

**Current Studies**

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| <b>Title:</b>                       | <b>ProCESS (Protocolized Care for Early Septic Shock)</b>  |
| <b>IRB # 107056</b>                 | Full IRB review with individual and proxy consent  |
| <b>Outline:</b>                     | <p>The Rivers Study (2007) found that aggressive, protocolized resuscitation improved mortality in patients with suspected septic shock. However in practice, physicians report that the invasive monitoring and blood transfusions advocated by Rivers can be impractical.</p> <p>ProCESS is a prospective, randomized, three-arm parallel-group trial of alternative resuscitation methods in early septic shock. The three arms are as follows:</p> <ol style="list-style-type: none"> <li>1.) EGDT (Early Goal Directed Therapy following the Rivers protocol (monitoring using a CVC).</li> <li>2.) PCS (Protocolized Standard Care) - intensive monitoring of patient using common ER equipment.</li> <li>3.) Usual care – currently TGH approved “Sepsis Alert”.</li> </ol> <p>The study will compare clinical efficacy of the three arms, will look at biologic mechanisms of sepsis and sepsis treatment, and also evaluate cost-effectiveness data.</p> <p>The initial resuscitation protocol will last around 6 hours in the ER, and then patients will have 3 follow-up visits, for blood draws, in the next 72 hours. Patients will be followed (medical record review) without direct contact until discharge or until day 60.</p> <p>Thus far, our site has enrolled 24 patients, putting us in the top five enrolling sites.</p> |
| <b>Principal Investigator:</b>      | David Orban, M.D., University of South Florida/TGH   |
| <b>Sub –I / Other physician(s):</b> | Drs. Richard Paula, Namita Kedia, David Wein, Brad Peckler, Vashun Rodriguez   |
| <b>Resident(s):</b>                 | Drs. James Bartlett, Tabitha Campbell, Ahmet Donmezer, Jennifer Fredericks, Tamas Gaspar, Aaron Osborne, Jack Reynolds, Nathan Stephens, Scott Stirling, and Jason Wilson  |
| <b>Research Coordinator(s):</b>     | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm  |
| <b>Funding:</b>                     | NIH - through the University of Pittsburgh.  |

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| <b>Title:</b>                       | <b>Evaluation of a novel solution, IRRISEPT™, containing a long-acting antimicrobial agent for irrigation of non-complicated skin and soft tissue infections in the emergency department: a pilot study</b>  |
| <b>IRB # 108527</b>                 | Full IRB review with individual English and Spanish consent  |
| <b>Outline:</b>                     | <p>Skin and soft tissue infections (SSTIs), including cutaneous abscesses, surgical site infections, and infected traumatic lesions, are commonly encountered in the emergency room. Currently, irrigation practices vary widely amongst physicians and facilities, and there is a need to standardize care especially in the face of increasing rates of community-acquired MRSA.</p> <p>IRRISEPT™ is a manual, self-contained irrigation device capable of produce 7-8psi of pressure as recommended by ACEP guidelines. The addition of CHG 0.05% to the irrigation solution may be effective in preventing the progression of infection.</p> <p>The aim of this pilot study is to compare usual irrigation techniques to irrigation using the IRRISEPT device. This will provide estimates for sample size calculation for future studies. A secondary aim is to determine the overall prevalence of MRSA colonization in the studied population.</p> <p>Patients fitting criteria will be enrolled in the emergency department. We will take wound and nares swabs, a digital photograph of the wound, and collect relevant data for each subject. Subjects will be randomized to receive either Usual Care or IRRISEPT irrigation. A blinded physician will then perform an assessment at 48 hours to determine whether the wound has improved, remained the same or progressed to further infection.</p> <p>Projected enrollment is 200 subjects over approximately six months.</p> |
| <b>Principal Investigator:</b>      | Dr. Richard Paula  |
| <b>Sub –I / Other physician(s):</b> | Dr. Tamas Gaspar<br>Daryl DeNittis, R.N., M.S.   |
| <b>Resident(s):</b>                 | Drs. Nicole Mead, Kant Shah, Scott Stirling, Tamas Gaspar, Aaron Osborne, Nadia Abrahamsen, Jason Wilson   |
| <b>Research Coordinator(s):</b>     | Erin Stirling, BPharm  |
| <b>Funding:</b>                     | Sponsored by IRRIMAX Corporation.  |

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| <b>Title:</b>                   | <b>Determination of Anatomic Variations of the Internal Jugular and Femoral Veins Using Ultrasound in the Emergency Department</b>   |
| <b>IRB # 106983</b>             | IRB minimal-risk review, with individual English and Spanish consent   |
| <b>Outline:</b>                 | <p>Central venous catheterization is an important and commonly done procedure in the emergency department. The internal jugular, subclavian and femoral veins are usually used for this access. Traditionally, physicians have relied on the use of anatomic landmarks and physical manipulations such as head rotation or leg rotation/abduction for the placement of central lines; however, studies have demonstrated that significant anatomic variations exist within larger percentages of study populations.</p> <p>This study aims to document this variation and provide further support for the use of ultrasound guidance in placing central lines in the emergency department.</p> |
| <b>Principal Investigator:</b>  | Dr. Charlotte Derr   |
| <b>Resident(s):</b>             | Drs. Megan Lasseter, Larry Land, Matthew Fucarino  |
| <b>Student(s):</b>              | Eric Zavallo, 4 <sup>th</sup> year USF Medical   |
| <b>Research Coordinator(s):</b> | Erin Stirling, BPharm  |
| <b>Funding:</b>                 | Internal   |
| <b>Approval Dates:</b>          | May 2009 – May 2010  |

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| <b>Title:</b>                   | <b>Bio-Availability P.O. vs. I.V – A study of ED Physician Practice Patterns</b>  |
| <b>IRB: 108275</b>              | Expedited chart review  |
| <b>Outline:</b>                 | <p>This study will look at the prescribing patterns of Emergency Department physicians. Specifically, the route of administration for a commonly used antibiotic – levofloxacin – with high bioavailability.</p> <p>Pharmacy reports will be requested for a six (6) month period January – June 2008 for patients receiving levofloxacin (either PO or IV) <b>AND</b> who were discharged from the ER. Based on current evidence-based practice, compliance to said will be determined and a cost will be assigned to both routes and applied to cases of non-compliance.</p> <p>This information may be used as a basis for future behavioral studies looking at the relationship between educational methods and information uptake in ER staff.</p> |
| <b>PI:</b>                      | Dr. Richard Paula   |
| <b>Student(s):</b>              | Lawrence Neuman, 3 <sup>rd</sup> year USF Medical Student   |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.  |
| <b>Data Assist(s)</b>           | Erin Stirling, BPharm   |
| <b>Funding:</b>                 | Internal  |
| <b>Approval Dates:</b>          | August 2009 – September 2010  |

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| <b>Title:</b>                   | <b>An open-label, randomized, multicenter Phase IIIb study to assess the efficacy, safety and tolerance of Beriplex P/N compared with plasma for rapid reversal of coagulopathy induced by coumarin derivatives in subjects with ACUTE MAJOR BLEEDING</b>  |
| <b>IRB # 108550</b>             | Full IRB review with individual and proxy consent  |
| <b>Outline:</b>                 | <p>Beriplex P/N is a Prothrombin complex concentrate used in many countries around the world as an alternative to fresh frozen plasma in reversing coumarin-induced coagulopathy.</p> <p>The primary objective of this study is to compare the hemostatic efficacy of Beriplex P/N vs. plasma in ceasing spontaneous or traumatically-induced major bleeding in subjects who have coumarin-induced coagulopathy.</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> <li>• Subjects with <b>acute major bleeding</b> (defined as life-threatening, requiring blood transfusion) <b>e.g. GI bleeds, intracranial hemorrhage etc.</b></li> <li>• INR <math>\geq 2</math> within 3 hours before start of study treatment</li> <li>• Male and female subjects aged 18 years or over</li> </ul> <p>Enrolled subjects will be randomized to receive either Beriplex or fresh frozen plasma (dosed accordingly). All subjects will receive vitamin K per local clinical practice.</p> <p>Efficacy will be measured by the adequacy of stopping an ongoing major bleed, and also by the proportion of subjects who reach an INR <math>\leq 1.3</math> by 30 minutes post-infusion.</p> |
| <b>PI:</b>                      | Dr. Richard Paula  |
| <b>Residents:</b>               | Drs. Jack Reynolds, Scott Stirling, Jason Wilson, Tamas Gaspar   |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm  |
| <b>Funding:</b>                 | Industry: CSL Behring  |
| <b>Approval Dates:</b>          | December 2009 – December 2010  |

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| <b>Title:</b>                   | <b>An open-label, randomized, multicenter Phase IIIb study to assess the efficacy, safety and tolerance of Beriplex P/N compared with plasma for rapid reversal of coagulopathy induced by coumarin derivatives in subjects with REQUIRING EMERGENCY SURGERY OR INVASIVE INTERVENTION</b>   |
| <b>IRB # 108551</b>             | Full IRB review with individual and proxy consent   |
| <b>Outline:</b>                 | <p>Beriplex P/N is a Prothrombin complex concentrate used in many countries around the world as an alternative to fresh frozen plasma in reversing coumarin-induced coagulopathy.</p> <p>The primary objective of this study is to compare the hemostatic efficacy of Beriplex P/N vs. plasma in ceasing spontaneous or traumatically-induced major bleeding in subjects who have coumarin-induced coagulopathy.</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> <li>• Subjects <b>requiring an emergency surgical or invasive intervention. Due to the nature of the procedure, withdrawal of anticoagulation therapy and plasma are also indicated</b></li> <li>• INR <math>\geq 2</math> within 3 hours before start of study treatment</li> <li>• Male and female subjects aged 18 years or over</li> </ul> <p>Enrolled subjects will be randomized to receive either Beriplex or fresh frozen plasma (dosed accordingly). All subjects will receive vitamin K per local clinical practice.</p> <p>Efficacy will be measured by the adequacy of stopping an ongoing major bleed, and also by the proportion of subjects who reach an INR <math>\leq 1.3</math> by 30 minutes post-infusion.</p> |
| <b>PI:</b>                      | Dr. Richard Paula   |
| <b>Residents:</b>               | Drs. Jack Reynolds, Scott Stirling, Jason Wilson, Tamas Gaspar  |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm   |
| <b>Funding:</b>                 | Industry: CSL Behring   |
| <b>Approval Dates:</b>          | December 2009 – December 2010   |

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| <b>Title:</b>                   | <b>A randomized, blinded, multi-center trial of the safety of intravenous oseltamivir for the treatment of influenza in patients aged <math>\geq</math> 13 years</b>  |
| <b>IRB: 108613</b>              | Full IRB review with individual and proxy consent   |
| <b>Outline:</b>                 | <p>A Phase II study to evaluate the safety of intravenous oseltamivir in the treatment of influenza.</p> <p>Patients will be included if they:</p> <ul style="list-style-type: none"> <li>• Are aged 18 years or over (TGH will not be enrolling patients under 18 at this point)</li> <li>• Have influenza diagnosed by virology testing or by a clinical diagnosis based on symptoms suggestive of influenza</li> <li>• Have less than 96 hours between onset of symptoms and first dose of IV study drug</li> </ul> <p>Enrolled patients will be randomized to receive either 100mg or 200mg IV oseltamivir via 2-hour infusion every 12 hours for 6 doses. If medically warranted, subjects may then continue for up to an additional 5 days of IV or oral oseltamivir.</p> <p>Safety, efficacy and pharmacokinetic assessments will be performed throughout the study.</p> |
| <b>PI:</b>                      | Dr. Charles Edwards (Internal Medicine) and Dr. David Orban (EM)  |
| <b>Residents:</b>               | Drs. Dennis Dixon,  |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm   |
| <b>Funding:</b>                 | Industry: Hoffman-La Roche  |
| <b>Approval Dates:</b>          | August 2009 – September 2010  |

**Pending Studies**

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| <b>Title:</b>                   | <b>Use of the VIDAS® BRAHMS PCT Test to Guide the Initiation of Antibiotic Therapy in Patients with Signs and Symptoms of Lower Respiratory Tract Infection (LRTI): A Prospective, Multi-center, Randomized, Single Blinded, Controlled Trial</b>  |
| <b>IRB:</b>                     | Pending  |
| <b>Outline:</b>                 | <p>This study aims to address the ever-increasing problem of over-prescribing of antibiotics in the ER. Specifically, it will use a biomarker of bacterial infection (procalcitonin – PCT) to guide antibiotic prescribing practices in patients presenting with lower respiratory tract infections.</p> <p>Patients who meet the criteria will be randomized to receive either PCT-guided care or standard of care and blinded assessments will be performed at Days 3, 5, 10 and 30.</p> <p>The sponsors anticipate enrolling a minimum of 796 patients across multiple sites within the US, over a 12 month period.</p> |
| <b>PI:</b>                      | Dr. Richard Paula  |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.   |
| <b>Data Assist(s)</b>           | Erin Stirling, BPharm  |
| <b>Funding:</b>                 | Industry: bioMerieux Inc.  |
| <b>Approval Dates:</b>          | Pending  |

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| <b>Title:</b>                   | <b>The BEACON (Best Expert Agreement for Care of Occult MI Nationally) Patient Registry.</b>  |
| <b>IRB#: 106821</b>             | USF/TGH Exempt review and HIPAA waiver.   |
| <b>Outline:</b>                 | <p>A multi-center data collection and follow-up registry to assess the process of care and health outcomes of patients presenting to the ER with suspected cardiac chest pain. A secondary objective of the study is to determine the impact of new technologies including the 80-lead PRIME ECG<sup>®</sup>. The study is composed of 2 parts:</p> <p>Part 1a) - Information on 30 patients with cardiac chest pain will be gathered <b>without</b> the available use of the PRIME ECG<sup>®</sup>.</p> <p>Part 1b) - Information will be gathered on an additional 30 patients with cardiac chest pain, <b>with</b> the use of the PRIME ECG<sup>®</sup>.</p> <p>Part 2 – The ER will collect information on approximately 150 cardiac patients per month, with the <b>option</b> of using the PRIME ECG<sup>®</sup>. This part of the study will last around 2.5 years or until the goal of enrolling 70,000 patients from all centers is achieved.</p> <p>Information gathered during the study includes lab results, ECG results, medical Hx, physical exam, and other data during a routine ER admission. Patients may also have follow-up at 30 days, and 1-year mortality will be assessed using the Social Security Death Index.</p> <p>The ED will receive quarterly reports of patient enrollment, outcomes and also the rate of compliance with AHA-ACC 1A recommendations for ACS patients; these reports may assist department quality improvement.</p> |
| <b>Principal Investigator</b>   | Dr. Richard Paula   |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.  |
| <b>Funding:</b>                 | Industry Sponsored – HeartScape, Inc. (currently on-hold during sales negotiation)  |
| <b>Approval Dates:</b>          | December 2008 – December 2011   |

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| <b>Title:</b>                   | <b>Evaluation of the predictive value of Multifunction Cardiogram (MCG) in determining Emergency Department chest pain patients safe for outpatient follow-up and diagnostic testing</b>  |
| <b>IRB:</b>                     | Pending   |
| <b>Outline:</b>                 | <p>The management of patients with acute chest pain is a common and difficult challenge for emergency physicians. Indeed, in an effort to avoid major adverse cardiac events (MACE – defined as diagnosis of cardiac ischemia, coronary artery occlusion, re-admission for chest pain, acute myocardial infarction, or death), thousands of patients with chest pain of non-cardiac origin or clinical irrelevant coronary artery occlusion are admitted to hospitals for observation and urgent diagnostic testing.</p> <p>A novel variation on standard 12-lead electrocardiogram analysis, termed Multi-Function Cardiogram (MCG), may have the diagnostic sensitivity for detecting relevant coronary artery stenosis to predict which patients require inpatient versus outpatient diagnostic work-ups for their chest pain.</p> <p>The goal of this study is to determine if MCG analysis of ED patients complaining of chest pain, without signs of ongoing STEMI or NSTEMI, can accurately predict which patients are safe for discharge and outpatient follow-up and which require hospitalization and further emergent testing.</p> |
| <b>PI:</b>                      | Dr. Richard Paula   |
| <b>Sub-I:</b>                   | Dr. Aaron Osborne   |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm   |
| <b>Funding:</b>                 | Industry:   |
| <b>Approval Dates:</b>          | Pending   |

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| <b>Title:</b>                   | <b>Pending – triage communication</b>  |
| <b>IRB:</b>                     | Pending  |
| <b>Outline:</b>                 | A social-behavioral study focused on aspects of communication between patients, nurses and physicians during triage assessment and the entire Emergency Room experience. |
| <b>PI:</b>                      | Dr. Eric Eisenberg (Interim Dean, College of Arts and Sciences)  |
| <b>Sub-I / residents:</b>       | Dr. Jason Wilson   |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm  |
| <b>Funding:</b>                 | Internal   |
| <b>Approval Dates:</b>          | Pending  |

**Completed Studies**

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| <b>Title:</b>                   | <b>Treatment of Post Concussion Symptoms – A Three Center Pilot Study</b>   |
| <b>IRB # 107355I</b>            | USF/TGH Expedited Review with minimal risk informed consent.  |
| <b>Outline:</b>                 | <p>A pilot study to collect data on the feasibility and effectiveness of computer-based education for patients who are post traumatic brain injury.</p> <p>Prior research has shown that in the acute setting, a brief psych-educational intervention is effective in reducing post-concussion syndrome (PCS). This study will evaluate whether this is also true in the sub acute and chronic population, and if the internet is an efficient way to deliver education.</p> <p>The end-goal is to design a multi-center, randomized, and controlled trial to evaluate different adult-healthcare educational methods.</p> <p>TGH will enroll ten (10) patients and provide each internet-based educational material. A symptom inventory will be completed before the intervention and one month after (via telephone). Immediately following the intervention, patients will be asked to evaluate the helpfulness of the material and complete a satisfaction survey.</p> |
| <b>Principal Investigator:</b>  | Heather G. Belanger, Ph. D. – James A. Haley VAH  |
| <b>Sub-I /Other physicians:</b> | Angela Drake<br>Richard Paula, M.D.   |
| <b>Research Coordinator(s):</b> | TGH - Daryl D. DeNittis, R.N., M.S.<br>Erin Stirling, BPharm  |
| <b>Funding:</b>                 | Internal  |
| <b>Approval Dates:</b>          | October 2008 – November 2009  |

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| <b>Title:</b>                   | <b>A prospective, multi-centre, observational study involving patients hospitalized with complicated skin and soft tissue infections (cSSTI) for IV antibiotic treatment.</b>   |
| <b>IRB # 107409</b>             | USF/TGH Expedited with minimal risk informed consent.   |
| <b>Outline:</b>                 | <p>An observational study to collect data on patients with a diagnosis of diabetic foot ulcer, surgical site infection, deep soft tissue abscess and/or cellulitis for which the <b>primary</b> treatment is IV antibiotics and hospitalization. The following data will be collected:</p> <ol style="list-style-type: none"> <li>1.) causative pathogens (including MRSA)</li> <li>2.) current clinical practice for treatment</li> <li>3.) clinical and economic outcomes (including a QoL questionnaire)</li> <li>4.) adverse outcomes related to treatment</li> </ol> <p>Patients who consent to participate in the registry will have information gathered as per the case report form at baseline, end of IV AB treatment, discharge and at Days 28-35. There are no additional or separate treatments, blood samples or cultures required, only what is current good clinical practice.</p> <p>The registry will be collected from approximately 50 hospitals across the US, enrolling about 1,200 patients in total. We expect to enroll up to 40 patients per month.</p> |
| <b>Principal Investigator:</b>  | Richard Paula, M.D.   |
| <b>Sub-I /Other Physicians:</b> | David Orban, M.D.   |
| <b>Resident(s):</b>             | Drs. Scott Stirling and Jason Wilson  |
| <b>Research Coordinator(s):</b> | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm   |
| <b>Funding:</b>                 | Industry Sponsored - Ortho-McNeil Janssen Scientific Affairs, LLC   |
| <b>Dates Approved:</b>          | December 2008 – January 2010  |

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| <b>Title:</b>                     | <b>Incidence of Neurologic Emergencies within the Florida NETT (Neurological Emergencies Treatment Trials) Network</b>  |
| <b>IRB # 106822</b>               | USF - Exempt with HIPAA Waiver  |
| <b>Outline:</b>                   | <p>A retrospective chart review to collect preliminary data on the incidence of seven types of neurologic emergencies in patients presenting to the ED, in order to aid the NETT Network to plan future studies.</p> <p>The review samples one week of ED admissions from each quarter of 2007 to collect data on the incidence of seizures, intracerebral hemorrhage, subarachnoid hemorrhage, traumatic brain injury, spinal cord injury, ischemic stroke and meningitis/encephalitis.</p> <p>Patients are identified through ED registration logs and patient records, and pre-existing information (e.g. age, gender, race, Hx, scan results, labs) is de-identified then recorded on a case report form.</p> |
| <b>Principal Investigator(s):</b> | Richard Paula, M.D., University of South Florida at TGH<br>Linda Papa, M.D., University of Florida.   |
| <b>Student/s:</b>                 | Larry Neuman, 3 <sup>rd</sup> Year USF Medical  |
| <b>Research Coordinator(s):</b>   | Daryl DeNittis, R.N., M.S.  |
| <b>Study Assistant(s):</b>        | Erin Stirling, BPharm   |
| <b>Funding:</b>                   | Internal – Associated with future NIH studies as part of NETT Network.  |
| <b>Dates Approved:</b>            | April 2008 – March 2009   |

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| <b>Title:</b>                       | <b>Validity of High Fidelity Simulation in E. M. Resident Clinical Evaluation.</b>   |
| <b>IRB # 107103</b>                 | USF/TGH IRB – Approval 5/08  |
| <b>Outline:</b>                     | <p>This study aims to determine the validity of the High Fidelity Simulation Program as a tool to evaluate EM residents in clinical situations.</p> <p>Eight (8) first-year EM residents completed the simulation as part of their end-of-year evaluation. They also completed the ACGME core and chief complaint competencies. Additional data on clinical performance in the ER was gathered monthly by faculty from another Florida Emergency Medicine program.</p> <p>The average ER evaluation score (during 1<sup>st</sup> yr) will be compared with the collective score earned at the simulation exercise in beginning of 2<sup>nd</sup> yr.</p> |
| <b>Principal Investigator(s):</b>   | Richard Stair, M.D. University of Florida<br>Bradley Peckler M.D., University of South Florida   |
| <b>Sub -I / Other physician(s):</b> | Dr. Richard Paula  |
| <b>Research Coordinator(s):</b>     | Daryl D.DeNttis, R.N., M.S.  |
| <b>Assistants:</b>                  | None   |
| <b>Funding:</b>                     | Internal   |
| <b>Approval Dates:</b>              | July 2008 – June 2009  |

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| <b>Title:</b>      | <b>The <u>I</u>ncreased <u>F</u>low <u>U</u>tilizing <u>S</u>ubcutaneously-<u>E</u>nabled Pediatric Rehydration II (INFUSE-Pediatric Rehydration II) Study: Subcutaneous Rehydration with Recombinant Human Hyaluronidase (<i>hylanex</i>) compared to Intravenous Rehydration in Infants and Young children With Mild to Moderate Dehydration</b>   |
| <b>Outline:</b>    | <p>This is a prospective, open-label parallel group study to assess the safety and efficacy of administering subcutaneous fluids using <i>hylanex</i> in the pediatric population. Inclusion criteria include otherwise healthy children from 1 month to 3 years of age presenting to the ER with mild to moderate dehydration (as determined by the Gorelick scale).</p> <p>Enrolled patients will be randomized to receive 20mL/kg of isotonic fluid either a) via the IV route, without <i>hylanex</i> or b) as a subcutaneous infusion augmented by 150 Units of <i>hylanex</i> in the inter-scapular area of the back.</p> <p>The primary endpoint will be the mean volume of fluid administered at a single infusion site. The study will also use various tools to assess other parameters such as pain at infusion site, flow rates at infusion site, and patient/guardian satisfaction with the treatment.</p> <p>The TGH ER aims to enroll 5 patients during the study period.</p> |
| <b>PI:</b>         | Dr. Neil Reinhardt   |
| <b>Assistants:</b> | Denise Fife  |
| <b>Funding:</b>    | Industry (Halozyme Therapeutics)   |

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| <b>Title:</b>       | <b>Hi-Fidelity Simulation in High Stakes Clinical Performance Examination (CPX)</b>   |
| <b>IRB # 107411</b> | USF IRB exempt study – approved December 2008   |
| <b>Outline:</b>     | <p>Hi-fidelity simulation is becoming accepted as a teaching tool for medical providers. Advanced simulations allow educators to test difficult clinical scenarios. The goal of this study was to test the diagnostic and treatment skills of a third year USF medical students faced with a simulated patient having evidence of a stable pneumothorax. Students are then expected to evaluate the teaching simulation in comparison to traditional methods.</p> <p>The case was one of a 12 cases in the “high stakes” Clinical Performance Exam. The patient with evidence of a stable pneumothorax was chosen to evaluate both diagnostic abilities and decision making in therapeutic options. Students were assessed using a university-wide standardized checklist: diagnosis, management, and interaction with the simulator. Immediately following the simulation they evaluated the experience.</p> |
| <b>PI:</b>          | Dr. Bradley Peckler   |
| <b>Student/s:</b>   | Students of the USF College of Medicine   |
| <b>Assistants:</b>  | Daryl DeNittis, R.N, M.S  |
| <b>Funding:</b>     | Internal  |

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| <b>Title:</b>        | <b>Breaking Bad News Education for Emergency Medicine</b>  |
| <b>IRB # 108347G</b> | USF IRB exempt study – approved September 2009   |
| <b>Outline:</b>      | <p>Breaking bad news (BBN) is a common task for emergency physicians. They need to be able to inform a patient's loved ones of an unexpected diagnosis or death with compassion and empathy, and often with little time to prepare. Despite the importance of this interaction, there are few formal training programs available and none that are practical for delivery to emergency physicians. We developed a 5-hour training session that was delivered during a regularly scheduled Emergency Medicine Grand Rounds.</p> <p>The purpose of this study is to evaluate the acceptability of this educational program to the aforementioned resident physicians and provide a basis for further study into BBN education.</p> |
| <b>PI:</b>           | Dr. Bradley Peckler  |
| <b>Resident/s:</b>   | USF-TGH Emergency Medicine Residents in 1 <sup>st</sup> , 2 <sup>nd</sup> and 3 <sup>rd</sup> year during 2008/09  |
| <b>Assistants:</b>   | Daryl DeNittis, R.N., M.S.<br>Erin Stirling, BPharm  |
| <b>Funding:</b>      | Internal   |

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| <b>Title:</b>             | <b>ACLS Skills Retention of 3<sup>rd</sup> Year Medical Students</b>   |
| <b>IRB # 107879I</b>      | USF IRB exempt study – approved May 2009   |
| <b>Outline:</b>           | <p>This is a study to evaluate the retention of skills and knowledge following an Advanced Cardiac Life Support (ACLS) course that will be given to rising third year medical students as a part of an introductory course to their clerkships. The initial course will be given at a point in the student's formal education process with minimal clinical application exposure and knowledge.</p> <p>The study will then evaluate the level of retention of ACLS knowledge and skills, which was initially provided at the <i>beginning</i> of 3<sup>rd</sup> year clerkships, during the <i>end of year</i> final Clinical Practical Exam (CPX). The evaluation will involve an ACLS scenario in which the student, who is the team leader, gets called to manage a code (major cardiac/respiratory event). The patient is a Laerdal™ Hi-Fidelity simulator. There will be different scenarios that are pre-programmed into the simulator with pre-defined outcomes and endpoints. There is a scoring system to determine a final grade, which will be used as the grade for this final CPX exam.</p> |
| <b>PI:</b>                | Dr. Bradley Peckler  |
| <b>Medical student/s:</b> | 3 <sup>rd</sup> year students of the USF School of Medicine - 2008   |
| <b>Assistants:</b>        | Daryl DeNittis, R.N., M.S.   |
| <b>Funding:</b>           | Internal   |