,000
Sanchez, P	NRN; IRB 0101- 047		Survey of Morbidity and Mortality Among Very Low Birth Weight Infants (401 to 1500 grams)	Govt Funding
Sanchez, P	NRN: IRB 012005-019		The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Govt Funding
Sanchez, P	NRN: IRB 012006-049		Early Onset Sepsis An NICHD/CDC Surveillance Study	Govt Funding
Sanchez, P	GCRC; IRB 012006-050		Nomogram for Gentamicin Dosing in Early Infancy (GCRC Protocol #P806-10-05; 11-01-2005)	GCRC
Sanchez, P	IRB 022006-042		Influenza in Children	None
Sanchez, P	NRN: IRB 022008-073		Evaluation of Systemic Hypothermia Initiated After 6 Hours of Age in Infants > or equal to 36 Weeks Gestation with Hypoxic- Ischemic Encephalopathy: A Bayesian Evaluation (Late Hypothermia Study for HIE)	Govt Funding

Sanchez, P	IRB 0586-146		Fetal IgM Response to Treponema Pallidum in Congenital Syphilis	None
Sanchez, P	IRB 0603-337		Neonatal Sepsis Database	None
Sanchez, P	IRB 0603-366		Immunizations in Preterm Infants	None
Sanchez, P	NRN; IRB 0603-393		Association of Apolipoprotein E (Apo E) Genotype with Brain Injury and Neurodevelopmental Outcome in Infants With Hypoxic-Ischemic Encephalopathy	Govt Funding
Sanchez, P	IRB 092005-031		Infections Associated with Cochlear Implants in Children	None
Sanchez, P	NIAID (CASG); IRB 092007-012		A Phase III, Randomized, Placebo-controlled, Blinded Investigation of Six Weeks VS. Six Months of Oral Valganciclovir Therapy in Infants with Symptomatic Congenital Cytomegalovirus Infection	Govt Funding
Sanchez, P	IRB 092007-026		Syphilis Among Pregnant Women and Infants	None
Sanchez, P	NRN; IRB 1003-662		Neurodiagnostic Evaluations Following Acute Perinatal Asphyxia	Govt Funding
Sanchez, P	NRN; IRB 102005-005		Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)	Govt Funding
Sanchez, P	Thrasher Foundation; IRB 102006-061		Influenza Vaccine Immunogenicity in Extremely Premature Infants – Clinical Study	\$12,568 Non-Profit
Sanchez, P	IRB 112005-036		Vancomycin Reduction in the NICU	None
Sanchez, P	NRN; PPRU IRB 112006-059		Phase II Randomized, Double Blind, Placebo Controlled, Safety and Pharmacokinetic study of a Single Dose of Inositol in Premature Infants	Govt Funding
Sanchez, P	NRN; New		Randomized Clinical Trial of Inhaled PGE1 in Neonatal Hypoxemic Respiratory Failure	Govt Funded
Sanchez, P	New		Systemic Hypothermia for Hypoxic-Ischemic Encephalopathy: MRI Findings and Outcome	None
Sanchez, P	PPRU; Novartis; IRB 032007-035		A multicenter, open-label, single-arm study to evaluate the single-dose pharmacokinetics and safety of Famciclovir After Administration of Famciclovir Oral Pediatric Formulation to Infants 1 Month of age to <1 year of age with herpes simplex or varicella zoster virus infections	gov't; for-profit \$3780/patient

Sanchez, P	PPRU; Astellas; IRB 012007-063		A Phase I, Open-Label Study of the Safety and Pharmacokinetics of Repeated-Dose Micafungin (FK463) in children (2-5 Years and 6-11 Years) and Adolescents (12-16 Years) With Esophageal Candidiasis or Other Invasive Candidiasis. Protocol Number: 9463-CL-2101	gov't; for-profit \$14,000/patient
Sanchez, P	PPRU; Astellas; IRB 082006-028		A Multi-Center, Open-Label, Single-Arm, Two-Step Study to Evaluate the Safety and Single-Dose Pharmacokinetics of Famciclovir and Multiple-Dose After Administration of Famciclovir Oral Pediatric Formulation to Children 1 to 12 Years of Age with Herpes Simplex Infection	gov't; for-profit \$14,900/patient
Sanchez, P	PPRU; IRB 032007-036		A Phase 1, Open-Label Study of the Safety and Pharmacokinetics of Repeated-Dose Micafungin (FK463) in Infants and Toddlers (>4 months to 24 Months of Age) with Esophageal Candidiasis or Other Invasive Candidiasis	gov't
Sanchez, P	PPRU; IRB 052007-033		Antimicrobial Pharmacokinetics in High-Risk Infant Study (PPRU #10824) and Urinary Proteomics in Antimicrobial / Antifungal-Treated Newborns	gov't; \$3,100/patient
Sanchez, P	PPRU; IRB 052008-070		Multiple Dose Pharmacokinetic Study of Meropenem in Young Infants (less than 91 days) with Suspected or Complicated Intra-Abdominal Infections.	gov't for-profit
Sanchez, P	PPRU; IRB 112006-021		Protocol MI-CP141: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate a Single Intravenous Dose of Motavizumab (MEDI-524), a Humanized Enhanced Potency Monoclonal Antibody Against Respiratory Syncytial Virus (RSV), for the Treatment of Children Hospitalized with RSV Illness (Version 1.0, 9/18/06)	\$10,498/patient
Sanchez, P	Medimmune, Inc.	2007-2009	NRN, NICHD Neonatal Research Network	\$10,498/patient
Savani (PI)	NIH R01HL 075930	09/30/03-09/29/07	Hyaluronan in Lung Vascular Development	\$275,000
Savani (PI)	NIH R01HL073896	04/01/04 - 03/31/09	Pulmonary Collectins, Hyaluronan and Macrophages	\$250,000
Savani (Co-PI)	NIH R01HL079090	12/01/04 - 11/30/08	PECAM-1 and Alveolarization	\$70,000

Sendelbach, D PI: Jody Dashe, MD	Observational Study		Serotonin Reuptake Inhibitor Use During Pregnancy: Perinatal Outcomes,	
Sendelbach, D	Compassionate use IRB# 042005-055		Safety and Efficacy of Varicella Zoster Immune Globulin (Human) (Varizig TM) in Patients at risk of Varicella Infection	
Sendelbach, D	Retrospective Chart Review IRB# 042008-010		Treatment of Neonatal Abstinence Syndrome: A Retrospective Comparison of Methadone Versus Neonatal Opiate Solution in Term and Near-Term Infants.	
Sendelbach, D	Observational study IRB No: 062005-066	Study essentially complete; awaiting Texas Birth Defects Registry Data	Pulse Oximetry Screening of Term and Near-term Neonates at 4 Hours of Age to Detect Asymptomatic Cyanotic Heart Defects	
Shaul, P (PI)	NIH 5R01HL 87564	08/01/06 - 05/31/10	Oxysterols, Estrogen Receptor Modulation and Vascular Disease	\$250,000
Wyckoff MH (PI)	AAP NRP Investigator Grant	Jan 2008 – Jan 2009	The ergonomics of neonatal cardiac compressions. (Clinical Study)	\$71,030
St. John, L. Wyckoff MH (Mentor)	AAP NRP Young Investigator Grant (application pending)	Sep 2008- Sep 2009	Effectiveness of Plastic Head Coverings for Hypothermia Prevention in Preterm Newborns (Clinical Trial)	\$7,483
Jaleel M, Brion LP, Wyckoff MH (PI)	None	Jan 2008- Jan 2009	Impact of changes in the 2006 Neonatal Resuscitation Program (NRP) recommendations for epinephrine usage in the delivery room. (Retrospective Clinical Study)	
Osterholt HC, Dannevig I, Wyckoff MH, Martinez R, Goulet E, Nakstad B, Saugstad OD, Savani RC	None	Jan 2008- Jan 2009	Newborn piglet resuscitation with 100% O ₂ is associated with increased lung 3-nitrotyrosine and decreased hyaluronan	None
St. John L, Wyckoff MH	None	Jan 2008- Jan 2009	Risk factors for the development of hypothermia in preterm neonates	None