

## ABSTRACT

Fisch, Nathan, Structure and Function of an Interdisciplinary Research Committee at a Hospital-Based Non-Academic Institution. Master of Science in Clinical Research Management (Biomedical Sciences), March 2011, 117 pp., 4 illustrations, reference list, 9 titles.

**Purpose:** Define the structure, function and activities of a trauma research committee and establish a Standard Operating Policy for a new committee.

**Hypothesis:** By surveying existing trauma research committees, a recommended organizational strategy and membership framework can be developed for the new trauma research committee.

**Design:** Level 1 Trauma Centers across the United States were asked how their trauma research committees are organized. The data was presented to the new committee and a model for committee operation was suggested.

**Results:** Using the model along with input from the trauma research committee's leadership, a Standard Operating Policy was developed. Members were asked to review the policy and agree to follow its policies and participate in trauma research.

STRUCTURE AND FUNCTION OF AN INTERDISCIPLINARY  
RESEARCH COMMITTEE AT A HOSPITAL-BASED  
NON-ACADEMIC INSTITUTION

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INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the  
Graduate School of Biomedical Sciences  
University of North Texas  
Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements for the Degree of  
MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

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## ACKNOWLEDGEMENTS

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Thank you also to the following institutions for participating in the survey that provided so much valuable insight into the operation of trauma research programs: Phoenix Children's Hospital, Phoenix, Arizona; Charleston Area Medical Center for Health Services and Outcomes Research, Charleston, West Virginia; Fletcher Allen Health Care/University of Vermont, Burlington, Vermont; Texas Children's Hospital, Houston, Texas; Tarrant County Hospital District dba JPS Health Network, Fort Worth, Texas; Duke University Medical Center, Durham, North Carolina; The Toledo Hospital & Toledo Children's Hospital, Toledo, Ohio; Grant Medical Center, Columbus, Ohio; Intermountain Medical Center, Murray, Utah; Bronson Methodist Hospital, Kalamazoo, Michigan; Helen DeVos Children's Hospital, Grand Rapids, Michigan; University of Kansas Hospital, Kansas City, Kansas; and the nine other facilities that requested to not be identified.

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## CHAPTER I

### INTRODUCTION

The internship site was Texas Health Harris Methodist Hospital Fort Worth (THFW), one of the flagship hospital facilities of Texas Health Resources (THR). The internship goal was to support the Trauma Research Committee's research efforts by improving the organization and efficiency of the committee. In the Spring of 2010, THFW held the first meeting of its Trauma Research Committee (TRC) to provide a forum for discussion and development of physician-initiated trauma research, support best practice and contribute to the body of trauma-related research while supporting the hospital's pursuit of Level 1 Trauma Center designation from the Texas Department of State Health Services (TDSHS). The TRC is composed of physicians from Trauma Surgery, Emergency Medicine, Neurosurgery, Orthopedics, Physical Therapy and several other supporting departments associated with the care of trauma patients.

In order to improve the organization and efficiency of the TRC, other trauma research committees at Level 1 Trauma Centers across the United States were contacted and asked to respond to a survey that asked about how their committees are organized. A report on the survey findings was produced and used to build a model for how the TRC should operate. Finally, a Standard Operating Policy was drafted for the TRC.

Additional work with the TRC included involvement in designing a protocol for a trauma study that aims to identify the factors most likely to predict outcomes in geriatric trauma patients. These factors will be used to develop a scoring system that can help patients and family members make more informed decisions when considering drastic surgery that may or may not improve the patient's outcome or quality of life. It is anticipated that a grant application to fund the study will be submitted to the National Institute of Health (NIH) in May 2011.

Further experiences during the internship related to the TRC included attending a meeting of the trauma administration. This meeting involved a review of criteria for the hospital to achieve Level 1 Trauma Center designation. Because of this meeting, the complexity of transitioning from a Level 2 to a Level 1 facility was appreciated. Additionally, two observational rotations in the Emergency Department (ED) took place where the interaction between the ED and the trauma surgeons was seen. These observational rotations helped the intern better understand the differences between the ED physicians and the trauma surgeons while also appreciating the need for good communication between them.

In addition to a supporting role with the TRC, the internship included close work with the Clinical Research Department, part of the Texas Health Research and Education Institute (THRE). THRE is a non-profit research organization within the THR network. THRE is currently involved in over 200 research studies that contribute to the prevention, diagnosis and treatment of disease across the THR network.

Work at THRE was largely administrative. A protocol was developed for a telemanagement study along with all the supporting documentation needed for Institutional Review Board (IRB) approval. Work was done to complete the IRB application submission for the telemanagement study and with the IRB staff and research staff to address the stipulations

from the IRB. The newly developed technology being used for the study was tested and input given on how to improve the software to make it easier for the research subjects to use the study devices and for the research coordinator to interact with the caregiver interface.

Assistance with the IRB application submissions for three other studies was also provided. One of the studies was for an Investigational New Device developed for use in surgery. The second study was for a data repository related to implantable pacemakers, defibrillators and related devices. The final study was an oncology study that contributed to The Cancer Genome Atlas project and established a repository of tissue samples for use in future research. Through THRE, there was also involvement in a site initiation visit, research subject visits and monitor visits.



## CHAPTER II

### INTERNSHIP SUBJECT

#### **Background and Literature Review**

##### *Defining Trauma*

Trauma is any injury physically or emotionally inflicted on a person. For the purposes of this document, the definition will be limited to the physical injuries that the American College of Surgeons (ACS) identifies as “traumatic” in nature<sup>1</sup>. Physical traumatic injuries fall under the following categories: bone fractures; dislocations; sprains and strains of joints and adjacent muscles; intracranial injury; internal injury of the thorax, abdomen, and pelvis; open wounds including animal bites, avulsions, lacerations, puncture wounds, and traumatic amputation; injury to blood vessels; burns; and injury to nerves and spinal cord<sup>2</sup>. Traumatic injuries do not include minor injuries such as superficial injuries that do not penetrate the hypodermis (the fat tissue layer just beneath the skin), bruises, foreign bodies such as splinters, and crush injuries not associated with fractures, internal injuries or intracranial injury<sup>1</sup>.

The impact of traumatic injury continues to grow as a public health problem in the United States. These impacts are measured in terms of years of productive life lost, prolonged or permanent disability, and financial cost. Trauma Centers are hospitals that prepare for the treatment of victims of traumatic injury, work to develop plans to care for large numbers of patients in the event of a disaster and create injury prevention programs in their communities<sup>1</sup>.

## *History of the US Trauma System*

Organized trauma care has its origins in military models of trauma care, usually developed during military conflict<sup>3</sup>. During World War II, a new triage system was instituted and wounded soldiers were evacuated through tiers of increasingly skilled medical care. In the Korean and Vietnam wars, the time from injury to best-suited treatment was sharply reduced by transporting seriously injured patients directly to acute care field hospitals that delivered immediate, organized trauma care. The advances in trauma care made by the military were slow to reach civilian health care<sup>3</sup>.

The first specialized civilian trauma center opened in 1941 in Birmingham, England. In the United States, civilian trauma centers began to appear around 1966<sup>1</sup> following publication of *Accidental Death and Disability: the Neglected Disease of Modern Society* by the National Research Council and the National Academy of Sciences. This publication raised public awareness about Emergency Medical Services (EMS) and trauma care. It outlined basics for subsequent improvements in EMS programs nationwide, but fell somewhat short in describing the need for a systematic approach to trauma care<sup>4</sup>.

In the years that followed, a number of important developments led to a more organized approach to the development of a national trauma system stemming from collaboration between government agencies and professional organizations, such as the ACS. The development of the current trauma system has led to an expansion of the scope of practice from individual surgical providers leading to clinical departments, to organized acute care facilities, to multidisciplinary, multi-institutional programs, finally to integrated state and regional healthcare systems<sup>1</sup>.

The EMS Systems Act of 1973 was an important piece of legislation affecting the development of regional emergency and trauma care systems<sup>3</sup>. When the act was written, regionalizing services was viewed as one way of distributing resources more fairly while

expanding access to health care systems. A large amount of federal funds were devoted to establishing an EMS infrastructure in over 300 EMS regions nationwide. However, the act failed to fully address the need for a nationwide trauma system<sup>3</sup>.

The Trauma Care Systems Planning and Development Act of 1990 was the first legislation to take a nationwide trauma system approach by working to improve both EMS and trauma center networks. Under this program, a panel of experts generated a model trauma care system plan to use in trauma system development for use across the United States<sup>3</sup>.

### *History of THFW*

THR is one of the multidisciplinary, multi-institutional organizations involved in the evolution of trauma care in the United States. THR is the largest faith-based, nonprofit health care delivery system in North Texas based on number of patients served. The system's primary service area consists of 16 counties in north central Texas and is home to more than 6.2 million people. THR was formed in 1997 with the merger of Fort Worth-based Harris Methodist Health System and Dallas-based Presbyterian Healthcare Resources and the later addition of Arlington Memorial Hospital. THR presently has 24 acute-care and short-stay hospitals that are owned, operated, joint-ventured or affiliated with the system. It has more than 4,100 licensed beds, employs more than 20,500 people, and counts more than 5,500 physicians with active staff privileges at its hospitals<sup>5</sup>.

THFW began providing medical services in Tarrant County in 1930 under the name Harris Methodist Hospital. Today, THFW is a full-service medical center with more than 710 beds. The hospital offers specialized care capabilities in many clinical areas, including trauma,

oncology, cardiology and women's services. There are more than 800 physicians affiliated with the hospital. THFW is designated as a Level 2 Trauma Center by TDSHS<sup>6</sup>.

### *Trauma Center Levels*

The ACS was founded in 1913 with the expressed purpose of improving care for surgical patients and educating surgeons. The ACS established the Committee on Trauma in 1922 to focus on improving the care of traumatically injured patients. This committee continues to work to establish a national trauma system, instead of simply developing individual trauma centers. This committee emphasizes that a national trauma system needs various levels of trauma centers to avoid wasting precious medical resources<sup>1</sup>.

The ACS is recognized for standardizing the evaluation of trauma center performance with its Verification Program<sup>3</sup>. The ACS' Committee on Trauma publishes *Resources for Optimal Care of the Injured Patient*. This book provides an overview of the essential and desirable requirements for trauma centers seeking to gain or maintain the different Trauma Center verifications<sup>1</sup>. State and local agencies often rely on ACS verification when designating Trauma Center Levels<sup>7</sup>. In the state of Texas, having ACS verification for the equivalent Trauma Level is required for designation<sup>8</sup>. The ACS views their classification scheme as a ranking of resource depth, not medical care quality. The current ACS verification process was initiated in 1987 and has evolved with each new edition of *Resources for Optimal Care of the Injured Patient*. Currently, the ACS has four Trauma Center levels. The general descriptions of these levels are described below<sup>1</sup>.

A Level 1 facility is a Trauma Center with regional coverage in terms of resources. A Level 1 Trauma Center must be able to provide definitive trauma care regardless of severity of

injury. A Level 1 facility must also be able to accept trauma patient transfers from any lower level facility in their region. This requirement means that a Level 1 facility must have the capacity to treat a large number of patients at any given time. The ACS has minimums on the number of trauma patients that a Level 1 facility admits annually. For Level 1 facilities, the ACS has the strictest guidelines for trauma surgeon availability compared to the lower levels of care. This facility must be able to provide leadership and total care for every aspect of injury, from prevention through rehabilitation. A Level 1 facility must have a dedicated Trauma Intensive Care Unit (ICU) team with surgical direction. In addition to acute care responsibilities, a Level 1 facility is responsible for providing leadership in education, research, and system planning<sup>1</sup>.

A Level 2 Trauma Center is a hospital that is expected to provide initial definitive trauma care regardless of the severity of injury; however, depending on geographic location, patient volume, personnel, and resource availability, a Level 2 facility may not be able to provide the same comprehensive care as a Level 1 facility. A trauma surgeon must still be available to a Level 2 Trauma Center at all times, but the surgeon's response times are less strict, as are the criteria for requesting a trauma surgeon. The ACS does not require that Level 2 facilities have a Trauma ICU. The ACS does not have minimums on the number of trauma patients that a Level 2 facility admits annually. While Level 2 facilities may be able to provide nearly the same level of care as a Level 1 facility, there may still be injuries that require transferring care to Level 1 Trauma Centers. Level 2 facilities must work with local and regional EMS providers to ensure that appropriate transportation is accessible for critically injured patients needing care at a Level 1 Trauma Center. In areas without a Level 1 facility, Level 2 facilities take responsibility for education and system leadership. Level 2 facilities are not required to perform trauma research<sup>1</sup>.

A Level 3 Trauma Center is often found in communities that do not have immediate access to Level 1 or Level 2 facilities. A Level 3 facility provides prompt assessment, resuscitation, emergency operations, and stabilization of patients with major trauma. A general surgeon must be available at all times at a Level 3 Trauma Center. If a patient requires more advanced care and is stabilized, then arrangements for appropriate transportation to a higher-level facility must be arranged with local and regional EMS providers. Planning for care of injured patients in these hospitals requires transfer agreements and standardized treatment protocols. The ACS believes that Level 3 facilities are generally not appropriate in an urban or suburban area with adequate Level 1 or Level 2 resources<sup>1</sup>.

A Level 4 facility provides advanced trauma life support before transferring patients to higher levels of care. Level 4 facilities are found in remote rural areas where no higher level of care is available. Level 4 facilities are unique in that they do not have to be hospital facilities; sometimes these are clinics with or without a physician immediately available. The ACS awards Level 4 verification to facilities that are willing to commit resources to provide optimal care given the limited resources. As such, the ACS pushes for these facilities to be an integrated part of a broader trauma care system<sup>1</sup>.

The ACS has separate verification standards for Pediatric Trauma Centers. This separation came after ACS recognized that pediatric hospitals provide specialized services that differ from adult care. As a result of this differentiation, there now exist comparable pediatric verifications Level 1 through 4. Some adult facilities are capable of committing matching resources to pediatric services and also earn a pediatric verification<sup>1</sup>.

Ultimately, the ACS encourages communication, education and ongoing support between facilities of all levels. As part of its efforts to create a national trauma system, the ACS includes

guidelines for Level 1 and Level 2 facilities to help rural medical facilities (Levels 3 and 4) through professional education, consultation, or community outreach programs and encouraging improvements in communication between these facilities<sup>1</sup>.

### *Level 1 Trauma Centers and Research*

The ACS requires any hospital aspiring to achieve Level 1 Trauma verification to incorporate trauma research and scholarly activity into its continuing operations. Research and scholarly activity are unique elements of Level 1 Trauma Centers and are considered essential to advancing trauma care in the United States. These facilities are able to accomplish trauma research because of the large volume of severely injured patients and the experience of the trauma surgeons in these facilities. There are two ways that a hospital can fulfill the research and scholarship requirements for Level 1 Trauma verification. The first way is to publish twenty peer-reviewed articles in journals included in the *Index Medicus* over a three-year period. The articles must be trauma related and must result from work related to the trauma center. There are also requirements that specify who must author the publications<sup>1</sup>.

The second path that a hospital can follow to fulfill the research and scholarship requirements for Level 1 Trauma verification involves the publication of fewer articles. A facility seeking Level 1 Trauma verification must publish ten peer-reviewed articles in journals included in the *Index Medicus* over a period of three years with the same restrictions on content and authorship as the previous method in addition to several other scholarly activities. The other activities that are required include leadership in major trauma organizations, evidence of peer-reviewed funding for trauma research, publication of case reports and case studies, and others<sup>1</sup>.

Because of the enormous number of personnel and facility resources necessary for patient care, education, and research, most Level 1 Trauma Centers are university-based teaching hospitals. There are a handful of community-based hospital systems that have committed the resources to obtaining Level 1 verification, although some of these hospitals later obtained university affiliations<sup>1</sup>.

THFW is not a university-based teaching hospital; however, the hospital has decided to take the necessary steps to achieve Adult Level 1 verification. Because Cook Children's Medical Center, a neighboring facility to THFW, is a dedicated Pediatric Level 2 Trauma Center, there are no efforts being made to pursue Pediatric Trauma verification at this time. To achieve the goal of Adult Level 1 verification THFW formed its TRC to coordinate, advise and direct the required trauma research efforts. The TRC met for the first time in the Spring of 2010 under the leadership of Committee Chair Michael Hickey, M.D. The TRC is composed of representatives from Trauma Surgery, Emergency Medicine, Orthopedics, Radiology, Pharmacy, Neurosurgery, Anesthesia and several other departments associated with the treatment and management of trauma patients<sup>9</sup>.

### **Specific Aims**

Since the first meeting of THFW's TRC, some research projects have been started, but the TRC has faced concerns over who should have membership on the TRC and what the overall function of the TRC should be within the THFW infrastructure. The TRC lacked operational guidelines to help direct the TRC towards meeting the requirements necessary to achieve and maintain a Level 1 Trauma Center designation from TDSHS.



### *Specific Aim 1*

*Define the structure of the TRC by determining who should have involvement (based on profession and experience in research), to what extent is their membership (leadership, full members, or support staff), and why those individuals are needed (their role on the committee).*

Most of the core membership and leadership roles were established prior to the first meeting of the TRC; however, the roles of statisticians, research study coordinators and other research personnel were not established or understood. To accomplish this aim other trauma research committees across the United States were contacted to establish a suggested membership framework for the THFW TRC and incorporated this into the TRC's Standard Operating Policy.

### *Specific Aim 2*

*Define the function and activities of the TRC.* As this is a new committee, there was some confusion as to what this committee should do. Initially, the TRC meetings were somewhat organized brainstorming sessions with some review of previous discussions and updates on ongoing research. The goal was to develop a better organization for the TRC through the incorporation of subcommittees and introduction of peer-review policies to increase the productivity and accountability of the TRC. Several of the questions asked of other trauma research committees were designed to help get the information needed to develop this organizational strategy.

### *Specific Aim 3*

*Establish a written Standard Operating Policy for the TRC, including what steps are required to approve a new protocol, what are the best practices of a TRC, and the organization*

*and hierarchy of committee membership.* The information learned in Specific Aims 1 and 2 was used to develop a Standard Operating Policy for the TRC to guide the TRC in their efforts to achieve and maintain Level 1 Trauma designation from TDSHS.

## **Significance**

Achievement of the Specific Aims has the potential to improve the productivity of the TRC, allowing them to fulfill the research requirements necessary to advance THFW to Level 1 Trauma Center designation. For the population served by THFW, this means that a higher level of care will be accessible in the community. Fort Worth is home to one Adult Level 1 Trauma Center, but the volume of patients they receive overwhelms the facility. Having a second Level 1 Trauma Center in Fort Worth can relieve some of the burden from the other facility and improve access to definitive health care for patients in the Fort Worth area.

The research performed by the TRC may lead to advances in the treatment of trauma patients across the nation or the world. Once the recommendations on how to improve the organization of the TRC were presented, the activity of the TRC became more refined. For example, physicians began to produce written outlines for research proposals and present them to the committee for review. Also, meetings became better organized and efforts to increase the frequency of the meetings are being discussed. It is anticipated that more improvement in the productivity of the committee will become apparent as the Standard Operating Policy is implemented.

While contacting Level 1 Trauma Centers across the United States, three sites requested a copy of findings from this study. They stated that while their trauma research programs have

been successful, they are eager to find new ways of improving their productivity. It may be several years before the impact of this project is fully understood.

## **Materials and Methods**

The internship began with a meeting with Lillie Biggins, Senior Vice President of Operations for THFW. In that meeting, the brief history of the TRC was discussed along with the goals of the committee. She provided memos, letters and outlines related to the formation of the committee as well as meeting minutes. She also walked through the current organizational chart and description of the committee membership based on department, e.g., Trauma Surgery, Emergency Department, etc. She explained how the hospital's bid to become a Level 1 Trauma Center depends heavily on the TRC generating the required research. This discussion provided enough information to develop the specific aims for this project.

Following the meeting with Lillie Biggins, a search for the ACS requirements for Level 1 Verification was conducted. These are clearly stated in the most recent edition of *Resources for Optimal Care of the Injured Patient*, published by the ACS Committee on Trauma. It was noted that having a trauma research committee is no longer a requirement of the ACS, only that the research be done. An internet search for trauma research committees was conducted to determine if any of the ones in existence post information on their operation. A few committees had limited information available. None of the information was specific enough to be of particular value in developing a new organization for the committee.

After becoming familiar with the requirements, arrangements were made to meet committee members and to get a better idea of the trauma surgeons' roles in the day-to-day operation of the hospital. This was accomplished by attending a meeting of the Trauma

Administration nurses in which details of THFW's efforts to achieve Level 1 Verification were discussed. After that meeting, the Trauma Administration nurses and trauma surgeons were followed during rounds in the Trauma ICU. The nurses and surgeons walked through the cases that were in the Trauma ICU including relevant medical history, care plans and anticipated short-term outcomes. Two days were spent observing in the Emergency Department to see interactions between the Emergency Department and Trauma Surgery. These observational rotations led to envisioning opportunities for research and understanding of the time demands on the Emergency Department and Trauma Surgery physicians.

From earlier conversation with Lillie Biggins, it was apparent that the TRC had questions about the role of a statistician on the committee. Ronald Isaacson, Director of Research Grants and Contracts, was contacted to find out what the THRE policy was for accessing statistical services. He stated that THRE has a contract with the University of North Texas Health Science Center to receive statistical support from the school. He provided detailed information on how to request a statistician from UNTHSC, when to contact them and which forms would be required. He also suggested that having a statistician at every meeting of the TRC would likely be an inappropriate use of resources.

The first meeting of the TRC during the internship took place on September 15, 2010. Following a brief introduction by Lillie Biggins, the meeting was called to order. The information provided by Ronald Isaacson shared with the TRC. The information seemed to alleviate the concerns of the TRC regarding the absence of a statistician as a standing member of the committee. Notes on events of the meeting were taken and initial thoughts on how to make improvements were outlined. At the end of the meeting, a strategy for improving the organization of the committee was shared. Even though the details still needed refinement, the

TRC was informed of the intent to contact other trauma research committees across the United States to ask how they operated.

Before contacting any facilities, a Practicum Proposal, that included a recruitment letter and a survey, was prepared. The recruitment letter cited the name of the study, the name of the principal investigator, what information was being asked for, what the information would be used for, and who to contact with questions. The letter formed the body of emails sent to Trauma Department Administrators at Level 1 Trauma Centers. The survey (Appendix A) was developed with input from Lillie Biggins to ensure that it addressed all of the needs of the TRC. The survey was sent with the recruitment email as an attachment. The survey was formatted so that the respondent could answer the questions, but was unable to change the questions. The Practicum Proposal was approved by the advisory committee and sent to the UNTHSC Institutional Review Board (IRB) for review. The UNTHSC IRB found that the study qualified for “Exempt” status because it involved research on organizations, but did not qualify as human subjects research.

While waiting for authorization to begin from the UNTHSC IRB, a list of the 126 Level 1 Trauma Centers verified by the ACS was found. Internet searches were conducted for contact information for each Level 1 facility listed. Once all approvals were acquired, calls were made to the listed facilities, and Trauma Coordinators, Trauma Program Managers, or Trauma Researchers were contacted. Once the appropriate person at each site was contacted, a brief description of the study was given and permission to email the recruitment letter and survey was requested. A document was developed to track which facilities had been contacted, emailed and had sent back a response.

The process of contacting sites took place between October 15, 2010 and December 1, 2010. On December 1, 2010, the data collection phase of the study came to a close. Of the one

hundred twenty-six (126) hospitals identified by ACS as Level 1 Trauma Centers, all were contacted. One hundred six (106) sites agreed to receive and look over the recruitment letter and survey. Twenty-one (21) sites returned completed surveys or enough data to be included in the study. Seventeen (17) of the twenty-one (21) sites had an active trauma research committee at the time they were contacted.

During the data collection phase of the study, there were two TRC meetings. Prior to the first meeting, Lillie Biggins requested that some ideas for potential research studies be presented. A suggestion for a vitamin C study based upon a literature search performed earlier was presented. After the meeting, Cory Collinge, M.D., the TRC Vice-Chair, requested that the literature search be narrowed to find studies involving vitamin C and orthopedic surgery outcomes. The information was emailed to him, but no information regarding a potential study related to that material has become available.

A subcommittee meeting intended to bring together key researchers for a potential study under development by Dr. Michael Hickey immediately preceded the second TRC meeting. Dr. Hickey hopes to obtain a grant from the National Institute of Health (NIH) to fund this study for up to five years. A grant writer from THRE was in attendance and helped outline the goals of the study, potential data points and challenges related to the NIH grant application process. The TRC meeting that followed was disorganized and little was accomplished. Discussions took place about potential studies, but no written material was supplied and several researchers that were expected to give updates were not in attendance. The meeting was adjourned a few minutes early despite starting fifteen minutes late.

With the close of the data collection phase for this study, data analysis began in earnest. Findings were presented to the TRC at the next meeting on December 15, 2010. Identified were

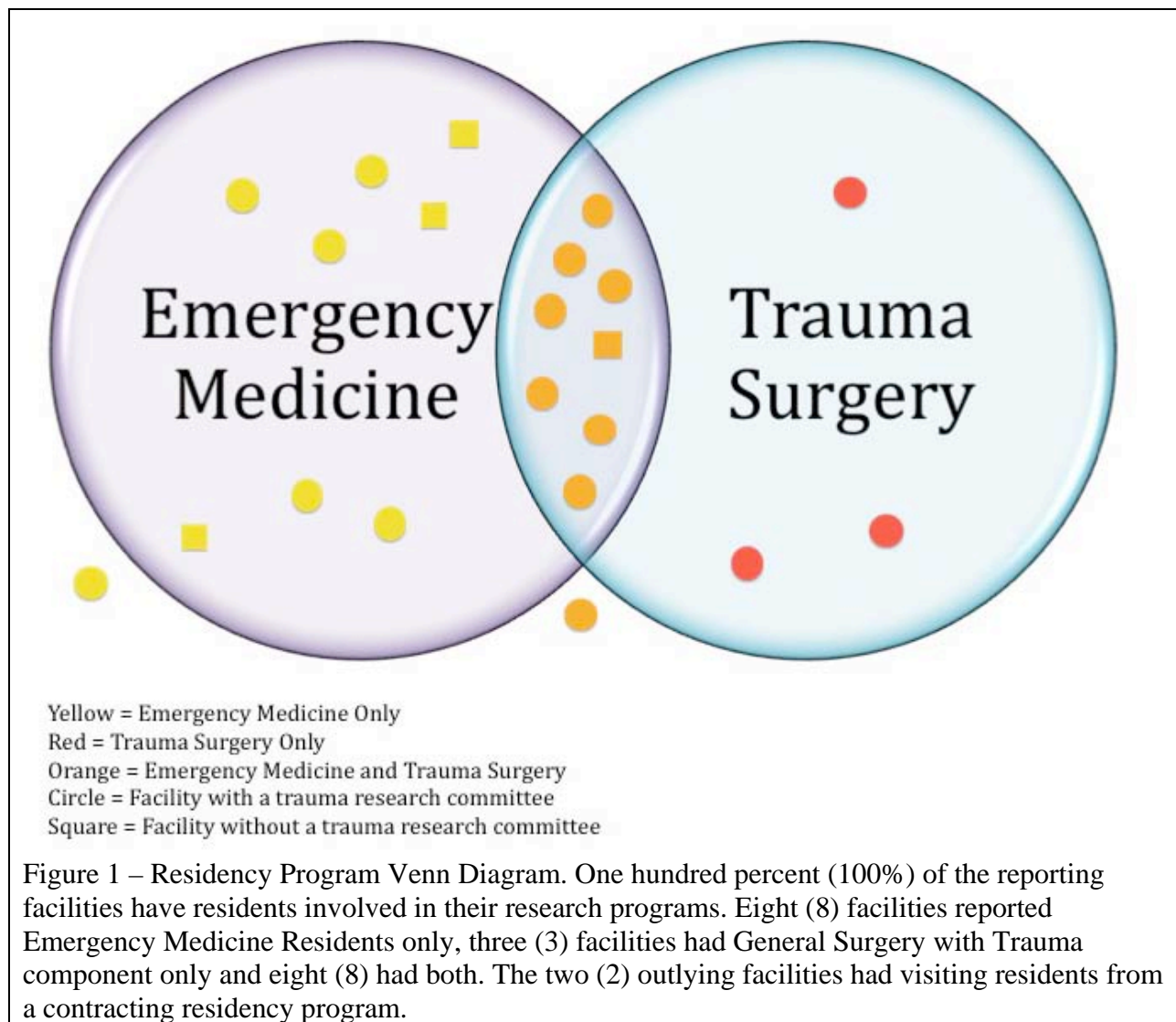
trends and activities that seemed most likely to improve the output of the TRC. The presentation (Appendix B) summarized the information reported by the responding sites, emphasized components that the TRC had already integrated, and attempted to highlight the elements of a successful trauma research committee. At the end of the presentation, recommendations were made on how to modify the activity of the TRC based on the data from the surveys and ACS guidelines.

## **Results and Discussion**

The recommendations made to the TRC on December 15, 2010, were as follows:

1. *Create a written Standard Operating Policy for the TRC to help guide the activities of the organization.* This document defines the anticipated roles of committee members, committee leadership and supporting roles. It also details the requirements and expectations for participation in the TRC, including attendance expectations, publication requirements and educator roles with regards to the hospital's Graduate Medical Education program. The document also serves as a written agreement between the TRC and each physician, which must be signed to participate in TRC activities.
2. *Work toward establishing a general surgery or emergency medicine residency.* Resident training can fulfill two of the four trauma-related scholarly activity requirements necessary to reduce the publication requirements for Level 1 Trauma Centers from 20 peer-reviewed articles to 10 articles. Additionally, research work performed by residents during their time at THFW can contribute to meeting the publication requirements of the ACS. One hundred percent (100%) of the reporting sites have resident involvement (See Figure 1). Two of the

sites reported that the residents at their facility were from programs based at other institutions, but the residents still contribute to the research programs.



3. *Hire a clinical research nurse coordinator.* Under the direction of a physician researcher, the coordinator can direct the data gathering efforts so that the physician can continue his/her clinical function. The search for a clinical research nurse coordinator has been ongoing now for over six months. This was included in the recommendations to emphasize that filling this position should be a priority.



4. *Include a basic and/or social scientist in the committee; e.g., epidemiologist.* The ACS strongly recommends including a basic or social scientist in research activities. Several of the participating facilities noted the utilization of an epidemiologist to fill the role of basic scientist and social scientist on their trauma research committee. Epidemiologists study patterns of health and illness and associated factors at the population level. Epidemiology is the cornerstone of public health research, identifying risk factors for disease and determining optimal treatment approaches to clinical practice and for preventative medicine. Epidemiologists are often well versed in biostatistics and may fill part of that role as well.
5. *Formalize a relationship between the TRC and IRB.* A member of the TRC is already a member of the IRB; however, the recommendation called for an IRB coordinator to attend a TRC meeting twice a year and update the committee on any changes to IRB policy and answer questions from the committee members. This was suggested to help the IRB reach a large group of researchers at once and allow the researchers to ask questions that may help them develop better protocols.
6. *Establish an official subcommittee for pre-review of protocols prior to IRB application submission.* The TRC's Pre-review Subcommittee, led by the TRC's IRB member, should perform pre-review of all trauma research protocols prior to IRB application submission. This pre-review is conducted to help investigators ensure a more favorable IRB review with fewer stipulations. The emphasis is on the IRB's review process, not on changing the research aims or study design.
7. *Establish an official subcommittee for manuscript review prior to submission for publication.* A Review Subcommittee should review manuscripts prior to submission to publishers. This subcommittee should review publication guidelines from the publisher and make sure that the

manuscript follows those guidelines. In addition, the subcommittee checks to make sure the specific aims are clearly stated and that the discussion of findings and conclusions drawn are supported by the data presented. This review is done to improve the likelihood of publication.

8. *Take time to review the journals listed in the Index Medicus in a formal meeting; look for journals in which researchers may be interested in publishing and search for publication guidelines from those journals.* This is particularly important for new researchers and

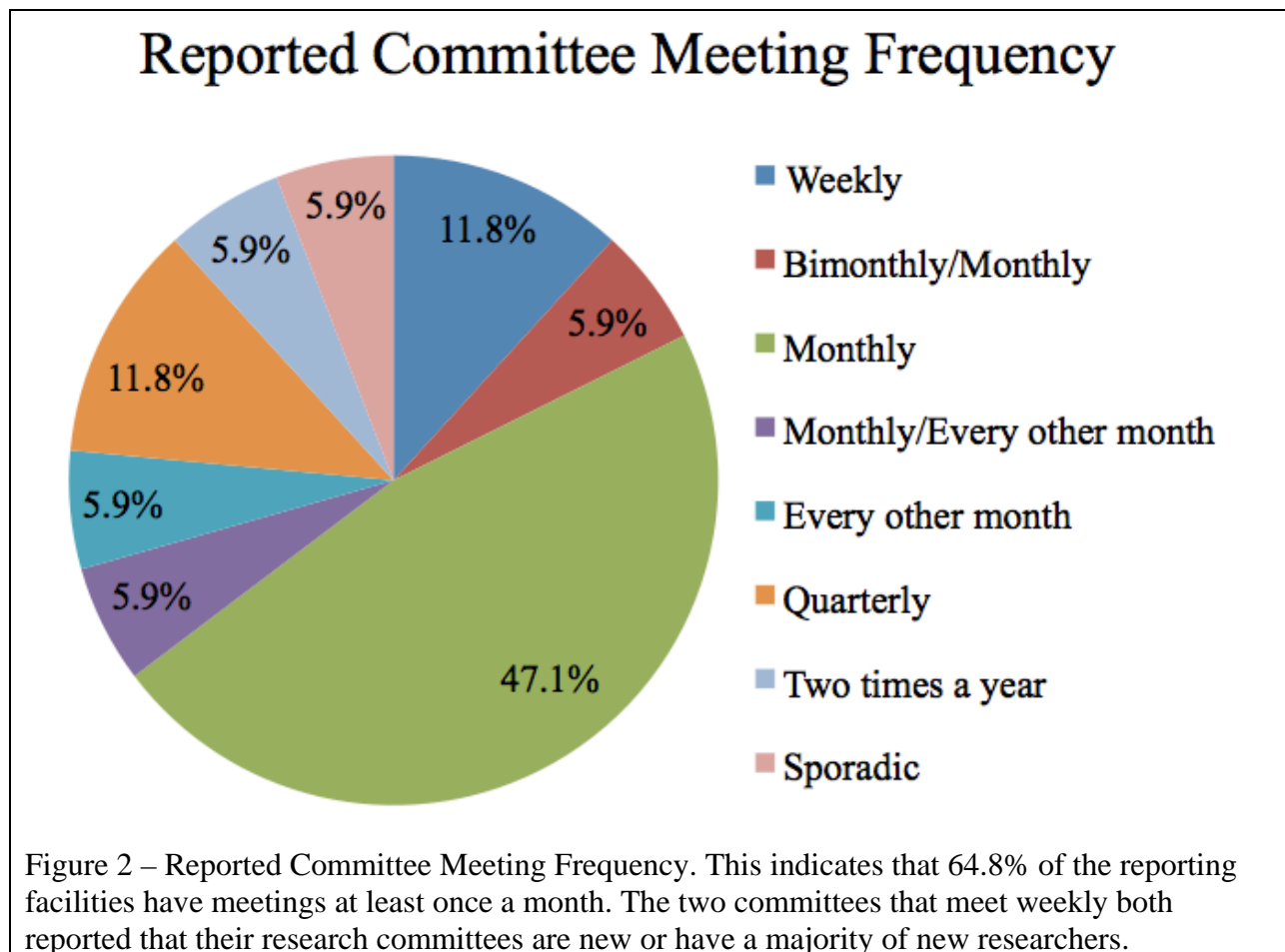
researchers who have not authored articles in several years. Early review of the guidelines from journals can help researchers plan data management and may help a researcher develop a more viable research proposal.

9. *Follow-up on the progress of previously discussed research proposals after each meeting.*

This was already being conducted by the TRC, but in an unorganized fashion. The Chair was encouraged to use the meeting minutes from the previous meeting to make sure all potential studies were briefly revisited. This recommendation came after at least one proposed study was forgotten about and even the physician who suggested the study was unable to recall the details. It was also recommended that researchers start producing written proposals instead of trying to recall details from memory. These proposals can then be distributed in advance and reviewed by the TRC so that more effective discussion can take place during the one-hour meetings.

10. *Increase meeting frequency to two times per month until at least 15 research projects have been approved by the IRB.* Based on the data collected from the surveys, facilities new to research or with a large percentage of physicians inexperienced in research meet more frequently; 65% of reporting committees meet at least once a month (See Figure 2). Facilities with fairly self-sustaining research programs or dedicated trauma research programs have

fewer meetings or no committee because communication is well established and research is a central part of daily activity within these programs. As the TRC is new and no new research has been initiated since the first meeting during the internship, an increase in meeting frequency was encouraged. This recommendation builds on the belief that more frequent interaction with the TRC will encourage researchers to think about research on a more regular basis.



11. *Obtain membership within national trauma organizations for trauma surgeons.* The ACS recommends obtaining membership and participating in regional and national academic societies, such as the ACS, the American Association for the Surgery of Trauma (AAST), or the Eastern Association for the Surgery of Trauma (EAST). These organizations provide a

forum to exchange information, get ideas for future research projects, develop contacts at other institutions for multicenter research, and learn about additional research funding opportunities. Membership in these organizations fulfills 1 of the 4 trauma-related scholarly activity requirements necessary to reduce the publication requirements for Level 1 Trauma Centers from 20 peer-reviewed articles to 10. Presenting research findings at the annual meetings of one of these organizations also fulfills 1 of the 4 trauma-related scholarly activity requirements.

12. *Establish a method for assessing the value of potential research projects to maximize the likelihood of publication.* Finding a way to quantitatively measure the value of a Trauma Research program can be challenging. Making such determinations is one of the committee's responsibilities. By holding researchers to high standards, more research projects will be publishable in journals. Some research may be determined to be of great value to the institution, but not likely to be publishable; however, such research projects should still be conducted and may need to be financed by THFW. It may take several years before the true value of a Trauma Research program becomes evident.
13. *Once research activities increase and researchers gain experience, the TRC should begin searching for opportunities to participate in multicenter research studies.* Multicenter research studies require that each facility contribute the agreed upon work for the study to be successful. Because of this, most multicenter research study developers look for researchers with a history of successful research. Multicenter research studies can lead to many opportunities for a researcher including opportunities for future research, funding and publication.

After making recommendations to the TRC, an appointment was made to meet with Dr. Michael Hickey, the TRC Chair, to develop a Standard Operating Policy for the TRC. A document was drafted to use as a starting point for that meeting. An internet search was also conducted for information on how to obtain membership in national trauma organizations. This information was given to Dr. Hickey before the scheduled appointment so he would have time to review it. A few days before the scheduled appointment, he sent a draft of a similar document he had presented to Lillie Biggins before the start of the internship.

During the meeting with Dr. Hickey, both drafts were reviewed and a decision was made to combine the two drafts into a single document. He also requested a listing of all Accreditation Council for Graduate Medical Education (ACGME) accredited surgical residency programs in the United States. He stated that he intends to contact the programs within one or two states and determine if THFW can host some of their residents instead of trying to build a new residency program in three years. Dr. Hickey felt that hosting residents would meet the ACS requirement and allow THFW to achieve Level 1 Verification. The requested list was obtained, and programs within two states of Texas were highlighted and forwarded to Dr. Hickey.

At the January TRC meeting, the efforts to generate a Standard Operating Policy for the TRC were briefly discussed and a final version was promised for the next meeting. The meeting showed organizational improvement over the previous meetings and there was more involvement by those in attendance. At the end of the meeting, Dr. Hickey requested that the researchers provide a written synopsis for each study discussed before the next meeting.

In a meeting with Dr. Hickey a week later, changes made to the Standard Operating Policy were reviewed. A few more revisions were made during the meeting, and a final draft was sent to Lillie Biggins to review. Lillie Biggins, Dr. Hickey, Dr. William Witham, and Dr.

Stephen Rush met on February 9, 2011, to review, revise and finalize the Standard Operating Policy. The document (Appendix C) received final approval on February 15, 2011. It was distributed by email to the TRC.

The TRC meeting on February 16, 2011, continued to show organizational improvement over the previous meetings. Three researchers presented information about studies they are planning. The first presenter had submitted a typed outline of his proposed study in advance of the meeting allowing the TRC to read it before the discussion. Feedback was focused on the written material and the presenter was asked to produce a formal proposal as soon as possible. The second presenter's notes were handwritten, but the discussion about the study remained focused on helping the presenter formalize a proposal. The final presenter had typed notes on data and conclusions that the TRC Chair felt warranted development of an abstract for the next meeting. The TRC Chair gave a report of the NIH grant process, and a couple more study ideas were shared.

Before the end of the TRC meeting and after a brief discussion, the members were asked to sign the Standard Operating Policy as a record of agreement to follow the guidelines of the document. Two points of concern to the TRC became apparent during the discussion. The first concern was that the "Members" were only the physicians. It was explained that the physicians are the ones ultimately responsible for producing the research and therefore are the ones identified as members. The second concern was with the change in meeting frequency. Initially, it was planned to implement the increase in meeting frequency right away, but scheduling conflicts and room availability were a problem that required more planning before implementation could take place. Once these points were discussed and verbal agreements made

to hold off on implementation of the bimonthly meeting schedule, the members in attendance signed and submitted their Standard Operating Policy agreements to the TRC Chair.

As of the completion of this document, no further meetings of the TRC have taken place so there is no way to determine if the Standard Operating Policy will have the intended effect. It is anticipated that more improvement in the productivity of the committee will become apparent as the Standard Operating Policy is implemented. It may be several years before the full impact of this project is understood.

## **Summary and Conclusions**

In the Spring of 2010, THFW held the first meeting of its TRC to provide a forum for discussion and development of physician-initiated trauma research, support best practice and contribute to the body of trauma-related research while supporting the hospital's pursuit of Level 1 Trauma Center designation from TDSHS. The TRC struggled in its infancy due to confused views over organizational strategy and a lack of definition to the function of the TRC. Other trauma research committees across the United States were contacted to establish a suggested membership framework for the THFW TRC. An alternative organization for the TRC was recommended and involved the incorporation of subcommittees and introduction of peer-review policies to increase the productivity and accountability of the TRC. A Standard Operating Policy was developed for the TRC that will help to guide the TRC in their efforts to achieve and maintain Level 1 Trauma designation from TDSHS.

## CHAPTER III

### INTERNSHIP EXPERIENCE

#### **Internship Site**

The internship site was THFW, one of the flagship hospital facilities of THR. The Clinical Research Department, part of THRE, served as the primary workspace for the internship. THRE is a non-profit research organization within the THR network. THRE is currently involved in over 200 research studies that contribute to the prevention, diagnosis and treatment of disease across the THR network. Most of internship work took place at the Clinical Research Department offices at THFW, but occasionally there were meetings at the THRE Administrative office in Arlington and at the Clinical Research Department offices at Texas Health Presbyterian Hospital Dallas (THD).

#### **Journal Summary**

In addition to work with the TRC, the internship involved several opportunities for interaction with clinical research coordinators and the clinical research administration. The internship involved a site initiation visit by a sponsor representative, research subject visits and monitor visits through THRE. The internship also involved primarily administrative involvement in four clinical research studies. The study with the most internship involvement was a telemanagement study. Work included development of the protocol for the study along with all the supporting documentation needed for Institutional Review Board (IRB) approval, assisting in



preparation of the IRB application, development of a study budget, and working with the IRB and research staff to address the stipulations from the IRB. The newly developed technology being used for the study was tested and input given on how to improve the software to make it easier for the research subjects to use the device and for the research coordinator to interact with the caregiver interface. When the study begins, patients admitted to any of the THR hospitals for heart failure are eligible for enrollment in the study. After the subject is discharged from the hospital, daily physiologic data will be sent along with answers to survey questions to a study coordinator via the study devices. Subjects will be monitored for ninety (90) days, and then asked to return the study equipment and complete a closeout survey. Subjects receiving standard of care will be asked to complete a closeout survey after ninety (90) days as well. As of completion of this document, the THR IRB has approved the study, but due to technology development delays, no subject recruitment efforts have taken place.

Work was done to assist with the IRB application submissions for three other studies. One of the studies was for an Investigational New Device (IND) developed for use in surgery. The IND is going to be compared to the FDA-approved standard of care device. The second study was for a data repository related to implantable pacemakers, defibrillators and related devices. This study is designed to obtain data to meet the requirements of the FDA for post-market approval monitoring of these devices. The final study was an oncology study that contributed to The Cancer Genome Atlas (TCGA) project and establishes a repository of tissue samples for use in future research. For all three of these studies, Informed Consent Forms were generated using the THR IRB template.

As part of the internship, additional training took place including Collaborative Institutional Training Initiative (CITI) training, the NIH equivalent training program, and the

THR required in-house online training system to learn the hospital's privacy policies and procedures in the event of an emergency. Additionally, training was given on how to safely ship infectious substances and dry ice according to the Code of Federal Regulations Title 49 and the 51<sup>st</sup> Edition International Air Transport Association (IATA) Dangerous Goods Regulations. Finally, Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) certifications were renewed.

Several meetings of the THR IRB were attended from the THFW campus. The THR IRB is a local IRB that convenes via video conference from multiple sites including THFW. The video conference system allowed for more board members from different sites to attend the meetings; however, this same system also hindered communication and slowed meeting progress. Due to a confidentiality agreement signed at each meeting, specifics of the meetings cannot be provided. In general, principal investigators presented their proposed research projects, followed by question and answer sessions, and then review and IRB ruling for each study. Additionally, studies were evaluated for continuing review and reported adverse events were evaluated by the IRB.

At the request of Lillie Biggins, data analysis was provided for the John Peter Smith (JPS)/THFW Work Group. JPS Connection is a program that lowers the cost of health care for patients who qualify for the program and live in Tarrant County. It is not insurance, but works similarly to insurance at JPS hospital and JPS clinics, but not other health care centers. The Work Group, with representatives from THFW and JPS, was formed to educate patients that are eligible or already enrolled in the program about how JPS Connection works, how to apply for and use the program, and to make sure they understand that it is only usable within the JPS Health Network. The Work Group tracks how many patients are eligible for the program, how

many received applications for the program, how many of those applications were turned in (often with help from a member of the Work Group), and how many of those people return to THFW.

The Work Group had collected data for over a year and requested a data analysis to help them evaluate the effectiveness of the Work Group in an effort to determine which areas they had done well in and which areas needed more attention. Several graphs were generated from the data, trends identified, and an interpretation of the data was presented to the Work Group. The Work Group was then asked to comment on the graphics and the interpretation of the data. The Work Group discussed the changes that accounted for sudden shifts in the data and made a decision to adjust some of the data gathering techniques they are using.

At the request of Lillie Biggins, a telephone conversation with a physician took place about two potential studies he wanted to initiate in the pre-hospital environment of an ambulance. He explained the two studies in detail. Concerns were shared about his proposed studies and he was advised to be clear in the protocols and with the paramedics carrying out the procedures that his studies will not delay transport of the patients, nor affect treatment or treatment decisions for these patients. The physician was then directed to Tamara Plant and Teresa Turbeville for further assistance with protocol development, funding and IRB policy.

The daily log detailing events during the internship can be seen below in Appendix D. Some of the details were left intentionally vague to protect the research, research subjects and the interests of the study sponsors.

## APPENDIX A

### TRAUMA RESEARCH COMMITTEE SURVEY

## Trauma Research Committee Survey

1. May the investigator include the name of your institution in the publish study?  
If so, please identify the institution.
2. Is your hospital considered a teaching hospital with access to basic scientists and research laboratory facilities?
3. Does your hospital have an Emergency Medicine Residency?
4. Does your hospital have a Trauma Surgery Residency?
5. What are the minimum requirements to be Committee Chair?
6. How is Committee Chair selected?
7. What are the minimum requirements to be Committee Vice Chair?
8. How is Committee Vice Chair selected?
9. What are the requirements to be a Committee member?
10. What departments are represented in your Committee's membership?
11. Are there other roles associated with the Trauma Research Committee that are not considered members? Statisticians? Clinical Research Coordinators? Upper management?
12. What is the frequency of Committee meetings?
13. What is the frequency of Subcommittee meetings?
14. What types of subcommittees does your Committee have?
15. Please describe the Trauma Research Committee/IRB relationship. For example, does the Trauma Research Committee approve protocols before an investigator goes to the IRB?
16. What kind of oversight does Trauma Research Committee perform?
17. What kind of peer-review does the Trauma Research Committee perform?
18. How are research findings communicated and used?

19. Are there any research/publication requirements/minimums for Committee members?
20. Are there any research/publication requirements/minimums for Committee leadership?
21. Has the trauma research performed at your facility had *measurable* value in the areas of quality and safety?

Please site examples of the measurable value of the trauma research.

## APPENDIX B

### FINDINGS PRESENTATION TO THE TRAUMA RESEARCH COMMITTEE

# Trauma Research Committees

Nathan Fisch, LP, BS  
15 December 2010

## Study Purpose

- *Specific Aim 1* - Define the structure of the trauma research committee by determining who should be members (based on profession and experience in clinical research), to what extent (leadership, full members, or support staff), and the justification for those individuals' participation in trauma research.
- *Specific Aim 2* - Define the function and activities of the trauma research committee.
- *Specific Aim 3* - Establish written Standard Operating Policies for the trauma research committee including what steps are required to approve a new protocol, what are the best practices of a trauma research committee, and the organization and hierarchy of committee membership.
- Achievement of these Specific Aims has the potential to significantly improve the productivity of a trauma research committee, allowing a Level 2 Trauma Center to fulfill the research requirements necessary to advance to a Level 1 designated Trauma facility.



## Study Design

- An attempt was made to poll all Level 1 facilities in the US, regardless of academic status. The information obtained was then modified to cater for institutions with limited access to academic facilities.
- Trauma Administrators at Level 1 Trauma Centers recognized by the American College of Surgeons were contacted by telephone to request participation in a survey. The survey asked for details about the operation of the trauma research committee at their site, if they had one.
- The data from the surveys was compiled and analyzed so that a recommendation could be made on how to improve the output and overall function of a newly formed trauma research committee at a non-academic Level 2 Trauma Center so that they can achieve the research criteria minimums of the American College of Surgeons for Level 1 Trauma Centers.
- Data from the survey and from the ACS' *Resources for Optimal Care of the Injured Patient 2006* were used to make the recommendations that follow.

## Demographics

- 126 Level 1 Trauma Centers recognized by the American College of Surgeons (ACS)
- 106 Facilities were successfully contacted and sent a survey to complete
- 33 Facilities responded
  - 12 Declined to participate stating that they do not have an active trauma research committee
  - 21 Completed and returned surveys
    - 17 Facilities have active trauma research committees
    - 4 Facilities completed surveys, but do not have active trauma research committees

## Committee Leadership

- The ACS strongly recommends that a clinically active trauma surgeon with experience and interest in research serve as committee chair
- All participating facilities had a trauma surgeon as committee chair
- Participating facilities reported that most were chaired by their Trauma Medical/Program Director
- A few facilities reported that the committee chair was appointed by the Trauma Medical Director or the previous chair
- Very few facilities reported having a vice chair, and no trend was noted in selection methodology

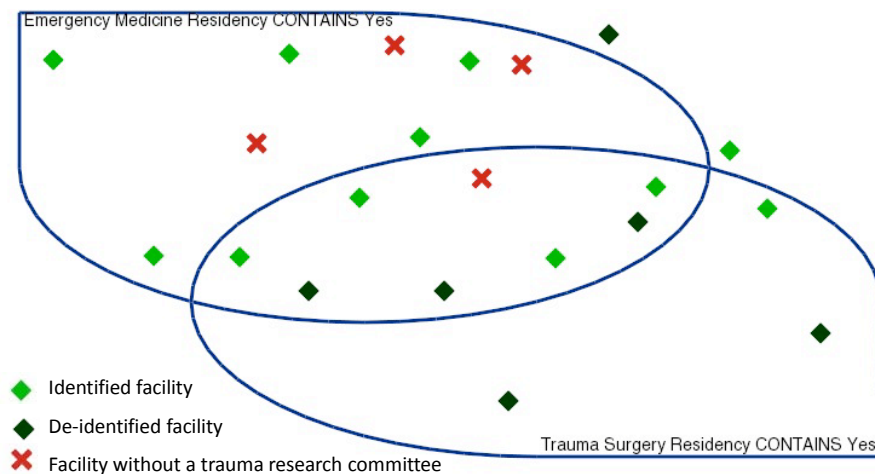
## Committee Membership

- Physicians with interest in trauma research
- Most frequently involved departments (reported from most frequent to least frequent): Trauma Surgery, Emergency Medicine, General Surgery, Nursing, Neurosurgery, Orthopedics, Rehabilitation, Critical Care Medicine, Pharmacy, Radiology, Anesthesiology, Toxicology
- Committee members are primarily responsible for developing a research question and protocol, interpreting the data, and authoring articles for peer-review and publication

## Supporting Roles

- Most frequently identified departments /individuals (reported from most frequent to least frequent):  
Statistician, Clinical Research Coordinator, Residents, Trauma Program Manager, Injury Prevention, Epidemiologist, Hospital Management, Trauma Registry, Physician Assistants, Clinical Dietician, Infectious Disease, Medical Informatics
- People /departments in supporting roles are essential to completing research. They help with study design, data gathering, protocol implementation, interdepartmental coordination, and fund acquisition
- Attendance by personnel in supporting roles usually varies depending on committee needs

## Residency Program Importance



## Residency Program Importance

- 16 Facilities reported having an Emergency Medicine Residency
- 11 Facilities reported having a Trauma Surgery Residency or General Surgery Residency with a Trauma Surgery component
- 8 of these facilities reported having both residencies
- 2 Facilities without either residency program
  - One stated that residents from a neighboring facility rotate with their Emergency Medicine group
  - The other stated that residents from a neighboring facility rotate with their Emergency Medicine group and their General Surgery group

## Important Notes on Residents

- The ACS strongly recommends involvement of surgical residents in ongoing research activities. Resident activities should include demonstration of participation and authorship of trauma-related publications.
- Residents can fulfill 2 of the 4 trauma-related scholarly activity requirements necessary to reduce the publication requirements for Level 1 Trauma Centers from 20 peer-reviewed articles to 10.
  - “Support of resident participation in institution-focused scholarly activity, including laboratory experiences, clinical trials, or resident trauma paper competitions at the state, regional, or national level.”
  - “Mentorship of residents and fellows, as evidenced by the development of a trauma fellowship program or successful matriculation of graduating residents into trauma fellowship programs.”

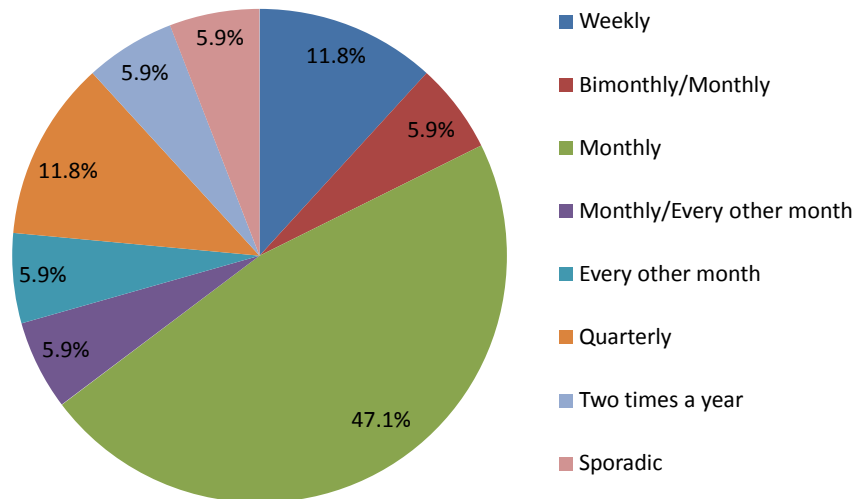
## Basic and Social Scientists

- Several of the participating facilities noted the use of an epidemiologist to fill the role of basic scientist and social scientist on their trauma research committee.
- Epidemiologists study patterns of health and illness and associated factors at the population level. Epidemiology is the cornerstone of public health research, identifying risk factors for disease and determining optimal treatment approaches to clinical practice and for preventative medicine.
- Epidemiologists are often well versed in biostatistics and may fill part of that role as well.

## Committee Activities

- Meeting frequency
- Trauma research committee (TRC) /Institutional Review Board (IRB) relationship
- Research Oversight
- Research Peer-Review
- Research Communication and Publication
- Measuring the Value of Trauma Research

## Committee Meeting Frequency



## Committee Meeting Frequency

- Facilities new to research or with a large percentage of physicians inexperienced in research meet more frequently
- 65% of reporting committees meet at least once a month
- Facilities with fairly self-sustaining research programs or dedicated trauma research programs have fewer meetings or no committee because communication is well established and research is a central part of daily activity within these programs

## TRC/IRB Relationship

- Most of the responding committees do not formally review new studies prior to IRB submission unless a pre-review is requested by the principal investigator
- Many TRCs have a designated liaison between the TRC and IRB who can help PIs ensure a more favorable IRB review with fewer stipulations
  - This person may chair a subcommittee of experienced researchers that can perform pre-reviews and provide feedback in a timely manner
  - Subcommittees of this kind usually meet sporadically and independently of the TRC, but do report when activity has taken place
- Several facilities indicated that the IRB provides up to two meetings a year to help educate and update TRC members on IRB policies and procedures

## Research Oversight

- Some committees limit access to the Trauma Registry to ensure the data is utilized in the manner it was intended
- Track the progress of trauma studies to make sure they are completed in a timely manner
- Provide assistance with data collection/analysis if principal investigator is unable to complete these tasks with existing resources
- Assist with protocol design and manuscript review
- Ensure that enough research is being done to meet verification requirements and, if necessary, assign studies

## Research Peer-Review

- Manuscript review prior to submission for publication to try to improve the likelihood of publication
  - This is often done by committee members with multiple published research studies
  - Several committees commented that this is done for all novice researchers while others stated that it is only done by request
- Act as test audience for presentations that will be made before regional or national convention audiences

## Research Communication and Publication

Communicating research findings is a *requirement* of the ACS

- Publication in journals included in the *Index Medicus*
  - Evidence of dissemination of knowledge to include review articles, book chapters, technical documents, Web-based publications, editorial comments, training manuals, and trauma-related course material
  - Display of scholarly application of knowledge as evidenced by case reports or reports of clinical series in journals included in MEDLINE
  - Participation as a visiting professor or invited lecturer at national or regional trauma conferences
- Several committees also have mechanisms in place for sharing research findings within their institutions



# Value of Trauma Research

- Finding a way to quantitatively measure the value of a Trauma Research program can be challenging
- Making such determinations is one of the committee's responsibilities
- By holding researchers to high standards, a greater percentage of completed research projects will be publishable in required journals and reduce the amount of wasted effort
- Some research may be determined to be of great value to the institution, but not likely to be publishable; however, such research projects should still be done and are often financed by the institution
- It may take several years before the true value of a Trauma Research program becomes evident
- The following slides site examples of the measurable value of trauma research at other institutions

## Value of Trauma Research

### Examples from other Institutions

- "Standardization of clinical guidelines"
- "Trauma Research has been used to develop or gauge the impact of changes in care"
- "Improved performance in the initial evaluation of injured patients in the ED"
- "Research on ventilator assisted pneumonia has instituted new care protocols for the ventilated patient that has dramatically reduced VAP numbers"
- "The process by which we share ideas and proposals helps us to identify areas of clinical practice where our data collection or practice guidelines can be improved"

# Value of Trauma Research

## Examples from other Institutions

- “The data from a multicenter study we took part in will be very useful in looking at and modifying current transfusion practices across the US”
- “More efficient assessments for C-spine injuries as a result of new protocol developed by a trauma research team”
- “We are currently researching radiology studies repeated at our institution on transferred patients; this has changed practice and we are now doing fewer repeat studies”

# Dedicated Research Program

## Information based off reported data from 3 facilities

- Sometimes used as an alternative to a trauma research committee
- Usually involves one or two physician/PhDs, a trauma research coordinator (typically a RN/BSN), and residents
- Often do most of their work off-site (medical college or university) and heavily tied to a residency program
- All reported having oversight from the General Surgery Director or someone in trauma administration

## National Organizations

- The ACS recommends obtaining membership and participate in regional and national academic societies, such as the American Association for the Surgery of Trauma (AAST), the American College of Surgeons (ACS), or the Eastern Association for the Surgery of Trauma (EAST).
- These organizations provide a forum for participants to exchange information, get ideas for future research projects, develop contacts at other institutions for multisite research, and provide some funding opportunities for research.
- Membership in these organizations fulfills 1 of the 4 trauma-related scholarly activity requirements necessary to reduce the publication requirements for Level 1 Trauma Centers from 20 peer-reviewed articles to 10.
- Presenting research findings at the annual meetings of one of these organizations also fulfills 1 of the 4 trauma-related scholarly activity requirements

## Potential Funding Sources

- National Institute of Health
- Centers for Disease Control and Prevention
- National Highway Safety Administration
- Department of Transportation
- Agency for Healthcare Research and Quality
- Robert Wood Johnson Foundation
- Howard Hughes Medical Institute
- United States Military – Office of Naval Research, Army Research Office, Air Force Office of Scientific Research, and Defense Advanced Research Projects Agency

Obtaining funding from a recognized government or private agency fulfills 1 of the 4 trauma-related scholarly activity requirements

## Recommendations

- Establish a written Standard Operating Policy for the trauma research committee to help guide the activities of the organization
- Work toward establishing a general surgery or emergency medicine residency
- Incorporate a basic and/or social scientist into the committee; i.e. – epidemiologist
- Hire a clinical research nurse coordinator
- Increase meeting frequency to two times per month until at least 15 research projects have been approved by the IRB

## Recommendations

- Formalize a relationship between the TRC and IRB
- Set up an official subcommittee for pre-review of protocols prior to IRB submission
- Follow-up each meeting on the progress of previously mentioned research proposals
- Set up an official subcommittee for manuscript review prior to submission for publication
- Obtain membership within national trauma organizations for multiple trauma surgeons

## Recommendations

- Take time to review the journals listed in the *Index Medicus* in a formal meeting; look for journals you may be interested in publishing to and look for publication guidelines for those journals
- Establish a method for assessing the value of potential research projects to maximize likelihood of publication
- Once research activity increases and researchers gain experience, start looking for opportunities to participate in multicenter research studies

## Contributing Facilities

- Phoenix Children's Hospital, Phoenix, Arizona
- Charleston Area Medical Center for Health Services and Outcomes Research, Charleston, West Virginia
- Fletcher Allen Health Care/University of Vermont, Burlington, Vermont
- Texas Children's Hospital, Houston, Texas
- Tarrant County Hospital District dba JPS Health Network, Fort Worth, Texas
- Duke University Medical Center, Durham, North Carolina
- The Toledo Hospital & Toledo Children's Hospital, Toledo, Ohio
- Grant Medical Center, Columbus, Ohio
- Intermountain Medical Center, Murray, Utah
- Bronson Methodist Hospital, Kalamazoo, Michigan
- Helen DeVos Children's Hospital, Grand Rapids, Michigan
- University of Kansas Hospital, Kansas City, Kansas
- Nine other facilities that requested to not be identified

## APPENDIX C

### TRC STANDARD OPERATING POLICY

Texas Health Harris Methodist Hospital Fort Worth  
Trauma Research Committee  
Standard Operating Policy

**Mission Statement:** To provide a forum for discussion and development of physician-initiated trauma research, support best practice and contribute to the body of trauma-related research while supporting the hospital's pursuit of Level 1 Trauma Designation.

**Committee Goals:**

- A. Develop a viable academic/research environment.
- B. Publish a minimum of ten (10) peer-reviewed articles in journals included in the *Index Medicus* every three (3) years. These articles must result from work related to the achievements at the trauma center. Of the ten (10) articles:
  - 1. Five (5) peer-review articles must be authored or co-authored by a member of the trauma team.
  - 2. One (1) peer-review article from each of the following six (6) disciplines:  
neurosurgery, emergency medicine, orthopedics, radiology, anesthesia and rehabilitation medicine.
- C. Of the seven (7) following trauma-related scholarly activities, four (4) must be demonstrated by the trauma service in accordance with American College of Surgeon guidelines:
  - 1. Leadership in major trauma organizations.

2. Peer-reviewed funding for trauma research (not drug company sponsored research).
3. Evidence of dissemination of knowledge to include review article, book chapters, technical documents, Web-based publication, editorial comments, training manuals and trauma-related course material.
4. Display of scholarly application of knowledge as evidenced by case reports or reports of clinical series.
5. Participation as a visiting professor or invited lecturer at national or regional trauma conferences.
6. Support of resident participation in institution-focused scholarly activity, etc.
7. Mentoring of residents and fellows.

**Leadership:** A clinically active trauma surgeon with experience and interest in trauma research leads the committee. The committee chair and vice chair are selected by the Senior Vice President (SVP) of Operations for Texas Health Fort Worth (THFW).

A. Chair responsibilities

1. Oversee all trauma research with the authority to modify any/all research activities prior to IRB approval.
2. Maintain and enforce publication and abstract deadline requirements for trauma researchers.
3. Monitor each trauma researcher's activities on a quarterly basis. Failure of a researcher to meet his/her research requirements will be addressed by the Chair or Vice Chair.



4. Participates in the training program for visiting residents and medical students.
5. Moderates a one (1) hour research meeting on the 1<sup>st</sup> and 3<sup>rd</sup> Wednesday of every month with the trauma surgeons, subspecialty participants, allied healthcare providers, IRB representative, Texas Health Research and Education (THRE) representative, administration and medical students. Note: All trauma researchers must attend a minimum of 50% of these meetings annually.
6. Establish and maintain a relationship with residency/medical school training programs and nursing schools to secure participants to conduct research in conjunction with the trauma surgeons and other subspecialties.
7. Monitor the trauma surgeons' scholarly activity – teaching, production of case reports, publications, national committee activities, etc.
8. Help design research projects and select appropriate researchers to conduct the studies.
9. Select and monitor the activities of the trauma research coordinator(s) with input from the trauma staff and subspecialty participants.
10. Select the data collectors with input from the trauma staff and subspecialty participants.
11. Record and monitor time spent on each investigator's research project and publication.
12. Collaborate with the committee's IRB member.

B. Vice Chair responsibilities:

1. Assist the Chair with any/all the tasks listed above.

2. In the absence of the Chair, the Vice Chair or his designee moderates a one (1) hour research meeting on the 1<sup>st</sup> and 3<sup>rd</sup> Wednesday of every month with the trauma surgeons, subspecialty participants, allied healthcare providers, IRB representative, Texas Health Research and Education (THRE) representative, administration and medical students.

**Members:** Physicians with an interest in trauma research. In particular, Trauma Surgery, Emergency Medicine, Neurosurgery, Orthopedics, Radiology, Medicine, Anesthesia, and Rehabilitation are represented in the committee membership. Committee members are primarily responsible for developing a research question and protocol, interpreting the data, and authoring articles for peer-review and publication.

A. Trauma surgery research physicians (group responsibilities):

1. Participate in the teaching of residents or medical students on a weekly basis per the scholastic guidelines.
2. Participate in the preparation of trauma related education material at the Chair or Vice Chair's request.

B. Trauma surgery research physicians (individual responsibilities):

1. Prepare and present one (1) quarterly Trauma Talk lecture on a trauma related topic every 2 years.
2. Participate in one (1) Injury Prevention Seminar per year.
3. Pursue membership and attend one (1) meeting per year for one of the following organizations: American College of Surgeons' Committee on Trauma, American Association for the Surgery of Trauma, Western Trauma Association, Eastern

Association for the Surgery of Trauma, Pacific Coast Surgical Association or other comparable regional/national trauma related association.

4. Submit and present one (1) clinical research abstract every three (3) years at a meeting of one of the following organizations: American College of Surgeons' Committee on Trauma, American Association for the Surgery of Trauma, Western Trauma Association, Eastern Association for the Surgery of Trauma, Pacific Coast Surgical Association or other comparable regional/national trauma related association.
5. Produce one (1) trauma-related case study per year that is published in a peer-review journal within the year. The trauma surgeon will be responsible for drafting the manuscript and presenting it to the Chair, Vice Chair or professional editor for editing. The author will then be responsible for promptly submitting the manuscript to the proposed peer review journal and completing all editing requests from the accepting journal in a timely manner.
6. Produce and publish one (1) trauma-related clinical research study every two (2) years. The study must be published in a peer-reviewed journal listed in the *Index Medicus*. The trauma surgeon will be responsible for drafting the manuscript and presenting it to the Chair, Vice Chair or professional editor for editing. The author will then be responsible for promptly submitting the manuscript to the proposed peer review journal and completing all editing requests from the accepting journal in a timely manner.
7. All trauma researchers must attend a minimum of 50% of the monthly trauma research committee meetings annually. Each researcher will provide a brief

update on his/her different projects and publications. Each researcher should also be prepared to provide greater detail if requested to do so by the Chair or Vice Chair.

8. Required to co-author one (1) clinical study every three (3) years with a subspecialty physician.

C. Other physician researchers (individual responsibilities):

1. Produce one (1) trauma-related case study every three (3) years that is published in a peer review journal within the year. The physician researcher will be responsible for drafting the manuscript and presenting it to the Chair, Vice Chair or professional editor for editing. The author will then be responsible for promptly submitting the manuscript to the proposed peer review journal and completing all editing requests from the accepting journal in a timely manner.
2. Produce and publish one (1) trauma-related clinical research study every three (3) years. The study must be published to a peer reviewed journal listed in the *Index Medicus*. The physician researcher will be responsible for drafting the manuscript and presenting it to the Chair, Vice Chair or professional editor for editing. The author will then be responsible for promptly submitting the manuscript to the proposed peer review journal and completing all editing requests from the accepting journal in a timely manner.
3. All trauma researchers must attend a minimum of 50% of the monthly trauma research committee meetings annually. Each researcher will provide a brief update on his/her different projects and publications. Each researcher should also

be prepared to provide greater detail if requested to do so by the Chair or Vice Chair.

**Support:** It is acknowledged that people working in a supporting role are essential to completing research in a timely manner. Support may come from a statistician, trauma clinical research coordinator, surgical residents, trauma program manager, the pharmacy department, hospital management, a basic scientist, and THRE. Support personnel help with study design, data gathering, protocol implementation, interdepartmental coordination and fund acquisition. Attendance by personnel in supporting roles will vary depending on the committee's needs.

A. Trauma Clinical Research Coordinator(s)

1. Current Registered Nurse licensed to practice in Texas with a Masters degree or higher and experience in emergency and/or intensive care nursing, trauma experience preferred. Research experience required.
2. Conduct Clinical studies according to Office of Human Research Protection (OHRP) and FDA regulations and guidelines. Be knowledgeable of the study protocol so that all study activities are completed correctly and completely.
3. Design and maintain organizational tools to conduct studies accurately and in compliance with GCP and ICH guidelines.
4. Utilize Trauma Administration approved tools and protocols
5. Utilize accepted standards of THR IRB, OHRP and FDA from pre-study to start-up to closeout.
6. Flexible with scheduling to help meet departmental/patient needs.
7. Integrate the ACS guidelines for trauma patient care into the continuum of patient care.

8. Contribute to research strategies.
9. Falls under the daily direction of the Chair and Vice Chair and will attend all research meetings.
10. Will assist in writing and editing publications.
11. Will assist the trauma research physicians and/or data collectors in preparing case studies, clinical studies, abstracts and posters for peer review publication or national meetings.
12. Will assist the Chair with a progress report on investigators and their support staff's research activities on a monthly basis and present this report on the meetings occurring on the 3<sup>rd</sup> Wednesday of each month.

B. Data collectors

1. Work assigned by the Chair or Vice Chair to be under the direction of researchers to work on individual projects.
2. Experienced in medical terminology.
3. Pull data from the electronic medical record or other available databases.
4. Experienced in writing.

- C. Statistician: As needed, the Chair or Vice Chair will request that a statistician be contacted through THRE to review protocols prior to submission and to assess data for publication.

**Rules of Trauma Research:**

1. The Chair and Vice Chair must approve pharmaceutical funded studies under the auspices of the Trauma Research Committee prior to protocol submission to the IRB.
2. All research and clinical studies must be approved by the IRB.
3. Publication authorship will list the lead author (individual who did the most work) first, and then additional authors based upon their contribution to the project.
4. The trauma service, trauma surgeons and THFW will be acknowledged in all publications, without exception.
5. Data collected from all clinical studies will be the property of THFW, without exception.
6. Every clinical study will have a Principal Investigator (PI) and at least one co-investigator. In the event the PI leaves the study (for whatever reason), the co-investigator will assume the PI position and a new co-investigator will be appointed by the new PI.
7. All lectures and electronically generated materials generated from a case or clinical study will be recorded on a DVD and maintained in the TRACC, PA library and hospital library.

**Trauma Research Committee and the THR IRB:** An active member of the THR IRB is also a member of the Trauma Research Committee. In addition to the regular member duties, this individual serves as liaison to the IRB. As liaison, this member helps investigators identify factors within protocols that are likely to complicate IRB approval. The IRB liaison is also asked to coordinate an annual meeting with an IRB representative to update the committee on changes to IRB procedure and federal research laws.

**Pre-Review:** The Trauma Research Committee's Pre-review Subcommittee, led by the IRB liaison, will perform pre-review of all trauma research protocols prior to IRB application

submission. This pre-review is conducted to help investigators ensure a more favorable IRB review with fewer stipulations. Protocols must be submitted to the Pre-review Subcommittee at least 15 days prior to the IRB's submission deadline.

**Oversight:** The committee tracks the progress of trauma studies to make sure they are completed in a timely manner. The committee also provides assistance with data collection and analysis if the principal investigator is unable to complete these tasks with existing resources. Members may request assistance with protocol design as well. This oversight is done to ensure that enough trauma research is done to meet the American College of Surgeons' verification requirements for a Level 1 Trauma Center.

**Research Communication and Publication:** Communicating research findings is a *requirement* of the American College of Surgeons. Members must publish in journals included in the *Index Medicus*. Other forms of research communication and publication are strongly encouraged including the following: review articles, book chapters, technical documents, web-based publications, editorial comments, training manuals, trauma-related course material, and participation as a visiting professor or invited lecturer at national or regional trauma conferences.

**Manuscript Review:** A pre-established Review Subcommittee shall review manuscripts prior to submission to publishers. This subcommittee reviews publication guidelines from the publisher and makes sure that the manuscript follows those guidelines. In addition, the subcommittee checks to make sure the specific aims are clearly stated and that the discussion of findings and conclusions drawn are supported by the data presented. This review is done to improve the likelihood of publication. Manuscripts must be submitted to the Review Subcommittee at least 30 days prior to the publisher's submission deadline.



**Value of Trauma Research:** Finding a way to quantitatively measure the value of a Trauma Research program can be challenging. Making such determinations is one of the committee's responsibilities. By holding researchers to high standards, a greater percentage of completed research projects will be publishable in required journals and reduce the amount of wasted effort. Some research may be determined to be of great value to the institution, but not likely to be publishable; however, such research projects should still be done and may be financed by THFW. It may take several years before the true value of a Trauma Research program becomes evident. In order to ensure that the value of trauma research at THFW is high, the Chair and Vice Chair may conclude that a research study will not fulfill the publication requirements of a committee member. If that committee member decides to continue forward with the study, a second study will need to be initiated to complete the publication requirements of the trauma research committee.

**Budget:** THFW will establish a budget for incidental expenses related to work done for the trauma research committee. The Chair and the SVP of Operations will control allocation of funds based on need and fund availability.

In signing this document, I \_\_\_\_\_ agree to comply with these policies as I participate in research as part of the Texas Health Fort Worth Trauma Research Committee.

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Signature

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Date

Approved by:

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Chair/Vice Chair Signature

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Date

## APPENDIX D

### INTERNSHIP JOURNAL

## **Week 1**

August 24, 2010

- Advisory committee meeting at site.

August 25, 2010

- Site orientation, ID badge, privacy and CITI training.
- Observed a subject visit in study comparing Coumadin to Test Drug X. Observed review of questionnaire, drug accountability and dispensing, and blood draw and coagulation time assessment. Saw how double-blinding was maintained by having the coagulation time encoded and interpreted by computer for RN.
- Sat in on tele-conference with information technology specialist. Tele-conference to determine logistics for trial in planning phase (pre-protocol). Reviewed costs of trial, technology and support agencies. Discussed wording for questionnaire and protocol.

August 26, 2010

- Began work on telecommunications protocol rewrite.
- Meeting with Lillie Biggins to obtain information on Trauma Research Committee for thesis proposal. Discussed goals of the committee, organization and roles of committee members, and my anticipated role in helping improve productivity of the committee.
- Attended Emergency Physician Advisory Board (EPAB) meeting with Lillie Biggins. Saw role of ED physicians in overseeing local EMS operations.

August 27, 2010

- Sat in on meeting with monitor to establish new site for ongoing research in an IND trial.
- Continued working on telecommunications protocol rewrite. Literature search and review of material pertinent to research study. Made contact with various departments to determine specifics for protocol (e.g. – can blood drawn from earlier in the same day be used for specific lab test later).

## **Week 2**

August 30, 2010

- Continued work on telecommunications protocol rewrite. Literature searches predominated work for the day. Completed background material and reference citations.

August 31, 2010

- Continued work on telecommunications protocol rewrite. Further communications with various departments to determine specifics for protocol. Learned of possible delay in technology availability. Scheduled meeting for September 1 to discuss possible implications for the study.
- Obtained information on the role of research in obtaining Level 1 Trauma designation. Reviewed goals of Trauma Research Committee. Performed literature search for support material.

September 1, 2010

- Attended Director's Stand Up meeting with Lillie Biggins and Tamara Plant.
- Observed how blinding process on Coumadin vs Test Drug X protocol had to be unblinded due to technology complications. Approved unblinded nurse ran lab test, faxed result to sponsor who faxed back code to enter in the computer so that the study nurse and subject were still blinded.
- Met with Tamara Plant to determine how to deal with the delay in technology availability for telecommunications protocol.
- Tele-conference with information technology specialist to discuss technology delay and technology concerns. Determined to leave protocol to include delayed technology, but to file for IRB approval one month later than originally planned. Planned for face-to-face meeting with technology specialist.
- Discussed further revisions to protocol and questionnaires based on tele-conference.

September 2, 2010

- Attended MedStar Grand Rounds. Covered 4 cases and outcomes for EMS calls and evaluated potential improvements to the EMS system that might help improve outcomes for future patients.
- Met (briefly) Drs. Withum and Smith. Invited by Lawan Smith to attend Trauma ICU rounds next week.

- Continued revisions to telecommunications protocol. Added to Risk/Benefit assessment, obtained electronic copies of all but one of the cited references and revised questionnaires.

September 3, 2010

- More work on telecommunications protocol. Met with Tamara Plant to review progress and get list of revisions to work on for next week. Also reviewed questions to be sent to information technology specialist for next Thursday's demo.
- Met with Lillie Biggins and members of the JPS/THFW Work Group. Saw steps being taken to help reduce costs for patients and THFW through partnership with JPS Connection. Was asked to come up with a way to look at the data they've collected to help determine what areas they have made the largest impact in and what areas they may need to work harder to improve upon. Took raw data and input it into Excel. Generated several graphs with trends to try to accomplish assignment.

### **Week 3**

September 6, 2010

- Labor Day Holiday. Did not go to office.

September 7, 2010

- Continued revisions to telecommunications protocol including addition of Source Document and Master Patient List.

September 8, 2010

- Continued revisions to telecommunications protocol.
- Sat in on informal meeting of research staff to discuss ongoing studies and recently conducted satisfaction survey.
- Met with Tamara Plant and Teresa Turbeville to go over telecommunications protocol.

September 9, 2010

- Continued revisions to telecommunications protocol.
- Began search for standards for Trauma Research Committees at other institutions.

September 10, 2010

- Sat in on IRB session at THFW. Saw PI present his proposed study to IRB and field questions. Saw how IRB reviewed studies that were up for annual renewal.
- Went with Trauma Administration nurses for rounds in Trauma ICU.
- Continued revisions to telecommunications protocol. Worked with Tamara Plant to finalize questions for daily survey, weekly survey and end-of-study questionnaires. Noted which information was needed to finalize protocol. Completed Master Stratification List and Source Document.

**Week 4**



September 13, 2010

- Read over minutes from past Trauma Research Committee meetings and agenda for the September 15<sup>th</sup> committee meeting. Organized notes to be easy to find material if researched material is useful during meeting.
- Completed online training for hospital's electronic records system.
- Received missing data for JPS/THFW Work Group. Completed data set and graphing for JPS/THFW Work Group. Emailed it to Lillie Biggins for review.
- Looked over some material for Informed Consent Form for the telecommunications protocol.

September 14, 2010

- Completed online THR courses on Confidentiality, Privacy Matters, Government Funded Program & False Claims, and Business Ethics & Compliance.
- Contacted Lillie Biggins to set up several meetings. First meeting with her to discuss JPS/THFW Work Group data that was forwarded to her for review. Also to set up potential meetings with Trauma Research Committees at JPS and Parkland.
- Contacted Dr. Gwartz to find out if any comparable research committees exist within the UNT system.

September 15, 2010

- Prepped for Trauma Research Committee meeting. Organized notes and re-read previous meeting minutes. Read over agenda.

- Attended Trauma Research Committee meeting. Was introduced to the attending committee members. Shared information obtained earlier on when it is appropriate to involve a statistician. Gave feedback on several proposed studies. Announced intention to contact other trauma committees to try to get information on how to better organize committee to increase productivity of the group.
- Posted several documents to Trauma Research Committee's resources web site including how and when to request a Statistician, research requirements to become a Level 1 trauma center, and a listing of approved journals to get credit for published research.
- Met with Lillie Biggins to discuss JPS/THFW Work Group data that was forwarded to her for review.

September 16, 2010

- Finalized presentation materials for JPS/THFW Work Group and emailed to Lillie Biggins for final approval. Approval given later in the day.
- Drove to Dallas to meet with Tamara Plant and information technology specialist to get hands-on with some of the technology for the telecommunications project. Made note of several concerns over current technology limitations, software settings, etc. Received feedback from information technology specialist on how to potentially present technology to patients for informed consent and wording of patient documentation for IRB review. Became aware of some technical issues that need to be addressed by THR before going to the IRB.
- Worked out details within telecommunications protocol with Tamara Plant. Sent working version with notes to PI for review and revision.

September 17, 2010

- Attended meeting focused on Improving Door to tPA Times in the ED.
- Further revisions to telecommunications protocol and review of internal THR data to determine which sites were most likely to have high/low recruitment potential.
- Worked on Internship Practicum Proposal. Researched requirements for Trauma Level 1 designation, history of HMFWS / THR, and notes over TRC meetings and anticipated outcome of internship work.

## **Week 5**

September 20, 2010

- Observational rotation in Emergency Department with the intention of seeing how the ED and Trauma Surgery interact on a day-to-day basis. Minimal contact between the departments throughout the day. Most of the cases were medical cases or minor traumas that did not require Trauma Surgery consultation.

September 21, 2010

- Spent the day performing literature searches for Practicum Proposal looking for the history of the current trauma designation system and the role of trauma research committees within that system. Reviewed American College of Surgeon guidelines for Level 1 Trauma designation.

September 22, 2010

- Continued work on Practicum Proposal.
- Sat in on call for telemanagement protocol involving THR IT security and HIPAA compliance.
- Met with Tamara Plant to discuss telemanagement protocol. Reviewed new developments from technology specialist and emailed new questions.

September 23, 2010

- Completed draft of Practicum Proposal and emailed it to Dr. Gwartz.
- Set up Emergency Department observational rotation for October 4<sup>th</sup>.
- Reviewed Task List from information technology specialist and noted some miscommunications. Contacted Tamara Plant to resolve.
- Redid CITI training for UNTHSC.
- Phone call with UNTHSC IRB to discuss IRB application for practicum. Emailed Dr. Gwartz to disregard submitted Practicum Proposal and advised that I would make revisions and try to email new version by end of the work day tomorrow.

September 24, 2010

- Continued communication between Dr. Gwartz and UNTHSC IRB office. Emailed tentative draft of Practicum Proposal to Dr. Gwartz. Emailed UNTHSC IRB Chair Brian Gladue, Ph.D. to schedule meeting.

- Met with Tamara Plant to discuss progress on telemanagement study. Noted need to revise protocol to add missing financial accountability for missing/damaged technology. Reviewed Task List from information technology specialist.
- Started filling out form for Exempt review for UNTHSC IRB
- Compiled questions to ask Trauma Research Committees. Emailed them to Lillie Biggins for review and suggested she share them with Committee members that may have questions to add/modify.
- Performed web search on THR website for IRB codes for clinical trials listed on Clinical Trials website.

## **Week 6**

September 27, 2010

- Worked on UNTHSC IRB application submission.
- Went with research staff to THRE Quarterly Staff Meeting in Arlington.

September 28, 2010

- Met with Dr. Gwartz to review Practicum Proposal. Noted revisions that needed to be made. Photo copied paperwork for IRB.
- Submitted Practicum Proposal to IRB with paperwork for IRB Exempt Review.
- Modified Practicum Proposal per Dr. Gwartz's suggestions and emailed 2<sup>nd</sup> draft to Advisory Committee. No responses by the end of the work day.

September 29, 2010

- Began drafting Informed Consent Form for telemanagement protocol using THR IRB's ICF Template. Completed draft and emailed to Tamara Plant for review and revision.
- Attended meeting with Trauma Administration to see what ongoing process were going on to maintain Level 2 Trauma designation. HMFWD due for Trauma designation renewal on September 11, 2011. Discussed with Lawan Smith what was needed for Level 1 Trauma designation and was told that the Research element is the primary limiting element and that HMFWD could apply for Level 1 designation on next cycle if Research element is established and functioning.
- No contact from UNTHSC IRB. Sent email requesting appropriate time to come by to obtain signatures from all members of Advisory Committee. Received feedback on Practicum Proposal from Teresa Turbeville, Tina Machu and Lillie Biggins. Set up meeting times.

September 30, 2010

- Finalized Practicum Proposal and printed copy along with 'Master of Science Research Proposal' Form for signatures. Emailed Practicum Proposal revisions to Advisory Committee. Obtained all signatures and submitted proposal to Graduate Office.
- Compiled list of missing documentation from information technology specialist that is needed for IRB application submission. Emailed to Tamara for review/revision.

- Read articles for potential trauma research study involving Vitamin C in post-op care. Noted that primary article still listed as “Published Ahead of Print” with missing components. Marked calendar to follow-up next week to see if article reaches print.
- Reviewed notes for THHMFJW/JPS Work Group meeting.
- Web search for more Trauma Research Committees to contact after UNTHSC IRB approves protocol.

October 1, 2010

- THHMFJW/JPS Work Group meeting. Presented graphs of data for review by Work Group. Was asked to make small revision and add missing data group. Emailed modified graphs to Lillie Biggins.
- Received approval email from UNTHSC IRB office. Stated “you are free to begin your research at any time.”
- Found and printed complete list of US Level 1 Trauma Centers from ACS website.
- Met with Tamara Plant to go over Clinical Trials website to confirm or revise listed status on each study.
- Worked with Tamara Plant to begin revisions to Informed Consent Form for telemanagement protocol.

## **Week 7**

October 4, 2010

- Observational rotation in Emergency Department with the intention of seeing how the ED and Trauma Surgery interact on a day-to-day basis. Saw two cases where the ED physician contacted the Trauma Surgeon. First case was assessed by surgeon and then left in the care of the ED physician. The second case led to neurosurgeon also being called and care being transferred to the surgical team.

October 5, 2010

- Made quick revisions to telemanagement protocol and emailed it to Tamara Plant for review.
- Continued revisions to telemanagement informed consent document.
- Conducted internet search for contact information for research administration at Level 1 Trauma Centers. Found for all Level 1 Centers in Alabama, Arizona, California and Colorado.

October 6, 2010

- Continued internet search for contact information for research administration at Level 1 Trauma Centers. Found for all Level 1 Centers in Connecticut, Delaware, and Washington, DC.
- Tele-conference with information technology specialist to discuss what we need from him for the IRB application submission. Set deadline for him to submit to us. Made plans to test study pulse oximeter on arthritic finger to ensure its function.
- Finalized telemanagement protocol.



- Met with Tamara Plant to review/revise telemanagement informed consent document.  
Finalized it.

October 7, 2010

- Attended training conducted by Tarrant County Public Health Department. Training for proper packaging and shipping of diagnostic/infectious specimens according to government regulations.

October 8, 2010

- Attended Basic Life Support Course. Received new certificate.
- Sat in on phone meeting of the Congestive Heart Failure High Impact Performance Initiative.
- Worked on HIPAA form for telemanagement study. Met with Tamara Plant to finalize it.  
Missing phone number for the coordinator (not yet determined).

## **Week 8**

October 11, 2010

- Attempted to contact Dr. Gullinese to inform him that 3 articles about scribes had been faxed to Clinical Research Office.
- Continued internet search for contact information for research administration at Level 1 Trauma Centers. Found for all Level 1 Centers in Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts and Michigan.

October 12, 2010

- Reviewed updated task list from information technology specialist and wrote notes to pass on to him and Tamara Plant at next contact.
- Continued internet search for contact information for research administration at Level 1 Trauma Centers. Found for all Level 1 Centers in Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, Nevada, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island and started on Texas.

October 13, 2010

- Delivered 3 articles to Dr. Gullinese's scribe, Katie Cantrell.
- Continued internet search for contact information for research administration at Level 1 Trauma Centers. Still in Texas.
- Met with Tamara Plant to review task list from information technology specialist. Teleconference with information technology specialist to help emphasize what exactly we need in order to make our IRB application submission deadline. Discussion with Tamara Plant over how to attach the Pulse Ox probe to the tablet base-station or TV remote. Made contact with public relations office to inquire about modifying a THR retractable badge holder. Directed to Joan Stockton. Email sent with same request.

October 14, 2010

- Meeting in Arlington about NSF Funds. Discussed potential aspects of 3<sup>rd</sup> phase for telecommunications study.
- Phone conversation with Lillie Biggins to get phone access for long distance calls to Level 1 Trauma Centers in US. Also scheduled an appointment to meet with her before Trauma Research Committee on 10/20.
- Completed internet search for contact information for research administration at Level 1 Trauma Centers.
- Reviewed and corrected recruitment email and committee survey questions.

October 15, 2010

- Developed contact log to keep track of which hospitals were successfully contacted, emailed and received a response from.
- Began calling Trauma Administration offices at Level 1 medical centers. Sent 12 surveys after making contact with personnel at those offices. Left messages at 13 other offices.

## **Week 9**

October 18, 2010

- Continued calling Level 1 Trauma Centers. Sent surveys to 19 sites. Contacted and left messages at 14 more offices.
- Phone call with Tamara Plant about telemanagement study. Principal investigator had contacted her with a significant last minute change. Discussion of what we needed to change

to make his alteration possible. Received message from her later in the day advising not to make any changes.

October 19, 2010

- Received completed survey from 1 hospital. Resent survey to 1 hospital, but to a different point of contact after email from original recipient suggesting that they were not the person to contact.
- Drove to Dallas office for meeting with Tamara Plant and information technology specialist for telemanagement study. Reviewed material for IRB application submission, noted some changes that needed to be made. Used technology from the study and noted potential complication for the subject; IT specialist stated he'd attempt software modification to fix the problem. Updated delivery date on IRB material from IT specialist is now 2359 on October 21<sup>st</sup>.

October 20, 2010

- Reviewed documents from IT Specialist for telemanagement study. Wrote notes on requested modifications and forwarded them on to Tamara Plant for further review.
- Wrote email to one hospital trauma research committee member in response to voice mail and attached survey.
- Met with Lillie Biggins to discuss research progress for trauma research committee. Discussed an article I'd found on vitamin C and a potential study.

- Attended meeting of trauma research committee. Toward the end of the meeting, presented progress report on research for the trauma research committee, made suggestion of using SharePoint web site to coordinate subcommittee meetings, and presented brief overview of Vitamin C report and suggested study idea. Met with Dr. Collinge after meeting to discuss the vitamin C article. He requested that I perform a literature search for articles specific to vitamin C usage in orthopedics.
- Met with Tamara Plant to go over documents from IT Specialist for telemanagement study. Worked with her to develop complete list of corrections and emailed them to the IT Specialist.
- Responded to emails from two other facilities regarding my requests for surveys. Received call back from another facility and emailed survey to that sight.

October 21, 2010

- Continued calling Level 1 Trauma Centers. New tally totals: contacted 90, sent 45 surveys, received 2 surveys back, 2 sites declined to participate.

October 22, 2010

- Conducted literature search requested by Dr. Collinge on the role of Vitamin C in orthopedics. Found 9 articles that may be of interest to him.
- No calls made to Level 1 Trauma Centers, but did respond to emails from previously contacted sites. New tally totals: contacted 90, sent 45 surveys, received 3 surveys back, 2 sites declined to participate.

## **Week 10**

October 25, 2010

- ACLS Class – Day 1
- Met with Tamara Plant about telemanagement protocol. Reviewed updated information from IT specialist and sent notes back to him. Discussed possibility of submitting protocol as an Expedited Review protocol. Made plans to talk to Sharron to determine if protocol qualified. Began IRB application submission online application.
- No calls made to Level 1 Trauma Centers, but did respond to emails from previously contacted sites. New tally totals: contacted 90, sent 47 surveys, received 4 surveys back, 2 sites declined to participate.

October 26, 2010

- ACLS Class – Day 2
- Began inputting information into IRB online application.
- No calls made to Level 1 Trauma Centers, but did respond to emails from previously contacted sites. New tally totals: contacted 90, sent 48 surveys, received 4 surveys back, 2 sites declined to participate.

October 27, 2010

- Continued work on IRB online application.

- Met with Tamara Plant about telemanagement protocol. Reviewed change to informed consent document. Reviewed work done on IRB application.
- Phone conference with IT specialist with updates on material for IRB application. Also reviewed research staff user interface and suggested changes.

October 28, 2010

- Went to Dallas THRE office for meeting with Tamara Plant and IT specialist. Assessed changes made to weight scale and requested further changes. Quick review of forms to be received from IT specialist for submission to IRB.
- Continued work on IRB online application with Tamara Plant.

October 29, 2010

- Read over IRB online application to ensure no errors. Met with Tamara Plant to review with her to make sure application is ready for submission. Discussed telemanagement protocol's budget and other missing documents for IRB application.
- Read articles suggested by Lillie Biggins.

## **Week 11**

November 1, 2010

- Sent and received multiple emails back and forth with IT specialist for telemanagement study. Reviewed documents from IT specialist for IRB review.

- Continued calling Level 1 Trauma Centers. New tally totals: contacted 94, sent 49 surveys, received 4 surveys back, 4 sites declined to participate.
- Met with Tamara Plant to review documents from IT specialist. Made new list of requested corrections and emailed them to IT specialist.
- Attempted to contact Sharon Wolff from THR IRB for input on telemanagement study IRB application submission. Left message requesting a call back.

November 2, 2010

- Contacted Sharon Wolff from THR IRB to request input on telemanagement study IRB application submission and emailed specific questions.
- Finalized documents from IT specialist and uploaded to IRB application submission.
- Continued calling Level 1 Trauma Centers. New tally totals: contacted 108, sent 59 surveys, received 5 surveys back, 4 sites declined to participate.

November 3, 2010

- Continued calling Level 1 Trauma Centers. New tally totals: contacted 110, sent 63 surveys, received 5 surveys back, 4 sites declined to participate.
- Worked with Tamara Plant to summarize a study budget for the telemanagement study's IRB application submission.

November 4, 2010



- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 125, sent 71 surveys, received 5 surveys back, 4 sites declined to participate. Began calling back hospitals that did not return initial phone call.

November 5, 2010

- Attended THR IRB meeting. 4 protocols reviewed over 2.5 hours. In attendance was UNTHSC IRB Chair Brian Gladue, Ph.D. who was brought in for consultation on a protocol under review. Discussed with Dr. Gladue the differences in how THR and UNTHSC operate their IRBs.
- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 125, sent 74 surveys, received 5 surveys back, 4 sites declined to participate. Continued calling back hospitals that did not return initial phone call.
- Finalized submission of telemanagement protocol to IRB and notified PI that he needed to submit it. Confirmed that PI successfully submitted the study for IRB expedited review.

## **Week 12**

November 8, 2010

- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 125, sent 83 surveys, received 6 surveys back, 4 sites declined to participate. Continued calling back hospitals that did not return initial phone call.

November 9, 2010

- Went to THRE Dallas office for meeting with Tamara Plant and IT specialist for AT&T study. Reviewed changes to functionality of Bluetooth pulse ox device. Set up meeting with IT specialist for November 18<sup>th</sup>.
- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 125, sent 87 surveys, received 7 surveys back, 4 sites declined to participate. Continued calling back hospitals that did not return initial phone call.

November 10, 2010

- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 125, sent 91 surveys, received 7 surveys back, 5 sites declined to participate. Continued calling back hospitals that did not return initial phone call.

November 11, 2010

- SICK DAY – out of office
- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 125, sent 91 surveys, received 8 surveys back, 5 sites declined to participate. Continued calling back hospitals that did not return initial phone call.

November 12, 2010

- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 125, sent 91 surveys, received 10 surveys back, 6 sites declined to participate. Continued calling back hospitals that did not return initial phone call. In addition, started sending emails to sites that had not returned survey. Email explained that title of study refers to how information will be used, not the study population and requested that if the survey was ignored because site was an academic institution, they please reconsider participating.
- Met with Tamara Plant to discuss work assignments in her absence.

### **Week 13**

November 15, 2010

- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 126, sent 91 surveys, received 11 surveys back, 8 sites declined to participate. Continued calling back hospitals that did not return initial phone call. In addition, finished sending emails to sites that had not returned survey.

November 16, 2010

- Continued calling Level 1 Trauma Centers. New tally totals: contacted all 126, sent 101 surveys, received 13 surveys back, 12 sites declined to participate. Continued calling back hospitals that did not return initial phone call. In addition, finished sending emails to sites that had not returned survey.

November 17, 2010

- Attended Trauma Research Committee subcommittee meeting for potential NIH funded study. Purpose of the meeting was to hash out details of the study and meet with the grant writer. Reviewed goals for the study and potential data points. Set up follow-up meeting for December 15<sup>th</sup>.
- Attended Trauma Research Committee meeting. Discussion of several potential studies and review and refinement of ideas from previous meetings. Still no studies formalized for presentation to IRB.
- Met with Teresa Turbeville and Dr. Gudimetla to discuss strategies to increase awareness of ongoing CME activities at THFW.
- Continued contacting Level 1 Trauma Centers. New tally totals: contacted all 126, sent 102 surveys, received 14 surveys back, 12 sites declined to participate. Continued calling back hospitals that did not return initial phone call.

November 18, 2010

- Went to UNTHSC campus to see a classmate's practicum defense in preparation for my own defense. Asked a few questions to help clarify unclear points. Made a list of do's and don'ts for my defense.
- Met with Daniel Gonzalez to discuss as study he is working on an IRB application submission for. Helped review ICF that sponsor had modified to meet THR IRB template guidelines and noted several corrections that will need to be made. Made plans to continue

assisting with his IRB application submission. Study will be referred to as IA Study for simplicity.

- Went to Dallas office to meet with IT specialist for telemanagement protocol. Discussed changes he and his team have made since the last meeting. Discussed how to communicate with study coordinator that a high priority alert has taken place. Made a list of questions for Tamara Plant to review and discuss at next meeting. Helped set up a secure wireless internet connection for device testing purposes.
- Continued contacting Level 1 Trauma Centers. New tally totals: contacted all 126, sent 103 surveys, received 16 surveys back, 12 sites declined to participate. Continued calling back hospitals that did not return initial phone call.

November 19, 2010

- Continued contacting Level 1 Trauma Centers. New tally totals: contacted all 126, sent 105 surveys, received 16 surveys back, 12 sites declined to participate. Continued calling back hospitals that did not return initial phone call. Consolidated collected data to ease analysis process.
- Received modified ICF for the IA Study from Daniel Gonzalez. He advised that it had been further modified by the sponsor. Began editing the modified document using the original THR IRB Template as a guide.

## **Week 14**

November 22, 2010

- Continued contacting Level 1 Trauma Centers. New tally totals: contacted all 126, sent 105 surveys, received 17 surveys back, 12 sites declined to participate. Continued calling back hospitals that did not return initial phone call. Consolidated collected data to ease analysis process.
- Completed editing the modified ICF for the IA Study using the original THR IRB Template as a guide. Noted several sections for the Sponsor to look over and revise. Emailed to Daniel Gonzalez to review before emailing to the Sponsor.

November 29, 2010

- Continued contacting Level 1 Trauma Centers. New tally totals: contacted all 126, sent 106 surveys, received 19 surveys back, 13 sites declined to participate.
- Addressed questions from IRB for telemanagement study making revisions to IRB application and ICF. Spoke to IT Specialist for the study to clarify IRB questions and received update on technology development for the study.
- Spoke to Daniel Gonzalez about additional revisions to IA Study's ICF.
- Drew up initial draft on ICF for PPP Study.
- Met with Tamara Plant to update her on progress with telemanagement in terms of IRB application submission, IT specialist, etc. Also discussed IA study progress and PPP study.

November 30, 2010

- Continued contacting Level 1 Trauma Centers. New tally totals: contacted all 126, sent 106 surveys, received 20 surveys back, 13 sites declined to participate.

- Continued modification of PPP Study ICF.
- Made additional revisions to IA Study's ICF and noted that, with approval from sponsor, ICF should only need to have format changes in order to finalize the document.

December 1, 2010

- Closed data collection for Trauma Research Committee study. Final tally totals: contacted all 126, sent 106 surveys, received 20 surveys back, 13 sites declined to participate. Began data analysis for Trauma Research Committee study.
- Continued modification of PPP Study ICF.
- Out of office for doctor's appointment in the afternoon.

December 2, 2010

- Began reviewing PPP Study protocol to confirm proper information is in the ICF draft.
- Moved from one desk to another to make room for new study coordinator.
- Performed literature search for telemanagement study to answer questions from IRB.

December 3, 2010

- Attended meeting of THR IRB. Saw how a study that had been deferred was reviewed and approved following confirmation that all the changes requested were made. Also saw how 2 other studies were reviewed. Saw how one study had been stopped due to safety findings.

- Attended meeting for JPS/THFW Work Group. Saw the impact of loss of a key member of the group and contributed to the discussion to formulate an interim solution until someone could be found to fill that vacancy.
- Met with Tamara Plant about telemanagement study and IRB questions. Made additional revisions to submission and discussed need to wait until next week to resubmit study. Also discussed events at previous Trauma Research Committee meeting.

## **Week 15**

December 6, 2010

- Continued reviewing PPP Study protocol to confirm proper information is in the ICF draft. Noted several times in the study protocol that it referenced documents that are unavailable at present. Made notes to share with Tamara Plant.
- Continued data analysis for Trauma Research Committee study.
- Sat in on teleconference for telemanagement study.
- Met with Dr. Gwartz to get Intent to Graduate form signed and submitted. Completed registration for Spring '10.

December 7, 2010

- Continued reviewing PPP Study protocol to confirm proper information is in the ICF draft.
- Continued data analysis for Trauma Research Committee study. Began generating presentation materials for December 15<sup>th</sup> Trauma Research Committee meeting.



December 8, 2010

- Continued generating presentation materials for December 15<sup>th</sup> Trauma Research Committee meeting.
- Attended welcome lunch for new study coordinator for THRE.
- Met with Tamara Plant and IT specialist for telemanagement protocol. Discussed progress on packaging for study materials. Also discussed timeline and anticipated delivery dates on study materials. Also discussed probable need to change one of the devices due to continued failure of one manufacturer to provide a working product. Discussed plan to take home and test different device configurations during the last 2 weeks of December.

December 9, 2010

- Continued generating presentation materials for December 15<sup>th</sup> Trauma Research Committee meeting.
- Finished adding new research coordinator to telemanagement study and final review for resubmission to IRB.

December 10, 2010

- Completed draft of trauma research committee presentation to show to Lillie Biggins for pre-review.

- Met with Tamara Plant to look over presentation before Tuesday meeting with Lillie Biggins. Returned to office to make revisions and finalize formatting. Emailed to Lillie Biggins to look over before Tuesday meeting.

## **Week 16**

December 13, 2010

- Attended THRE's holiday luncheon.
- Resubmitted telemanagement protocol to THR IRB after addressing stipulations.
- Reviewed presentation material for Trauma Research Committee in preparation for discussion with Lillie Biggins on Tuesday.

December 14, 2010

- Made quick revisions to TRC presentation, then met with Lillie Biggins to discuss the presentation. Made a few notes and revisions based on discussion. Sent handout for committee members to Kathy Huerta to include in meeting materials.
- Continued working on ICF for PPP study. Sent questions to sponsor's representative to help clarify questions over protocol and to help with ICF.
- Began transferring data from JPS/HMFW Work Group from Excel to Inspire Data to see if better data management could be achieved.

December 15, 2010

- Attended TRC subcommittee meeting. Saw the delay caused by late distribution of materials for the meeting. Listened to how the protocol design changed throughout the meeting and was refined to try to improve the feasibility of the study being approved for NIH funding.
- Attended TRC meeting. Presented findings from my research to the committee and presented recommendations to improve research output of the TRC. Lillie Biggins and Teresa Turbeville from my Practicum Committee in attendance for the meeting. Talked briefly with Dr. Hickey following the meeting to set up a time to meet with him to start drafting a Standard Operating Policy for the TRC. He referred me to his nurse to set up an appointment.
- Talked with IRB Coordinator about PPP study. Discussed how to get the IRB application put together given the unusual nature of the study. Noted missing elements in the study design so I can email concerns to the sponsor.

December 16, 2010

- Called Dr. Hickey's nurse to get appointment for December 21<sup>st</sup> to start work on Standard Operating Policy.
- Performed online search for membership requirements, processes and fees for the American College of Surgeons, American Academy for the Surgery of Trauma, and the Eastern Association for the Surgery of Trauma.
- Began to draft a "Standard Operating Policy" for the Trauma Research Committee.

December 17, 2010

- Met with Lillie Biggins and Rosalind Washington to discuss how to interpret the raw data from the JPS/HMFW Work Group. Discussed a need to improve data collection and to find explanations for why unexpected data points were found.
- Continued work to draft a “Standard Operating Policy” for the Trauma Research Committee. Began putting together a package of material for Dr. Hickey with information on ACS guidelines for trauma research, membership requirements for national trauma associations, some information about trauma research programs at other Level 1 Trauma Centers, a complete list of journals in the *Index Medicus*, etc.
- Reviewed action items from subcommittee meeting to see if I had anything to work on before the upcoming subcommittee meeting.

## **Week 17**

December 20, 2010

- Completed rough draft of Trauma Research Committee’s Standard Operating Policy. Printed a copy and completed packet for Dr. Hickey.
- Met with Tamara Plant about PPP study and discussed conversation I had with Teri Blythe and Sharon Wolff the week before. Noted information we needed to obtain from the study sponsor. Tried to take complete notes so I can contact them after the holidays.
- Showed Tamara Plant a folding hand cart that was stored in the office and asked if it was what was needed for the telemanagement study. Helped find it online and place order. Also helped with order placement for other equipment for the study.
- Went to AutoZone to buy cheap bungee cord for the telemanagement study.

December 21, 2010

- Attended Trauma Research Committee subcommittee meeting for NIH Grant. Subcommittee continued modification to protocol design and grant application. Seems like work is starting to reach an end point. Still trying to get a researcher with R-01 project history to be involved with study.
- Received (for some reason) 2 completed surveys today after the deadline. Replied with “Thank you. I appreciate your response. Have a wonderful holiday.” Data looked at, but not included for analysis. Neither site wanted to be identified so I’m not worried about it.
- Went to meet with Dr. Hickey at his office for 1300 scheduled appointment, but he was unable to make the appointment. Left package of material for him to review along with a request to be contacted with a new appointment day/time. Was advised that appointment would be following the New Year.

December 22, 2010

- Sent emails back and forth to sponsor for PPP study requesting a complete list of all the sponsor’s devices that the study will record data from.
- Email communication with IT specialist for telemanagement study regarding the technology package I will be testing over holidays. It will be sent in the packaging the patient will receive. Once I have it, I will make sure packaging fits well and is stable on the folding hand cart for the study coordinator.

- Received phone call from PPP study sponsor's representative to try to coordinate a conference call. Suggested that they coordinate with Tamara Plant and Teri Blythe since I'm not a THRE employee.

December 23, 2010

- Email communication with IT specialist for telemanagement study regarding the technology package I will be testing over holidays. Planned to meet in Dallas to receive package and quick training on use of the technology.
- Re-read PPP study protocol.

December 24, 2010

- Met with IT specialist in Dallas. Checked to make sure the size of the new packaging would work with the hand cart we have for the study coordinator. Determined that 2 could easily be placed on the cart and possibly up to 4 if carefully stacked. Received a tablet device, base station, and pulse oximeter.
- Returned to Fort Worth office and put hand cart back into storage space. Listened to voice message from PPP study representative. Tried to call back, but only got recording. Sent email to Tamara Plant and Teri Blythe explaining what was said in voice message and forwarded an email from the PPP study representative to them.

**Week 18**

January 5, 2011

- Met with members of the JPS/THFW Work Group to try to identify why anomalies were found in the data. Information used to make changes to a presentation that will be given on Friday to the Work Group.
- Sat in on teleconference for PPP study along with Tamara Plant and Teri Blythe. Requests for additional information for IRB application submission were made and a timeline agreed upon. After call, discussed what we needed to do to complete IRB application submission. Emailed draft of ICF to Tamara Plant for review.
- Met with Tamara Plant for telemanagement study phone conference with IT support personnel from THR. Walked through how data would flow. At the end of the call, agreed to meet with IT support and IT specialist from Dallas in Arlington office on Monday afternoon.

January 6, 2011

- Met with co-presenter for Friday's Work Group presentation. Divided presentation material and reviewed her recommendations that she intended to present. Noted areas of data gathering that needed improvement.
- Read over R-01 study's updated protocol.
- Attempted to reach Dr. Hickey's nurse to set up an appointment to meet with him to develop a draft of a Trauma Research Committee Standard Operating Policy. Left voice message.
- Made appointment with UNTHSC Career Services to work on improving Resume/CV.
- Called Dr. Gwartz to find out what I needed to do in order to complete graduation requirements. Set an appointment to meet with her after my meeting with Career Services.

January 7, 2011

- Met with Lillie Biggins and Rosalind Washington to review talking points for Work Group presentation. Noted some quick changes to make.
- Met with Work Group and gave presentation to group which included a representative from JPS. Many points of discussion arose and changes planned for data gathering and for how work would be carried out.
- Updated Resume and CV. Emailed them to UNTHSC Career Services in preparation for next week's meeting.
- Found online the International Committee of Medical Journal Editors' guidelines for claiming authorship of research articles and posted it to Trauma Research Committee's SharePoint web site.
- Began drafting Practicum Report using UNTHSC guidelines.

## **Week 19**

January 10, 2011

- Continued work on initial draft of Practicum Report. Redesigned graphic from TRC Presentation for Practicum Report.
- Went to Arlington for scheduled meeting for telemanagement study. On arrival, discovered that meeting had been cancelled. Returned to Fort Worth office.



- Called Dr. Hickey's nurse to request meeting with Dr. Hickey regarding Standard Operating Policy for the TRC.
- Met with Tamara Plant to discuss developments in telemanagement study.

January 11, 2011

- Drove to Dallas office for meeting for telemanagement study. Reviewed with IT Specialist the updates to the tablet software and then requested changes to the provider software interface.
- Received a fax of Dr. Hickey's initial draft of a Standard Operating Policy. Reviewed and annotated it for meeting with Dr. Hickey on Thursday.

January 12, 2011

- Continued review of material received from Dr. Hickey.
- Met with Tamara Plant to discuss a cancer study in Dallas. Received material to review. Spent most of afternoon reading through this material.
- Sat in on conference call for telemanagement study.

January 13, 2011

- Continued reviewing material from meeting with Tamara Plant.
- Emailed telemanagement study protocol and supporting documents to Ailiya Raza, the IT project director for the study.

- Emailed IT specialist for telemanagement study with complications encountered with the tablet device.
- Met with Dr. Hickey to discuss Standard Operating Policy for the trauma research committee. At his request, began looking for a list of all ACGME accredited surgical residency programs in US. Also received assignment to consolidate my draft of the Standard Operating Policy with his.
- Went to UNTHSC for meeting with Career Services to review and edit resume and CV.

January 14, 2011

- Meeting at UNTHSC regarding thesis.
- Found list requested by Dr. Hickey and emailed it to his secretary.
- Talked to Lillie Biggins about Dr. Roger Blair and a study he was consulted on from a local EMS agency. She requested that next week I contact him to help him assess the feasibility of conducting the protocol based on my knowledge of EMS.

## **Week 20**

January 17, 2011

- Continued reviewing material from meeting about *expO* study.
- Emailed Lillie Biggins with question about EMS study.
- Received information about conflict of interest from final study doctor for PPP study.

- Emailed Lillie Biggins, Tamara Plant and Teresa Turbeville with information about a course in Dallas on presenting data.

January 18, 2011

- Went to a meeting in Dallas with the IT specialist and Tamara Plant to discuss technologies for the telemanagement study. Received software update for one of the technologies and made requests for changes to the caregiver interface.
- Emailed the local Principal Investigator for the expO study to request a meeting.
- Continued reviewing material for the expO study.

January 19, 2011

- Attended meeting of TRC subcommittee to discuss upcoming R-01 study submission to NIH. Saw how group dynamic started to come together as deadline for submission approached. Also noted continued group stress over the last minute attempts to include a co-PI with previous R-01 experience to improve likelihood of NIH approval.
- Attended meeting of the full Trauma Research Committee. Very well attended with good involvement from all present. Several studies were followed up on and requests from Dr. Hickey for written protocols for the next meeting were made. Ideas for studies were discussed and drafts of study outlines promised. I discussed efforts to draft a Standard Operating Policy for the TRC and explained that I intended to deliver it to Dr. Hickey by Monday and hopefully to the rest of the committee by the end of next week.

- At the request of Lillie Biggins, called the office of Dr. Blair to discuss a potential study involving the local EMS service. Spoke with a receptionist and left a message.
- Began combining my draft of the TRC's Standard Operating Policy (SOP) with the one provided by Dr. Hickey. Added annotations as I went through the document so that Dr. Hickey would know of significant proposed changes and can review my questions prior to meeting with me later next week.
- Called the office of the local Principal Investigator for the expO study to set up a meeting. Left voicemail with his nurse.

January 20, 2011

- Completed combining the two drafts of the TRC's SOP. Emailed combined draft of TRC's SOP to Dr. Hickey and Lillie Biggins along with a request for a meeting with Dr. Hickey to discuss annotations and finalize SOP so it can be distributed to TRC.
- Emailed Daniel Gonzalez about the expO study's IRB application.
- Spoke on the phone with Dr. Blair about 2 potential studies he is interested in developing a protocol for and submitting to IRB. First study involving assessing the effectiveness of an abbreviated stroke assessment tool for use in ambulances and emergency departments. The second proposed study involving the use of transcranial Doppler in the pre-hospital setting. Received fax of the abbreviated stroke assessment tool. Also expecting an email with more detail about the Doppler study. Sent email to Tamara Plant to make sure she was aware of Dr. Blair's intention to conduct the 2 studies.

January 21, 2011

- Agreed to meet with the PI for the expO study on Monday in Dallas.
- Met with Tamara Plant to discuss what was needed to get expO submitted to the IRB. Began work on the ICF. Completed ICF except for conflict of interest information for PI.

## **Week 21**

January 24, 2011

- Talked with Teri Blythe about PPP study's ICF. Email sent to sponsor requesting clarification on missing information from protocol. Sent draft of PPP ICF to Teri Blythe.
- Phone conversation with Daniel Gonzalez about expO study's IRB application. Left for Dallas earlier than originally planned to assist him with IRB application.
- Arrived at Dallas office and worked with Daniel Gonzalez on expO study's IRB application. Started compiling a list of questions for the sponsor and the PI.
- Met with PI for expO study. Learned that he was anticipating over 2000 subjects instead of the 1000 we had originally anticipated. Also learned that he wants a Spanish version of all documentation for the study. Discussed what he expected from the research coordinator and the time commitment he expected from that individual.

January 25, 2011

- Went to Dallas office to meet with Tamara Plant and IT specialist for telemanagement study. Received update to software for study technology. Discussed changes to caregiver interface.

Also learned about delays with some of the wireless technologies and discussed how to address these delays.

- Worked on expO study's IRB application with Daniel Gonzalez. Finished compiling questions for sponsor and emailed them.
- Met with Tamara Plant to discuss questions about expO study's IRB application. Also discussed meeting I had with expO study's PI.

January 26, 2011

- Continued working on Practicum Report document.
- Attended meeting of TRC subcommittee to discuss upcoming R-01 study submission to NIH. Subcommittee decided that more time was needed for revision before the protocol could be submitted. Now attempting to complete protocol for April 20<sup>th</sup> deadline. Several revisions discussed to protocol document. Discussed need to have a statistician involved in protocol design at this stage and need to have Dr. Hall attend future meetings to take advantage of his knowledge of R-01 application procedures and research experience and to get him up to speed on the project.
- Brief discussion with Dr. Hickey about the TRC's SOP. Agreed to meet with him on January 27<sup>th</sup> to further revise the document. Emailed Lillie Biggins to find out if she had anything she wanted me to discuss with him regarding the document.
- Sat in on teleconference for telemanagement study. Learned of delay from IT department due to system upgrade.

January 27, 2011

- Continued working on Practicum Report document.
- Met with Dr. Hickey to revise the TRC SOP. Finalized draft and faxed a copy to Dr. Hickey for his records. Emailed a copy to Lillie Biggins for review and final approval.
- Worked on IRB form for expO study.

January 28, 2011

- Continued working on Practicum Report document.
- Met with Lovey Henderson to update the data reporting document for the JPS/THFW Work Group. Emailed a copy to Lillie Biggins for approval.

## **Week 22**

January 31, 2011

- Continued working on Practicum Report document. Additional literature searches performed to expand Background/ Literature Review section.
- Met with Tamara Plant to discuss the telemanagement and expO studies. Made a list of technical difficulties to discuss with the IT specialist for the study. Also found a way around the initial log in complication discovered last week.

February 1, 2011

- Snow day, worked from home. Meeting in Dallas postponed until Thursday.
- Continued working on Practicum Report document.

February 2, 2011

- Snow day, worked from home.
- Continued working on Practicum Report document.

February 3, 2011

- Snow day, worked from home. Meeting in Dallas cancelled for this week. Agreed to have teleconference on Friday.
- Continued working on Practicum Report document.

February 4, 2011

- Snow day, worked from home. Teleconference on for telemanagement study. Reviewed list of requested changes with the IT specialist. Received update on the anticipated availability of technologies for the study and updated timeline for technology implementation and study launch date.
- Continued working on Practicum Report document.

**Week 23**



February 7, 2011

- Listened to voice message from Dr. Blair. The message was broken up, but he requested follow up on the information he had sent to me. I emailed Tamara Plant and Teresa Turbeville asking what to do.
- Called Lovey Henderson to find out if Lillie Biggins had availability to meet and discuss TRC's SOP document. Called Dr. Hickey's office to request he attend the same meeting. Set meeting for February 9<sup>th</sup> at 1pm.
- Talked on the phone with Daniel Gonzalez about the expO study. Made a list of new questions for the sponsor and sent emails to Tamara Plant and Daniel Gonzalez to find out if they had the answers to those questions or additional questions to add. Modified ICF based on communication from the sponsor. Emailed the modified ICF to Tamara Plant for review.
- Met with Tamara Plant to finalize ICF document and Bill 1 form for expO study. Sent ICF and HIPAA documents to sponsor for final approval.
- Continued working on Practicum Report document.

February 8, 2011

- Drove to Dallas for meeting with Tamara Plant and IT specialist for telemanagement study. Received a weight scale to test when software update becomes available. Discussed a new way to update software on the tablet devices. While in the meeting, received package containing tablet devices and base stations for the study. Reviewed packing slip and noted missing item. Made photocopies of serial numbers for all devices before releasing them to IT specialist.

- Tried to call Dr. Blair's office, but was directed to his office manager's voice mail. Left message requesting a call back.
- Continued working on Practicum Report document. Got into contact with Carol Williams at the American College of Surgeons Trauma Office to get clarification on information for my Practicum Report. Waiting for response.

February 9, 2011

- Completed the online NIH researcher training.
- Continued working on Practicum Report document. Contacted the librarian at UTHSCSA's RAHC - Harlingen Library to find out how to cite Texas Administrative Code.
- Attempted to contact Dr. Blair again, but his office was closed due to weather. Later received information that he had been contacted and that the matter was out of my hands.
- Met with Lillie Biggins, Dr. Michael Hickey and 2 other Trauma Surgeons to review and finalize the Trauma Research Committee's Standard Operating Policy. With some modification, the document was finalized and an electronic version sent to Lillie Biggins.
- Made attempts to get date for Practicum Defense set, but was unable to get it done today.

February 10, 2011

- Went to UNTHSC to meet with Dr. Gwartz. Was able to get date/time for Practicum Defense agreed upon. Made arrangements for the lecture hall for my defense. Obtained signatures from Dr. Gwartz and Dr. Machu.
- Continued working on Practicum Report document from home.

February 11, 2011

- Completed HIPAA document for PPP study. Emailed it to Teri Blythe for review.
- Continued working on Practicum Report document from home.

## **Week 24**

February 14, 2011

- Continued working on Practicum Report document. Reviewed internship log to make sure that I have timeline correct for the document.
- Received update from IT specialist for telemanagement study. Further delay in remote updating of the tablet devices. More testing ongoing with information to come later in the week.
- Received an email from Dr. Gwartz with comments over my Practicum Report draft that I had emailed to her last week.

February 15, 2011

- Continued working on Practicum Report document. Made revisions based on comments from Dr. Gwartz. Further review of internship log to make sure that the timeline reported in my document was correct.

- Received email confirmation from Lillie Biggins to send the final draft of the TRC Standard Operating Policy to the committee. Sent to Kathy Huerta for distribution. Also placed a copy on the TRC SharePoint site.
- Received an email from Dr. Judy Opalek at Grant Medical Center in Columbus, Ohio. She requested follow-up information on the survey she had filled out. I tried to answer her questions and sent the talking points from my presentation to the TRC.
- Phone call with IT specialist for telemanagement study to try to get the tablet device for the study remotely updated. Initial effort failed, but later in the day made contact again with a successful method for updating. Begin testing new version of the software in the morning with the associated new technology component.

February 16, 2011

- Attended the TRC Subcommittee meeting for the R-01 study being developed. Dr. Hall and Dr. Bae from UNTHSC were in attendance as well. Dr. Bae made several suggestions on how to modify the statistical information to improve the scientific output of the study. Dr. Hall also suggested adding a quick retrospective data collection to the study before the R-01 submission to help justify funding to the NIH. Efforts were made to distribute the work load to make the retrospective study happen in time to make the May deadline for submission. Next meeting tentatively scheduled for March 2<sup>nd</sup>.
- Attended the TRC meeting. At the meeting, several of the physicians presented updates on their potential studies. One had distributed a hard copy of an outline of his proposal and asked for feedback on how to improve the study. Another had hand written notes and was asked to prepare a formal presentation of the material for the next meeting. A third presenter

had a formal presentation that was nearly a completed abstract. She was asked to have a draft distributed for the next meeting as well. I was asked to present the Standard Operating Policy to the TRC. There was concern over the increased frequency of meetings, but most in attendance agreed to sign a copy of the document and submitted them to Dr. Hickey.

- Continued working on Practicum Report document. Called Dr. Gwartz for clarification of a couple of comments she had sent me. Made minor revisions.

February 17, 2011

- Attended a meeting in Dallas for the telemanagement study. Worked with the IT specialist to get the study devices I was testing to communicate with each other as expected. After setting up the devices, began testing with simulated patients to make sure data was moving well in both directions. Emails sent to appropriate IT support personnel to make sure problems are corrected before implementation.
- Called Philips Medical about two AEDs in the Dallas office which need new batteries and defibrillator pads. Got price quotes and a call back number. Passed information on to Tamara Plant.
- Helped Daniel Gonzalez address IRB stipulations for IA study.
- Continued working on Practicum Report document.

February 18, 2011

- Called Roche Diagnostics to inquire about an INR monitor for one of the ongoing studies. Made a list of questions to answer for Monday in order to get an INR monitor for the ongoing studies.
- Went to UNTHSC to submit “Declaration of Intent to Defend” form. Contacted UNTHSC Human Resources Office to make sure that I was not shown as an active employee within their system so I can graduate on time.
- Continued working on Practicum Report document. Emailed an updated draft to Dr. Gwartz for further review.

## **Week 25**

February 21, 2011

- Continued working on Practicum Report document. Finished first draft of “Materials and Methods” section. Printed a copy to edit from.
- With Tamara Plant, called Roche Diagnostics’ representative back to inquire about an INR monitor for one of the ongoing studies. May have found a way to get the monitor at no cost.

February 22, 2011

- SICK DAY. Continued working on Practicum Report document from home.

February 23, 2011

- Continued working on Practicum Report document. Reordered the “Materials and Methods” section and used part of it as my “Results and Discussion” section.
- Met with Tamara Plant and helped her make revisions to a PI-initiated protocol related to the R-01 study.
- Sat in on conference call for the telemanagement study. Sent email to IT specialist about security concern regarding the “Caregiver Portal” under development for the study. Changed my Test Patient for the study so that I can help test the data flow from the tablet device to the THR electronic medical record.

February 24, 2011

- Met with Tamara Plant and IT specialist for telemanagement study in Dallas. Confirmed that data was passing from the test devices to the THR electronic medical record test environment. Made sure all the devices for the study were communicating with each other. Sat with the IT specialist and made a list of requested changes for the “Caregiver Portal” including changes to security and data access, changes to how alerts were displayed, and offered to work on a document that the IRB will have to approve with instructions on how the subjects should set up the technology packages.
- Continued working on Practicum Report document.

February 25, 2011

- Received final email correspondence from Carol Williams at the ACS with regards to my questions about the Pediatric Trauma Center verification system.

- Continued working on Practicum Report document. Completed the “Results and Discussion” section.

## **Week 26**

February 28, 2011

- Continued working on Practicum Report document.

March 1, 2011

- Met with Tamara Plant and the IT specialist for the telemanagement study along with a new IT specialist hired to assist with development of the study software. Discussed packaging and preparation for study initiation. Also set up devices with a software update, which had an immediately obvious flaw that needed to be addressed by the IT specialists. Plans made for further software testing later in the week.
- Attended meeting with University of Texas Arlington representative about a 15-month BSN degree program offered online through their system.

March 2, 2011

- Worked on R-01 Retrospective Pre-study application with THR IRB.
- Met briefly with Tamara Plant to get information for R-01 Retrospective IRB application



March 3, 2011

- Teleconference with Tamara Plant and two IT specialists for the telemanagement study. Made a “to-do” list for study start up.
- Continued work on R-01 Retrospective Pre-study application with THR IRB. Modified patient master list and data collection sheet and sent to Tamara Plant to review before sending to PI for approval.
- Reviewed NIH article on “Implementation Science Research” and emailed Tamara Plant about potential research opportunities that may be possible with this emerging realm of research study.
- Continued working on Practicum Report document.

March 4, 2011

- Telephone call with Dr. Gwartz about internship close-out procedure. I was also informed that she would email an update of suggested revisions to Practicum Report.
- Informed Lillie Biggins, Tamara Plant and Teresa Turbeville of when my internship close-out would take place.
- Attended meeting of JPS/THFW Work Group.
- Received the suggested revisions from Dr. Gwartz. Continued working on Practicum Report document.

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