

EXHIBIT H

Retrospective Research Studies

RETROSPECTIVE RESEARCH

Location	Study Title	PI's Name	IRB Approval Date	DMC Number
Children's Hospital of Michigan	Pulmonary Conduit Study	WALTERS III,HENRY L.	2/23/2011	11004
Children's Hospital of Michigan	Optimal Management of Critical Left Ventricular Outflow Tract Obstruction. A Congenital Heart Surgeons' Society Study	WALTERS III,HENRY L.	2/23/2011	11008
Children's Hospital of Michigan	Prospective Analysis of Clinical and Molecular Characteristics of MRSA/VRE Dual Infection	Martin, Emily Toth	1/3/2011	11390
Children's Hospital of Michigan	of Children Presenting to an Outpatient Pediatric Urology Clinic	Wolfe-Christensen, Cortney Brett	1/19/2011	11404
Children's Hospital of Michigan	Mastoiditis in Children	Abdel Haq, Nahed Mustafa	3/17/2011	11480
Children's Hospital of Michigan	Outcomes for Families of Children Hospitalized with Asthma in a Diverse, Urban Pediatric Population: A Descriptive Study	Ball, Allison Lynn	4/7/2011	11488
Children's Hospital of Michigan	Ideal Duration of an ECMO Trial, Is There Consensus?	Gonzalez , Raquel	3/25/2011	11491
Children's Hospital of Michigan	Matrix Metalloproteinase System and the Complications of Prematurity	Prasun , Pankaj	3/25/2011	11495
Children's Hospital of Michigan	Is Pharmacologic Intervention Really Required in Children with ITP?	Chitlur, Meera B	2/16/2011	11501
Children's Hospital of Michigan	Effect of Music on Weight Gain in Preterm Neonates: A Randomized Controlled Trial	Chawla, Sanjay	3/11/2011	11505
Children's Hospital of Michigan	Infantile Orbital Cellulitis: Ten Years Review	Zegarra-Linares , Ricardo	12/19/2011	11521
Children's Hospital of Michigan	The Role of Patient-Provider Communication and Illness Management Behavior among Children Diagnosed with Type 1 Diabetes	Carcone, April Marie-Idalski	4/26/2011	11528

TOTAL	540
Hospital	Total
Children's Hospital	271
Detroit Receiving	140
Harper Hospital	70
HVSH	8
Hutzel	1
RIM	9
SGH	39
DMC	2

Children's Hospital of Michigan	Frequency of Failure to Thrive in Children with Suspicious Burns Compared to Children with Accidental Burns	Angelilli, Mary Lucrezia	2/15/2011	11533
Children's Hospital of Michigan	Longitudinal Assessment of Risk Factors For and Impact of Pseudomonas Aeruginosa Acquisition and Early Anti-Pseudomonal Treatment in Children with Cystic A retrospective comparison of epidemiology, clinical presentation and outcomes of influenza strains for	Abdulhamid, Ibrahim F.	3/22/2011	11536
Children's Hospital of Michigan	influenza A (novel H1N1, seasonal H1N1 and H3N2) and influenza B and A randomized treatment comparison	Martin, Emily Toth	4/28/2011	11540
Children's Hospital of Michigan	of Post-Operative Pain Management for Pediatric Patients Undergoing Trichotomous Outcome Prediction in Critical Care (The TOPICC Study)	Reynolds , Richard	4/28/2011	11546
Children's Hospital of Michigan	Protocol version 3.0, dated October 10, 2011	Meert, Kathleen Lynn	4/29/2011	11550
Children's Hospital of Michigan	Prospective Yield Study of Children with Severe Traumatic Brain Injury (TBI) in PECARN: Pilot Feasibility for a Randomized Controlled Trial of Progesterone for Severe TBI (Progesterone Yield Study), Protocol v. 1.0, 04/19/11	Mahajan, Prashant V.	5/4/2011	11553
Children's Hospital of Michigan	Translating an Adult Ventilator Computer Protocol to Pediatric Critical Care - Protocol Version 1.01 dated October 9, 2012	Meert, Kathleen Lynn	5/3/2011	11559
Children's Hospital of Michigan	Cardiac Resynchronization Therapy in the Failing Congenital Heart	Sanil, Yamuna	5/9/2011	11575

Children's Hospital of Michigan	Emergency Department Utilization by Children with a Single Cardiac Ventricle Following Stage II Surgical Palliation	Mastropietro, Christopher W.	6/7/2011	11587
Children's Hospital of Michigan	Social Work, Psychology, Asthma Specialist and Protective Service Involvement and the Relationship to Asthma Related Deaths: A 15 Year Retrospective Chart Review	Secord, Elizabeth Ann	7/22/2011	11595
Children's Hospital of Michigan	Clinical Analysis of the New CLSI Breakpoints for Ertapenem among Extended Spectrum Beta-Lactamase (ESBL)-Producing Enterobacteriaceae Treated with Ertapenem	Kaye, Keith Steven	6/30/2011	11608
Children's Hospital of Michigan	Prevalence and Implications of Obesity in Adults with Congenital Heart Disease	Aggarwal, Sanjeev	6/15/2011	11611
Children's Hospital of Michigan	Children with Enuresis and ADHD: A Separate Entity?	Kovacevic , Larisa	7/12/2011	11640
Children's Hospital of Michigan	Pediatric Urolithiasis: Single Center Experience Metabolic Work-Up, Role of Diet, and Detection of Markers for Early Kidney Damage	Kovacevic , Larisa	7/12/2011	11641
Children's Hospital of Michigan	Slipped Capital Femoral Epiphysis (SCFE): Evaluating the Incidence of Complications in Single-Screw Fixation Compared to Other Treatment Procedures	Reynolds , Richard	7/11/2011	11646
Children's Hospital of Michigan	Impact of Intra-Operative Cryoablation with Pulmonary Valve Replacement on Ventricular Tachyarrhythmia in Patients with Repaired Tetralogy of Fallot	Kobayashi , Daisuke	7/15/2011	11650
Children's Hospital of Michigan	Skin and Soft Tissue Infections (SSTI) in Children: Risk Factors for Admission and Clinically Important SSTI	Velasco Masson , Jaime	8/9/2011	11681

Children's Hospital of Michigan	A Case Series of Lead Toxicity in Adopted Chinese Infants	Warrick , Brandon	9/6/2011	11689
Children's Hospital of Michigan	Comparative Analysis of Early vs. Delayed Repair of Congenital Diaphragmatic Hernia	Donoghue, Lydia J.	8/31/2011	11703
Children's Hospital of Michigan	Prevalence and Implications of Obesity in Children with Congenital Heart Disease	Aggarwal, Sanjeev	8/19/2011	11728
Children's Hospital of Michigan	SBIRT Implementation	Kulwicki , Donica	9/13/2011	11731
Children's Hospital of Michigan	Incidence of Junctional Ectopic Tachycardia After Tetralogy of Fallot Repair	Delius , Ralph	12/15/2011	11768
Children's Hospital of Michigan	Imaging Findings in Pediatric Urological Conditions	Wolfe-Christensen, Cortney Brett	1/4/2012	11781
Children's Hospital of Michigan	Pacifier Use in Infancy and Possible Decreased Risk for Obesity	Amer, Ahdi A.	10/6/2011	11790
Children's Hospital of Michigan	Using a System-Wide Database to Reduce Workplace Violence in Hospitals	Arnetz, Judith	10/5/2011	11804
Children's Hospital of Michigan	Retrospective Review of Ethanol Lock Therapy in Clinical Use in Hematology/Oncology Stem Cell Transplant Patients	McGrath, Eric John	10/6/2011	11806
Children's Hospital of Michigan	Evidence-Based Evaluation and Management of Pediatric Skin and Soft Tissue Infections	Dornbush , Jessica	4/16/2012	11812
Children's Hospital of Michigan	Passive Peritoneal Drainage Following the Fontan Procedure	Mastropietro, Christopher W.	11/1/2011	11830
Children's Hospital of Michigan	Parental Knowledge of Placement of Car Restraint Systems Pre and Post Educational Intervention in a Pediatric Emergency Department	Perez , Vanessa	11/21/2011	11834
Children's Hospital of Michigan	Out Patient in a Bed: A Novel Approach to Comprehensive Acute Burn Care Delivery	Schaewe , Heather	11/17/2011	11871
Children's Hospital of Michigan	Comparison of Sink and Bathtub Burn in Children	Gonzalez , Raquel	11/17/2011	11872
Children's Hospital of Michigan	2011-194: Bacillus Outbreak Case Control Study	Kaye, Keith Steven	12/14/2011	11883

Children's Hospital of Michigan	Persistent Pulmonary Hypertension of the Newborn (PPHN): A Descriptive Study of Use of Fluid Volume	Mydam , Janardhan	11/18/2011	11902
Children's Hospital of Michigan	Isolated Fallopian Tube Torsion in Adolescent Females	Gonzalez , Raquel	11/17/2011	11909
Children's Hospital of Michigan	Neonatal Herpes Simplex Virus Infection	Bajaj, Monika	1/23/2012	11932
Children's Hospital of Michigan	In Market Safety Surveillance of Laundry Detergent Using Poison Control Center Data	Smolinske, Susan C.	4/3/2012	11941
Children's Hospital of Michigan	Short Term Outcomes of Pediatric Gastroenteritis, a Pilot Study	Rao, Jayashree	2/1/2012	11961
Children's Hospital of Michigan	Fluoroscopic and Non Fluoroscopic Imaging Modalities in Ablation of Supraventricular Tachycardia in Children and Young Adults	Sanil, Yamuna	1/27/2012	11967
Children's Hospital of Michigan	Adolescent Health Study	Franklin, Marilyn	2/2/2012	11969
Children's Hospital of Michigan	Long-Term Outcomes of Pediatric Patients after Endoscopic Fenestration and Shrinkage Fulguration of Suprasellar Arachnoid Cysts	Sood, Sandeep	1/26/2012	11974
Children's Hospital of Michigan	Epidemiology of Invasive Fungal Infections at a Tertiary Care Pediatric Hospital Over 11 - Year Period	Agarwal , Roshani Rajkumar	4/5/2012	11976
Children's Hospital of Michigan	Tracheostomy in Children: Cardiac versus Respiratory	Rosner, Elizabeth Anne	2/9/2012	11977
Children's Hospital of Michigan	A Molecular Epidemiology Study of Acinetobacter Baumannii from the Detroit Medical Center	Kaye, Keith Steven	5/21/2012	11985
Children's Hospital of Michigan	Effectiveness of a Color-Coded Medication System	Diver, Jessica Lynne	7/10/2012	11993

Children's Hospital of Michigan	Ketamine as an Adjunct to Propofol for Esophago-Gastro-Duodenoscopy in Pediatric Patients: A Randomized Placebo Study	Jwaida, Bassam	2/23/2012	11998
Children's Hospital of Michigan	Re-Hospitalization Following Neonatal Cardiac Surgery: Risk Factors and Outcomes	Soliman , Amira	3/2/2012	12000
Children's Hospital of Michigan	Time Limited Observational Study of the Moderately Preterm Infant (29 and 0/7 to 33 and 6/7 Weeks) (Weeks Gestational Age)	Shankaran, Seetha A.	3/6/2012	12014
Children's Hospital of Michigan	Assessment of Knowledge of Children and Their Parents Regarding Their Endocrine Diagnosis: Impact of Educational Intervention	Edwin, Chandra Madan	3/22/2012	12025
Children's Hospital of Michigan	Predicting Outcomes Following Transport among Neonates with Encephalopathy	Gallagher , Stephanie	4/27/2012	12032
Children's Hospital of Michigan	Ventricular Repolarization Abnormality Risk Assessment: Can the Corrected JT Interval be Used in Place of the Corrected QT Interval?	Hartman , Robert J.	4/17/2012	12036
Children's Hospital of Michigan	Unbalanced Atrioventricular Septal Defect: A Congenital Heart Surgeons' Society Inception Cohort Study	Walters, Henry L.	5/29/2012	12038
Children's Hospital of Michigan	A Long-Term Prospective Observational Safety Study of the Incidence of and Risk Factors for Fibrosing Colonopathy in US Patients with Cystic Fibrosis Treated with Pancreatic Enzyme Replacement Therapy: A Harmonized Protocol Across Sponsors PROTOCOL No. C	Abdulhamid, Ibrahim F.	4/25/2012	12046
Children's Hospital of Michigan	Hypoglycemia in Extremely Low Birth Weight Small for Gestational Age Infants	Puthuraya , Subhash	3/30/2012	12053

Children's Hospital of Michigan	Changes in the Cerebral Tissue Oximetry Secondary to Induction of Anesthesia: A Retrospective Review to Elicit the Comparison Between Inhalation and Intravenous Induction	Zestos, Maria M.	4/18/2012	12072
Children's Hospital of Michigan	Palliative Care Needs of Children with Tracheostomy and Long-Term Home Mechanical Ventilation	Guglani , Lokesh	4/20/2012	12076
Children's Hospital of Michigan	Aiming for Normal Oxygenation and Ventilation in Extremely Premature Ventilated Infants (<1,250 Grams): Are We There Yet?	Altaany , Dima	4/5/2012	12077
Children's Hospital of Michigan	Evaluation of One-Leg versus Two-Leg Spica Cast for Treatment of Femur Fractures	Jones , Eric T	4/26/2012	12081
Children's Hospital of Michigan	Incidence and Predictors of Linezolid Toxicity among Pediatric Patients	Steinke, Leah M.	5/8/2012	12091
Children's Hospital of Michigan	Antimicrobial Stewardship Survey	Sacin , Carlos	5/21/2012	12095
Children's Hospital of Michigan	SNAPSHOT! Photography Program and Research Study	Schlosser , Katelyn	6/21/2012	12096
Children's Hospital of Michigan	Evaluation of Treatment and Recovery for Pediatric Patients with Meniscal Tears	Kalra , Kunal	5/7/2012	12098
Children's Hospital of Michigan	Retrospective Chart Review of Neonates & Infants Undergoing Direct Laryngobronchoscopy (DLB)	Zestos, Maria M.	5/10/2012	12105
Children's Hospital of Michigan	Allergic Colitis in Exclusively Breastfed Infants: A Ten Year Retrospective Study with Review of Literature	Co , Maridine	5/4/2012	12110
Children's Hospital of Michigan	Outcomes Following Linezolid Therapy in Complicated Skin and Soft Tissue Infections: A Multi-Center Retrospective Study	Martin, Emily Toth	6/19/2012	12111
Children's Hospital of Michigan	High Frequency Jet Ventilator in Hypercapnic Respiratory Failure Secondary to Respiratory Syncytial Virus Bronchiolitis	Naranya Gowda , Kesheva	6/13/2012	12116

Children's Hospital of Michigan	Neurodevelopmental Effects of Donor Human Milk vs. Preterm Formula in ELBW Infants	Shankaran, Seetha A.	5/14/2012	12117
Children's Hospital of Michigan	Short Title: The MILK Trial Evaluation of a Universal Bed Model for Post-Operative Care after Spinal Fusion Surgery	Reynolds , Richard	6/19/2012	12154
Children's Hospital of Michigan	Improved Inter-Ventricular Interaction and Left Ventricular Function Following Melody Valve Placement	Arya , Swati	9/24/2012	12163
Children's Hospital of Michigan	Measurement of Systemic Blood Pressure by Analyzing Heart Sounds - A Pilot Study	Kapur, Gaurav	7/12/2012	12177
Children's Hospital of Michigan	A Pilot Study of Self and Parent-Administered Reflexology for Adolescents with Recurrent Headaches	Fouladbakhsh, Judith M.	7/3/2012	12202
Children's Hospital of Michigan	Role of Exhaled Nitric Oxide in Monitoring Asthma Control in Children	Seth, Divya	8/1/2012	12213
Children's Hospital of Michigan	A Study of Quality Improvement Intervention in the Evaluation and Management of Pediatric Sepsis at Children's Hospital of Michigan	Mahajan, Prashant V.	8/6/2012	12231
Children's Hospital of Michigan	Oral-Health Related Quality of Life in Children with Hemophilia	Harpham , Shane A.	8/10/2012	12241
Children's Hospital of Michigan	Prevalence of Aortic Stiffness and Its Impact on Ventricular Function in Patients with Repaired Congenital Heart Disease	Bhat , Deepti P	7/26/2012	12242
Children's Hospital of Michigan	Clinical Predictors of Recurrence of Supraventricular Tachycardia in Children With and Without Congenital Heart Disease	Bhat , Deepti P	7/26/2012	12243

Children's Hospital of Michigan	A Description of Factors Leading to Diagnoses of Latent Tuberculosis Infection (LTBI) as Determined by the Tuberculin Skin Test (TST) and T-SPOT.TB and Factors Affecting Treatment Acceptance Amongst Employees in an Urban Medical Center	Upfal, Mark J.	7/25/2012	12245
Children's Hospital of Michigan	Caudal Block as Primary Pre-Emptive Anti-Emetic and Secondary Pre-Emptive Analgesic in Pediatric Patients Undergoing Orchiopexy	Rajan , Sankar	7/26/2012	12246
Children's Hospital of Michigan	Use of Joy Dishwashing Soap and Tap Water for Burn Dressing Changes	Shanti, Christina M.	8/23/2012	12247
Children's Hospital of Michigan	Specialized Neuroimaging of Posterior Fossa Tumors to Aid Surgical Resection	Sood, Sandeep	8/1/2012	12251
Children's Hospital of Michigan	Sequelae of Long-Term Shunting Systems in Patient with Arachnoid Cysts	Sood, Sandeep	10/31/2012	12258
Children's Hospital of Michigan	Bicycle Associated Injuries and Risk Factors: An Urban Pediatric Emergency Department Perspective Do All Children Presenting to the Pediatric Emergency Department with Secondary Post Tonsillectomy Hemorrhage Require Admission to the Hospital?	Whitcomb , Valerie	9/5/2012	12264
Children's Hospital of Michigan	Natural History of Pelizaeus-Merzbacher Disease and PLP1-Related Disorders	Arora , Rajan	8/9/2012	12266
Children's Hospital of Michigan	Autonomic Nervous System Testing Using Heart Rate Variability in the Young with Syncope	Kamholz, John A.	8/15/2012	12273
Children's Hospital of Michigan	The Efficacy and Safety Profile of Bortezomib in Pediatric Heart Transplant Recipients	Patange, Amit R.	4/19/2012	12274
Children's Hospital of Michigan		Zinn , Matthew D.	10/5/2012	12293

Children's Hospital of Michigan	Stratification of Intermediate Grade Pediatric Renal Injuries Into Low Risk and High Risk	Santucci, Richard A.	9/11/2012	12296
Children's Hospital of Michigan	Relationship Between Vancomycin Serum Concentrations and Clinical Outcomes Among Children with MRSA Bacteremia	Sok , Allison	9/17/2012	12297
Children's Hospital of Michigan	Racial Variation in Risk Factors for Hypertension and Dyslipidemia in Pediatric Patients Presenting with Type 2 Diabetes Mellitus	Lightbourne , Marissa	9/20/2012	12300
Children's Hospital of Michigan	Evaluation of a Morphine Weaning Protocol in Pediatric Intensive Care Patients	Kuhns , Jennifer	9/24/2012	12326
Children's Hospital of Michigan	Evaluating the Relationship Between Right Ventricular Contractility as Measured by dP/dT and Right Ventricular Function in Patients with Systemic Right Ventricle	Bhat , Deepti P	9/24/2012	12328
Children's Hospital of Michigan	Incidence and Risk Factors for Rehospitalization Following Orthotopic Heart Transplantation in Children	Aggarwal , Sanjeev	9/28/2012	12336
Children's Hospital of Michigan	PICC Lines in the ICU - Is the Infection Rate Different Than a Temporary CVC? Does an IV Team Play a Role in Infection Prevention?	Kaye, Keith Steven	10/8/2012	12338
Children's Hospital of Michigan	CLABSI Reporting - How Accurate is Preventionist Reporting? To Correlate Clinical Outcome at 12 Months with Demography, Clinical Presentation, Lab Parameters, and Renal Histology and Induction	Kaye, Keith Steven	10/8/2012	12339
Children's Hospital of Michigan	Treatment of Children with Lupus Nephritis	Adabala , Murty	9/5/2012	12343
Children's Hospital of Michigan	Fourteen Year Experience Using Mandibular Distraction Osteogenesis in the Management of the Upper Airway Obstruction and Feeding Difficulties in Infants with Pierre Robin Sequence	Rozzelle, Arlene Anne	9/21/2012	12345

Children's Hospital of Michigan	Evaluating the Impact of Obesity in Critically Ill Children: A Retrospective Chart Review Pilot Project	Kline , Andrea	11/29/2012	12347
Children's Hospital of Michigan	Risk Factors for Infection after Complex Pediatric Cardiac Surgery Bleeding and Thrombosis During ECMO (BATE) Protocol Version 1.00 Dated September 26, 2012	Mastropietro, Christopher W.	10/24/2012	12349
Children's Hospital of Michigan		Meert, Kathleen Lynn	11/9/2012	12355
Children's Hospital of Michigan	Investigating How Parents Help Their Child with Phenylketonuria (PKU) Cope with Feeling Different	Zwiesele , Sheila	10/16/2012	12359
Children's Hospital of Michigan	Pediatric Ataxia in Emergency Medicine	Arora , Rajan	10/19/2012	12361
Children's Hospital of Michigan	Neonatal Cytomegalovirus Infection Natural History of Individuals with Biotinidase Deficiency Identified by Newborn Screening in Michigan	Bajaj, Monika	10/23/2012	12365
Children's Hospital of Michigan		Jay , Allison M.	11/30/2012	12367
Children's Hospital of Michigan	PEAK Plasma versus Coblation and Electric Cautery: A Comparison for Tonsilectomy and Adenoidectomy Surgical Interventions in Post-Transplant Patients with Native Vesicoureteral Reflux and Other Urinary Tract Malformations; Single Center Experience	Lane , Jennifer C	7/2/2012	12376
Children's Hospital of Michigan	Epidemiology and Management of Complicated Urinary Tract Infections (cUTIs) in Hospitalized Adults and Children	Romero Olvera , Mauricio	12/10/2012	12383
Children's Hospital of Michigan		Kaye, Keith Steven	11/21/2012	12394
Children's Hospital of Michigan	Validation Study of the Composite Score to Identify VWD in Children	Chitlur, Meera B	11/29/2012	12400
Children's Hospital of Michigan	Pericarditis in Children	Abdel Haq, Nahed Mustafa	11/9/2012	12405
Children's Hospital of Michigan	Presentation of Acute Chest Syndrome to the Pediatric ICU	Hines, Patrick C	11/20/2012	12410

Children's Hospital of Michigan	Texting Medication Reminders for Better Asthma Control in Children and Teens	Secord, Elizabeth Ann	12/13/2012	12420
Children's Hospital of Michigan	Intravenous Drug Users (IVDU) in the Intensive Care Units (ICU) - Infection Pattern and prognosis	Kaye, Keith Steven	12/12/2012	12430
Children's Hospital of Michigan	Atypical Thrombotic Microangiopathy Syndrome: Are Genetic Test Necessary?	Bajracharya , Prabesh	12/14/2012	12437
Children's Hospital of Michigan	Understanding the Patterns and Characteristics of Parental Vaccine-Refusal in an Urban Setting	Hidalgo , Nicole	12/14/2012	12443
Children's Hospital of Michigan	Do Blood Product Transfusions Actually Elevate the PRA Level in Patients Awaiting Heart Transplant for Congenital Heart Disease?	Zinn , Matthew D.	12/21/2012	12452
Children's Hospital of Michigan	A Retrospective Study of Esophageal Varices at Children's Hospital of Michigan, 1998-2013	Haidar-Alame , Sara	3/13/2013	12457
Children's Hospital of Michigan	Lateral Humeral Condyle Fractures in Children: Do Cannulated Screws Offer an Advantage over K-Wire Fixation?	Kalra , Kunal	1/4/2013	12466
Children's Hospital of Michigan	Histopathologic Findings in the Placenta of Neonates with Ischemic Perinatal Stroke	Cortez, Josef Misael C.	1/31/2013	12479
Children's Hospital of Michigan	Is There a Correlation Between Demographics and Non-Compliance in Patients Treated for Talipes Equinovarus (Clubfoot)?	Yassir , Walid K	2/6/2013	12504
Children's Hospital of Michigan	Management of Hypertension in Pediatric Pheochromocytoma/Paraganglioma: A Single Center Experience	Romero Olvera , Mauricio	2/18/2013	12509
Children's Hospital of Michigan	Proposed Diagnostic Criteria for Left Ventricular Noncompaction	Singh, Harinder R	2/14/2013	12515
Children's Hospital of Michigan	Quality of Life Survey in Patients with Pediatric Chronic Kidney Disease	Kapur, Gaurav	2/21/2013	12520

Children's Hospital of Michigan	A Comparison of Different Intravenous Fluids in Children Recovering from Pediatric Cardiac Surgery	Gajula , Viswanath	3/15/2013	12525
Children's Hospital of Michigan	Persistent Pulmonary Hypertension of the Newborn with Transposition of the Great Arteries Management and Prognosis	Sallaam , Salaam	2/20/2013	12527
Children's Hospital of Michigan	Risk Factors and Outcome of Resistant Hospital Acquired Infections (Re-Open of Closed Study)	Kaye, Keith Steven	2/28/2013	12530
Children's Hospital of Michigan	The Endothelial Progenitor Cells as Biomarkers of Altered Fetal Programming of Angiogenesis	Chouthai, Nitin S.	4/10/2013	12531
Children's Hospital of Michigan	Total Hip Arthroplasty in a Pediatric Population	Reynolds , Richard	2/28/2013	12533
Children's Hospital of Michigan	Nicardipine Use Following Pediatric Cardiac Surgery	Uribe , Diego Arango	3/25/2013	12534
Children's Hospital of Michigan	Presence of Thalamic Abnormalities in Patients with Electrical Status Epilepticus During Slow Wave Sleep (ESES)	Agarwal , Rajkumar	3/14/2013	12553
Children's Hospital of Michigan	Risk Factors for Extubation Failure after Neonatal Cardiac Surgery	Laudato , Nina Marie	3/25/2013	12566
Children's Hospital of Michigan	Infectious Complications after Surgical Treatment of Blount Disease	Bhargava, Ashish	3/25/2013	12567
Children's Hospital of Michigan	Retrospective Chart Review of Neonates and Infants, with Congenital Heart Defects, Undergoing Palliative Cardiac Surgery	Zestos, Maria M.	4/2/2013	12580
Children's Hospital of Michigan	Long Term Followup of Children Diagnosed with Functional Gastrointestinal Disorders, Following Application of Rome III Criteria	Madani, Shailender	3/28/2013	12585
Children's Hospital of Michigan	Global Pediatric Emergency Poisoning Surveillance System	Mahajan, Prashant V.	4/16/2013	12603

Children's Hospital of Michigan	Extended Spectrum b-Lactamase Producing Gram-Negative Bacteria in Community Acquired Urinary Tract Infections in Children	Abdel Haq, Nahed Mustafa	4/22/2013	12606
Children's Hospital of Michigan	Impact of Antimicrobial Resistance in the Pediatric and Neonatal Intensive Care Unit Settings: Implications for Infection Control	McGrath, Eric John	4/23/2013	12613
Children's Hospital of Michigan	Laryngomalacia: A Review of Diagnosis, Management and Treatment of 300 Patients at Children's Hospital of Michigan Based on a Proposed Disease Severity Score Using Dead-space Calculation to Determine Length of Mechanical Ventilation in Children after Cardiopulmonary Bypass for Repair of Congenital Heart Disease	Patel , Sweeti	7/12/2013	12614
Children's Hospital of Michigan	Body Weight and Kidney Length in Pediatric Patients	Heidemann, Sabrina M.	3/28/2013	12616
Children's Hospital of Michigan	Post-Extubation Upper Airway Obstruction after Pediatric Cardiac Surgery	Romero Olvera , Mauricio	4/17/2013	12617
Children's Hospital of Michigan	Pharmacotherapy Practice Patterns and Outcomes in Bronchiolitis	Green , Jack	3/25/2013	12627
Children's Hospital of Michigan	Impact of Pharmacist-Led Pediatric Antimicrobial Stewardship Rounds A Retrospective Study of Raynaud's Phenomenon at Children's Hospital of Michigan 1993-2013	Mahajan, Prashant V.	5/8/2013	12633
Children's Hospital of Michigan	Abnormal MRI Findings in Pediatric Patients Receiving Methotrexate A Retrospective Study of the Efficacy, MRI Changes and Developmental Outcome of Infants Exposed to Levetiracetam and Phenobarbital for Seizure Control	Steinke, Leah M.	4/26/2013	12639
Children's Hospital of Michigan	Atrial Transseptal Puncture Using Surgical Electrocautery in Children With and Without Congenital Heart Disease	Sahai, Shashi	5/28/2013	12649
Children's Hospital of Michigan	Evaluation of Operative versus Non-Operative Treatment of Medial Epicondyle Fractures	Williams , Mitchel Todd	5/16/2013	12656
Children's Hospital of Michigan		Ubaidulhaq , Muhammad	5/21/2013	12664
Children's Hospital of Michigan		Singh, Harinder R	11/16/2013	12684
Children's Hospital of Michigan		Jones , Eric T	7/10/2013	12699

Children's Hospital of Michigan	Prognostic Model for Neonatal Mortality, Morbidities and Neurodevelopmental Outcomes of Very Low Birth Weight Infants	Chawla, Sanjay	8/1/2013	12701
Children's Hospital of Michigan	Family/Clinician Communication in Care for Children with Asthma	Schim, Stephanie Myers	7/30/2013	12702
Children's Hospital of Michigan	Pediatric Emergency Department Presentation of Adults with Congenital Heart Disease	Yu , Jennifer	10/7/2013	12714
Children's Hospital of Michigan	TPN Associated Cholestatic Jaundice in Patients with Necrotizing Enterocolitis	Klein, Michael D.	8/8/2013	12734
Children's Hospital of Michigan	Incidence of Subdural Hemorrhages in Infants with Severe Hypoxic Ischemic Encephalopathy	Saleem, Sheena	10/31/2013	12742
Children's Hospital of Michigan	Appropriate Timing of Stoma Reversal in Surgical Necrotizing Enterocolitis Patients	Klein, Michael D.	8/8/2013	12744
Children's Hospital of Michigan	Improving the Timing of Surgical Intervention in Necrotizing Enterocolitis	Klein, Michael D.	8/8/2013	12747
Children's Hospital of Michigan	Review of Pediatric Gunshot Wounds for the Past 10 Years	Langenburg, Scott E.	9/4/2013	12749
Children's Hospital of Michigan	Evaluation of treatment of a failed Ahmed valve in the setting of Congenital Glaucoma and the success of these treatments in the setting of Sturge Weber Syndrome	Roarty, John D.	10/22/2013	12756
Children's Hospital of Michigan	Placental Pathology among Neonates Meeting the Criteria for Therapeutic Hypothermia	Pappas, Athina	9/9/2013	12765
Children's Hospital of Michigan	Early Ultrasound in Pediatric Appendicitis: Can Ultrasound Improve Diagnostic Certainty	Bonfanti , Nathaniel	11/12/2013	12779
Children's Hospital of Michigan	Prospective Validation of the Use of Ventilation Index and Vasoactive Inotrope Score to Predict Outcome in Children Undergoing Surgery for Congenital Heart Disease	Miletic, Kyle Gaetano	8/14/2013	12782

Children's Hospital of Michigan	Advanced MRI Imaging Techniques in Non Accidental Head Trauma	Saleem, Sheena	10/31/2013	12786
Children's Hospital of Michigan	Acute Kidney Injury after Surgery for Congenital Heart Disease in Adolescents and Adults	Valentine, Kevin Michael	8/14/2013	12787
Children's Hospital of Michigan	Transfusion Associated Necrotizing Enterocolitis in Premature Infants	Bajaj, Monika	8/13/2013	12791
Children's Hospital of Michigan	Effectiveness of Using Continuous IV Ondansteron in Chemotherapy - Induced Nausea and Vomiting in Pediatric Cancer Patients	Tran , Rosanna	9/6/2013	12801
Children's Hospital of Michigan	Descriptive Study of Non-Accidental Trauma in Children Less than 2 Years Old in a Large Tertiary Care Children's Hospital	Fichadia , Utkarsh	5/6/2014	12802
Children's Hospital of Michigan	Herpes Simplex Virus (HSV) Infection in Young Infants	Mahajan, Prashant V.	8/23/2013	12806
Children's Hospital of Michigan	Assessment of the Feasibility and Validity of Candidate Pediatric Sepsis Quality of Care Measures	Mahajan, Prashant V.	10/21/2013	12809
Children's Hospital of Michigan	Impact of Exogenous Corticosteroid Administration on Levels of Arginine Vasopressin in Children after Surgery for Congenital Heart Disease	Miletic , Kyle	8/28/2013	12811
Children's Hospital of Michigan	Utility of the Pediatric Symptom Checklist	Barnett, Douglas	10/29/2013	12818
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Sinai-Grace Hospital	Evaluation of Whether ED Triage Point-Of-Care Capillary Glucose Testing Decreases ED Length of Stay and Time to Treatment of Hyperglycemic and Hypoglycemic States	Peterson M.D., Joseph	8/13/2014	13175
Sinai-Grace Hospital	A Systematic Analysis of Nephrotoxicity Associated with Vancomycin and Piperacillin/Tazobactam	Kaye, Keith Steven	6/18/2014	13197
Sinai-Grace Hospital	Quantitative One Year Follow-Up on Non-Hospice Live Discharges from Medical ICUs Comparing Positive versus Negative Palliative Care Screens	El-Baba , Firas	9/12/2014	13219
Sinai-Grace Hospital	Risks of Chorioamnionitis Associated with Foley Induction of Labor in GBS Positive Patients	Nagy , Regina D.	12/14/2015	13549
Sinai-Grace Hospital	Efficacy of Ertapenem in Bacteremia from AmpC Beta-Lactamase Producing Enterobacteriaceae	Kaye, Keith Steven	6/16/2015	13551
Sinai-Grace Hospital	Safety and Efficacy of Direct Oral Anticoagulant (DOAC) Use in Patients Who Completed Catheter-Directed Thrombolysis	Donnan , Kirsten	9/9/2015	13639
Sinai-Grace Hospital	Evaluating the Impact of Beta-Antagonist Prescribing in Heart Failure Patients With or Without Pulmonary Disease	Nguyen , Sarah	9/24/2015	13640

Sinai-Grace Hospital	Evaluation of a Venous Thromboembolism (VTE) Transitions of Care Process Involving the Direct Oral Anticoagulants (DOACs) in the Emergency Department and Observation Unit	Mohammad , Insaf	9/9/2015	13641
Sinai-Grace Hospital	Is the size-based radiology evidence correlated with the biochemistry marker for evaluating the short-term therapeutic response to radioembolization on liver metastasis of neuroendocrine tumor?	Yu , Haiying	12/17/2015	13648
Sinai-Grace Hospital	Evaluation of vancomycin population analysis of profile (PAP) minimum inhibitory concentration (MIC) in patients with high inoculum MRSA infections	Rybak, Michael Joseph	10/14/2015	13668
Sinai-Grace Hospital	Analysis of Risk Factors Associated in Gram-Negative Infections of Neurosurgery Patients	Chopra, Teena	10/21/2015	13673
Sinai-Grace Hospital	Evaluation of outcomes associated with concurrent bacteremia in the setting of methicillin-resistant Staphylococcus aureus (MRSA) pneumonia	Rybak, Michael Joseph	10/13/2015	13681

HUD- HDE (FDA approval of an HDE, permits the marketing of HUD with safety data capture requirements)

Location	Study Title	PI's Name	Sponsor +/-or Manufacturer (Holder of HDE)	IDE # (if device study)	IRB Approval Date	DMC#
Children's Hospital of Michigan	Berlin Heart EXCOR Pediatric Ventricular Assist Device	Delius , Ralph	Berlin Heart	H100004	5/21/2012	12146
Children's Hospital of Michigan	The Melody Transcatheter Pulmonary Valve	Forbes, Thomas J.	MEDTRONIC, INCORPORATED	H080002	2/25/2010	
Children's Hospital of Michigan	Contegra Pulmonary Valved Conduit	Walters, Henry L.	Contegra		2/23/2012	12930
Children's Hospital of Michigan	Synthes Vertical Expandable Prosthetic Titanium Rib (VEPTR)	Yassir , Walid K	SYNTHES, INC.	H030009	5/14/2013	12641
Children's Hospital of Michigan	Multicenter Access and Distribution	Ratanatharathorn, Voravit	NATIONAL BONE MARROW		7/28/2011	12097
Detroit Receiving Hospital	Epitel (Cultured Epidermal Autografts) for Humanitarian Use in Patients with Deep Dermal and Full Thickness Burns Greater than 30% Total Body Surface Area (TBSA) "HUD"	White, Michael	Genzyme	H990002	6/26/2015	13583
Harper University Hospital	Enterra Therapy A Humanitarian Device Exemption Use Protocol of TheraSphere for Treatment of Unresectable Hepatocellular Carcinoma	Gazayerli , M. Mounir	MEDTRONIC, INCORPORATED	H990014	6/17/2010	13082
Harper University Hospital	Graftmaster RX Coronary Stent Graft System for Free Coronary Perforations	Harvill, Monte L.	MDS NORDION		4/17/2008	
Harper University Hospital	The Outcome after Endovascular Therapy of Intracranial Aneurysms Using Cordis ENTERPRISE Neurovascular Stent	Schreiber, Theodore	ABBOTT LABORATORIES	H000001/S2	3/23/2010	
Harper University Hospital	Impella RP System HUD: H140001	Xavier, Andrew R.	CORDIS NEUROVASCULAR, INC.		12/20/2007	
Harper University Hospital	MicroVention Low-profile Visualized Intraluminal Support (LVIS) or LVIS Jr. Humanitarian Use Device ("LVIS HUD")	Schreiber, Theodore	Abiomed	H140001	5/14/2015	13500
Harper University Hospital		Naraayanan, Sandra	Microvention Inc	H130005	10/1/2015	13590
Huron Valley-Sinai Hospital	JOSTENT	Degregorio , Michelle	ABBOTT LABORATORIES	H000001	12/10/2013	
Sinai-Grace Hospital	Use of JOSTENT Coronary Stent Graft and JOSTENT GraftMaster for the Treatment of Coronary Artery Perforation	Mahmood, Syed A.	ABBOTT LABORATORIES	H000001	5/6/2008	
Sinai-Grace Hospital	MicroVention Low-profile Visualized Intraluminal Support (LVIS) or LVIS Jr. Humanitarian Use Device ("LVIS HUD")	Naraayanan, Sandra	Microvention Inc	H130005	10/1/2015	13590

Coverage with Evidence Development (CED) Projects

Location	Project Title	Date of IRB approval only if a requirement by CMS and/or sponsor for IRB oversight
Children's Hospital of Michigan	Implantation of the Medtronic Melody Transcatheter Pulmonary Valve (TPV) in Patients with Dysfunctional Right Ventricular Outflow Tract (RVOT) Conduits: A Post-Market Approval Study	1/26/2012
Harper University Hospital	Medtronic CoreValve U.S. Continued Access Study (High Risk and Extreme Risk Patients)	1/11/2012
Harper University Hospital	Medtronic CoreValve U.S. Expanded Use Study	9/13/2012
Harper University Hospital	Medtronic CoreValve SURTAVI Trial	9/13/2012
Harper University Hospital	The Medtronic CoreValve U.S. Pivotal Trial	9/9/2010