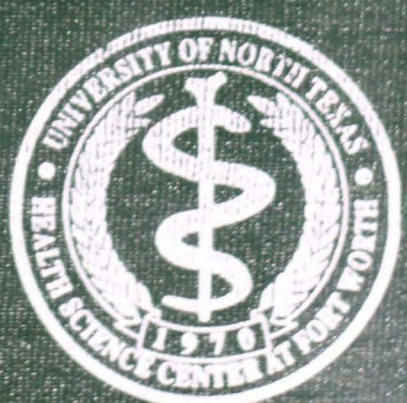
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ABSTRACT

Plascencia, Xochitl. A Phase II Clinical Study to Evaluate the Efficacy and Safety of rhThrombin in Subjects Undergoing Arterial Bypass Surgery and AV Graft Formation for Hemodialysis. Master of Science (Clinical Research Management), May 2005, 78 pp., 2 tables, bibliography, 21 titles.

This phase II, randomized, double blind study will evaluate the safety and efficacy of topical recombinant human thrombin in subjects undergoing arterial bypass surgery and AV graft formation for hemodialysis. The surgery department at The University of North Texas Health Science Center is one of six sites participating in this study. The primary objective of the trial is to evaluate the safety of rhThrombin; secondary objectives include estimating time to hemostasis and evaluating the immunogenicity of the rhThrombin product. If there is indication of surgical bleeding at the anastomotic sites, a single application of rhThrombin or placebo is applied in combination with an absorbable hemostatic sponge.

A PHASE II CLINICAL STUDY TO EVALUATE

THE EFFICACY AND SAFETY OF rhTHROMBIN

IN SUBJECTS UNDERGOING

ARTERIAL BYPASS SURGERY

AND AV GRAFT FORMATION

FOR HEMODIALYSIS

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Dean, Graduate School of Biomedical Sciences

A PHASE II CLINCIAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF rhTHROMBIN IN SUBJECTS UNDERGOING ARTERIAL BYPASS SURGERY AND AV GRAFT FORMATION FOR HEMODIALYSIS

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the Graduate School of Biomedical Sciences at the 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

Xochitl Plascencia

Fort Worth, Texas

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I would like to take this opportunity to thank all the people that have helped me through graduate school. First of all I would like to thank my family for all of their never-ending support while attending graduate school. I would also like to thank Dr. Reeves for his patience and support during my internship and while writing this report. In addition I would like to thank my committee members, Dr. Peska and Della Weis for providing a positive learning experience and for sharing their knowledge and expertise.

Finally, I would also like to acknowledge all the staff in the surgery department of the patient care center, for making my internship experience more delightful.

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CHAPTER I

INTRODUCTION

The Association of American Medical Colleges Task Force on Clinical Research defines clinical research as a component of medical and health research intended to produce knowledge essential for understanding human disease, preventing and treating illness, and promoting health (Friedman, 1998). A clinical trial is defined as a research study conducted in humans which is designed to answer specific questions using scientifically controlled conditions with specified methodologies and endpoints (Gallin, 2002). Clinical research trials are essential in determining whether or not a drug is safe and effective. There are four phases that investigational drugs go through before they are allowed to be out in the market. Before beginning phase I of a study, there is usually a pre-clinical research and development phase. During this time the initial synthesis of the study drug is accomplished and animal testing takes place. Phase I is the initial introduction of an investigational new study drug into humans. Phase I is usually conducted in healthy individuals and the primary goal is to determine the safety profile of the drug. Phase II trials tend to evaluate the safety and initial efficacy. Subjects enrolled in this phase tend to have the disease necessary for use of study drug. Phase III studies are conducted to gather additional information about the effectiveness and safety of the drug and to determine the overall benefit-risk relationship of the drug. Finally, phase IV studies are usually referred to as post-marketing studies. During this phase, additional

safety information is identified and the drug's safety during routine use is evaluated. Each phase can range from two to ten years depending on the complexity of the clinical trial (Gallin, 2002).

A phase II, randomized, double blind study of the safety and efficacy of topical recombinant human thrombin in patients undergoing peripheral arterial bypass surgery and arterio-venous graft formation for hemodialysis is the focus of the prospective drug study to be carried out in the surgery department at The University of North Texas Health Science Center. The primary objective of this study is to evaluate the safety and efficacy of recombinant human thrombin when used in different types of surgeries. Prior to signing an informed consent, subjects will have to meet inclusion and exclusion criteria set by study protocol. Study specific assessments and procedures will be performed after the informed consent is signed and dated. If bleeding at the anastamosis is found to necessitate intervention, a single application of either rhThrombin or placebo in combination with an absorbable hemostatic sponge to each anastomosis requiring hemostasis will be applied by the surgeon. The safety and efficacy of rhThrombin will be determined by measuring the incidence and severity of adverse events and of laboratory abnormalities. Occurrence of hemostasis within 600 seconds of application of the study drug at the anastomotic surgical site, incidence of anti-rhThrombin product antibodies, and time to hemostasis will also be measured.

CHAPTER II

INTERNSHIP SUBJECT

Significance

This study tests the safety and efficacy of rhThrombin on subjects undergoing peripheral arterial bypass surgery and AV graft formation. Currently there are other commercially available topical agents used for hemostasis, such as gelatin sponges and topical bovine thrombin. Although they are useful, they have not always achieved quick and successful results (Schenk, 2002). Some studies have reported that postoperative bleeding can occur when topical bovine thrombin is used, which may be induced by the formation of antibodies to bovine thrombin (Christie et al, 1997). Most studies agree that the development of antibodies is most common in patients who have been exposed to topical bovine thrombin more than once (for more than one surgical procedure) (Christie et al, 1997). Therefore, it is important for surgeons to become aware of the possibility of consequences that may occur by the use of bovine thrombin, and reconsider other alternative hemostatic methods (agents).

Background

Bovine thrombin is widely used topically to promote hemostasis during vascular surgery. Bovine thrombin is derived from bovine prothrombin that is isolated from the plasma collected in a USDA approved establishment in the United States (CMJI, 2004). The bovine prothrombin is treated with bovine lung thromboplastin to yield bovine

thrombin and all the starting materials, reagents and processing is conducted only in the US (CMJI, 2004). Bovine thrombin is currently available from three companies; all of which have differences in the preparations and purity of the product. The use of topical bovine thrombin has occasionally been associated with hemorrhagic complications (Christie et al, 1997). These complications may occur due to the formation of antibodies against bovine thrombin and/or Factor V, which may cross react with human factor V (Vannorsdall and Wai, 2003). Therefore, it is expected that the rhThrombin used in this study will significantly stop bleeding during vascular surgery with little formation of antibodies to bovine thrombin. RhThrombin is currently being tested in four different types of surgical settings; spinal surgery, hepatic resection, arterio-venous graft formation and peripheral arterial bypass surgery. The latter two types of surgeries are the focus of this report.

Peripheral arterial disease (PAD) is a vascular disease that affects blood vessels especially of the extremities. It is a common circulatory problem in which the arteries supplying blood to the limbs become clogged or partially clogged (Mayo Foundation, 2004). PAD affects approximately 8 to 12 million people in the United States, including five percent of adults over the age of fifty (Hirsch, 2001). The earliest symptom in patients with PAD is intermittent claudication, which is defined as muscle pain or cramping in the legs triggered by walking, that usually disappears after rest. This pain is usually associated with inadequate blood supply to the muscles (Oureil et al, 2001). Treatment for the disease can include diet, exercise, cessation of smoking, and decreasing the blood cholesterol level (Mayo Foundation, 2004).

As the disease progresses, the arteries may become extremely clogged and pain may be present at all times. Usually the blockage of the arteries must be causing significant symptoms or be limb threatening before surgery is considered. One type of surgery considered is a femoropopliteal bypass (fem-pop), which is done to bypass diseased blood vessels above or below the knee. The blood is redirected through another blood vessel or a graft material is sewn to the existing artery and blood is rerouted through it (Oureil, 2001).

In hemodialysis, an artificial kidney (dialyzer) is used to remove waste products from the blood and restore the body's chemical balance (Margous, 1995). More than 300,000 people in the United States receive hemodialysis to treat their end-stage-renal disease, as a way to prolong their life (Ruggeneni, Mayo Foundation). Vascular access must be created surgically on an arm or a leg to allow the patient's blood to be conducted to the artificial kidney; for example, arterio-venous (AV) graft implantation connects an artery to a vein underneath the skin, thus allowing repeated needle sticks and long-term dialysis. Grafts and fistulas are the most common, and both have significant failure rates with an estimated 30 to 50 percent requiring repeat surgeries for revision accesses (Schenk, 2002).

Hemostasis is defined as the arrest of bleeding, achieved through blood vessel constriction, formation of a platelet plug or formation of a blood clot as a result of blood coagulation (Guyton, 1998). Blood coagulation occurs in three steps, first prothrombin activator is formed in response to rupture or damage to blood vessels. Second prothrombin activator catalyzes the conversion of prothrombin into thrombin, and finally

fibrinogen is converted to fibrin and a clot is formed (Guyton, 1998). Factor V is an essential cofactor for the conversion of prothrombin to thrombin. Because this step is the final common pathway linking the intrinsic pathway and extrinsic coagulation cascades, factor V plays an essential role for hemostasis (Sarfati, 2004). Bovine thrombin has been associated with abnormalities in hemostasis. Such abnormalities may include prolonged prothrombin times, partial thromboplastin time, severe bleeding or thrombosis (Christie, et al). These hemostatic effects appear to be related to the formation of antibodies against bovine thrombin and/or factor V which in some cases may cross react with human factor V, potentially resulting in factor V deficiency.

The safety and efficacy of bovine thrombin is uncertain. There have been reports that indicate no direct correlation between bovine thrombin exposure and graft thrombosis (Vannorsdall, 2003) or no evidence of antibody induced coagulopathy and no correlation between the presence of bovine protein antibodies and serious adverse effects (Winterbottom, 2002). On the other hand, multiple reports have suggested some correlation between the exposure and use of bovine thrombin to postoperative bleeding potential for sensitization and clinical allergic responses when used for hemostasis in hemodialysis (Christie et al, 1997). It has also been linked to elevated thrombin time (PT) and activated partial thromboplastin time (aPTT) after surgery (Christie et al, 1997). When mice were exposed to topical bovine thrombin, auto antibodies against clotting factors developed, suggesting that this could be used as a model for the human immune response to bovine thrombin (Schoenecker, 2001). Almost all reports seem to agree that the more exposure a person receives to bovine thrombin through surgical procedures, the

higher the likelihood that the person might develop hemostatic abnormalities. Therefore, it is important for the patient and the surgeon to become aware of the possible outcomes.

Materials and Methods

This study will be testing the safety and efficacy of rhThrombin in two different types of surgeries (under two different protocols). Topical rhThrombin will be tested in subjects undergoing peripheral arterial bypass surgery and AV graft formation for hemodialysis. Subjects are identified in the clinic (or hospital) by the principal investigator (PI) or sub-investigators. The PI explains the study, and if the subject agrees to volunteer, the PI informs the clinical coordinator. Subjects will have to meet specific inclusion and exclusion criteria before being enrolled in the study. Inclusion criteria for a subject undergoing arterial bypass surgery include the following: subjects must be 18 or older at the time of treatment, subjects must have a normal platelet count and fibrinogen greater than or equal to the lower limit of normal, and serum creatinine must be less than or equal to 1.4 mg/dL. If subject is female and of childbearing age, the subject must have a negative pregnancy test within 14 days of treatment. If subject is a sexually active male or a sexually active female of child-bearing potential, the subject must agree to use a medically accepted form of contraception from the time of enrollment to completion of all follow-up study visits. Subjects having known antibodies or hypersensitivity to thrombin or other coagulation factors, known bleeding or hematologic disorder, surgery within 30 days of study enrollment/treatment and concurrent serious acute or chronic illness or infection will be excluded from the study. If subject meets inclusion and exclusion criteria, then the subject is enrolled in the study. Subjects undergoing AV graft

formation for hemodialysis have similar inclusion and exclusion criteria. Once inclusion and exclusion criteria are met, subjects are given the written informed consent. The document is explained in detail, and they are encouraged to ask any questions. After the informed consent is obtained, the subject is enrolled in the study. Discussion of informed consent is usually done during pre-op visit, a copy is provided to the patient and a second copy is placed in their medical chart (ZymoGenetics, 2003).

Once subject is enrolled, specific assessments must be obtained. These are obtained on screening day, day 0 (day of surgery), day 0 two hours after surgery, day 1 and day 28. Such assessments include medical history, laboratory work-up, vital signs, and physical exams. Screening day is considered any day prior to surgery (no more than 14 days prior to surgery). Table 1 indicates the order of laboratory draws that must be followed in order to maintain continuance with study protocol (ZymoGenetics, 2003).

Table 1: Laboratory Time & Events Schedule

Event	Screening	Day 0: Pre-Surgery	Day 0: 2 hrs Post surgery	Day 1	Day 28
Serum Chemistries	X	X*	X	X	X
Serum Pregnancy Test	X**				
Coag Panel	X	X*	X	X	X
CBC	X	X*	X	X	X
Anti-PTA/ Anti-CHO antibody assays	X	X			X
Anti-rh Thrombin Ab assays	X	X			X
Research Sample	X	X	X	X	X

*** CBC, Coags, and Serum Chem should be repeated only if it has been > 14 days since screening testing. Note: if pregnancy test was done > 14 days from Day 0, it should be repeated as well**.**

A physical exam and medical history will be performed at screening, and only a physical exam will be performed on Day 0, Day 1 and daily until patient is discharged from hospital, and Day 28 when patient returns for follow-up. Prior to surgery, the hospital pharmacist will be informed of new subject enrollment and surgery date for the patient. The pharmacist will randomize patient with IVRS (Interactive Voice Response System). The unblinded pharmacist will pick the appropriate vials for each subject based on the IVRS randomization assignment, write the subject's initials and randomization number on the outer label, tear off the outer label and affix to a pharmacy log. Recombinant human thrombin and placebo are supplied as a sterile, lyophilized powder for reconstitution. The composition of the placebo is identical to the vehicle of the study drug product; and blinded vials will be supplied for the study. Open-label vials will also be provided for use as rescue therapy or to treat sites other than the primary hemostasis evaluation site. The two vials provided are reconstituted with 10 ml of normal saline. Once reconstituted the contents are transferred into a sterile cup for application of sponge. A surgifoam sponge is measured and cut into 2 cm x 1 cm pieces and are placed in the cup with study drug. The surgifoam must soak in study drug for at least 60 seconds before using (ZymoGenetics, 2003).

Administration of study drug or placebo is similar for both protocols. After closure of the proximal peripheral vascular bypass anastamosis or after completion of an arterio-venous graft, the vascular clamp will be released to check for significant bleeding

from the anastamoses. If the bleeding is found to require intervention, the surgeon will apply the appropriate amount of randomized blinded study agent using an absorbable gelatin sponge circumferentially around the anastamoses requiring hemostasis. The sponge will be held in place with a gauze pad and time to hemostasis (TTH) will be measured for a maximum of 600 seconds, checking every 30 seconds in between. The surgeon and a second person (anesthesiologist) will rate the amount of bleeding between 0 and 10, with 10 being excessive bleeding. They will also assess the amount of bleeding as mild, moderate or severe. TTH and bleeding assessments will be recorded in the source document by the clinical coordinator in the operating room. If hemostasis has not been achieved within 600 seconds, and further use of thrombin is medically indicated, the surgeon will remove the test sponge and apply open-label rhThrombin or another topical hemostat using a clean sponge. Bovine thrombin or products containing bovine thrombin should not be used (ZymoGenetics, 2003).

At the request of subject or surgeon or if, after enrollment, it is determined that the subject is not suitable for arterial bypass with synthetic conduit (or for AV graft formation for dialysis access) as defined in the protocol, the subject may be withdrawn from the study. The subject may also be removed if, after randomization and prior to application of any study determined therapy, the surgeon chooses to use an alternative method to control hemostasis. The subject may also withdraw from the study at any time if they choose to withdraw. Day 28 is the last visit of the study and is usually conducted at the clinic. Lab draws (hereafter referred to as labs) are obtained and the PI or sub-investigator performs a physical assessment. The labs are then processed and mailed to

the sponsor. Upon completion of day 28 the subject concludes the study. Table 2 is a summary schedule of the time and events that are to be performed for this particular study (ZymoGenetics, 2003).

Table 2: Time and Events Schedule

Event	Screening	Baseline, Day 0 pre-surgery	Day 0: 2 hrs Post Surgery	Day 1	Day 28
Informed Consent	X				
Eligibility Assessment	X				
Medical History	X				
Height and weight	X				
Physical Exam	X	X		X	X
Vital Signs	X	X	X	X	X
Lab work-up	X	X	X	X	X
Blood sample drawn and shipped	X	X	X	X	X
Concomitant Medications		Ongoing from baseline	→	→	→
Adverse Events		Ongoing after treatment	→	→	→

Results

Since the sponsor has not met their desired enrollment goal, the study remains open. Therefore, results are not available at this time. However, the surgery department has been approached as a possible site for phase III of this trial. One of the limitations

that have been recently amended to the study is the age range allowed for participation. Per study protocol, only patients between the ages of 18-75 years of age were allowed to participate, now the age criteria has been opened to include anyone over the age of 18. In addition, even though multiple blood draws are still required, some of the lab tests are no longer needed, such as obtaining fibrinogen levels and obtaining Factor XIII samples. Due to the patient's underlying disease progression, some required lab draws were unattainable early on. The goal of the PI is to try and obtain labs at the same time other labs are drawn for patient care, in order to minimize the number of venipunctures. Another change to the protocol has been the addition of femoral to femoral bypass surgeries. This change allowed the site to increase enrollment. One of the limitations that the site continues to encounter is that the vascular surgeons have been performing more AV fistulas as opposed to AV grafts which has caused enrollment in the AV graft study to be low. The PI and sub-investigators are aware of the inclusion and exclusion criteria of this study protocol, but are not able to make exceptions to the types of surgeries they perform, since they only perform surgeries that provide the most favorable outcomes for the subjects.

Discussion and Summary

This study is testing the safety and efficacy of recombinant human thrombin when used to control bleeding associated with two different types of surgeries. The goal is to be able to provide surgeons with an alternative hemostatic agent to bovine thrombin which is what is currently available in the market. The sponsor in this study is hoping to enroll at least 40 subjects (per surgery type), where half of the subjects will receive

rhThrombin and half will receive placebo. As a result of slow enrollment, the sponsor has kept sites open in order to meet their desired enrollment goal. The surgery department has successfully enrolled eight subjects in the peripheral arterial bypass protocol and two in the AV graft implant protocol. Due to previous inclusion and exclusion criteria, a few patients were not enrolled. Since the amendments have been made to the protocols, enrollment has increased for the department. Presently, enrollment has been stalled in the surgery department due to the closing of Osteopathic Medical Center of Texas (OMCT), which was the main hospital used by the department for all of their clinical trials.

Because this is a phase II trial, it is important to note that the safety and efficacy of rhThrombin are the primary endpoints of this study. Therefore, every subject enrolled was carefully monitored and any side effects were always noted and reported. For example, of the eight patients enrolled in the peripheral arterial bypass protocol, only one subject experienced a serious adverse event. The PI agreed that the event was not related to the study product but more to the progression of peripheral arterial disease. Most of the subjects reported similar side effects after surgery, such as post-operative pain or incisional pain. These events had usually cleared by the end of study visit or Day 28. Other side effects reported included post-operative fever or nausea and vomiting. Some of the adverse events noted pertained to the pre-existing conditions of the subjects. Since this is a double-blinded study, neither the PI nor the clinical research coordinator are aware of which patients received rhThrombin or placebo; therefore, it is not possible to correlate any of the adverse events with rhThrombin.

Overall, I felt both of the rhThrombin clinical trials were well written and not complicated to follow. These studies certainly provided me with a well-rounded concept of how clinical trials are supposed to be conducted and all that is involved in a clinical trial. Because both protocols were quite similar, it did not take long for me to learn each protocol from the inclusion/exclusion criteria to the schedule of labs that were to be drawn before and after surgery. At times I felt too many labs were being requested by the sponsor, but because this was a safety and efficacy phase II trial, all labs requested were important. In general, I did not encounter any problems in conducting the trials, and did not feel these trials were complicated in any way compared to other clinical trials that were going on at the same time in the surgery department.

CHAPTER III

INTERNSHIP EXPERIENCE

Internship Site

The internship site where I completed the clinical research internship was in the surgery department of the Patient Care Center at The University of North Texas Health Science Center in Fort Worth. The department consists of eight surgeons and one ear, nose, and throat (ENT) physician and their nursing and office staff. All of the physicians practiced at Osteopathic Medical Center of Texas (OMCT) which was located across the street from the college, since the closing of the hospital all of the physicians are practicing at other hospitals in town including Plaza Medical Center, Baylor All Saints and Harris Northwest in Azle. The recent closure of OMCT has impacted the clinical trials in the surgery department since all the studies are inpatient clinical trials. Since all of the surgeons practice at Plaza Medical Center, the Institutional Review Board (IRB) office of the university has submitted all study protocols to Plaza's IRB.

The surgery department averages about 15-20 clinical trials per year, all trials are surgery related inpatient clinical trials. Currently the department has seven studies that are open, one that has been recently initiated and three pending IRB approval. All of the studies are multi-center trials and most are either phase II or phase III trials. The duration of each study varies and depends upon whether or not enrollment has been met by the site. For instance, the peripheral arterial bypass surgery trial and AV graft trial have a

specific goal of enrolling at least ten patients per trial, and once the subject is enrolled the subject does not complete the study till approximately 28 days later. Some of the other studies do not require additional follow-up after the patient is discharged from the hospital while others require additional follow-up visits. Any of the lab work-up required by each study is usually conducted in the hospital laboratory or at an off-site lab. For instance, one of the pain studies requires screening labs, therefore the coordinator obtains the labs and ships them to Covance Laboratory to process and obtain results, and then the coordinator receives the results via fax and mail. All data related to the study is maintained in-house until the site has been closed. Once a particular study has been closed for at least a year, the data is then placed in storage facilities off-campus.

Journal Summary

During this internship I learned various aspects of clinical trial implementation, but certain activities were more relevant to the nature of the studies I was most involved in. Such activities included the informed consent process and patient enrollment. The time spent in the operating room, in the laboratory, inputting data into the electronic case report form and verifying data with the study monitor were additional duties I have learned. Each activity was essential in coordinating clinical research trials in order to follow good clinical practices.

The informed consent process is probably the most important process of any clinical trial. It is very important because without the signing of the informed consent form a subject cannot participate in a clinical trial. During this process the informed consent is reviewed with the potential subject in detail and subjects are permitted to ask

as many questions as possible. In most of the cases the study was explained to the potential subject by the PI during a routine office visit. At the time of the visit, the subject was provided with a copy of an informed consent to read over; therefore, discussion of the informed consent process was done during the subject's pre-operative visit in order to allow them to have enough time to read the informed consent form. After the informed consent form was signed, a copy was provided to the subject and a second copy was placed in the patient's medical chart; the original was always maintained with the subject's source document.

For every patient enrolled in this study, the clinical research coordinator and I were always in the operating room to assure that the protocol was followed correctly. The surgeons were usually pretty good about paging the research coordinator at least thirty minutes prior to the use of the study drug. The coordinator was responsible for picking up study drug from the pharmacy and reconstituting the drug in the operating room. As mentioned previously, once the drug was reconstituted, the drug was placed in a sterile cup filled with surgifoam so the sponge would absorb the drug. The coordinator was also responsible for noting the times that the surgifoams were applied and reminded the surgeons when it was time to check the anastomoses sites. Meanwhile, I recorded the data that was reported by the coordinator in the source document. Once the patient had reached hemostasis, the study drug vials were returned to the pharmacy for accountability. This procedure was followed for every patient enrolled in the study, sometimes we (coordinator and I) were in the operating room for 25 or 30 minutes and sometimes we were in there for an hour, it just depended on the surgery case.

Because this study required multiple blood draws, the time spent in the hospital laboratory processing the labs was also a crucial activity. The following steps were followed for every research sample obtained from a subject at screening, baseline, two hours post-op, day one and day 28. First, the capped tubes were centrifuged at room temperature at 2500 x g for ten to fifteen minutes. The plasma was then transferred using a plastic pipette into the polypropylene centrifuge tubes provided. These tubes were centrifuged again for an additional ten minutes in order to obtain platelet free plasma. Next, the plasma was then aliquoted into cryovials using supplied pipette. Each cryovial had to contain at least 50 microliters of plasma, each cryovial was labeled with the subject's initials, screening and randomization number. The cryovials were immediately placed in a - 70 F freezer, until they were ready to be shipped to sponsor.

This particular study utilized electronic case report forms (eCRFs) for all their data. Once the patient had been discharged from the hospital, a copy of their medical chart was obtained. Medication records, physician's progress notes, laboratory results, nurse's notes and physician orders were obtained and organized in a binder which would become the source document for the subject. The entire chart was reviewed and all data was transferred to the written case report form, which would then be transferred to the eCRF. The use of eCRFs allowed immediate identification of an incorrect entry; and allowed the study monitor to view the eCRF immediately. So, by the time the study monitor would make site visits, she would ensure that there was a source for all the information on the eCRF. As a student, I was able to spend time with different study

monitors and observe how each monitor's studies differ depending on the type and complexity of the study.

My experience at the internship site was very positive; both coordinators in the department were always willing in taking the time to teach me all that was essential for conducting a clinical trial under good clinical practices. Even though my main focus was to participate in the rhThrombin trials, I was able to experience other clinical trials as well, which kept the experience interesting and very fast-paced. I had never been in the operating room prior to working in the surgery department. I recall the first time I was in the operating room with the clinical coordinator observing the surgery of the second patient enrolled in the femoral-popliteal bypass study. I was not sure what to expect. However, being there with the coordinator made it much easier to follow the protocol even though I had read and had become familiar with it beforehand. One of the other things I was able to experience was the integration of classroom knowledge into a real world experience. Obtaining correct regulatory forms and information, making sure that the informed consent process was followed appropriately and preparing for and being part of audits are a few examples of such experiences. In order for students to learn about clinical research I believe it is essential for those students to participate in internships covering a variety of clinical studies. A detailed day-to-day description of my activities is attached in the Appendix of this report.

APPENDIX

DAILY JOURNAL

Monday May 24, 2004

Arrived at Patient Care Center (PCC) – Surgery floor (5th floor); met with Christopher Hayes clinical research coordinator.

Met Della Weis, RN on-site mentor; orientation to staff and general overview of studies that are currently open for enrollment.

Walked to Osteopathic Medical Center of Texas (OMCT) across the street to 4 Tower (surgery floor) with Della and Chris.

Back in PCC, Della provided me with study manuals for both research studies that will be the focus of my research proposal.

Spent most of the afternoon reviewing study protocol.

Tuesday May 25, 2004

Walked to OMCT with Della and Chris to the Cath Lab, was present for angiogram procedure.

Went to lab in PCC (5th floor) where certain labs are processed and all study lab supplies are kept. Also went to 3rd floor of PCC where freezer is located.

Walked to OMCT to Medical Records Department.

Back in PCC, I separated the chart into different categories such as all lab summaries, physician's notes, history and physical reports, orders, nurses' notes, discharge notes and radiology notes.

Met with Della to complete the source document forms.

Loose paper filing in abdominal abscess study binders.

Accompanied Della to clinical trials office.

Assignment: Review patient's medical record tomorrow morning to determine if patient meets inclusion/exclusion criteria for 499C08 (AV graft study).

Wednesday May 26, 2004

Called ITS department to obtain computer access.

Reviewed Mr. P's medical history on Meditech.

Was present as Della explained and reviewed fem-pop bypass study information to new patient and his wife.

Walked to OMCT to review study information to Mr. P (AV graft study), Della and Chris explained study and informed consent. Will return once he talks to Dr. DeLange and to his family.

Walked to Microbiology lab in the hospital to pick up specimens; was instructed on how to mail infectious diseases material.

Replaced forms in study instruction manual for both protocols 499C07 and 499C08.

Attended Grand Rounds (12:00-1:00).

Reviewed protocol 499C08.

Downloaded protocol 499C07 in Della's computer, once download complete, began entering data into electronic case report form (eCRF). Dr. DeLange called this afternoon and stated Mr. P has agreed to participate in study.

Walked to hospital to see Mr. P, Della, Chris and I met with him and his family both agreed to study participation.

Thursday May 27, 2004

Walked to hospital with Chris to pick up Mr. P's blood draws

Walked to hospital lab, observed Chris process labs per study protocol, obtained lab kit assigned for patient.

Visited Mr. J at OMCT for follow-up he was enrolled on Urokinase study.

Continued entering information into eCRF for 499C07 protocol.

Assignment: review subject #4003 chart for adverse events and note medications subject has been taking and currently taking.

Lunch.

Informed by Dr. DeLange that Mr. P's surgery might be postponed due to cardiac complications, will let us know this afternoon.

Continued entering information into eCRF.

Reviewed common terminology criteria for adverse event.

Informed by Dr. DeLange that Mr. P was cleared by cardiologist for surgery.

Informed by Dr. DeLange that he has a new patient for study 499C07 (fem-pop) in clinic at this time. Made a copy of informed consent, Chris and I went to speak with patient and her son about the study.

Friday May 28, 2004

Called medical records at OMCT, spoke with Brandi regarding missing nursing notes for #4003.

Observed Della filling out source documents for other studies.

Lunch.

Walked to OMCT outpatient to meet Mr. M for pre-op visit. Della answered questions he had, informed consent signed and copy was given to him. Screening labs and vitals were obtained.

Went to OR for AV graft surgery, followed study protocol and recorded all information in source document chart, left operating room (OR) at 4:45 p.m.

Went to lab at OMCT, Chris processed Mr. M's labs while I observed.

Tuesday June 1, 2004

Attempted to complete source document for Mr. P.

Mr. M is scheduled for surgery this afternoon, made sure his study chart had all required source document forms.

Made extra copies of informed consent forms for 499C07 and 499C08.

Called ITS regarding computer access.

Reviewed TriaLink Investigator Reference Manual for eCRFs.

Lunch.

Went to OR for Mr. M's surgery (fem-pop), was in OR from 12:40-5:40 p.m.

Wednesday June 2, 2004

Off in a.m. due to dental emergency.

Continued filling out source documents for Mr. P and Mr. M.

Walked to OMCT with Della and Chris to obtain Day 1 lab draws from Mr. M.

Processed Mr. M's labs while Chris and Della supervised.

Thursday June 3, 2004

Informed by Della that Cynthia (AV graft and fem-pop) study monitor will be here tomorrow.

Walked to OMCT with Della and Chris to

Pick up copies of nurses notes from Medical Records.

Went to microbiology lab to add new patients to intra-abdominal abscess study.

Follow-up visits for three patients, including Mr. M.

Copied Mr. M and Mr. P's hospital chart.

Lunch.

Completed eCRFs.

Friday June 4, 2004

Typed two patient narratives

Organized source documents for Mr. S and Mr. P

Cynthia C. here- she is the clinical research associate (CRA) and monitor for the Zymogenetics studies.

Typed 3rd narrative.

Walked to clinical trials office, Della met with Donna the grant coordinator.

Lunch.

Met with Cynthia, she reviewed information she found from source document and eCRF with Della and I.

Walked to OMCT to medical records to pick up additional charts.

Cynthia reviewed 2nd source document (Mr. P) and asked that we have all eCRFs completed by end of next week.

Monday June 7, 2004

Spent most of the day updating eCRFs .

Lunch.

Walked to OMCT to finish copying Mr. M's medical record chart.

Walked to clinical trials office to obtain dry ice.

Removed frozen labs from freezer and prepared for shipping.

Reviewed calendar for tomorrow, must complete eCRFs for all three patients enrolled by 6/09/04 per study monitor.

Tuesday June 8, 2004

Started the day with continuation of completing eCRFs, informed by Della that style sheets for lab data are all set up and lab results can now be entered.

Dr. Peska referred a potential study volunteer for 499C07 study.

Continued inputting data in eCRF.

Walked to OMCT, met with Mr. F, Della explained study, answered his questions and he agreed to participate in study. Informed consent signed and screening labs obtained.

Lunch.

Informed by Dr. Yurvati that he has a patient scheduled for a fem-pop tomorrow morning. He has mentioned study to patient, obtained informed consent, binder and lab kit.

Walked to OMCT, Della reviewed patient's hospital chart briefly. I explained study and informed consent to patient while Della and Chris observed. Mr. S reviewed informed consent and signed it.

Finished entering all data in eCRF for all three patients. Dr. DeLange informed Della of scheduled AV graft surgery for Friday 6/11/04.

Della called patient, spoke with her and explained reason for call. Patient not interested and refusing participation in study at this time. Dr. DeLange was informed.

Wednesday June 9, 2004

Arrived at 7:15 a.m. for Mr. F's surgery. Mr. S not eligible for study according to Della.

Walked to OMCT, picked up study vials and picked up lab draws, processed research labs and placed in freezer.

Returned to PCC and assisted Della with paperwork.

Returned to OR at 10:50 a.m. followed study protocol, out of OR by noon.

Lunch.

Made list of things to do since Della won't be here in the morning.

Walked to OMCT to obtain 2 hours post-op labs, processed research labs and stored in freezer.

Copied Mr. P's medical chart.

Thursday June 10, 2004

Reviewed Mr. P's medical chart.

Follow-up visit with Mr. O, followed Della's instructions, nurse obtained labs.

Processed labs.

Completed medication source document for Mr. P.

Made extra copies of source documents.

Lunch.

Followed Chris this afternoon for follow-up visit.

Observed Della as she called Dr. DeLange's patient for AV graft study.

Walked to OMCT to follow-up on Mr. F.

Made copy of informed consent and new source document for AV graft study patient.

Friday June 11, 2004

Walked to OMCT, reviewed informed consent with Mrs. S and she signed reviewed medical chart and patient did not meet inclusion/exclusion (I/E) criteria.

Follow-up visit for Mr. F, began copying his chart.

Organized all Zymogenetics lab kits in PCC lab.

Lunch.

Entered data on eCRF and filled out source document.

Informed of change of exclusion criteria for 499C08.

Monday June 14, 2004

Walked to OMCT, picked up record from medical records and finished copying Mr. F's chart.

Picked up dry ice from clinical trials office.

Finished source document for Mr. F and Mr. P.

Lunch.

Began entering data into eCRF.

Walked to OMCT-outpatient to see Mrs. C for informed consent process .

Finished entering data on eCRF.

Tuesday June 15, 2004

Met with Della this morning to review today's agenda.

Two monitors here for intra-abdominal abscess study.

Worked on research proposal all morning.

Met with Della to answer queries from intra-abdominal abscess study.

Lunch.

Mailed frozen lab samples.

Worked on research proposal all afternoon.

Met with Dr. Reeves to review research proposal.

Wednesday June 16, 2004

Met with Della this morning, she will be busy with monitors today.

Worked on research proposal this morning.

Mr. S here for Day 28 visit, last day of study.

Processed labs at hospital laboratory.

Attended Grand Rounds.

Entered Day 28 data on Mr. S's eCRF.

Typed SAE's for particular study.

Informed by Dr. Yurvati that he had potential study patient for 499C07.

Attended dinner meeting with Della and Chris. Topic was "Treatment Options for Serious Gram Positive Infections – Beyond Vancomycin".

Thursday June 17, 2004

Walked to OMCT this morning with Della and met with new study patient. Della explained study and informed consent, patient agreeable to study participation.

Walked to microbiology lab and pharmacy to inform them of new study patient.

Back in PCC worked on research proposal all morning.

Lunch.

Reviewed how to appropriately fill out SAE forms.

Left early today due to dental appointment.

Friday June 18, 2004

Walked to Dialysis Center with Della to meet with unit manager.

Met with a couple of people to discuss the use of freezer.

Met with Della to review serious adverse events (SAEs) for intra-abdominal abscess study.

Worked on research proposal.

Lunch.

Left early and worked on research proposal in library.

Monday June 21, 2004

Met with Della upon arrival.

Walked over to EAD 3rd floor to discuss use of freezer.

Walked to Dialysis Center and met with unit manager.

Back in PCC to check with Nina regarding patient appointment follow-ups.

Organized lab kits and shipping boxes in laboratory.

Walked to OMCT with Della.

Reviewed protocol for ACL study.

Lunch.

Continued reviewing ACL-study Investigator's meeting binder.

Dr. Yurvati referred patient for fem-pop study.

Entered lab results in eCRF for Mr. S.

Filed paperwork in regulatory binder of ACL study.

Reviewed CRFs for ACL study.

Tuesday June 22, 2004

Arranged kits in laboratory.

Walked to dialysis center, dropped off lab tubes for Mr. P's Day 28 visit.

Back in PCC, reviewed and made notes of study protocols with Della.

Della and I talked with Dr. Peska regarding supervision while Della is out of town.

Picked up labs from dialysis center and dropped off at OMCT laboratory processed research labs.

Lunch.

Replaced case report forms (CRFs) in binder.

Provided copy of research proposal to Dr. Reeves, Dr. Peska and Della.

Continued making notes that I will need when Della goes out of town.

Received input from Della regarding research proposal.

Wednesday June 23, 2004

Worked on research proposal till Della arrived this morning.

Called OMCT for Mr. P's lab results.

Provided lab results to Dr. DeLange for him to sign off.

Lunch and Presentation.

Completed Data Clarification Forms (DCFs) that Della received this morning.

Reviewed last minute details with Della.

Thursday June 24, 2004

Upon my arrival I informed Chris I was here.

Began completing DCFs.

Walked to OMCT with Chris.

Walked to clinical trials office, Chris met with Donna.

Returned to PCC and continued working on DCFs.

Lunch.

Completed DCFs and received additional ones thru fax.

Entered data in eCRF.

Organized medical record chart for patient in intra-abdominal abscess study.

Friday June 25, 2004

Checked Della's voicemail, noted message and informed Chris of message.

Completed two DCFs that were received yesterday afternoon.

Assisted Chris with DCFs that he had pending.

Lunch.

Continued working on DCFs, Chris reviewed all DCFs.

Studied for MCAT.

Monday June 28, 2004

Called OMCT – medical records to request copy of hospital chart for Mrs. J.

Studied for MCAT all morning.

Lunch.

Continued studying for MCAT.

Called Mr. M to remind him of follow-up appointment, left message on answering machine.

Met with Dr. Reeves, reviewed and discussed research proposal.

Tuesday June 29, 2004

Called OMCT- outpatient regarding Mr. H's pre-op visit.

Studied for MCAT.

Faxed forms requested by ICON.

Lunch.

Studied for MCAT.

Walked to OMCT outpatient department (OP) to see Mr. H, Chris reviewed informed consent with him and screening labs obtained.

Processed screening labs, copy of screening form provided to pharmacist, picked up copy of chart from medical records.

Back in PCC obtained baseline-day 1 lab kits.

Continued studying for MCAT

Wednesday June 30, 2004

Met with Chris to review agenda for today.

Walked to clinical trials to give paperwork to Donna.

Dr. DeLange signed Mr. H's informed consent.

Faxed subject enrollment form to Pfizer.

Studied for MCAT till 11:45 a.m.

Lunch.

Obtained Day 28 lab kit for Mr. M.

Organized source document for Mrs. J.

Continued studying for MCAT.

Informed by nurse that Mr. M is in hospital.

Walked to OMCT – Rehab Center to see Mr. M.

Back in PCC received two additional DCFs, completed and mailed today.

Organized lab kits for tomorrow and labeled all cryovials.

Thursday July 1, 2004

Arrived here early this morning, checked Mr. H's lab results.

Walked to OMCT to pick up Mr. M's and Mr. H's labs.

Walked to hospital pharmacy to pick up study drug vials and went to OR at 0820, followed study protocol, left OR at 10:00.

Processed labs in hospital laboratory and placed cryovials in freezer.

Returned study drug vials to pharmacy.

Back in PCC, called interactive voice recognition system (IVRS) to confirm treatment.

Lunch.

Returned to OMCT, obtained two hour post-op lab draws from Mr. H, processed labs and placed in freezer.

Chris and I Met with Dr. DeLange to discuss Mr. M's SAE, called Cynthia (monitor) regarding SAE.

Met with Dr. Peska to discuss research proposal.

Dropped by Graduate School Office to discuss research proposal.

Filled out paperwork for Mr. M's reimbursement for participation in study.

Friday July 2, 2004

Dropped off research proposal at Graduate School office.

Met with Chris to discuss Mr. M's SAE.

Walked to OMCT to check on Mr. H and picked up Day 1 labs, copied medical record.

Processed labs at hospital laboratory and placed cryovials in freezer.

Began organizing Mr. H's source document.

Began completing written case report forms for Mr. H.

Lunch.

Entered data into eCRF for Mr. H.

Entered missing data into eCRF for Mr. P and Mr. M.

Typed patient narrative.

Monday July 5, 2004

Checked in with Chris this morning, called OMCT-Medical Records for copy of Mr. H's chart.

Studied for MCAT and left at 1:30.

Tuesday July 6, 2004

Della back from vacation today, provided her with update.

Met with Mrs. J in clinic today for post-op follow-up.

Reviewed Mr. H's source document with Della, clarifications made on eCRFs.

Lunch.

Studied for MCAT till Della returned.

Walked to OMCT for potential study patient for central line infection study.

Processed labs in PCC lab, observed Chris do a blood smear on slide.

Returned to Chris's office to make patient labels.

Wednesday July 7, 2004

Studied for MCAT till Della arrived.

Met with Della; Cynthia study monitor here.

Met with Della and Chris to discuss status of all studies and new potential studies.

Lunch provided by home health agency.

Reviewed chart for potential study volunteer.

Met with Mr. F for Day 28 visit.

Walked to OMCT to drop off Mr. F's labs and processed research labs shipped all frozen cryovials.

Met with Cynthia (study monitor) to review some of her findings.

Thursday July 8, 2004

Picked up research proposal from graduate dean's office.

Met with Della walked to clinical trials office, Della discussed reimbursement issues with grant coordinator.

Studied for MCAT.

Informed by Della that two potential patients for ACL study have been referred.

Met with Cynthia (study monitor), she reviewed all of her findings and made suggestions.

Lunch.

Walked to OMCT to obtain "last day of treatment" lab draws for Mrs. W (central line study) and processed labs.

Studied for MCAT.

Corrected most of queries for Zymogenetics study.

Friday July 9, 2004

Reviewed agenda with Della.

Walked to OMCT to pick up copies of medical charts from Medical Records department.

Received package with clinical trial supplies and stored supplies in lab.

Organized source document for Mr. H and Mr. M.

Filled out SAE for and SAE form for IRB.

Lunch.

Studied for MCAT till end of day.

Monday July 12, 2004

Worked on eCRFs for Zymogenetics studies all morning.

Lunch.

Della out so I studied for MCAT.

Walked to OMCT, made copies of patient's medical chart, picked up information from medical records.

Back in PCC, organized Mrs. W's medical chart.

Faxed information to Cynthia regarding Mr. M's SAE.

Left early due to dental appointment.

Tuesday July 13, 2004

Labeled Mrs. W's source document and organized medication administration records (MARs).

Studied for MCAT.

Lunch with Della.

Studied for MCAT all afternoon.

Wednesday July 14, 2004

Met with Della, discussed ACL study and Impala training, completed training.

Completed paperwork for patient reimbursement.

Studied for MCAT.

Lunch.

Studied for MCAT.

Assisted Della with shipping of infectious disease products.

Walked to OMCT to drop off Form 1572 to hospital administrator.

Began re-typing SAE forms for Tigecycline study (intra-abdominal abscess study).

Thursday July 15, 2004

Helped Della rearrange office all morning.

Lunch with Della and Chris.

Stored older study files in boxes to make room for new study binders.

Worked on SAE forms with Chris.

Walked to OMCT with Chris to enroll new patient in central line study.

Friday July 16, 2004

Received message from Chris, informed Della of message.

Spent most of the morning in Dr. DeLange's office to download study protocols onto his computer and he signed all source document forms.

Began completing written CRF for central line infection study.

Lunch.

Assisted Chris with retyping of SAE forms.

Studied in Library.

Monday July 19, 2004

Studied till Della arrived.

Sheila (study monitor) here to monitor central line catheter study.

Walked to OMCT pharmacy with Della and Sheila, monitor met with pharmacist.

Della and I walked to outpatient, met with Chris as he explained Fentanyl study to potential patient.

Returned to PCC, met with Mrs. J here for follow-up (intra-abdominal abscess study).

Lunch.

Reviewed information with Sheila and noted changes that need to be made to CRF.

Reviewed study manuals about clinical trials provided by Della.

Studied in library.

Tuesday July 20, 2004

Off today for a social work conference.

Wednesday July 21, 2004

Began organizing SAE forms for Chris.

Walked to OMCT to check on Mr. V (pain study patient).

Continued organizing SAE forms and watched instructional videos on fentanyl patch.

Lunch provided by home health coordinator.

Returned to OMCT, Mr. V now in PACU, patient randomized to fentanyl patch and study drug device applied.

Completed organization of SAE forms.

Returned to OMCT for hourly assessment of Mr. V.

Discussed ACL study with Della; she called two persons for possible study participation.

Organized lab with new lab kits for ACL study.

Discussed my participation with pain study and nightly assessments with Chris.

Reviewed ACL protocol till end of day.

Thursday July 22, 2004

Discussed with Della about volunteering for nightly assessments for patient on pain study.

Helped Della file paperwork in regulatory binders.

Walked to OMCT, met with Ms. Norris (Sr. Vice President of Patient Affairs), also met with Katherine (unit director) to discuss pain study.

Returned to PCC, continued helping Della with filing.

Returned to OMCT for Mr. V's assessment.

Lunch.

Della gone, studied for MCAT.

Walked to OMCT with Chris, he provided in-service about pain study to unit director and floor nurses.

Left at 3:30 p.m.

Returned to OMCT at 8:15 p.m. for Mr. V's assessment, stayed the night in room that is connected to patient's room, patient's wife also stayed the night.

Completed assessment at 12:30 a.m. and 4:30 a.m., left information in patient's room for Chris to pick-up the next day.

Friday July 23, 2004

Off today due to overnight hospital stay.

Monday July 26, 2004

Assisted Chris this morning in setting up two monitors in library.

Met with Della.

Walked to OMCT to meet with Mr. S for ACL study participation; she reviewed study protocol and informed consent; patient agreeable to participation, Della obtained labs.

Returned to PCC, observed Della process labs, packaged labs for shipping.

Lunch.

Walked to library with Della to drop off additional source documents for monitors to review.

Obtained Day 28 kit for Mr. H, labeled cryovials and filled out lab form.

Met with Mr. H for Day 28 visit.

Walked to OMCT and dropped off labs, processed research labs, entered data into eCRF.

Tuesday July 27, 2004

Reviewed ACL protocol.

Helped Della answer queries for Wyeth Study (intra-abdominal abscess study).

Walked to OMCT to one-day surgery, Della met with recovery nurses to explain ACL study.

Walked to clinical trials office.

Walked to Dr. Hull's office to provide information regarding ACL study.

Dropped by Dr. Steve Buchanan's office to obtain signature for his participation as sub-investigator.

Completed queries for Wyeth study, Della reviewed and signed.

Lunch.

Studied for MCAT.

Completed reimbursement form for Mr. H.

Studied for MCAT till 5:00 p.m.

Wednesday July 28, 2004

Studied for MCAT.

Walked to OMCT-one day surgery, met with Mr. S's wife briefly.

Returned to PCC, continued studying for MCAT.

Walked to OMCT to one day surgery enrolled Mr. S to ACL pain study, obtained lab draws. Patient discharged made copy of his medical chart.

Returned to PCC, processed labs and packaged for shipping.

Lunch.

Completed reimbursement forms for Mr. V.

Obtained lab results, printed results and placed in source document.

Observed Della fill out CRF for Mr. S.

Thursday July 29, 2004

Studied for MCAT.

Downloaded protocol 499C08 in Dr. DeLange's office computer.

Della and I talked to patient (Mrs. H) about participation in 499C08 study while she was in clinic with Dr. DeLange.

Returned to downloading protocols in Dr. DeLange's computer.

Faxed additional information that was requested by Cynthia.

Lunch provided by MRI company.

Entered lab results for Mr. H on eCRF.

Informed by Della that Mrs. H did not meet I/E criteria for 499C08.

Began reading book provided by Della, titled "Protecting Study Volunteers in Research".

Left early due to dental appointment.

Friday July 30, 2004

Continued reading research book.

Filed all correspondence in regulatory binders.

Lunch.

Assisted Chris with filling out SAE form for Mr. M.

Finished reading book and studied till 5:00 p.m.

Monday August 2, 2004

Studied till Della arrived.

Met with Della, she will be leaving tomorrow due to family emergency, made a list of things to do while she is gone.

Reviewed ACL study protocol with Della.

Began correcting DCFs for intra-abdominal abscess study.

Lunch.

Obtained Dr. Berbel's signature for all DCFs and SAE form.

Studied from 4:00 – 5:00 p.m.

Tuesday August 3, 2004

Filed all DCFs in source documents.

Obtained lab kit for Mr. S's last day of treatment visit.

Chris and I drove to Dr. Daniel's office to see Mr. S, obtained patient log and medication, Chris obtained lab draws and vital signs.

Returned to PCC, processed labs, froze until ready for shipping.

Lunch.

Reviewed patient diary log, measured VAS, accounted for medications.

Filled out reimbursement form for Mr. S and Dr. Daniels.

Shipped Mr. S's labs to Covance.

Filed additional correspondence in regulatory binders.

Retyped SAE form.

Studied from 4:00 – 5:00 p.m.

Wednesday August 4, 2004

Obtained signatures from Dr. DeLange.

Met with Chris and reviewed how to fill out CRF for ACL study patient.

Filled out CRF.

Reviewed central line infection study protocol and materials.

Studied from 11:45 – 12:15 p.m.

Lunch.

Studied from 1:00 – 4:00 p.m.

Typed SAE report form for ACL study, Chris reviewed and took to IRB office.

Dr. Weis here to talk to Chris about potential study patient for pain study.

Organized all DCFs for Chris to be mailed out tomorrow.

Thursday August 5, 2004

Obtained signature from Dr. Buchanan for SAE form.

Assisted Chris in organizing CRF binders for study monitors (intra-abdominal abscess study).

Completed CRF inventory form and made copy, envelope ready to be mailed.

Informed by Chris that Mr. H (previous study participant) is in hospital, checked with study monitor regarding any adverse event (AE) reporting.

Helped Chris organize regulatory binder for Ortho-McNeil Study.

Reviewed Ortho-McNeil study protocol.

Lunch.

Continued reviewing study manual.

Briefly reviewed study manual for another pain study.

Studied for MCAT till 4:30 p.m.

Helped Chris make copies and gather information for study monitors.

Friday August 6, 2004

Met with Chris this morning .

Studied for MCAT.

Met with first study monitor, reviewed corrections that need to be made to CRFs.

Met with second monitor, reviewed corrections.

Met with Chris after his meeting, reviewed corrections that monitors noted.

Helped Chris correct CRFs and obtain copies of patient's medical record/chart.

Corrected CRFs all afternoon while Chris met with third monitor.

Received two new AE reports from Wyeth.

Continued assisting Chris with corrections.

Left today at 4:30 p.m.

Monday August 9, 2004

Organized all CRF binders and source document binders for Wyeth study.

Filed all monitor DCFs and CRF inventory forms.

Met with Chris to discuss corrections, reviewed how to type a "Note to file".

Completed SAE forms for Tigecycline reports and Chris reviewed forms.

Began typing "Note to File" memos.

Lunch.

Continued working on "Note to File" memos.

Filed correspondence for ACL study.

Obtained Dr. Buchanan's signature for end of study participation for ACL patient.

Received e-mail from Cynthia regarding amendments to protocols.

Printed amendments and Chris provided to IRB office.

Left at 3:15 p.m.

Tuesday August 10, 2004

Met with Chris, reviewed agenda for today.

Studied until needed by Chris.

Met with Randy (study monitor), reviewed what corrections need to be made.

Lunch.

Continued working on corrections.

Received queries by fax.

Met with Chris and second study monitor to discuss CRF findings.

Left at 3:00 p.m.

Wednesday August 11, 2004

Filed all "Note to File" memos in source documents.

Completed queries received yesterday.

Organized Della's office.

Walked to EAD to pick up forms from graduate school office.

Answered additional queries for Wyeth and urokinase study, returned queries for Chris.

Lunch.

Left early due to Chris not feeling well.

Note: Off on August 12 and 13 for MCAT

Monday August 16, 2004\

Met with Chris this morning, discussed potential patients for Zymogenetics study.

Chris called Dr. Hull's office, talked to Juanita regarding ACL study patients.

Filed all paperwork in Della's office.

Walked to Dr. Hull's office, provided copy of protocol synopsis and copy of informed consent to Juanita (Dr. Hull's nurse).

Made copy of source document forms for fem-pop study.

Was present for site visit meeting.

Lunch.

Reviewed Wyeth CRF binders for corrections.

New study patient referred by Dr. Yurvati.

Walked to OMCT to enroll patient, labs obtained and processed.

Tuesday August 17, 2004

Upon arrival checked Mrs. B's lab results, all within normal ranges.

Called Cynthia (study monitor) regarding type of surgery Mrs. B will have since amendment has not been approved by IRB.

Walked to OMCT, picked up Mrs. B's morning labs, processed and placed in freezer.

Picked up study drug and went to OR; study protocol followed; returned empty vials to pharmacy.

Lunch.

Called IVRS to confirm study drug treatment.

Began completing written CRFs for Mrs. B.

Walked to OMCT for Mrs. B's two hour post-op lab draws, obtained lab draws, processed research labs and placed cryovials in freezer.

Copied Mrs. B's hospital chart.

Worked on eCRF and source document.

Wednesday August 18, 2004

Filed paperwork in Della's office.

Three study monitors here to review CRF and source document binders for intra-abdominal abscess study.

Informed by Dr. DeLange of potential study for pain study.

Walked to OMCT to talk to patient about study participation, will return later once he talks to Dr. DeLange about his surgery.

Visited Mrs. B, obtained Day 1 labs, processed and placed in freezer; copied the remaining part of Mrs. B's hospital chart.

Lunch.

Continued working on eCRF with Stephanie.

Shipped all of Mrs. B's frozen research samples.

Attended going away reception for Dr. Rudick.

Thursday August 19, 2004

Met with Carla in Graduate School office this morning.

Continued working on eCRF.

Called OP regarding study patient.

Walked to OMCT to enroll patient (Mrs. Mc), Chris explained purpose of study to patient and family, research labs obtained, processed and placed in freezer.

Went to see Mrs. B, doing well, may go home today.

Lunch.

Worked on eCRF for remaining of afternoon.

Friday August 20, 2004

Checked Mrs. Mc's labs this morning prior to surgery.

Walked to OMCT at 9:00, patient not ready for surgery, obtained baseline labs and processed.

Picked up study drug vials, walked to OR; study protocol followed, left OR at noon, returned empty vials to pharmacy.

Called IVRS to confirm treatment.

Lunch in PCC for Dr. Buchanan.

Walked to OMCT for Mrs. Mc's two hour post-op labs, obtained labs, copied remainder of Mrs. B's chart, processed labs and stored in freezer.

Finished entering information for Mrs. B and Mrs. Mc.

Monday August 23, 2004

Completed internship diary.

Della back today, met with her to update her on what's been going on.

Worked on eCRFs and source document for Mrs. Mc.

Lunch.

Walked to OMCT, visited with Mrs. Mc, going home today; copied remainder of hospital chart.

Returned to PCC and continued working on eCRFs.

Reviewed clinic chart to determine if patient (Mrs. K) eligible for fem-pop study.

Della called Mrs. K, talked with her daughter about study, will see both for pre-op.

Finished completing eCRF.

Left today at 5:15 p.m.

Tuesday August 24, 2004

Obtained signatures from Della and Dr. Peska for graduate school forms.

Met with Dr. Reeves briefly, signed forms and set up a time to meet with him and Della next week.

Made copies and organized new binder for new study patient for 499C07.

Lunch.

Met with Della, verified that copies were made of all DCFs.

Met with Sheila (study monitor) for central line infection and ACL study.

Continued checking on DCFs for Wyeth study.

Met with Sheila, she reviewed CRF and source document binders, addressed corrections that needed to be made, Della made all corrections; will return tomorrow to review ACL study information.

Wednesday August 25, 2004

Met with Dr. Bens from 9:00-9:30.

Began typing patient narratives for Mrs. B and Mrs. Mc.

Walked to OMCT to outpatient, met with Mrs. K and her daughter, Della explained study and patient agreeable to participate, labs drawn and processed, provided patient information to pharmacist for randomization.

Walked to clinical trials to pick up dry ice, shipped all frozen labs.

Returned to PCC, Dr. DeLange signed Mrs. K's informed consent.

Left at noon today due to illness.

Thursday August 26, 2004

Checked Mrs. K's lab values this morning.

Walked to OMCT with Della, picked up Mrs. K's baseline labs, processed labs and placed cryovials in freezer.

Continued typing patient narratives.

Returned to OMCT, in OR by 11:00, followed study protocol, returned study vials to pharmacy.

Back in PCC by 12:20, Della called IVRS to confirm treatment.

Lunch.

Met with Sheila (study monitor), edited corrections on CRF for ACL study.

Returned to OMCT for two hours post-op lab draws for Mrs. K; obtained labs and processed.

Returned to PCC, began printing information for Mrs. K's source document.

Returned to OMCT to drop off tubes for labs to be drawn in the morning.

Friday August 27, 2004

Walked to OMCT with Stephanie, met with Mrs. K, may go home today, picked up labs that were drawn this morning.

Made copies of patient's medical chart, processed research labs and placed cryovials in freezer.

Returned to PCC, organized source document and began filling out CRFs.

Met with Dr. Rudick briefly and with new associate dean.

Lunch.

Entered all information in eCRF for Mrs. K in Della's office, informed by Dr. Yurvati that Mrs. K is going home today.

Monday August 30, 2004

Della in a meeting this morning, typed patient narratives for Mrs. B and Mrs. Mc.

Observed Della filling out survey/questionnaire for potential DVT study.

Reviewed DCFs that were received Friday afternoon.

Checked with Nina and Cornelia regarding follow-up appointments for Mrs. B and Mrs. Mc.

Lunch.

Della in meeting this afternoon, shipped Mrs. K's frozen samples.

Completed DCFs for mailing today, made copies of DFCs and filed all copies.

Helped Stephanie type a summary of pain study to provide to physician's nurse.

Tuesday August 31, 2004

Printed lab values, entered in eCRF and filed copies in source document.

Met with Dr. Reeves and Della.

Returned to PCC filled out reimbursement paperwork.

Worked on medical school essay.

Walked to OMCT pharmacy to check on tubing for PCA pump.

Returned to PCC, conference call at noon, met with Della afterwards to discuss conference call.

Lunch.

Worked on essay.

Walked to OMCT to see new pain study patient in recovery.

Returned to PCC worked on DCFs.

Wednesday September 1, 2004

Continued working on DCFs for intra-abdominal abscess study.

Worked on essay till lunch.

Attended Grand Rounds.

Returned to PCC, Chris and Della talked to Dr. Berbel regarding Mrs. G (study patient).

Met with Dr. DeLange, he signed off I/E criteria in eCRF and corrected query.

Met wit Mrs. B for follow-up appointment.

Received additional lab kits, organized in laboratory.

Returned to OMCT with Della and Stephanie to do 4:00 p.m. assessment on Mrs. G.

Returned to PCC to inform Dr. Berbel of Mrs. G's complaints, patient discontinued from study.

Thursday September 2, 2004

Met with Della this morning, study monitor here today, completed remaining DCFs.

Assisted Chris and Stephanie filling out DCFs.

Began organizing source document for Mrs. G, printed information from Meditech for Stephanie, began filling out CRF.

Lunch.

Dropped off paperwork at graduate school.

Worked on medical school information all afternoon.

Friday September 3, 2004

Dropped off completed forms to Amanda in graduate school office.

Finished all queries, waiting for Dr. Berbel to sign.

Dr. Berbel signed all DCFs, organized DCFs for mailing.

Lunch.

Worked on medical school information.

Monday September 6, 2004

Off due to labor day holiday

Tuesday September 7, 2004

Received one more query, helped Della obtain information.

Assisted Della filling out other queries from other studies.

Lunch.

Worked on school work all afternoon.

Della called Dr. Daniel's office regarding ACL study patients.

Wednesday September 8, 2004

Organized SAE forms for Wyeth Study.

Invited by Dr. Buchanan to observe surgery.

Stephanie and I were in OR from 10:00 a.m. to 1:00 p.m. for a right thyroid lobectomy.

Lunch with Della.

Worked on school paperwork.

Della and I met with Dr. Hull briefly to discuss ACL study.

Thursday September 9, 2004

Helped Della all morning long with filing paperwork from different studies.

Lunch.

Continued filing paperwork most of the afternoon.

Della talked to Patricia at Dr. Daniel's office regarding new patient for ACL study.

Della called patient, left message on answering machine.

Continued working on medical school information.

Friday September 10, 2004

Helped Della with filing all morning.

Lunch.

Worked on medical school applications .

Walked to OMCT to see Mrs. I, Chris talked to her about pain study, watched patient information video, she agreed and signed IC.

Saturday September 11, 2004

Attended North Texas Association of Clinical Research Professionals Meeting at UNTHSC.

Listened to speaker Phillip Waldron, topic was "FDA Bioresearch Monitoring".

Monday September 13, 2004

Walked to OMCT outpatient, Della and I met with Mr. W regarding ACL study, patient agreed and he signed IC and Della obtained labs.

Returned to PCC, processed labs and prepared for shipping.

Obtained folder to begin source document for Mr. W.

Lunch.

Checked with Kathy, Dr. DeLange's nurse regarding patient undergoing AV graft revision, Della and I reviewed patient's chart, she talked with Dr. DeLange regarding patient participation; Della called patient (Mr. S) and patient's daughter.

Met Mrs. B for her Day 28 visit; vital signs obtained and labs obtained.

Walked to OMCT lab, dropped off labs and processed research labs; dropped off cryovials in freezer.

Returned to PCC, Della called Mr. S, she explained study to patient, patient agreeable, reviewed I/E criteria, patient does not meet criteria; Della informed Dr. DeLange.

Tuesday September 14, 2004

Printed Mrs. B's lab results.

Entered lab data in eCRF in Della's office.

Dr. DeLange informed us of potential new patient for AV graft study, patient scheduled for surgery today.

Della and I walked to OMCT – outpatient surgery, Della met with patient and daughter, discussed study, both agreeable, daughter signed IC, obtained labs and waited for lab results.

Received lab results, patient clear for surgery, Dr. DeLange informed and pharmacist also informed.

Ready for OR at 12:15 p.m., surgery started and study protocol followed.

Returned to PCC at 1:45, Della called IVRS to confirm treatment.

Lunch.

Began organizing source document for Mrs. O.

Returned to OMCT at 3:30 for two hours post-op labs, processed research labs and placed cryovials in freezer.

Wednesday September 15, 2004

Here by 8:30 a.m., Della received results of labs from Covance for Mr. W.

Walked to OMCT to one day surgery; met with Dr. Daniels prior to surgery.

Returned to PCC, met wit Mrs. Mc and her daughter for Day 28 visit, nurse obtained labs.

Walked to OMCT dropped off labs and processed research labs, placed cryovials in freezer.

Returned to PCC, Della finished with meeting, walked to OMCT to inform Mr. W that he was not eligible for study after all.

Returned to PCC, began organizing Mrs. O's source document.

Lunch with Stephanie.

Began entering lab data on eCRF for Mrs. B and Mrs. Mc.

Went to see Mrs. O at Fort Worth Dialysis Center for Day 1 labs, processed research labs and placed cryovials in freezer.

Made sure all paperwork complete before leaving.

Thursday September 16 and Friday September 17, 2004

Off both days for medical school interview

Monday September 20, 2004

Met with Della to discuss agenda for today.

Walked to Dr. Hull's office with Della to pick up some forms, walked to clinical trials to drop off all forms.

Returned to PCC, worked on Mrs. O's source document.

Lunch.

Obtained lab kit for Mrs. K's day 28 visit, walked to OMCT dropped off labs for processing and processed research labs, placed cryovials in freezer.

Entered data on eCRF for Mrs. O.

Corrected queries for other patients on eCRFs.

Completed source document for Mrs. O.

Tuesday September 21, 2004

Met with Della this morning; provided me with paperwork for Dr. Peska and Dr. Buchanan to sign.

Della talked to monitor for new DVT study.

Printed off Mrs. K's lab results and entered in eCRF.

Met with Della after her meeting.

Obtained signatures from Dr. Peska and Dr. Buchanan.

Lunch with Stephanie.

Picked up all frozen samples and prepared for shipping.

Assisted Della with filing.

Faxed all monitoring visit letters to Covance.

Reviewed CRF and source document for a past study patient enrolled in Urokinase study.

Wednesday September 22, 2004

Met with Della, tagged all pages that Dr. DeLange needs to sign.

Checked with nurses regarding any potential study patients.

Began typing internship site journal.

Attended Grand Rounds.

Continued typing.

Thursday September 23, 2004

Met with Della this morning.

Walked to clinical trials office, met with Donna, calculated costs of extra labs.

Filed additional regulatory documents in regulatory binder for ACL study.

Continued typing journal.

Lunch.

Walked to OMCT to enroll new patient in central-line infection study (Mrs. A).

Returned to PCC, processed labs and prepared for shipping.

Continued working on journal till I left at 4:30 p.m.

Friday September 24, 2004

Met with Della this morning; Della received a call from pharmacist regarding adjustment made on antibiotic for Mrs. A.

Walked to OMCT, Mrs. A not in her room, visited with husband briefly.

Back in PCC, printed forms for Della and she talked to Dr. Berbel about new patient enrolled in central line study.

Continued working on journal.

Met with Dr. Bens briefly to discuss thesis.

Returned to PCC, continued working on journal.

Lunch with Stephanie.

Continued working on journal.

Monday September 27, 2004

Here by 9:00 a.m. today, informed by Della that Dr. DeLange has referred a new patient for fem-pop study, obtained lab kits and CRF binder.

Walked to OMCT, Della met with patient and her daughter, Della had discussed study to patient on Friday, daughter agreeable and signed IC, obtained screening and baseline labs.

Walked to pharmacy, provided copy of screening information to pharmacist for randomization; processed research labs and placed cryovials in freezer.

Returned to PCC, obtained patient enrollment form.

Worked on journal until needed in OR.

Walked to OMCT – OR, picked up study drug and study drug protocol followed, returned to PCC, Della called IVRS for treatment confirmation.

Lunch.

Worked on journal, printed information for Mrs. L's source document.

Walked to OMCT for two hours post-op labs, also met with Mrs. A obtained last day of treatment labs, processed Mrs. L's labs.

Organized Mrs. L's source document and began filling out.

Dr. DeLange here this afternoon, obtained needed signatures.

Tuesday September 28, 2004

Cynthia (study monitor) here this morning, will review four of the source document binders.

Labeled all source document binders for Urokinase study and placed with corresponding CRF binder.

Walked to OMCT, saw Mrs. L, Della obtained Day 1 labs, processed research labs and placed cryovials is freezer.

Lunch.

Worked on journal.

Began filling out written CRF for Mrs. L.

Worked on journal till end of day.

Wednesday September 29, 2004

Walked to OMCT visited Mrs. L, copied all of her medical chart, also copied Mrs. A's medical chart.

Dropped off some paperwork at clinical trials office.

Back in PCC, organized Mrs. L's copies and printed missing information from Meditech.

Lunch.

Continued working on Mrs. L's source, had questions regarding physical assessment forms.

Typed journal till end of day.

Thursday September 30, 2004

Corrected queries with Della all morning long, also corrected source document binders.

Lunch.

Continued typing journal, made additional corrections to source documents.

Continued typing journal till end of day.

Friday October 1, 2004

Met with Della this morning to discuss errors found in source documents.

Continued working on journal.

Lunch with Stephanie.

Continued working on journal till end of day.

Monday October 4, 2004

Met with Della this morning upon her arrival.

Worked on medical school application.

Della asked that I review source documents for fem-pop and AV graft studies and tag all lab results that require Dr. DeLange's signature.

Lunch.

Walked to graduate school office, met with Carolyn Polk.

Returned to PCC, continued tagging source document binders.

Assisted Stephanie with typing documents.

Dr. Yurvati referred patient for fem-pop study.

Dr. DeLange also referred patient for fem-pop study.

Tuesday October 5, 2004

Stopped by graduate school office.

Met with Della once she arrived.

Reviewed practicum report guidelines.

Lunch and presentation at Baylor All Saints Medical Center, title of program "AE Reporting and Analysis of the Basics".

Continued reviewing thesis guidelines.

Attended IRB meeting with Chris and Della.

Wednesday October 6, 2004

Met with Della upon her arrival.

Began working on thesis/internship practicum report.

Dr. DeLange referred patient for rhThrombin study; Della and I met with patient and his wife.

Met with Mrs. L for follow-up.

Attended Grand Rounds.

Typed IND reports and SAE forms, Chris reviewed.

Worked on thesis throughout the afternoon.

Thursday October 7, 2004

Called medical records at OMCT to have charts pulled.

Organized SAE forms with Della.

Walked to OMCT with Stephanie, obtained charts and obtained copies of missing information.

Organized copies in source document binders.

Lunch.

Worked on thesis.

Met with Della to discuss what needs to be done before she goes out of town.

Helped Stephanie type SAE forms.

Friday October 8, 2004

Della here later today, informed by Chris that OMCT has closed.

Worked on thesis through out the morning.

Helped Stephanie retype SAE forms.

Met with Dr. Aschenbrenner from 12:00-12:45 p.m.

Back in PCC met with Della, Chris and Stephanie.

Walked to clinical trials office met with Wendy and Dr. Clearfield.

Met with Dr. Buchanan and entire surgery department to discuss closing of hospital.

Continued helping Stephanie with SAE forms.

Called Sue at Renal Dialysis Center regarding Mrs. O's blood draws.

Monday October 11, 2004

Met with Chris this morning, Larry (study monitor) here today, walked him to OMCT pharmacy.

Began entering data on eCRF for Mrs. L.

Walked to OMCT – Rehab Center.

Larry (microbiologist) from OMCT lab dropped off study binders.

Lunch.

Worked on thesis.

Drove to FW Dialysis Center to pick up Mrs. O's Day 28 labs, met patient briefly and obtained vital signs from patient's nurse.

Returned to PCC, dropped off labs at Quest Diagnostics, processed research labs and placed cryovials in freezer.

Tuesday October 12, 2004

Met with Chris upon arrival this morning.

Worked on Mrs. O's source document, updated medication list.

Obtained study drug shipment forms from regulatory binder.

Walked to OMCT pharmacy, provided forms to pharmacist for him to fill out before study drug can be shipped out.

Call from Cynthia (study monitor) regarding correct way to ship study drugs.

Lunch.

Met with Dr. Reeves from 1:00-1:45 p.m.

Walked to OMCT pharmacy, obtained study drug and placebo vials, and shipped. Also shipped frozen sample for Mrs. O.

Wednesday October 13, 2004

Checked Della's voicemail and email upon arrival.

Worked on thesis this morning.

Attended Grand Rounds.

Walked to One-Stop mail, picked up shipping box, shipped additional study drug vials.

Made copies of Investigator's Brochure and Protocol for all studies that are currently open.

Chris provided copies to Wendy in Clinical Trials office.

Emailed Cynthia regarding lab value ranges for Quest Diagnostics.

Worked on thesis.

Thursday October 14, 2004

Received SAE forms via fax from ZymoGenetics.

Worked on SAE reports, Chris reviewed and Dr. DeLange signed.

Made copies of reports, sent to IRB office and filed in regulatory binder.

Walked to OMCT-laboratory dropped off information to Larry, and obtained box with lab kits and shipping containers.

Lunch.

Worked on internship practicum report.

Friday October 15, 2004

Checked eCRF for lab style sheets.

Entered data on eCRF for Mrs. O.

Left PCC at 11:30.

Worked on report in library till 3:00 p.m.

Saturday October 16, 2004

Attended North Texas Association of Clinical Research Professions Fall Symposium in Dallas.

Speakers were Michael Smit and Tamara Norton.

Monday October 18, 2004

Study monitor here this morning, walked her to OMCT medical records department, had charts pulled she will review.

Met with Della upon her arrival.

Worked on internship practicum report.

Lunch.

Assisted in storing of study drugs.

Assisted Stephanie retype SAE forms/reports.

Worked on internship practicum report.

Tuesday October 19, 2004

Met with Dr. Reeves and Dr. Aschenbrenner .

Met with Della upon return to PCC.

Worked on internship practicum report.

Lunch.

Corrected SAE forms for 499C07 and 499C08.

Met with Cynthia (study monitor), noted corrections to be made.

Wednesday October 20, 2004

Met with Chris briefly this morning.

Made copies of SAE forms and dropped at clinical trials office.

Filed SAE forms in regulatory binder.

Met with Dr. DeLange.

Lunch.

Met with Cynthia, reviewed additional correction.

Met with Della to review corrections.

Began making corrections on eCRF.

Thursday October 21, 2004

Met with Dr. Reeves briefly this morning.

Updated journal.

Worked on internship practicum report.

Lunch.

Worked on eCRF corrections all afternoon.

Obtained signatures from Della and Dr. Roque regarding intent to defend.

Met with Dr. Aschenbrenner to discuss medical school.

Friday October 22, 2004

Off today, Della and Chris at investigator's meeting in Florida.

Monday October 25, 2004

Worked on internship practicum report.

Obtained physician signatures for Form 1572 and financial disclosure forms.

Lunch.

Obtained additional physician signatures.

Met with Della to discuss status of studies .

Checked with Cathy, Dr. DeLange's nurse regarding Day 28 follow-up for Mrs. L.

Tuesday October 26, 2004

Assisted Della and Chris cleaning and organizing storage room.

Obtained additional signatures from Dr. Peska.

Dropped off Intent to Defend form at graduate office.

Worked on internship practicum report.

Lunch.

Obtained lab kit and extra test tubes for Mrs. L's Day 28 visit.

Drove to Fireside Lodge with Della and Stephanie, met Mrs. L for Day 28 visit.

Returned to PCC and processed labs, placed cryovials in freezer.

Wednesday October 27, 2004

Picked up frozen samples and dropped off at Quest Diagnostics.

Packaged frozen sample for shipping.

Checked eCRF for lab style sheets.

Obtained signatures from Dr. DeLange.

Attended Grand Rounds (12:00 – 1:00 p.m.).

Worked on internship practicum report.

Thursday October 28, 2004

Met with Della and Carlene (study monitor) most of the morning to discuss new study.

Lunch.

Worked on internship practicum report.

Friday October 29, 2004

Received lab results for Mrs. L, called Quest regarding missing labs.

Filed lab results in source document.

Worked on internship practicum report.

Lunch with Della, Stephanie and Lisa.

Completed journal for the day.

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