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Promoting Good Clinical Practice: Application of Regulatory Binders in a Physical Therapy Research Setting

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PROMOTING GOOD CLINICAL PRACTICE: APPLICATION OF REGULATORY BINDERS IN A PHYSICAL THERAPY RESEARCH SETTING

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CHAPTER 1:

Introduction

The International Conference of Harmonisation (ICH) identifies *Good Clinical Practice* (GCP) as an international standard on the ethical and scientific quality for the design, conduct, recording, and reporting of human subject research trials. [1] The ICH is unified between the European Union, Japan, and United States to facilitate communal agreement that compliance of these standards are assured. These standards should also be consistent of the Declaration of Helsinki, which is the World Medical Association's perspective on ethical principles in medical trials of human subject research.[2] The ICH was developed to serve as a current guideline for federally regulated research; however, it is equally applied to other clinical investigations that involve the welfare of human subjects.[3] The principles of ICH Good Clinical Practice are summarized below:

1) Clinical trials should be conducted according to the ethical principles stated in the Declaration of Helsinki and applicable regulatory requirements.
2) Before a trial begins, a risk-benefit ratio should be conducted. A trial should only have anticipated benefits that justify the risks.
3) The rights, safety, and well-being of the human subjects are the single most important consideration and should exceed over the research interests of the investigator and society.
4) Any available nonclinical and clinical information on the investigated product should be ample support on the proposed clinical trial.
5) Clinical trials should have a clear and detailed protocol.

6) Clinical trials should be conducted under the approval of the Institutional Review Board (IRB) or Independent Ethics Committee (IEC).
7) All medical care and medical decisions required for the human subject should always be under the responsibility of a qualified physician.
8) Each individual involved in performing the clinical trial should be qualified through: education training and experience to perform the research tasks.
9) Voluntary informed consent should be obtained from each subject before performing research.
10) All clinical trial information should be recorded, handled, and stored so that reporting, interpretation, and verification is accurate.
11) All records of subjects that can be identified should be protected to respect the privacy and confidentiality rules according to the appropriate regulatory requirement(s).
12) Investigational products should be manufactured, handled, and stored according to the approved protocol and should follow good manufacturing practice (GMP).
13) A system of procedures should be implemented at every aspect of the clinical trial to assure quality.

The history that led to the implementation of these standards was unfortunately built upon the ill-timed and regrettable decisions of human research. The decisions became the reasons how human rights in medical research were shaped. The beginning of ethical standards of human subject protection started with the Nuremberg Code. Also known as the "Doctor Trials," the code was established as a means for the voluntary consent of human subjects in research.[4] These principles declared that all experiments conducted on humans should be only for the good of society, and that no harm should ever be made. What led to these decisions were

the misfortunate judgments made from the Nazi experimentations at the Nuremberg trials after World War II. Physicians conducted medical experiments in concentration camps in which the United States and chief prosecutor of the time, Telford Taylor, labeled as "murder trials".[4] Adoption of the Nuremberg code formed the current influence on voluntary informed consent, and human rights of subjects in medical research.

By the late 1950s, the approved drug Thaliomide was used in Europe, but the Food and Drug Administration (FDA) did not approve its use in the United States because of its lack of evidence in effectiveness. The drug was prescribed as an anti-nausea medication for pregnant women. Unknown effects of the drugs included severe infant deformities.[5] The FDA soon required that all drug manufacturers were required to prove the effectiveness of their products before introducing them into market. Since this event, the World Medical Association issued the Declaration of Helsinki primarily as an address to physicians who are involved in the conduct of human subject research and research that include identifiable human material and data.[6] The ethical principles guiding clinical research have been revised eight times since 1964, with the most recent submission in 2008. The message of the Declaration of Helsinki states that the duty of the physician is to "promote and safeguard the health of patients including all those involved in research".[6] They consider international ethical, legal, and regulatory norms and standards. What is also explained in these principles are the defining view of medical research combined with medical care, and research that is considered "non-therapeutic".[6] The physician is to consider that if the research is justifiable for its preventative, diagnostic, or therapeutic value, then there is good reason that the human subject's health will not be adversely affected. The research conducted on humans should also be based from the results of laboratory and animal experimentation.

In the United States, the Tuskegee Syphilis Study sustained for nearly 40 years (1895 – 1972).[7] What was supposed to be the study in finding treatment programs for African-Americans with syphilis, turned into an injustice design brought from the study investigators.[7] The study involved nearly 600 African-American men, in which 200 did not have the disease in the first place. Researchers misinformed the patients', telling them they were being treated for "bad blood," and that they would receive free medical care.[7] The subjects were not given information about the purpose of the study, or information that there was the widely used penicillin, available for the treatment of their disease.[8] The study led to a class-action lawsuit and a $10 million out-of-court settlement.[8] By 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research created a basic set of ethical principles and guidelines on how to assure that research is conducted in an ethical manner. The principles became known as the Belmont Report. The first principle is "Respect for Person." Autonomy is the basis of the description for this principle, stating that all individuals should be treated as autonomous agents, as well as persons with diminished autonomy. The second principle is "Beneficence." While the term generally is termed for actively doing good upon others, the meaning ethically is to treat persons with respect and protect them from harm, and also make an effort to secure their well-being. The research must always maximize the possible benefits, and minimize any possible harm. Lastly, the third principle is "Justice." Each person should be equally treated, according to individual need, effort, societal contribution, and merit. The Tuskegee Syphilis study portrayed injustice by depriving effective treatments amongst disadvantaged, rural African-American men.[8]

In the United States, the FDA monitors federally regulated investigative studies for the development of drugs. Regulations within the Code of Federal Regulations (CFR), a codification

of general and permanent rules published by the Federal Register of the Federal Government,[9] are implemented by the FDA. Title 21 and 45 are indicative of the regulations on protecting of human subjects involved in clinical trials. Determined by the Department of Health and Human Services and the FDA, the scope of Title 21, parts 50 and 56 applies other rights and safety of human subjects. All regulated clinical investigations must follow the general requirements of informed consent, safeguards for children involved research, perform parental or guardian permissions for the assent of children, and follow the requirements for research in prison institutions. Part 56 highlights the IRB general organization and function. Lastly, Title 45 Part 46, or also known as the common rule, outlines the basic additional protections for pregnant women, fetuses and neonates, prisoners, and children.

While investigative studies that are federally regulated are monitored by the FDA, it is important to remember that all research studies that involve humans should use historical ethical guidelines. However, since not all studies are followed by the FDA, many go unnoticed. In instances such as investigator-initiated research trials, the Institutional Ethics Committee, (IEC), or the IRB determine the ethics of these studies on a local level. Because the IEC/IRB follows the federal standards of the FDA, it is automatically applied that all studies that are approved by the local IEC/IRB, should follow federal regulations as well. Professional journals are advised to refer to what the International Committee of Medical Journal Editors (ICMJE) states is the uniform requirement for ethical considerations in the conduct of human subjects research.[10] This has helped standardize ethics in human subject research.

There are many clinical sites that pursue research clinical trials. It is the interest of the principal investigators that the responsibility of protecting human subject rights, safety, and well being are met. The largest industry in clinical research is the pharmaceutical industry.[11] The

industrialization of clinical research has grown a significant amount with the addition of research management systems, such as clinical research organizations (CROs).[11] CROs aid in clinical trial management and provide assistance in regulatory services. And while many small investigative sites are not part of the industry of clinical research, all of them have to follow the same rules in regards to ethical protections of human subject research. Studies that are not managed by sponsors, or a CRO, are known as private investigative sites. These sites consider the principal investigator as the sponsor, in which they are acknowledged as investigator-initiated research studies. An example of small investigative sites that have not been included in the large industrialization of clinical research is the spectrum of physical therapy research. Physical therapy clinical trials are not usually associated with the pharmaceutical industry, however can possibly be included in the device industry. The American Physical Therapy Association, which has become one of the most recognized organizations representing the profession, continues to report the expansion of research in the field. As part of the Vision 2020 strategic plan, basic clinical research is mentioned to be an element essential to the physical therapy profession.[12] The science behind physical therapy has existed for years with research starting in the early 1940s. This included the start of the clinical trials for the Salk vaccine to eradicate polio in the United States by the 1960s.[13] According to the APTA, physical therapy is "a dynamic profession with an established theoretical and scientific base and widespread clinical application in the restoration, maintenance, and promotion of optimal physical functions".[14] The term "physical therapy" is also synonymous with the word "physiotherapy". The practitioner of PT is known as a physiotherapist or a physical therapist. Physical therapists undergo proper higher education, licensure, and continuing education courses to maintain their role in the most current and up-to-date techniques and services.[14] In addition, physical therapists assume a leadership role in patient

rehabilitation, prevention, and health maintenance. Lastly, physical therapists help in the development of health care policy by ensuring that services of PT are available, accessible, and optimal.[14]

Minimal knowledge exists regarding how federal regulations apply to physical therapy research, but there is the justifiable assumption that all federal regulations should apply. Only a modest recognition is identified from the local IEC/IRB committees that overlook human subject clinical trials in physical therapy. The 2011 strategic plan of the Section of Research (SOR) in the APTA emphasizes the effort of increasing research education opportunities, but does not overlook the responsibility of the physical therapy researcher in practicing good clinical practices for the protection of human subjects in research trials.[12]

Twenty-first century medicine strives to evolve into an evidence-based practice, requiring real evidence that the determined way of treatment is the best option for the patient.[15] The APTA has made recognition on its website that the PT profession should equally do the same. The key topic of implementing evidence-based practice in PT is emphasized in the Clinical Research Agenda. The goal of the APTA is to guide every practicing PT to understand that research is important to their clinical practice. Younger generation physical therapists should participate in research projects so that the future of PT practice is built upon factual evidence rather than experience.[16] The main goal is that research should establish clinical practice, and that treatment should be decided upon evidence. Lastly, research evidence should be valid.

Valid and qualitative evidence in research is important to physical therapy research. "Quality," defined by the ISO 9000 addresses this as a set of standards in which an organization fulfills customer quality requirements and applicable regulatory requirements.[17] Aiming to enhance customer satisfaction and achieving continual improvement are also acknowledged in

the ISO. Quality evidence is important in clinical trials because the core components of research help ensure that patient protection follow the compliance of ICH GCP, and validates the integrity of data. The customers of clinical trials are those that benefit from the development of drugs, devices, and methods of preventative medicine, whether they are the research subjects, patients with a particular illness for which the study is being investigated for, physicians treating the patients, or for society.[18]

One requirement of qualitative evidence is maintaining essential documentation. According to GCP, a well-documented research study is compliant with federal guidelines. The use of a "regulatory binder" in a federal regulated study is the ideal way of essential documentation.[3,19] A "regulatory binder" is essentially the place where all essential documents that are related to the study are stored, maintained, and updated. In an investigator-initiated trial, essential documents may not require the use of the standard "regulatory binder," but that it should be similarly enacted. Essential documents help validate data, support the well-known saying that "if it's not documented, it didn't happen".[20] Section 8 in the ICH's Guideline for GCP outlines all relevant essential documents.

The need to improve the ethical standards of human subject research has no doubt rooted from the growth in the clinical research industry. The DHHS recognized four trends in clinical research of recent times that have gained attention signifying several steps need to be taken in improving the oversight of clinical research trials.[21] These steps include the strengthening of government oversight on clinical trials by efforts of the NIH and FDA. How can physical therapy research trials be included in these efforts? The 2011 strategic plan of the APTA Section of Research already is taking the initiative of undertaking education and training opportunities.[12] Other steps that follow are parallel to the steps that the DHHS recommends to strengthen

oversight. Increased expectation of evidence of full research compliance, monitoring plans requiring new guidelines, and penalties towards principal investigators who violate important research practices are some of the recommendations that DHHS implements. For physical therapy research, helping the profession practice good clinical practice can be an essential first step in being a well-recognized research spectrum. Most PT research trials are investigator-initiated and do not require the maintenance of a regulatory binders like sponsored-trials frequently require of their research sites. However, it may be equally important to include this practice. The profession of PT is recognized by the community as a leader in optimal treatment of patients. Creating better quality clinical treatment for the patients of PT requires the improvement of research practices in physical therapy. Therefore, increased quality in PT research may ultimately enhance clinical practice and increase satisfaction of patient-customers of PT.

CHAPTER 2:

Background and Literature Review

Research in the area of physical therapy is highlighted in the APTA's Section of Research, and the *Clinical Research Agenda* (CRA).[22] With the intent to identify clinical research questions that challenged physical therapists, the editorial advisory panel (EAP) helped format the CRA based on a patient/client management model. The most current CRA, which was published in 1999, contained a final report of 72 questions. Ten years later since the succession of the CRA, an evaluation found that changes should occur.[16] Suggestions should include a revised CRA that emphasizes the comprehensive perspective of physical therapy research. In

addition, the authors recommend an abbreviated name of "Research Agenda" which should be used to interpret physical therapy research that goes beyond the spectrum of "clinical research." The importance in better recognizing the different areas of science in physical therapy and encouraging programs for junior investigators of physical therapy researchers have become the authors' highlights for the revision. There has been no recent publication of a revised CRA.

Evidence-based medicine (EBM) is described as "the use of current best evidence in making decisions about the care of individual patient".[15] Evidence-based medicine, or evidence-based practice (EBP), in physical therapy entitles the importance of research because of the need for evidence prior to practice. Several authors[23,24,25] analyzed trends in EBP in the physical therapy setting and found that the use of EBP in physical therapy is necessary, because the quality of patient care is better when evidence from literature is used. Nonetheless, the biggest significant barrier in performing any type of research in the PT profession is the lack of time necessary to conduct research.[23,24,25,26,27] This is especially true in clinic-based research sites, where time is centered around patient treatment and not necessarily focused on research. In an academic setting, research is conducted under situations of a laboratory and the role of patient treatment is not part of the responsibility. Secondary to the lack of time available to the physical therapist, there are the challenges and barriers that also emphasize: 1) the confusion of applying research findings into actual practice, 2) assessing and interpreting evidence and applying it to the clinicians' skill, judgment, and experience, and 3) logical considerations such as lack of technological skills to complete a literature search, or providing time to understanding new methods when under constant pressure of the healthcare environment.[24]

Providing research literature to practicing physical therapists have improved after online databases became widely available. The databases, such as PubMed, Physiotherapy Evidence

Database (PEDro), and the APTA's "Hooked on Evidence" tool, are improving access to literature for PTs.[25] However, there is still little strategy available describing how to determine the best way in improving EBP in physical therapy. Some suggestions found in the literature for improving EBP include: 1)determining how to effectively change the culture of management in order (changing the attitudes of those who are in charge of clinic) to better recognize the needs for research in practice,[24] 2) considering the logistics of clinic-based physical therapy research ,[26,27] 3) and providing educational opportunities to PTs.[25] Regarding *how* research should function in a physical therapy clinic is a concept that has not been recently analyzed. The recruitment of a *research coordinator*,[27] or *research assistant*,[26] should aid in the development and operation of a clinical trial in the physical therapy setting. The benefit of another research team member is the addition of an extra hand in conducting these research duties that the principal investigator is unable to accomplish due to their time constraints. Fitzgerald and Delitto[26] have emphasized the idea of assembling a data safety and monitoring board (DSMB) to help guide physical researchers in conducting their research ethically.

The ethical concern for research in PT practice is another issue that goes hand in hand with conducting EBP. Research is built upon the consideration that human subject well-being is more important than the interests of the research. In 1996, the Delphi technique was used to determine what issues are of concern in PT clinics. The Delphi technique was a questionnaire format that was applied to experts in the field. The group of experts responded that a future issue in the ethics of PT practice is "adherence to ethical guidelines for human subjects in clinical research".[28] Ethical research is emphasized in the APTA's *Guide for Professional Conduct* stating that physical therapists engaged in research should ensure the consent of subjects, confidentiality of the data on individual subjects and the personal identities of subjects, and the

well-being of all subjects in compliance with facility regulations and laws of the jurisdiction in which the research is conducted.[29] In an analysis of human ethical protection in six physical therapy journals between the years 1996-2001, it was found that less than half (48%) of the journals reported both research ethics committee approval and informed consent of subjects.[30] At least 29% had no information on either protection. While most articles describing data obtained from clinical trials reported research ethics committee approval and informed consent (64%), all other articles (qualitative methods research, chart reviews, and case reports) had low rates.

Since it has been determined that the guide of professional conduct that all PT research using human subjects should facilitate under the jurisdiction on which the research is conducted, nearly all research of physical therapy should essentially follow federal regulations. The conclusion of Henley & Frank[30] proves that no uniform policy exists in physical therapy journals in reporting ethical requirements for PT research. The *Journal of Physical Therapy* was the most detailed out of the six journals reviewed, proposing that articles submitted should include confirmation of IEC/IRB approval and proof that informed consent was conducted during the research trial is concluded. In a study determining ethical effects on research subjects, participants reported continued concern about their involvement in studies.[31] Some of the reasons included worries about their confidentiality, expectations not met, anger, disappointment, and "loss of face" (follow-up). Despite some positive outcomes that were found in the study, the investigators found that ethical issues continue even after a trial. The consideration that follow-up to ensure ethical protection was completed was part of the conclusion that the investigators stated.

Research studies in clinic-based physical therapy continue to be a topic of discussion. Literature reveals that existing evidence on how evidence-based medicine is performed in PT

research settings and adhering to ethics in PT research is limited. Strategies to help break the barriers and challenges of pursuing research in clinic-based PT research continue to be studied.

Specific Aims

The APTA has determined that the major problem with pursuing research in physical therapy clinics is lack of time. They are open for suggestion on how to approach this problem so that future research in physical therapy can be put into clinical.[32] The forward movement of the APTA on bringing evidence-based research into clinical practice can be best understood by how research is organized in the clinic site. Since lack of time is an issue, additional assistance in administrative duties may be the best place to start. Administrative duties in research include essential documentation that reflects GCP. Federally regulated research sites heavily incorporate GCP to clinical trials as a regulatory decree from the FDA. The level of GCP determined from a clinical trial can classify how good the research is. Therefore, a research trial in a physical therapy clinic can try to incorporate the same levels of responsibilities that are included in a federally regulated clinical trial.

Administrative responsibilities in research may be an overlooked duty for the busy physical therapist. Their main duty in the clinic is to serve patient-care. Nearly 25 years ago, Morrissey et al[27] introduced the idea of adding a research coordinator to assist in the management of physical therapy research studies. One of the major responsibilities of this individual would be providing administrative support of the research. Such duties include preparation of annual reports and brief close-out reports, preparing annual written evaluations of research committee members, and assume primary tasks in the research committee. The concept

of a research coordinator was derived in the understanding that an essential prerequisite in developing a clinical research program in physical therapy is administrative support. While the results of the investigation were successful, it was recommended that the idea be brought into the academic setting. This idea in a clinical setting has not been addressed.

This idea of using a research coordinator in managing physical therapy studies correlates with how a clinical research coordinator (CRC) functions during a research trial in a federally regulated clinical trial. A trained CRC from a recognizable organization such as ACRP and/or SoCRA, is capable of understanding how GCP works in clinical trials. If the individual has knowledge of the science of physical therapy, they may be a valuable individual in the clinical physical therapy research setting. Introducing essential documentation may be the first step in implementing GCP. Therefore, this practicum project proposed to test how essential documentation might improve evidence-based research in a physical therapy research setting, with the following specific aims:

Aim #1: To establish good clinical practice (GCP) - the incorporation of Regulatory Binders as a means for practicing essential documentation will be applied to 3 investigator-initiated research studies at Ben Hogan Sports Medicine physical therapy clinic with an established research section.

Aim #2: To determine the effectiveness of Regulatory Binders - will be used and maintained in the Ben Hogan Sports Medicine physical therapy clinic for four months.

Aim #3: To evaluate the quality of research after incorporation of Regulatory Binders - a Checklist of Measures will be applied.

After evaluating how effective essential documentation succeeds in a physical therapy research clinic, a suggestion to the APTA Research Section may suffice. Since the improved quality of the research may induce increased quality of care of patients, this method may be a simple concept considered in evolving how research may be practiced in a physical therapy clinic.

Significance

Good clinical practices (GCP) are not well-understood concepts amongst physical therapy researchers. Henley and Frank[30] found that nearly 29% of published physical therapy research between the years 1996-2001 did not report information on Research Ethics Committee Approval, informed consent, or confidentiality. Nearly two thirds of physical therapy clinical research involves children, yet 55% of articles reviewed had ethical protection.[30] The APTA has established that this is primarily due to the lack of time that the physical therapists face during a trial. Additionally, promoting good clinical practices in a physical therapy clinical research environment is a task with which researchers are not especially familiar.

A trained clinical research coordinator (CRC) with appropriate human subject research education, who understands federal and local regulatory requirements, and is trained in GCP was able to pursue the specific aims of this project. The CRC also has a background in Athletic Training; thus, the student intern conducting this practicum project was ideal for comprehending the research knowledge of physical therapy. The potential barriers and alternative approaches in

this project were the sources specific for implementing a regulatory binder in a physical therapy clinic. There are virtually no resources that address either how a CRC should pursue their job in physical therapy research or how to organize essential documents of research. However, the approach to the aims of the project acquired from sources retrieved from various regulatory agencies such as ACRP, SoCRA, the FDA, and OHRP.

The results of this research study are important for allowing other physical therapy research clinical sites to recognize the magnitude and importance of good quality research evidence. An individual, who specializes in GCP and is knowledgeable on how human research trials should function may be an essential team member in present and future investigations. This study may be a suggestion to the APTA, that the methods used in this research study may increase potential evidence-based research into clinical practice.

The four-month time frame was attainable for this project because it enabled reasonable sustainable use of a CRC. The responsibilities of the CRC were discussed prior to starting the project with the principal investigator. It took the CRC nearly 1 month to create 3 functional regulatory binders. Throughout the project, the CRC also carried out regular research activities delegated by the principal investigator.

Developments of life-long health promotion and disease prevention of aging adults will most likely require to the services of physical therapy to help maintain healthy lifestyles. It is estimated that the world's population of individuals 60 and over will more than triple, from 600 million to 2 billion by the year 2050.[33] In order for the profession of physical therapy to evolve with patient healthcare, they must stay ahead of the game in clinical practice. This strategy of adding a CRC in a physical therapy research team is proof that once quality of research improves, clinical practices are significantly better.

Material and Methods

Initial screening of documents was recorded for each study before the creation of the regulatory binder. This screen was a basic listing of what each study had in terms of essential documents. Afterwards, a Checklist of Measures was generated by incorporating 31 elements from the ICH Guidelines for Good Clinical Practice and methods from Sather et al.[34] These 31 elements are presented in *Table 1*.

Table 1: 31 Elements of Good Clinical Practice

Regulatory Essential Documents (4)
Organized, complete, and availability of all regulatory documents
CV's and certifications are on file and accessible
Protocol and outcome measures are available and current
Normal ranges are up to date and present

Patient Records Essential Documents (7)
Medically significant study events are noted in patient's official medical record (Documentation of enrollment, consent, report of any protocol deviations, and/or if they are complete with the study)
Data report forms are complete and current; where corrections are made appropriately
Data is properly recorded
Patient records are readily available
Patient records are adequate
Measurements and questionnaires are documented and available
Dropouts and reasons are recorded

Patient Consents (5)
Consent forms found in each patient's file
Forms are signed by patient and dated appropriately
Assent forms and parental permission forms are signed and dated appropriately
Currently updated consent forms used
Consent forms written with required elements standardized by IRB

Adherence to Protocol (4)
Meets inclusion/exclusion criteria
Performs study procedures correctly
Approved methods used
Protocols written with required elements standardized by IRB

Institutional Review Board (5)
Approvals granted on all study documents
Documentations of approvals are stored

Continuing review of IRB review obtained IRB stamp is visible Periodic progress reports are submitted to IRB **Site Operations (6)** Appropriate Delegation of Authority Adequate investigator involvement in conducting or supervising clinical trial Investigator Role in consent process present Permitted tasks are listed for each study staff SOPs (Standard Operating Procedures) written and are used Maintenance of staff training records, GCP certifications, and area of research

The Checklist of Measures was applied to two of the on-going research studies at the beginning. The two research studies, which are entitled "The effects of isolated hip strengthening on outcomes following anterior cruciate ligament reconstruction," (ACL Study) and "The relationship between hip and shoulder mobility and injuries at the shoulder and elbow in overhead athletes," (UCL Study) were approved by the Texas Health Resources IRB in 2009, and are long-term investigative projects. The initial screen of documents was used as a guide while implementing the Checklist of Measures. A score was then calculated by dividing the number of completed elements from the total of 31 elements. The overall percentage calculation was retrieved, as well as calculations from each subsection in the Checklist of Measures. Additional comment sections in the Checklist of Measures provided any details that were specific to the scoring. A high score indicates compliance with GCP standards, and a low score decreased compliance. Compliance to GCP standards represents the measure of quality in the research.

Assembly of the regulatory binders for each study occurred after calculating the scores. Paper documents, along with electronic files, were incorporated into the system. The final product was a dual electronic-paper method that referred documents to their original paper or electronic file source. Patient records were an already established system managed by the

principal investigator, therefore maintenance continued. To help with the organization and maintenance of the binders, a Standard of Operation Procedures (SOP) was also written.

The project took four months to complete. After creation of the regulatory binders, research duties were conducted in conjunction with the binders. The regulatory binders were functional to the studies as research activities occurred. The binders were used during: essential document record-keeping, IRB documentation and correspondence recording, maintain updated protocols and informed consent forms, providing blank set copies of data collection sheets, records of protocol deviations and note-to-files, and record of any site visits or audits. After the four month period, the Checklist of Measures was reapplied to the two on-going studies, and to a newly approved study title "Study of anterior cruciate ligament reconstruction rehabilitation outcomes within Texas Health Resources" (ACL Retro Study). After rescoring, the scores obtained after using regulatory binder were then compared from the score obtained prior to regulatory binder use. Analysis of the study involved investigating the differences of before and after using regulatory binders in the three different research studies. The subsections of the Checklist of Measures were also examined to indicate specific changes that took place after using the regulatory binders.

Results and Discussion

This practicum study evaluated the effectiveness of using Regulatory Binders in improving the quality of research and establishing good clinical practice at a physical therapy clinical site. To accomplish the goals of this study, a Checklist of Measures was used to obtain scores before and after use of Regulatory Binders for 2 clinical trials. The results of the practicum revealed a significant improvement in the score of the Checklist of Measures at the

end of the four-month period. The overall scores for before and after using regulatory binders showed considerable differences (*Figure 1*) in both the ACL and UCL studies. The ACL Study overall scored 45.2% (14 elements/31 elements) before the use of regulatory binders and increased to a 83.8% (26/31) after using the binders during the study. The UCL study scored an overall 51.6% (16/31) and increased to 90.3% (28/31) after implementation of the binders. Scoring for the ACL Retro study pre- binders was not calculated because the study was still undergoing pre-review by the IRB. No elements from the Checklist of Measures were applicable to the ACL Retro study at the time; therefore a score of 0% was given.

The Checklist of Measures has 6 subsections that were analyzed in this study. A total score of 31 signifies the total possible elements that each study can complete. Subsections and their total number of elements are as follows: regulatory essential documentation (4 elements), patient record documentation (7 elements), patient consents (5 elements), adherence to protocol (4 elements), Institutional Review Board (standards of IRB practice) (5 elements), and site operations (6 elements). *Figures 2-6* show differences between the scores of the subsections before and after using regulatory binders.

As shown in *Figure 2,* scoring of the elements prior to the use of regulatory binders are separated accordingly. Regulatory essential documentation for the UCL study scored 50% (2/4 elements), patient records essential documentation at 28.6% (2/7 elements), the process of patient consenting at 60% (3/5 elements), adherence to protocol at 75% (3/4 elements), standard practices of IRB at 80% (4/5 elements), and site operations scoring at 33.3% (2/6 elements). *Figure 3* indicates the scores of the elements after the use of regulatory binders. The scores were as follows: regulatory essential documentation scored 100% (4/4 elements), patient records essential documentation at 100% (7/7 elements), no change of score for the patient consenting

(60% - 3/5 elements), adherence to protocol score of 100% (4/4 elements), no change of score of IRB (80% - 4/5 elements), and site operations complete at 100% (6/6 elements). *Figure 4* represents the separate scoring of the 6 elements prior to the use of regulatory binders. The scores indicates that before the ACL study used regulatory binders, regulatory essential documentation scored 50% (2/4 elements), patient records essential documents at 28.6% (2/7 elements), patient consents at 20% (1/5 elements), adhering to protocol at 75% (3/4 elements), standard practices of IRB at 80% (4/5 elements), and site operations scoring 33.3% (2/6 elements). After using regulatory binders, the ACL study indicated the following scores in the each of the subsections: regulatory essential documentation at 100% (4/4 elements), patient records essential documentation 85.7% (6/7 elements), patient consenting at 60% (3/5 elements), adherence to protocol at 75% (3/5 elements), practices of IRB at 80% (4/5 elements), site operations scored at 100% (6/6 elements). For all three of the studies, regulatory essential documentation measured at a remarkable 100%, which is a score of 4/4 elements, after the use of the regulatory binders. There was also a 66.7% increase in site operations for both of the studies.

Patient records documentation was also found to have a significant increase in scores after using the regulatory binders. Both the ACL and UCL study had a score of 28.6% (2/7), but the scores increased to 85.7% and 100%, respectively. Patient consenting in the ACL study scored 20%, compared to 60% in the UCL study. However, the ACL Study patient consenting increased by 40%, compared to no change of score in the UCL study. The adherence to the protocol score increased by 25% in the UCL Study, but remained the same in the ACL study. Both studies did not have a difference in scores for the subsection Institutional Review Board.

Regulatory binders led to the improvement in the organization of the essential documentation in all three studies. There was significant improvement in regulatory

documentation, patient records documentation, and site operations. This is likely due to the requirements of systemization in regulatory binders. Both paper and electronic documentation were incorporated in the regulatory binders. What was mainly lacking in the regulatory essential documentation prior to using the regulatory binder was strictly organization, completion, and availability of regulatory documents. Patient consenting scores after using regulatory binders was 60% in both studies. This score was met after analysis of all patient consent forms in each patient study file. After an analysis of patient study files, both studies neglected to have appropriate patient, parental, and assent signatures and date. The IRB score remained the same because there were minimal changes to documentation. The availability and accessibility of the electronic IRB (eIRB) allowed for this. The principal investigator was also guided by the eIRB to understand requirements that needed to be fulfilled (e.g., forms, deadlines, etc.), and all correspondences to the IRB coordinator is automatically kept track in the eIRB.

Unfortunately, the score from the ACL Retro Study revealed a lower score than the ACL and UCL studies. This is because of the inability to fulfill 17 elements during the time period of this project. The study did not receive IRB approval until October; therefore, some elements (such as patient records documentation, patient consenting, adherence to protocol, Institutional Review Board (IRB approval), and site operations) could not be appropriately graded into the scoring system. The score of 45.2% (14/31), in actuality, is a score prior to full application of a regulatory binder. Even if this score is a measure of what elements existed after applying a regulatory binder, it does not prove significance because the regulatory binder made was not functional prior to the start of the actual study.

The uses of regulatory binders in these three studies show that there is an increase in quality of the research projects. Since the elements of the Checklist of Measures were derived for

ICH's *Guideline for Good Clinical Practice*, the elements were a reflective score of GCP. This guideline for GCP signifies the set of standards that reflects the quality of a human subject research study. Using regulatory binders reveals good documentation practice. When documentation is practiced, research management at the site is improved. This may explain why there was a significant similarity increase in regulatory and patient record documentation with site operations.

In the future, the Checklist of Measures can also be as a guide for quality assurance and improvement in physical therapy human subject research. Quality assurance in research trials promotes GCP.The strategy to do this is conducting local audits within a clinical trial. The method of how the Checklist of Measures was applied in this research can be compared to how a local audit can be implemented in a trial. This may be especially beneficial in physical therapy human subject trials because quality improvement in a research study may lead to better evidence-based research.

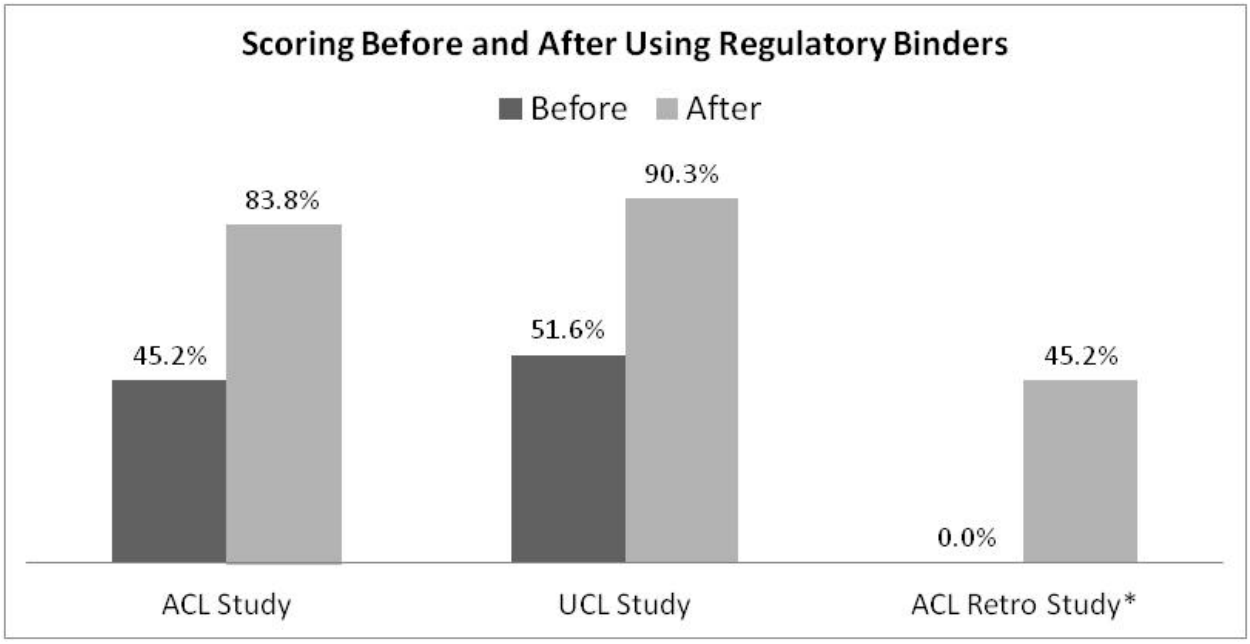

Figure 1: Overall score between before and after using the regulatory binders. *Scoring of the ACL Retro study was not applicable before using regulatory binders because study was not IRB approved. The score of 45.2% signifies only to applicable elements graded after IRB approval. Study activities did not officially begin until after grading period. 17 elements were not graded.

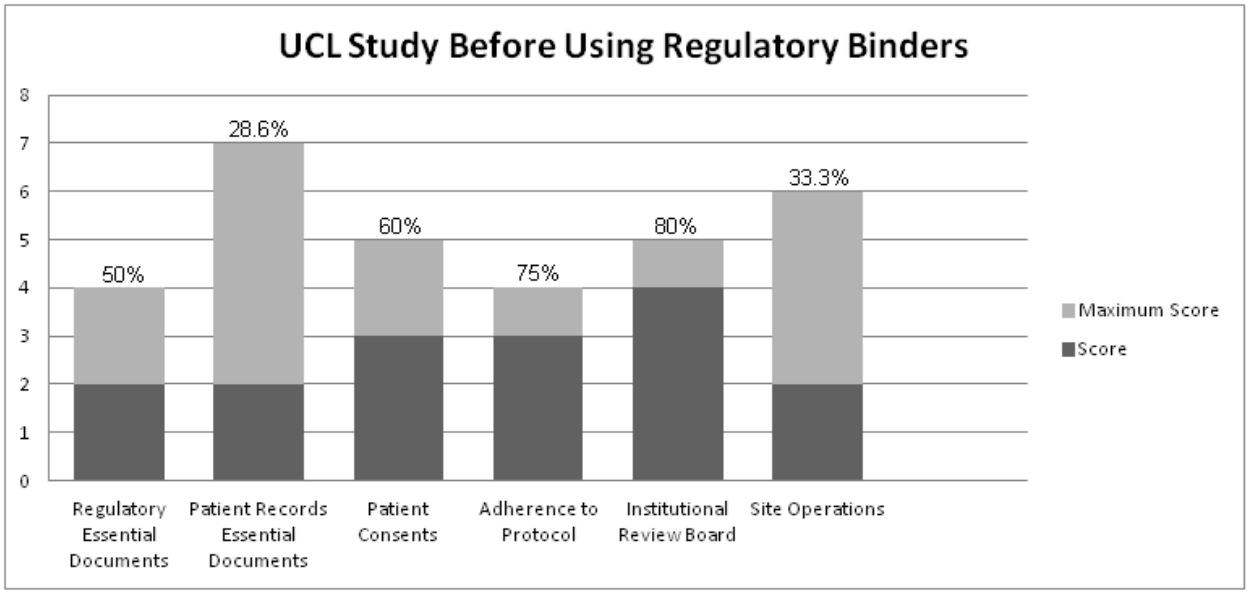

Figure 2: Subsection scoring in Checklist of Measures of UCL study before use of regulatory binders.

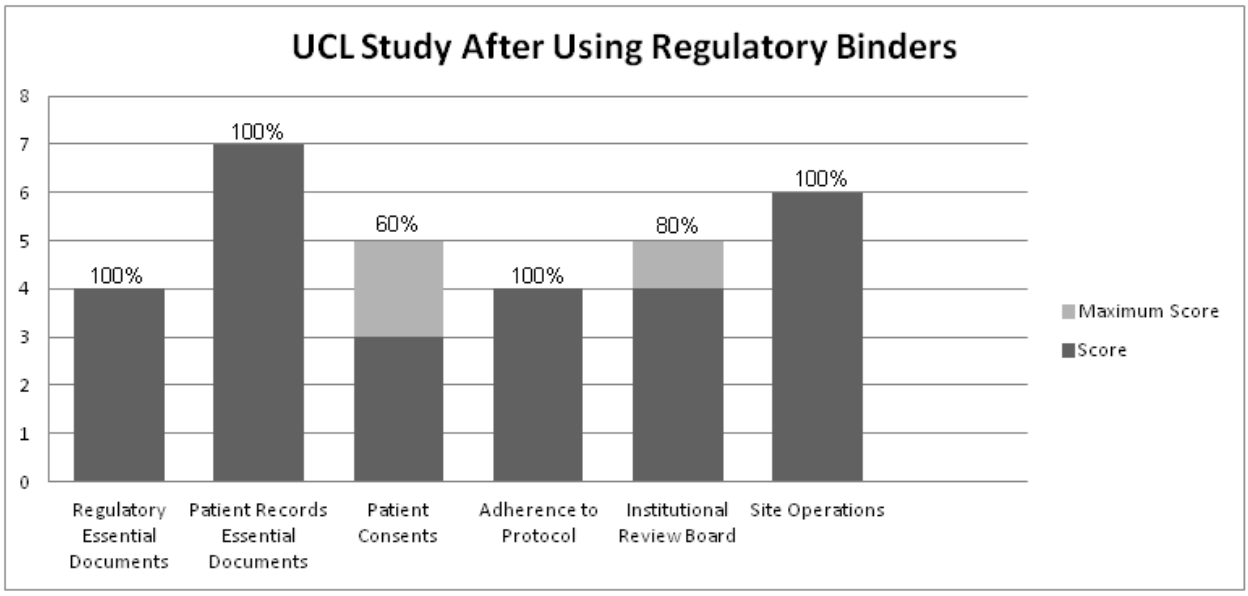

Figure 3: Subsection scoring in Checklist of Measures of UCL study after use of regulatory binders.

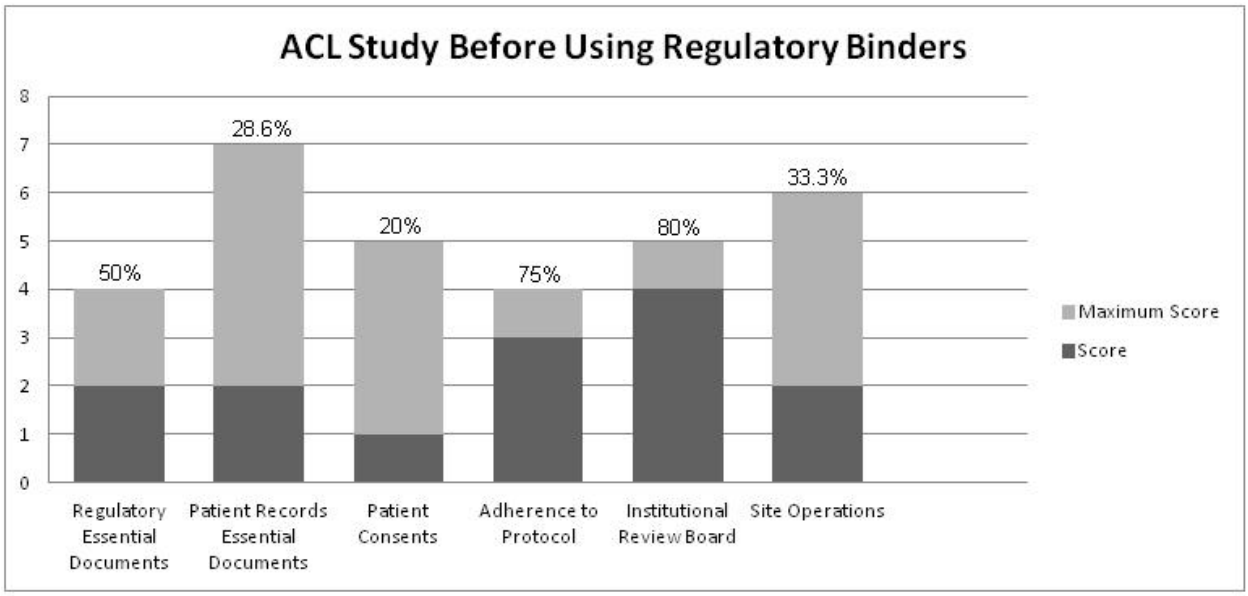

Figure 4: Subsection scoring in Checklist of Measures of ACL study before use of regulatory binders.

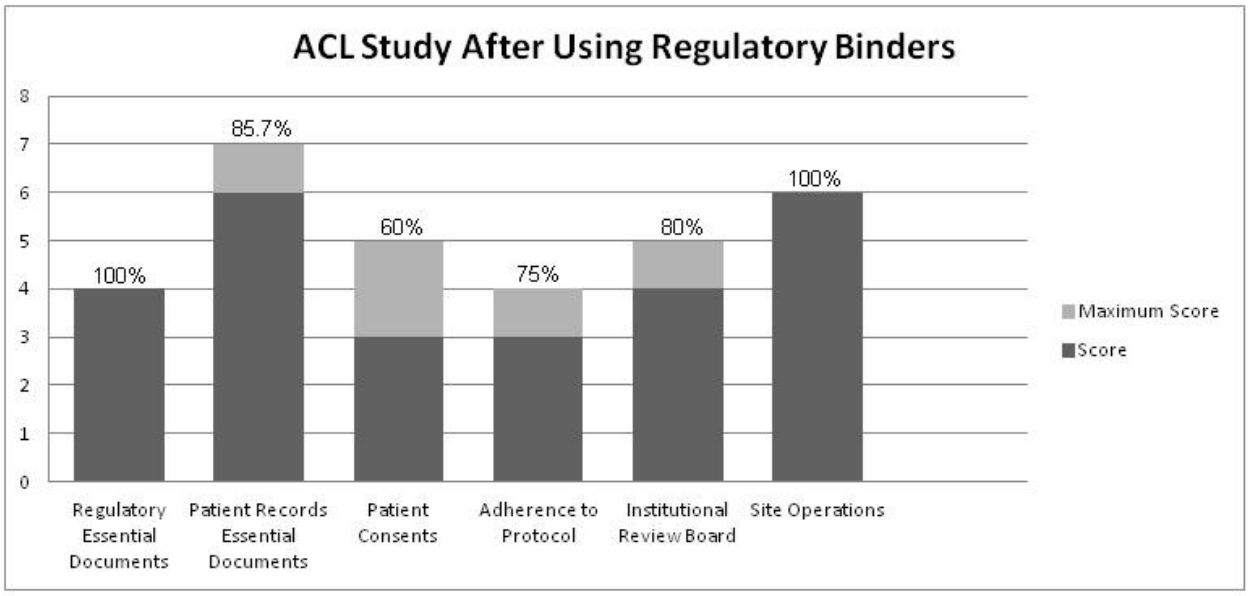

Figure 5: Subsection scoring in Checklist of Measures of ACL study after use of regulatory binders.

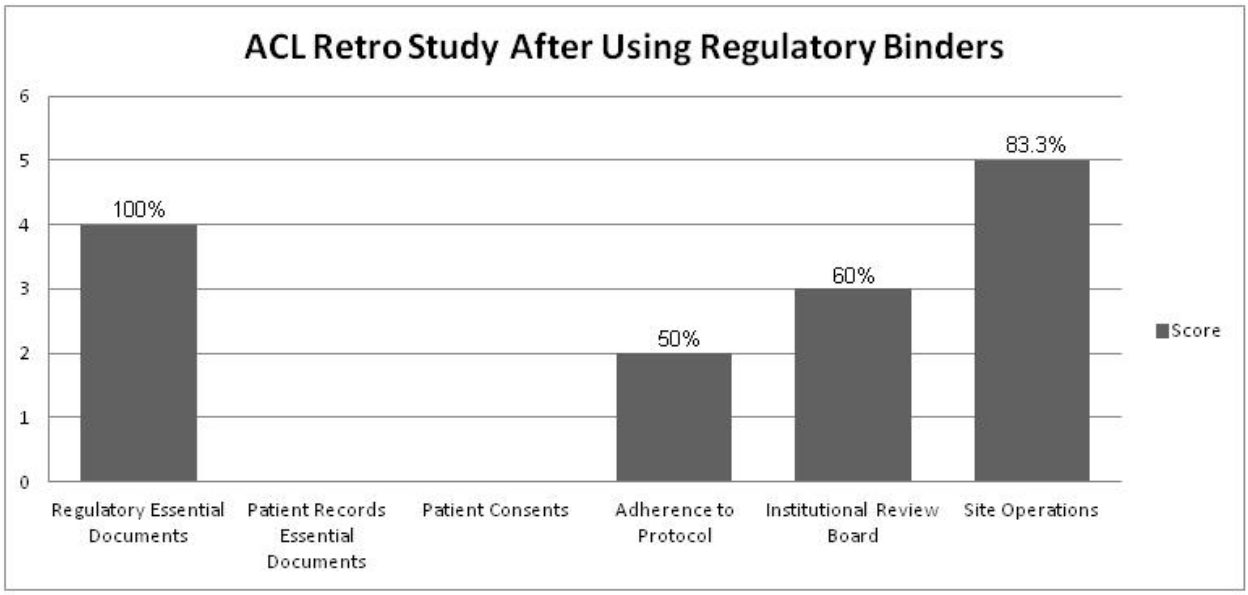

Figure 6: Subsection scoring in Checklist of Measures of ACL Retro study after use of regulatory binders. *Scoring was not applicable before using regulatory binders because study was not IRB approved. The scores are reflective only for elements that were applicable for grading. Study activities did not officially begin until after grading period. 17 elements were not graded.

Summary and Conclusions

The World Health Organization estimates that the world's population of individuals 60 and over will be 2 billion by the year 2050.[33] Most of these aging adults will require the services of PT to maintain healthier lifestyles. This predicted trend might reflect physical therapists as new leaders in healthcare. Better healthcare require the current and best evidence-based medicines. As a growing profession, the field of PT must also expand research efforts to help bring evidence into practice. Without better research practices in PT, the goal of increasing evidence-based practice can be inevitably difficult to reach. This goal can be reached by reducing the barriers in conducting PT research and increasing awareness of ethical protection. There should be efforts to create uniform policy in reporting ethical protections and most importantly, monitoring these protections.

Acknowledging plans to help monitor PT human subject research trials and creating opportunities in educating and training PT researchers of good clinical practice standards are strategies emphasized in this dissertation. Recruiting individuals with expertise in the field of research management may be essential in helping with the lack of time physical therapists face. Using regulatory binders to organize essential documents similarly to how federally regulated clinical trials use them, and conducting audits throughout the research trial may help increase research compliance. Increased compliance, with evidence that research trials have maintained ethical protections, means good quality peer-reviewable research. Avoiding historical ethical mishaps and guiding PT research in the right direction are beneficial to improvement. Most importantly, what can be determined in the next few years of promising research for physical therapy could be that: physical therapists as new leaders in the research industry.

CHAPTER 3:

Internship Site and Experience

The Texas Health Ben Hogan Sports Medicine center is located at 800 5th Avenue, #150 Fort Worth, TX 76104 and is affiliated with Texas Health Resources. The center consists of a team of professionals, including orthopedic physicians, physical therapists, athletic trainers, and licensed massage therapists, that are trained in techniques specific for the recovery of the active-lifestyle patient. Examples of rehabilitation include: injury treatment and rehabilitation, return-to-sport after injury, and sport-specific training. The Ben Hogan Sports Medicine team is experienced in the treatment of injuries from various sports including soccer, basketball, football, baseball, softball, golf, volleyball, gymnastics, swimming, hockey, skiing, and tennis.

The center offers post-professional residency programs in athletic training and sports physical therapy in addition to an established research agenda in sports medicine. The programs are directed and supervised by Craig Garrison, PhD, PT, ATC, SCS. The programs aid in the preparation for future sports therapists and athletic trainers practicing in the field of sports medicine. The direction of implementing evidence-based research into clinical practice is one of the major marks in the research agenda of the APTA. Therefore, residents also are guided on how to integrate research into daily clinical practice in the sports therapy setting. Residents are given the opportunity to participate in their own research studies as well as assist with the current research studies guided by Craig Garrison, who is the principal investigator. Current research studies include 1) the effects of hip strengthening on rehabilitation outcomes after anterior cruciate ligament (ACL) reconstruction, 2) factors that determine return to sports after ACL reconstruction, 3) the relationship between hip and shoulder mobility and injuries at the shoulder

and elbow in overhead athletes, and 4) retrospective analysis of ACL reconstruction rehabilitation outcomes within Texas Health Resources.

A high volume of patients are seen, and many are potential study subjects. The principal investigator is responsible for all key activities for the research trials. He allocates certain duties to physical therapy and athletic training residents. Because I was a clinical research coordinator pursuing an internship, Dr. Garrison assigned responsibilities for me that are specific for the management of clinical trials. Responsibilities included maintenance of essential documents, recruitment of potential subjects, screening and enrollment of subjects, participation in the informed consent and child assenting process, communicating with the IRB, assisting in writing protocols and other study documents, data collection, and data monitoring and verification. These privileges allowed me to actively be part of the research team, while learning a great deal of experience in clinical research management.

One particular duty that was assigned to me was meeting with the auditor. The principal investigator and study staff were unfamiliar with the tasks that would take place during an audit. Fortunately, I was able to acquire sources from additional mentors at the site as well as use my knowledge to go through the audit. During the audit, I helped by providing the newly created Regulatory Binders, and guiding the auditor locate where research documents were. The results of the audit revealed that research Ben Hogan Sports Medicine needed additional assistance from an individual who would be responsible for duties as a CRC.

Another remarkable experience I had at this site included assisting another principle investigator pursue IRB approval for their study. The study was under a 3 year pre-review period and was provided a grant from the Texas Research Education Institute. Since the principle investigator lacked time in pursuing requirements by the IRB, I took the role in communicating

and editing the application for the study. Before the approval of the study, I also created a Regulatory Binder ahead of time.

The Texas Health Ben Hogan Sports Medicine center was an ideal site for pursuing a clinical research management internship. Every person on staff provided professional assistance and supported my internship until the end. Craig Garrison was an outstanding mentor, providing me countless opportunities to pursue a successful internship.

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Appendix A: Checklist of Measures

Checklist of Measures

Protocol: The Effects of Isolated Hip Strengthening on Outcomes following anterior cruciate ligament reconstruction

Investigator: Craig Garrison, PhD, PT, ATC, SCS

Sub-Investigator: N/A

Research Assistants: N/A

Regulatory Essential Documents (4)

Y N N/A Organized, complete, and availability of all regulatory documents

Y N N/A CV's and certifications are on file and accessible

Y N N/A Protocol and outcome measures are available and current

Y N N/A Normal ranges are up to date and present

COMMENTS: Regulatory documents are stored in the eIRB with updated and previous versions of study documents available with log-in. In addition, study documents are on the shared drive, under the PI's folder. Certifications of investigators are in the clinic, either hung-up in the clinic's patient area, placed in the eIRB, or present within each study staff's personal file. The presence of normal ranges for data collection and outcome measures are not accessible to study staff, however the PI is aware of what they are, what publication they are derived from, and the location of these values.

Patient Records Essential Documents (7)

Y N N/A Medically significant study events are noted in patient's official medical record (Documentation of enrollment, consent, report of any protocol deviations, and/or if they are complete with the study)

Y N N/A Data report forms are complete and current; where corrections are made appropriately

Y N N/A Data is properly recorded

Y N N/A Patient records are readily available

Y N N/A Patient records are adequate

Y N N/A Measurements and questionnaires are documented and available

Y N N/A Dropouts and reasons are recorded

COMMENTS: There is a record of incomplete documentation in patient files. Medical records show minimal documentation of study participation. Data report forms, or case report forms, are completed by the PI, however are not in all patient files. Case report forms are re-written into an electronic file database, and originals are stored in either the patient's medical record or study file. Patient study files are available, but disorganized in a manner of incomplete numbering of subjects, incomplete documentation, and names present on each study file. Presence of a master log is missing, however the database that is used, maintains record of subject data and is maintained and used also as a "tracker" to aid the PI. The subject identifier of subjects are not mentioned in the ACL database. Rather the medical record number is used. A separate subject identifier is used when written on the study file folders. There are errors in labeling of subject identifiers to subjects including 2 mis-counts, 1 repeat, and 1 subject with no record of being in the ACL Subject List. Dropouts and reasons for dropouts are no where

recorded. Records of outcome measure scores (IKDCs) and questionnaires are accessible on the shared drive. In addition, case report forms are also used as a replacement with the source document, which creates some inconsistency. The database is also inconsistent with the hard data.

Patient Consents (5)

Y N N/A Consent forms found in each patient's file

Y N N/A Forms are signed by patient and dated appropriately

Y N N/A Assent forms and parental permission forms are signed and dated appropriately

Y N N/A Currently updated consent forms used

Y N N/A Consent forms written with required elements standardized by IRB

COMMENTS: Consent forms are not found in all patient files. Some consent and assent forms are incompletely filled by presence of no signatures, wrong dates of signing certain forms, and wrong date of births. There is the record of 3 subjects not consented into the study. The most updated consent forms were used with required elements standardized by Texas Health Resources IRB, however the time stamp was not correct and had to be updated. There were a few informed consent forms that were used with the wrong time stamp.

Adherence to Protocol (4)

Y N N/A Meets inclusion/exclusion criteria

Y N N/A Performs study procedures correctly

Y N N/A Approved methods used

Y N N/A Protocols written with required elements standardized by IRB

COMMENTS: Methods in protocols are approved and up to date. Patient's that are screened into the study meet inclusion/exclusion criteria. Research staff performs study procedures correctly as per approval by the IRB. One aspect of grouping of subjects in the protocol is not correctly implemented. The protocol states that there are two groups being tested in the study, however, the third group (the "return-to-sport" group) is not accurately stated. The collected data presents a large portion of RTS subjects that underwent approved protocol methods.

Institutional Review Board (5)

Y N N/A Approvals granted on all study documents

Y N N/A Documentations of approvals are stored

Y N N/A Continuing review of IRB review obtained

Y N N/A IRB stamp is visible

Y N N/A Periodic progress reports are submitted to IRB

COMMENTS: No records of periodic progress reports are submitted to the IRB. All documents for study are approved and stamped. Approval letters are present, along with present in the eIRB. IRB correspondences are kept within email inbox.

Site Operations (6)

Y N N/A Appropriate Delegation of Authority

Y N N/A Adequate investigator involvement in conducting or supervising clinical trial

Y N N/A Investigator Role in consent process present

Y N N/A Permitted tasks are listed for each study staff

Y N N/A SOPs (Standard Operating Procedures) written and are used

Y N N/A Maintenance of staff training records, GCP certifications, and area of research specialty

COMMENTS: The study does have a delegation of authority that is monitored by the PI. The PI is involved in conducting and supervising the clinical trial by participating in the consent process, data management, and analysis. However, delegation of authority and assigned tasks for additional research staff are not documented and human subject research training nor conflict of interest forms have not been completed for study staff involved in research. There is also no presence of an SOP for conducting the clinical trial or maintaining site operations. Staff education training records and certifications are submitted to the IRB, but are not documented or filed in the site.

FINAL SCORE: 14/31 = 45.2% **DATE SCORED: July 20, 2012**

Checklist of Measures

Protocol: The Effects of Isolated Hip Strengthening on Outcomes following anterior cruciate ligament reconstruction

Investigator: Craig Garrison, PhD, PT, ATC, SCS

Sub-Investigator: N/A

Research Assistants: Racella de Guzman (Research Coordinator), Gina Wolf (Athletic Training Resident), Matthew Pennucci (Athletic Training Resident), Joseph Hannon (Physical Therapy Resident

Regulatory Essential Documents

Y N N/A Organized, complete, and availability of all regulatory documents

Y N N/A CV's and certifications are on file and accessible

Y N N/A Protocol and outcome measures are available and current

Y N N/A Normal ranges are up to date and present

COMMENTS:The eIRB is still the original storing house for all updated and previous version of study documents, however paper versions of protocol, informed consents, and research authorization forms are also kept organized in the Regulatory Binder. All CV's and certifications are in a Study Team binder that is easily accessible and maintainable. Blank copies of outcome measures (IKDC, SportCord test, and data collection sheet) are accessible to study staff for immediate access. Normal ranges are updated by the PI by keeping up with the publications they are derived from.

Patient Records Essential Documents

Y N N/A Medically significant study events are noted in patient's official medical record (Documentation of enrollment, consent, report of any protocol deviations, and/or if they are complete with the study)

Y N N/A Data report forms are complete and current; where corrections are made appropriately

Y N N/A Data is properly recorded

Y N N/A Patient records are readily available

Y N N/A Patient records are adequate

Y N N/A Measurements and questionnaires are documented and available

Y N N/A Dropouts and reasons are recorded

COMMENTS: Patient study files are maintained by a Study Event Tracking form to minimize the occurrence of missed study activities and/or study documents. Medical records do not show documentation of study participation; however the hospital does not require out-patient clinics to bill research subjects. Case report forms continue to be a not well understood concept, however emphasis on documentation with data collection has been improved. There is still some confusion on source documentation and case report forms. They are not well-defined in this study. The result is a decreased adequacy in clear data maintenance. Patient study files are organized by subject numbers with no direct identifiers. A Master List was created to aid in tracking the enrollment date, medical record number, and contact information of the study. It was recommended that the Master List be fused with the electronic database of the ACL subjects in the future. Dropouts and reasons for subjects no longer participating in the study have been documented. Since data management has not been clearly maintained during the trial, the PI continues to be the only person with knowledge of how the data is interpreted. Some suggestions were made towards data collection and management in the future.

Patient Consents

Y N N/A Consent forms found in each patient's file

Y N N/A Forms are signed by patient and dated appropriately

Y N N/A Assent forms and parental permission forms are signed and dated appropriately

Y N N/A Currently updated consent forms used

Y N N/A Consent forms written with required elements standardized by IRB

COMMENTS: Minor deviations to patient consents were documented to prevent the occurrence in the future. Three Note-to-Files were created for subjects who were not originally consented into the study, but re-consented. During a site visit audit, it was found that the currently updated consent forms were not being used. Action was immediately taken and the stamp on the consent forms was fixed accordingly. The consent forms that had a wrong stamp was noted as a deviation.

Adherence to Protocol

Y N N/A Meets inclusion/exclusion criteria

Y N N/A Performs study procedures correctly

Y N N/A Approved methods used

Y N N/A Protocols written with required elements standardized by IRB

COMMENTS: There continues to be an uncertainty on how study procedures are conducted during the research trial. While all methods in the protocol were done correctly, the timeline of events were not clear. There is a large group of subjects labeled as "return-to-sport," who are not performing the study tasks mentioned in the protocol. Rather, only subjects who are labeled as "group 1," or "group 2" are. The suggestion made to this was that protocol specifies the activities of the "return-to-sport" group versus the other.

Institutional Review Board

Y N N/A Approvals granted on all study documents

Y N N/A Documentations of approvals are stored

Y N N/A Continuing review of IRB review obtained

Y N N/A IRB stamp is visible

Y N N/A Periodic progress reports are submitted to IRB

COMMENTS: All IRB related documents are stored conveniently in the Regulatory Binder and the eIRB. No record of period progress reports are submitted to the IRB. Continuing review periods are the time when periodic progress is submitted, however the IRB has become unaware of protocol deviations that have been illustrated by the auditor.

Site Operations

Y N N/A Appropriate Delegation of Authority

Y N N/A Adequate investigator involvement in conducting or supervising clinical trial

Y N N/A Investigator Role in consent process present

Y N N/A Permitted tasks are listed for each study staff

Y N N/A SOPs (Standard Operating Procedures) written and are used

Y N N/A Maintenance of staff training records, GCP certifications, and area of research specialty

COMMENTS: A standard Delegation of Authority log is now placed in the Study Team Binder with description of assigned tasks for each additional research staff. The Study Team Binder also keeps track of all study staff CVs, research education training, certifications and licenses, and conflict of interests. An SOP was created to aid in the appropriate conduct of the clinical trial and maintenances of the binders.

FINAL SCORE: 26/31 = 83.8% **DATE SCORED: October 17, 2012**

Checklist of Measures

Protocol: The relationship between hip and shoulder mobility and injuries at the shoulder and elbow in overhead athletes

Investigator: Craig Garrison, PhD, PT, ATC, SCS

Sub-Investigator:

Research Assistants: N/A

Regulatory Essential Documents (4)

Y N N/A Organized, complete, and availability of all regulatory documents

Y N N/A CV's and certifications are on file and accessible

Y N N/A Protocol and outcome measures are available and current

Y N N/A Normal ranges are up to date and present

COMMENTS: Regulatory documents are stored in the eIRB with updated and previous versions of study documents available with log-in. In addition, study documents are on the shared drive, under the PI's folder. Certifications of investigators are in the clinic, either hung-up in the clinic's patient area, placed in the eIRB, or present within each study staff's personal file. Outcome measures and data measurement sheets are available in the clinic, and easily accessible to all staff. The presence of normal ranges for data collection are not accessible to study staff, however the PI is aware of what they are, what publication they are derived from, and the location of these values.

Patient Records Essential Documents (7)

Y N N/A Medically significant study events are noted in patient's official medical record (Documentation of enrollment, consent, report of any protocol deviations, and/or if they are complete with the study)

Y N N/A Data report forms are complete and current; where corrections are made appropriately

Y N N/A Data is properly recorded

Y N N/A Patient records are readily available

Y N N/A Patient records are adequate

Y N N/A Measurements and questionnaires are documented and available

Y N N/A Dropouts and reasons are recorded

COMMENTS: Patient medical records do not show documentation of enrollment, consent, report of any protocol deviations, and/or if they are presently or complete with the study. Data report forms are completed and maintained by the PI, then are re-written into an excel file (where data of all subjects are stored). The originals are stored in the patient's study file, and a copy is made to be stored in the medical file. The study files are organized so that all subjects are in a filing cabinet in the PI's office. The subject identifier and name of the subject are present on each folder. A master log is incorporated in the excel file where data is gathered, but the numbers of the subject do not correlate with the subject identifier. In addition, no controls are mentioned in the excel file/data sheet. There are no records of any dropouts and reasons except evidence in the excel file where data is missing.

Patient Consents (5)

Y N N/A Consent forms found in each patient's file

Y N N/A Forms are signed by patient and dated appropriately

Y N N/A Assent forms and parental permission forms are signed and dated appropriately

Y N N/A Currently updated consent forms used

Y N N/A Consent forms written with required elements standardized by IRB

COMMENTS: There are consent forms present in each patient file, but 11 consent forms has no PI signatures, 1 has no adult consent signature, 1 has no child assent signature, and 1 has no parent permission signature. There is 1 repeat where the subject is used as a control, but also listed in another group. The appropriate consent forms were used in following approval periods. The consent forms are appropriately written in accordance with standards of the IRB.

Adherence to Protocol (4)

Y N N/A Meets inclusion/exclusion criteria

Y N N/A Performs study procedures correctly

Y N N/A Approved methods used

Y N N/A Protocols written with required elements standardized by IRB

COMMENTS: The protocol is followed accordingly, with minimal changes/amendments. However, there are a few deviations present in the study that does require an additional amendment to reflect an accurate protocol. When patients are screened into the study, the doctor is usually does a pre-screen while referring them to the PI. Once the patient arrives into clinic, the PI does an official screen before consenting them into the study. This official screen is not

documented, but is followed as correctly stated in protocol. There are no other conflicts with the adherence to protocol.

Institutional Review Board (5)

Y N N/A Approvals granted on all study documents

Y N N/A Documentations of approvals are stored

Y N N/A Continuing review of IRB review obtained

Y N N/A IRB stamp is visible

Y N N/A Periodic progress reports are submitted to IRB

COMMENTS: There are no submissions of periodic progress reports. All documents for the study have approval and stamps. Approval letters, applications of initial study submission, amendments, and continuing reviews, are present in the eIRB, but not in paper documentation.

Site Operations (6)

Y N N/A Appropriate Delegation of Authority

Y N N/A Adequate investigator involvement in conducting or supervising clinical trial

Y N N/A Investigator Role in consent process present

Y N N/A Permitted tasks are listed for each study staff

Y N N/A SOPs (Standard Operating Procedures) written and are used

Y N N/A Maintenance of staff training records, GCP certifications, and area of research specialty

COMMENTS: The study is maintained similarly to the other research studies. There is a delegation of authority, but is not document, only monitored by the PI. The PI is involved in

conducting and supervising the clinical trial by participating in the consent process, data management, and analysis. Human subject research training and conflict of interest forms have not been completed for study staff involved in research. There is also no presence of an SOP for conducting the clinical trial or maintaining site operations. Staff education training records and certifications are submitted to the IRB, but are not documented or filed in the site.

FINAL SCORE: 16/31 = 51.6% **DATE SCORED: July 23, 2012**

Checklist of Measures

Protocol: The relationship between hip and shoulder mobility and injuries at the shoulder and elbow in overhead athletes

Investigator: Craig Garrison, PhD, PT, ATC, SCS

Sub-Investigator: John Conway, MD; Mike Macko, PT

Research Assistants: Racella de Guzman, BS (Research Coordinator), Gina Wolf, BS (Athletic Training Resident), Matthew Pennucci, MS (Athletic Training Resident), Joseph Hannon, PT (Physical Therapy Resident)

Regulatory Essential Documents

Y N Organized, complete, and availability of all regulatory documents

Y N CV's and certifications are on file and accessible

Y N Protocol and outcome measures are available and current

Y N Normal ranges are up to date and present

COMMENTS: All updated and previous regulatory documents are maintained in paper version, stored in the Regulatory Binder, and electronic version, stored in the eIRB. CV's and certifications, along with all other required research education requirements, and conflict of interests are stored in the Study Team binder. Blank copies of outcome measures (UCL data measurement sheet, all questionnaires) are easily accessible to all study staff. The presence of normal ranges are not accessible, however the PI is aware of the publications that they are derived from. The study team asks of the PI's assistance for normal ranges.

Patient Records Essential Documents

Y N Medically significant study events are noted in patient's official medical record (Documentation of enrollment, consent, report of any protocol deviations, and/or if they are complete with the study)

Y N Data report forms are complete and current; where corrections are made appropriately

Y N Data is properly recorded

Y N Patient records are readily available

Y N Patient records are adequate

Y N Measurements and questionnaires are documented and available

Y N Dropouts and reasons are recorded

COMMENTS: Patient study files are organized by subject number and correspond with the Master List. Patient medical records do not shot documentation of enrollment into study, however the hospital does not require this in out-patient clinics. Data report forms (UCL data sheets), questionnaires, and other study documents are completed kept in the study files. Data collection is organized in an excel file that interpreted easily for the three groups involved in the

study: the surgical group, the conservative, and the controls. Data and other study events are documented in the Study Events Tracking Form.

Patient Consents

Y N Consent forms found in each patient's file

Y N Forms are signed by patient and dated appropriately

Y N Assent forms and parental permission forms are signed and dated appropriately

Y N Currently updated consent forms used

Y N Consent forms written with required elements standardized by IRB

COMMENTS: There continues to be 11 consent forms that are not signed by the PI, 1 adult consent with no subject signature, 1 with no child assent signature, and 1 with no parental permission signature. These have been recognized, but a plan of action has not been taken. The appropriate consents forms were used in the corresponding approval periods, and the consent forms are appropriately written according to standards of the IRB. The process of informed consent is documented as well.

Adherence to Protocol

Y N Meets inclusion/exclusion criteria

Y N Performs study procedures correctly

Y N Approved methods used

Y N Protocols written with required elements standardized by IRB

COMMENTS: An amendment was created recently to reflect the most accurate procedures in the protocol. Documentation of protocol deviations revealed numerous minor deviations. The

amendment allowed for a decrease number of deviations to occur afterwards. In addition, the Study Events Tracking form documents the inclusion/exclusion criteria, and the study procedures during each follow-up visit.

Institutional Review Board

Y N Approvals granted on all study documents

Y N Documentations of approvals are stored

Y N Continuing review of IRB review obtained

Y N IRB stamp is visible

Y N Periodic progress reports are submitted to IRB

COMMENTS: Submissions of period progress reports are not performed, however a continuing review reflects the progress of the study. Minor protocol deviations have not been reported. Suggestions were given on relaying the deviations during a site visit audit instead. All documentation of IRB correspondences, along with all IRB related documents, are kept in the Regulatory Binder as well as the eIRB.

Site Operations

Y N Appropriate Delegation of Authority

Y N Adequate investigator involvement in conducting or supervising clinical trial

Y N Investigator Role in consent process present

Y N Permitted tasks are listed for each study staff

Y N SOPs (Standard Operating Procedures) written and are used

Y N Maintenance of staff training records, GCP certifications, and area of research specialty

COMMENTS: A Delegation of Authority log has been placed in the Study Team Binder. There is descriptions of responsibilities for each research staff member. Adequate investigator involvement included supervision of duties and conducting responsibilities as principal investigator. An SOP was created and the ability to maintain staff records is able due to this document.

FINAL SCORE: 28/31 = 90.3% **DATE SCORED: October 17, 2012**

Checklist of Measures

Protocol: Study of Anterior Cruciate Ligament Reconstruction Rehabilitation Outcomes within Texas Health Resources

Investigator: Mike Macko, PT

Sub-Investigator: Craig Garrison, PT

Research Assistants: Racella de Guzman (Research Coordinator)

Regulatory Essential Documents (4)

Y N N/A Organized, complete, and availability of all regulatory documents

Y N N/A CV's and certifications are on file and accessible

Y N N/A Protocol and outcome measures are available and current

Y N N/A Normal ranges are up to date and present

COMMENTS: The regulatory binder contains paper versions of documents from the eIRB. The approved protocol and study documents are stamped and placed in an organized fashion in the

binder. PI is aware of publications that reflect the normal ranges of the IKDC questionnaire. The study team binder holds the staff's CV's and certifications.

Patient Records Essential Documents (7)

Y N N/A Medically significant study events are noted in patient's official medical record (Documentation of enrollment, consent, report of any protocol deviations, and/or if they are complete with the study)

Y N N/A Data report forms are complete and current; where corrections are made appropriately

Y N N/A Data is properly recorded

Y N N/A Patient records are readily available

Y N N/A Patient records are adequate

Y N N/A Measurements and questionnaires are documented and available

Y N N/A Dropouts and reasons are recorded

COMMENTS: The study has not started because of final pending of grant/contract approval. There has been no patient records developed yet because no enrollment of subjects have occurred.

Patient Consents (5)

Y N N/A Consent forms found in each patient's file

Y N N/A Forms are signed by patient and dated appropriately

Y N N/A Assent forms and parental permission forms are signed and dated appropriately

Y N N/A Currently updated consent forms used

Y N N/A Consent forms written with required elements standardized by IRB

COMMENTS: The study has not started consent process since it is in final pending approval. The study does not use consent forms, but requires verbal consent and research authorization from each subject.

Adherence to Protocol (4)

Y N N/A Meets inclusion/exclusion criteria

Y N N/A Performs study procedures correctly

Y N N/A Approved methods used

Y N N/A Protocols written with required elements standardized by IRB

COMMENTS: Since the study has not started, the inclusion/exclusion criteria or study procedures has not been put into effect as of yet. The protocol has been written to the standards of the IRB and has been approved. The methods used are also approved by the IRB.

Institutional Review Board (5)

Y N N/A Approvals granted on all study documents

Y N N/A Documentations of approvals are stored

Y N N/A Continuing review of IRB review obtained

Y N N/A IRB stamp is visible

Y N N/A Periodic progress reports are submitted to IRB

COMMENTS: All study documents demonstrate approval. They are stored in the eIRB, but the regulatory binder reflects paper versions with visible stamps as well. No continuing reviews have

been obtained because it has not been a year since start date. No periodic progress reports have been submitted to the IRB.

Site Operations (6)

Y N N/A Appropriate Delegation of Authority

Y N N/A Adequate investigator involvement in conducting or supervising clinical trial

Y N N/A Investigator Role in consent process present

Y N N/A Permitted tasks are listed for each study staff

Y N N/A SOPs (Standard Operating Procedures) written and are used

Y N N/A Maintenance of staff training records, GCP certifications, and area of research specialty

COMMENTS: As far as all operations in getting the study approved by the IRB, the site has managed to successfully devise appropriate delegation of authority and permitted tasks listed, adequate involvement of the investigator in the trial, and maintenance of staff records kept organized in the study team binder. An SOP has been written to enable standardized procedure for organizing the regulatory binder.

FINAL SCORE: 14/31 = 45.2% DATE SCORED: October 18, 2012

Appendix B: Standard Operating Procedures

STANDARD OPERATING PROCEDURES

TITLE: How to Maintain the Regulatory Binder	
EFFECTIVE DATE: November 1, 2012	PAGE: 1 of 3
APPROVED BY: Study Coordinator_____ Investigator_____ Investigator_____	DATE: _____ _____ _____

PURPOSE

The *Regulatory Binder* is available to help maintain regulatory compliance and adhere to high standards of practice in the conduct of research involving human subjects.

SCOPE:

These procedures apply to all individual positions listed below:

- Principal Investigator
- Sub-Investigator(s)
- Research Coordinator
- Physical Therapy Residents participating in research
- Athletic Training Residents participating in research

RESPONSIBILITIES:

- Keep the binder current, up-to-date, and organized for easy use and accessibility
- Store binder in a safe and secure location, but accessible to all study staff
- Refer to Study Team Binder for additional study staff information

PROCEDURES

Procedure	Description	Person(s) Responsible
1.0 Binder Tab Maintenance	Main tabs should be listed accordingly: *Protocol, IRB, Approved Consent Forms, Screening & Enrollment, Data Collection, Protocol Deviations and Note-to-Files,* and *Site Visit Log.* Sub-tabs should be visible within each tab (e.g., different colored paper).	Principal Investigator Sub-Investigator(s) Research Coordinator Physical Therapy Residents participating in research Athletic Training Residents

		participating in research

2.0 Protocol	Documented describing objective(s), design, methodology, statistical considerations, and organization of trial.	Principal Investigator Sub-Investigator(s) Research Coordinator Physical Therapy Residents participating in research Athletic Training Residents participating in research
2.1 Place current IRB approved protocol inside plastic protector 2.2 Remove the previous version from the plastic protector and place in hole-punched binder. 2.2.1 Arrange in descending order from approval date behind plastic protector		

3.0 Institutional Review Board	Initial application of the study Amendments Continuing Reviews Approval letters Correspondences	Principal Investigator Sub-Investigator(s) Research Coordinator Physical Therapy Residents participating in research Athletic Training Residents participating in research
3.1 Print initial application from eIRB 3.1.1 Print changes to application and highlight changes 3.1.2 Arrange in descending order in sub-tab "Study Application" 3.2 Print amendments from eIRB 3.2.1 Highlight amendment number and title 3.2.2 Arrange in descending order in sub-tab "Amendments" 3.3 Print continuing reviews from eIRB 3.3.1 Highlight continuing review number and title 3.3.2 Arrange in descending order in sub-tab "Continuing Reviews" 3.4 Print study approval letters 3.4.1 Arrange in descending order in sub-tab "Outcome Letters/Approvals"		

3.5 Print IRB correspondences 3.5.1 Arrange in descending order in sub-tab "Correspondences"

4.0 Approved Consent Forms	IRB approved and validated with stamp	Principal Investigator Sub-Investigator(s) Research Coordinator Physical Therapy Residents participating in research Athletic Training Residents participating in research
4.1 Place current IRB approved/validation stamped Adult Consent Form inside plastic protector 4.2 Remove the previous version from the plastic protector and place in hole-punched binder. 4.2.1 Arrange in descending order from approval date behind plastic protector 4.3 Repeat 4.1-4.2.1 with Parental Permission form, Child Assent form, and Research Authorization form		

5.0 Data Collection	Data reports and required paperwork	Principal Investigator Sub-Investigator(s) Research Coordinator Physical Therapy Residents participating in research Athletic Training Residents participating in research
5.1 Place blank copy of data collection sheets in plastic protectors		

6.0 Protocol Deviations and Note-to-Files	Collection of Minor, Moderate, or Major protocol deviations Note-to-Files relevant for protocol	Principal Investigator Sub-Investigator(s) Research Coordinator Physical Therapy Residents participating in research

		Athletic Training Residents participating in research
6.1 Current copy of protocol deviations should be maintained in sub-tab "Protocol Deviation Log" 6.1.1 Mention of electronic location of protocol deviation sub-tab "Protocol Deviation Log" 6.2 Note-to-Files should be maintained in the "Note-to-File Log" 6.2.1 Arrange Note-to-Files in descending order.		

7.0 Site Visit Log	Reports of any compliance visits (e.g., audit) and record of correspondences	Principal Investigator Sub-Investigator(s) Research Coordinator Physical Therapy Residents participating in research Athletic Training Residents participating in research
7.1 Reports of site visits from auditor should be stored in sub-tab "Monitoring and Auditing Reports" 7.2 Records of correspondences to and from auditor should be stored in sub-tab "Correspondences"		

Appendix B: Daily Journal

May 21, 2012

First day of Internship
9:30 - 11am: I was introduced to a few of the staff members, mainly the PT tech, some physical therapists that were on duty, and the front desk personnel. Craig was currently working with a patient, but was able to show me around before Jeff, the PT tech took over. Jeff gave me a more detailed tour. He showed me where some important paperwork (such as rehab programs) were kept, information about a few exercise equipment, and where the offices/desks of the therapists and residents were. He also introduced some clinical research studies that he was currently aware of in the clinic. I asked Jeff to explain to me what the SportCord test was and what he knew about the ACL and UCL studies.
11:30 - 12pm:

- Craig sat with me in front of the computers to introduce me to the K: drive, which is the shared drive for all staff
- He explained how to get to the research folder
- Showed me most recent versions of the protocols to the ACL and UCL study
    - Each study involved pediatrics, so he also showed me the child assent form, parental permission form, along with the informed consent and HIPAA
- Upon seeing the documents, he also briefly explained the purpose of the two main studies

1 - 3pm:

- Read and familiarized myself with study protocol for the ACL study and came up with a list of questions to ask Craig
- Met with Craig around 2:40 to ask him my questions
- What I found:
    - I will be involved with the informed consent process as soon as possible and I will be signing my name under the "Research Coordinator" section
    - The way how he recruits subjects for the ACL study is by communication from other therapists and the schedule at the front desk (he noted that he thinks there can be a more efficient way with recruitment)
    - Recruits UCL subjects from Dr. Conway
    - Learned where research data is stored: 1) patient charts, 2) the computer, 3) in a filing cabinet in his desk
    - He feels there can be a more efficient way to organize the K: drive
    - Regarding a COI question I asked: There are a few PTs on staff, plus his residents, that are involved with the research studies. They all participate in pilot studies to eliminate bias of measurement.
    - There is another ACL study that is retrospective that needs to get started. There is a grant on it, and it has basically been on "Hold" for 2 years. He would like me to get started with this.
- Participated in conversing with a few of the staff members today and introduced myself

3:00 - 6:15pm:

- Observed the SportCord test twice and how Craig measured data, calculated data, inputted them into SPSS, and stored them in the appropriate places
- Helped Craig a little on data calculations
- Briefly met Dr. Conway
- Craig dismissed me at 6:15

May 25, 2012

9:30 - arrived to clinic and checked-in with Craig. Headed off to Volunteer Services and spoke to Nan Branch about hospital requirements for interns.
9:45 - 10:30:

- Jeff logged me into computer so I can access research files
- Read and printed out UCL studies that (I think) are the most up to date IRB accepted
- Spoke with Amanda about UCL study and learned that there will be a staff meeting on Wednesday at 12pm

10:30:

- Spoke with Craig about updates to UCL study and how recruitment is done
- Craig walked me to Dr. Conway's clinic to speak with Heather, his nurse
- Discussed with Heather how I can be part of the recruitment process - she will e-mail me, along with Craig, about scheduled UCL subjects on her list
- Retrieved Heather's contact information in case I have further questions. Also met with Billie, her soon-to-be replacement

11:00:

- Sat with Craig as he called Sharon Wolf, his main contact with IRB
- Will need to fulfill requirements with IRB:
- Send copies of paperwork to Adrian

11:20:

- Spoke with Mike Macko, physical therapist on staff who is also involved with research in the clinic
- He has interests in getting the ACL retrospective study (not related to SportCord program study) started
- I will keep in contact with him about scheduling a meeting to discuss his requirements
- Rounded-up all paperwork, scheduling, and emailing for the day and was dismissed at 12pm- Craig was very busy today in clinic and had no time to sit with me to discuss research

June 4, 2012
* Craig Garrison is out-of-office *
1:30-3:00:

- Met with Mike Macko about ACL retrospective study
- Discussed the purpose of the study and the current status
- Asked questions regarding specific aims of the study and what the IRB has already discussed with him
- Agreed that I would assist in protocol editing, contacting with IRB, and helping with data collection
- Data collection will require questionnaire and phone calling

- Study will require getting in contact with past patients and asking them to fill out an outcome form that will assess their activity after rehabilitation from the Ben Hogan center
- Mike called Sharon Wolf to ask particular questions regarding me as an addition to the study staff
- Agreed to begin working on protocol revisions this week and keeping in contact via email (if I am not able to log onto eIRB yet)

June 5, 2012 (at home)

- Read protocol for ACL retrospective study
- Registered for eIRB
- Completed CITI (Biomedical) Training
- Turned-in all needed paperwork to Adrienne

June 8, 2012 (clinic)

- Arrived at clinic at 9:15 to meet Craig
- Asked Adrienne about how I can be "linked" to the current studies through the eIRB
- Prepared for my committee meeting today by summarizing what I have been thinking for the last week
- Decided that I wanted to see if creating a Regulatory Binder for the Ben Hogan clinic will be beneficial compared to other clinical trial research centers - I thought about this a few days ago after realizing that a lot of the documents stored in the K drive were hard to locate. It also helped that Craig hinted that he needed to find an efficient way of getting through to these documents. Other concerns I had were the number of places important documents were stored (ie... filing cabinets, data stored in different computers, etc). I did a google search on "how to create a regulatory binder," since I have heard of them before from my Intro to Clinical Research class and was amused to find there were academic research centers that actually advises how to make one when starting a research project. In my mind, I thought something like the sort would definitely help with the organization of the research projects at Ben Hogan.

12:00 - 1:00pm:

Introduced my idea to Dr. Gwirtz, Dr. Reeves, and Dr. Shi at the committee meeting today and they all thought it was a great idea. I had talked to Craig about it before and he already told me that he approved it. I think my challenge with this will be creating a "Thesis" project without making it feel like I am just doing administrative duties. I figured my purpose of the project would be to see how the quality of the research improves in rehabilitation research, using regulatory binders.

1:15-1:30:

I wrapped up all my things and talked to Craig some more about my ideas. Since he is busy today, I decided that I would head home to continue brainstorming about my research proposal. I also had to start editing Mike's ACL retrospective study to get another (3rd) peer review from the IRB. I asked Craig how I can start the informed consenting part of the ACL and UCL studies, and he said next week we will definitely find opportunities to do so. First, I would observe how he consents the subjects. I'm already starting to get excited about this part.

3:00-4:00:

At home and I decided to do some edits to ACL retrospective study. I am changing the

formatting of the original and will send to Mike to see if he likes it. Definitely keeping the formatting similar to the ACL and UCL studies to keep it uniform.

June 11, 2012
10:15 - 1:00pm
Mostly worked on protocol development for the ACL retrospective study today. Dissected Mike's protocol for the ACL retro study and basically re-organize it similarly to all of Craig's other studies (for uniformity). I have some questions to ask Mike like study hypotheses, inclusion and exclusion criteria, the intended flow chart of the study, and study population for statistical reasoning. Finished off with almost completing the Risks and Benefits part of the protocol. Tomorrow I will try to schedule a time to meet with Mike. I will also see if Dr. Conway has any new UCL patients and hopefully get a chance to observe the informed consenting, if there are any patients.

June 12, 2012
9:30 – 11:15am
Checked up on any new UCL patient. There is one scheduled today, and probably others after assessment. Finished editing the ACL retro study by hand, and then emailed Adrienne about how I can put these edited versions on my page for the eIRB. For now, I told Mike and he said he will pull-up the Word documents and put them in the K drive for me to edit it electronically.
11:15 – 2:30pm
Started working on research proposal draft. (Note: Must finish by June 30th and submit for IRB). A UCL eligible study patient came in around 2:30. The PT resident was informed about it and I asked her if I can observe the consenting process. I was asked to grab the needed paperwork, which was the informed consent and HIPAA form. She asked the patient if they would like to be part of the study. I observed the PT resident with the informed consent process. It took a surprisingly short time compared to what I'm used to. I didn't know what else to do in regards to my duties, so I left the resident do the data collection.
2:30 – 5:00pm
Finished the Summary and Problem/Hypothesis part of the research proposal and emailed Craig reminders. Talked to Craig about what I observed in the informed consent today.

June 13, 2012
9:30 – 12pm
Organized plans for the regulatory binder and it's contents. I looked online for some examples and found the UNTHSC Office of Clinical Trial's recommendations. I decided to base most of the contents with this. I also worked on devising a plan on how new patients can be accurately informed consented while not taking away the therapist's time with them. It's a difficult task as I found out that the therapist has 1 hour with them to talk specifically about their injury, their treatment, and then be able to ask them for permission for research. So far, the system they have works. Basically it is to ask the patient if they would like to be part of the study, explain that their name will not be used, only their measurements. The measurements are taken regardless of being part of the study. As of right now, I feel like the problem is that sometimes the patient's are not aware fully of what they are involved in. I think it's because the method for the research is very simple. I feel like this is good, and bad.

12:00 – 1:00pm
I was invited to a Journal Club lunch meeting with the AT and PT residents. I learned some interesting things that pertained to return-to-sport techniques for Baseball and Softball athletes.
1:00pm – 3:00pm
Talked to Craig about some ideas on how to better the consenting process. He said tomorrow we will have 4 patients for me to watch the process with him doing the consenting. Maybe it will help me better understand what's supposed to be done.
Around 2, I got to participate in a reliability Y-balance measure with Craig. It's done to test the reliability of measurements between therapists who measure data for the research. After Craig's turn measuring me, the AT resident did.
I worked on finishing up the ACL retro protocol today. I then called Adrienne to clear up the process of submitting it for review. I reformatted the protocol to fit the THR standard, so I had to ask her since it wasn't mentioned in the Dec. 8 review notes. I finally finished uploading the edited documents onto the eIRB and submitted it on my part. The next step is for Mike to do the final submission. Since Mike was busy, I printed out the reformatted protocol to show him what I submitted. He should be able to make changes and re-submit before final submission.

June 14, 2012
9:30 – 11:00am
Checked-in with Heather to see if there were any new UCL patients today. I also checked the front desk to see any new ACL patients today. We have the 4 Craig mentioned back-to-back this afternoon. I then went to work to see the progress of the ACL retro submission. I had to call Adrienne because it went missing in my account! Adrienne explained that it didn't have to get PI final submission because it already had the first time. I didn't know that and explained that I thought it had to because I got a note at the end of my submission that the PI had to approve it. I had to explain to Mike what just happened since he wanted to make some changes to my edits. Hopefully, Beverly (our IRB analyst) will reply back with some reviews and so we can add Mike's edits along with Beverly's edits. We know now that this is the process.
11:00am – 4:00pm
Did another Y balance with the PT resident this time doing the measurements. I had a chance to perform an informed consenting with a new ACL patient. Some observations I made were that it was easy to verbally tell the patient what they were getting into, but having them really understand the paperwork in front of them was a hurdle. Most of the time, these patients are not interested about where their data is going, just as long as they are treated. When we were told about this in class, I keep remembering GCP's. What do I do in a situation like this? Since I've worked in research before, everything was scripted and structured. Should I try to do that in a clinical setting like this?

June 15, 2012
9:30 – 12pm
I had the opportunity to do my first child assent today. I also did another adult consent. Today there was not much happening and so I worked on my research proposal. I asked Craig if creating a quality management system was a good way to add to my protocol. He suggested conducting a mock audit before and after the use of regulatory binders.
12pm – Lunch with Craig and the residents

1pm
Did some literature search on quality management systems. I think I'm going to base a mock audit by producing a quality assurance program. I wrote in my ideas in my research proposal and handed a copy to Craig so that he can see what he thinks. In the meantime, I need to get in touch with someone more familiar with quality assurance.

June 18, 2012
Today I worked on revising the ACL retro study. Our new IRB analyst reviewed and suggested changes to the protocol. I had to call her to clear up some confusion she had on the review. She assisted me by letting me know that in order for the consenting process can take place over the phone, I will have to write a telephone script and mention that we are requesting for a waiver for informed consent. The fact that we are asking over the phone if we can have them fill-out a questionnaire, it is "implied consent" if they return the questionnaire back to us. She also suggested that we do not email or fax the questionnaire. I had to speak with Mike about this since it's not in our plans.

I started typing up a telephone script. After speaking to Mike, he did not agree with not including email and fax. This got me thinking that if patient confidentiality is the problem, we should only include the subject number with the questionnaire so that only we know who they are, and no one else.

June 19, 2012
I dropped by Conway's office first thing in the morning to talk to Billie about any new UCL patients today. We talked about how I can start dropping by Mon and Fri to see the next day's schedule. Today, I had to get my badge so I went to Volunteer Services to do what I needed to do. I came back to the office to continue working on the ACL retro study's edits. After finishing, I spoke to Mike about the edits and where he can easily find the new "Summary" and "Telephone Script" in the K drive. He will have to review these edits before I can send them back to the eIRB.
I continued working on my research proposal today. While I was researching ideas for how to do a statistical analysis on my regulatory binders, I got nervous that it wasn't going to be a sufficient project for actual "data." Since my proposal is due in 2 weeks, and Craig was going to be out for NATA next week, I abruptly left clinic and went looking for Dr. Gwirtz at school today. She helped me tremendously. So, I finished today basically understanding what I'm going to analyze out of doing this binder project.

June 20, 2012
I spent a lot of time today on my own working in front of the computer. I mainly did literature searches on what I can find on anything related to Quality Assurance in clinical research. I came up with a list of measures using the details of another study that did quality assurance measuring in research done in a VA hospital. While it was a different setting than mine, I knew I'd be able

to use the same type of protocol they did. I also read ICH's Guideline for GCP. After lunch, I showed Craig my list of measures and he suggested that instead of using a binary statistical analysis, that I just rate how many measures are completed before and after the making of binders. I don't know why I didn't think of that, it is so much easier!
There was a motion capture analysis being done today so I took the time to observe it. I'm aware that it's another study going on, but I haven't been exposed to the details. I was also curious on how they set things up because I've seen the same technology with the Biomechanic's lab I've worked at school. After watching, I unfortunately had to leave because I had set-up a meeting with another coordinator at 4pm. This coordinator was a past CRM student that also did an internship, so I asked him a lot of questions pertaining to how he organizes things. He was very insightful on how I might organize my binders and he also gave me tips on how to basically work as a CRC. He also invited me to watch him do an informed consent when the time comes. I took the offer since I am curious how another CRC consents with patients during treatment (which is basically what I'm doing now here in the clinic).

June 21, 2012
Today was a busy day as I started organizing the binders. I figure I start organizing them now because next week I will finish working on my proposal since Craig will be gone. I won't be consenting anyone next week and therefore will be just doing my own work. So, planning the binders took all morning and I didn't actually start pulling out the binders until after lunch. Organizing just 3 binders took 4 hours. Reason being is I had to create a system on how to connect paperwork and the electronic files. Not to mention, I spent a lot of time figuring out where the original electronic files were in the K drive. I also started organizing the master patient log. It exists, but I'm pretty sure it's incomplete. For the sake of better organization, I will plan to do some data mining and get things to where they should be.
Finished off the day by talking with Mike about the ACL data set that I organized (eliminated non-eligible patients). He noted some interesting things pertaining to responsible physician, no. of patient per therapist at ben Hogan, amongst other things. After finishing this chat, I went to work on some of the suggested edits he'd like for the telephone script. I also started organizing for this study as paperwork is beginning to pile up.

June 25, 2012
I finished working on the edits for the ACL retro study. Basically, I went through each page in the eIRB and made the necessary changes. Also, I made a new template for the Pedi-IKDC form so that it looks similar to the Adults IKDC template. I edited the protocol and the informed consents so that it matches the eIRB form. Afterwards, I spoke to Mike and told him to try looking at what I've worked on so that I can re-submit again. I still need to figure out how to increase the communication between consenting patients and getting someone to measure them for studies. It's hard because lately I've been working on my proposal, edits to 1 project, and then getting used to the process of how they are currently consenting. I'm also placed in the backroom and am almost completely unaware when any eligible patient comes in for any of the studies. Usually, Craig lets me know.

June 26, 2012
Billie let me know that we have at least 1 patient eligible for the study today. As I waited for them to come down (by periodically checking with the front desk if anyone coming in for a UCL study was here), I worked on my research proposal. The only thing that needs to be done with my proposal is the background, but it's taking a surprisingly long time. I can't gather enough sources that is applicable only to essential documentation in clinical research.
I was told the patient just came in by Amanda. I guess the front desk girls told her. I gathered the child assent, parental permission form, and HIPAA. As I walked into the waiting room, I didn't even know who the candidate was, so I just asked for anyone with a UCL injury. After walking them to the treatment table, I started my consenting process while Amanda gathered supplies needed for measurements. My consent went the 30sec-1min as expected, and so I left for the therapist to do their job. Again, I had another weird feeling while consenting. I'm definitely not used to the limited time available.
After some time went by, I haven't heard from Billie in awhile, so I left for the day.

June 27, 2012
It turned out Billie had a patient lined up for a 4pm appointment. I didn't get the email until today. I felt a minor frustration as I still can't figure out a way to get things coordinated with finding eligible patients. Luckily, the patient probably wasn't eligible as Mike wasn't aware of any UCL's coming in the afternoon yesterday.
Today was all about working on my research proposal. What a daunting task finding articles that relate to quality assurance, monitoring in clinical research, measuring quality in clinical trials, and ethics in physical therapy clinical trials. I'm getting there though as I am digging deeper into literature.

June 28, 2012
I came in today and tried out my new computer on my new workspace (which is basically the space between Craig and Mike). I'm happy to be closer to the front desk. Maybe now I can overhear if the front desk calls over a potential study patient. Mike also told me that the Pedi-IKDC might not have normative data. Billie also called me and told me she had a patient. I told her, have them wait there, I'm heading up to try to talk to them instead of waiting for them here at the clinic.
It turned out that my idea worked as planned. I met the patient while he was waiting to get his surgery scheduled. I talked to him about the study and I had him sign the informed consent in a semi-private area. The only question he asked was if he was still eligible if he was moving in August. I answered that something always can be worked out with scheduling issues. After he got his surgery scheduled, I walked him down to the physical therapy clinic. As soon as I got into the clinic, I eliminated any waiting time by having seated the patient onto a treatment table and have him fill out questionnaires right away. Since Mike was busy, Jeff went ahead and did the measuring. After he finished, Mike commented that the process went smoothly. I think it did too, except I forgot to have him sign a research authorization form. Frustrated, I tried not to think about it too much. I focused more that the new process of consenting patients may work in the long run. I promise to be better about remembering necessary paperwork (after all these regulatory binders are up and running, they should be)!
Later in the afternoon, I saw a patient who was looking for Amanda about getting measured for the UCL study. I got to meet them and get their story. He wasn't sure if he was in the UCL study,

just that Amanda told him to come see her to get measured for his elbow. I tried looking for his name in the master log, but I couldn't find it. I jotted down his name and told him that we'll call him if there if there is information he should know.

June 29, 2012
Today, I finished working on my research proposal. I plan on turning it in to my committee after I take the time to edit it a little bit more.

July 2, 2012
I worked a little bit more on the eIRB for the ACL retrospective study. I also completed the two amendments needed for the ACL and UCL studies (the ones where I am being added as a study coordinator). I generally had a short day because there was not much for me to do today. However, I made sure that I started organizing for my binder plan by finding more sources online on how to start a regulatory binder.

July 3, 2012
I continued working on my proposal as I got Dr. Gwirtz's suggestions this morning. I checked in with Billie about any new UCLs. I started finding out how I can organize a patient's log. Basically, the main things I will need to do are to find ways to organize a masters list of all the patients, and find an efficient way of figuring out when study patients are scheduled to get measured for their particular study. It turned out the two potential UCL patients weren't eligible.

July 4, 2012
Holiday

July 5, 2012
Today I completed the following tasks: finished my proposal with Dr. Gwirtz's suggestions, I finished organizing a patient's log in a separate binder, determined that three new documents will be added to each new and existing patient's file (demographics sheet, subject individual visit log, and checklist of requirements), and I started brainstorming ways how to separate "completed study subjects," from those that are still in it. That will be my next task. I also decided that to figure out how study patients are known to get measured, a shared calendar will be made by me to add who to expect for measurements. So generally, if a patient's 4 weeks appointment is already scheduled, I will note on the calendar that that patient needs to get measured. This way, everyone may know who needs to get measured *before* they come in. Craig confirmed the idea and hopes that it will work.

July 6, 2012
I added Craig's edits to my research proposal. I'm still waiting for Dr. Gwirtz's edits. I also looked up IRB submitting instructions at UNTHSC and figured that my project may be eligible for exempt protocol review. The next review date is on 7/22. I started working on instructions on

how to file certain documents. I figured it would be the start of a standard operating procedure. Next week, I need to start organizing completed subjects in both the ACL and UCL studies.

July 9, 2012

The start of the week requires that I finish and turn-in my research proposal. Craig finalized my edits, and my advisory committee emailed me back today with approval. I worked on more brainstorming on how to better the flow of patient-subject study re-visits. The paper-method system of scheduling makes it difficult to know when patient's come in the first place. But, the front desk does a great job in notifying therapists that their patient is here. My problem is, study patient's may come in regularly for therapy visits – and we have to track when they need to get measured for the study. On top of that, that day is usually the come-back date with the consulting physician.

July 10, 2012

I spent most of the day looking through the ACL patient files and compiling a Master Log. I realized that there are two patient identifiers being used: the subject identifier and the medical record number. I drafted the Master Log, but did not complete it. The clinic was busy today and there were a few UCL subjects that came in for re-visits.

July 11, 2012

I received IRB approval for my Regulatory Binder project today. So, I officially initiated my research by judging how I will start retrieving data from going through all the study documents. I already started organizing the Regulatory portion of the binder, but the patient log is more difficult. The log needs to be customized for each study.

July 12, 2012

I continued to edit what the Study Event Tracking Form will look like for the ACL and UCL studies. It turns out that it's easier to have plans for scheduling and event tracking in one detailed page. Slowly am I trying out a new system of trying to get patient demographic information. It would benefit Craig by basically having all information needed from the electronic dataset in the patient's folder. All that should be done is that the researcher (Craig) will just input the data into the computer. This reverses the habit of inputting the data, and then creating a patient file.

July 13, 2012

Today, I finished analyzing UCL patient study files. I found some faults that were not corrected. These will be recorded for my research. Next week, I will begin separating the files with three different data sets: Controls, Surgical, and Conservative. I also still need to complete the ACL Master Log as well.

July 16 2012
The beginning of the week calls for more organizing. I continued updating the UCL and ACL Master logs and organizing a functional patient log binder. After the end of the day, I found that using the patient log will be much more beneficial to a study coordinator, and not for the PI. I find that I'm developing a system for a coordinator and not for a PI. Still, I told Craig about the patient logs and how it is operated. At some point, I assume I will need to create an SOP for maintaining the logs on a daily basis.

July 17 2012
I had a long day today. I completed the UCL and ACL Master log and added it to the K drive, separated the completed (6 months) study subjects and controls into file boxes in an effort to let more space be available in the PI's filing cabinet, made more comments about what is missing from patient files, and started finding a way on scheduling existing study subjects. The last task deemed the most challenging and something I put as a last item on my to-do list. However, I spent about 2 hours in the end of my day to try to come up with a system. I realized that a start of finding out when patients need to come in is adding a Study Events tracking log into each present subject's file. That way I will know their projected, and maybe, actual date of their re-visits.

July 18 2012
I spent the whole entire day figuring out how to create a system of finding out when study subjects come in for what measurements. The goal is to make it easier for therapist to let it be known about when patients need to get measured. It would tremendously help Craig as there would be another reminder of these frequent measurements. I also learned today a little bit about daily scheduling. I've talked to the front desk a lot more this week to figure out minor things like where the patient medical files are, how to operate MediServe, and how they schedule patients. This would help me by allowing me to be accessible when working with patients that are also study subjects.

July 19 2012
Today I had the opportunity to begin my new system of consenting patients. It's basically just adding the two documents that should make data collection an easier process: the Demographics page and Study Events tracking page. It's working. I hope it continues to be this way. Also, I had the chance to educate the new residents about human subject research training and promoting good clinical practice. I made it brief and to the point. Then, I emphasized that they needed to complete their HCCS training in order to be part of the study. The rest of the day, I continued finding subjects that are coming in for their re-measurements. I developed an excel table that tells subjects that continue to be in the study, and that what measurements they need. I will have to update this every day to make it accurate.

July 20 2012
I left early today so that I can immediately turn in my research proposal to the GSBS.

July 23, 2012
Today I got an email from the IRB saying that we are going to be having a compliance officer visit to overview the compliance of the ACL study. It was a surprise to my PI and I both since this never happened before for the clinic. I was glad that I had my regulatory binders already started. Except, a lot of work needed to be done in terms of getting things together for patient files. I emailed Nathan to set-up a short meeting on what I should do to prepare for the compliance officer. For the rest of the day, I started creating a list on what needed to get done to prepare for the visit.

July 24, 2012
I had a few UCL measurements today that I made sure that I got their return-visit date into the calendar. It helped that I gave the data collection sheet to Craig ahead of time to prepare for the re-visit patients. I also think that taking out the patient study file was essential to help make sure that the study even tracking log and all source data was complete. I had my meeting with Nathan today, in which he gave me some pointers on what to expect for the meeting with the compliance officer.

July 25, 2012
I started the day with a meeting with Craig. The meeting was to inform him about the things that I needed to do to prepare for the compliance meeting. I also told him what to expect, from the point of view of Nathan. I spent the day preparing by making sure all the patient study files did not have obvious presentable identifiers except the code given to them during initial enrollment, and printing out past regulatory files that I extracted out of the eIRB (just to make sure a copy of the paper documents are present).

July 26, 2012
I made sure all the ACL binders and files were organized for the compliance officer tomorrow. Today we finally submitted the ACL retro study to the eIRB. After making sure some patients that were measured today, I didn't have much else going on. I decided to leave a little earlier today.

July 27, 2012
Today I came into clinic a little early to wait for the compliance officer to come in. The meeting was longer than expected as he explained his process for investigating the project. Today he overviewed where all data is collected and what he will be looking for in terms of regulatory. I showed him my regulatory binders and he mainly looked at the approval dates, outcome letters and correspondences. There seemed to be a problem with the IRB not giving us an appropriate

approval date even if we filed for a continuing review. The large aspect of his concerns was going to be patient files. He told me that having a number of assents in our study pointed the reasoning why he was told to come in. I explained the patient log and my process for screening/enrolling. He had concern with placement of source data. In the end, we were able to work things to a level of appropriate compliance.

July 30, 2012
The whole day was devoted to working with the UNTHSC joint project. I did my best transferring the information from their informed consent into the THR template. I also went through the protocol with Craig today outlining some of the changes he'd like to make. After finishing up with track changes, I sent a lengthy email to Dr. Patterson and Dr. Connors about what needed to be done.

July 31, 2012
I did my round with checking with upstairs to see if any new UCL's were present. I also created an NTF – "Note-to-File" template. Mr. Chen told me it was a good idea to create NTF's on consent forms that we did not get signatures on. Since it's a minimal risk study, I am hoping that that an NTF is all we need to stay compliant. I filled-out the NTF template and got lucky enough to use it right away with one of our subjects who needed signatures. We had a few UCL measurements today that were taken care of as well.

August 1, 2012
I spent the whole day with Mr. Chen. He started the day looking at the regulatory binder and study staff binder. I observed what aspects of the binders he was looking for. He made some suggestions like printing out the application of initial studies, continuing reviews, and amendments, along with all past versions of protocols and consent forms, into the regulatory binder. He also told me to read THR policy of human subject research before he comes back on Monday so that I can ask him questions pertaining to our studies. I also attend the clinic's 2nd journal club of the year. I look forward to listening in to more of these as it opens me up a little bit more to orthopedic research I haven't heard of.

August 2, 2012
I started the day looking up what Mr. Chen told me read through before he comes back on Monday. The document basically outlines all the details that THR has on human subject research. I emailed Adrienne about the concern I have over the ACL Retro study. I also talked to Craig today about his experiences with his past coordinators at the Hawkins Foundation. It brought up an interesting discussion, as I've been doing some of my own searches of job opportunities in orthopedic sponsors around the DFW area. Some of the supporters of the Hawkins group are from these sponsors. I spoke to Adrienne over the phone and she said she

would check with Ms. Tanya Poe about the situation. I should be hearing from Ms. Poe soon. I still haven't heard from Dr. Patterson from UNTHSC either.

August 3, 2012
Absent from clinic because I was invited to attend an IRB meeting. Since today is a short day, and Craig will be out of clinic early, I decided to be off.

August 6, 2012
David Chen came in again today to continue auditing our ACL study. He gave me more suggestions on how to run a better clinical trial and possibly how they can be implemented in the Ben Hogan PT clinic.

August 7, 2012
Today I started researching the requirements for an SOP. Craig and I discussed this briefly this morning, and he said it would be a good idea to have this for future use. Obviously, I can't make an official SOP, but at least I can start parts of it up. I think this would be a great project for future CRM interns here too. We also set-up a meeting to discuss a future study/project that I may be able to help initiate. I waited for 1 new UCL patient to consent today, while also coordinating 2 more re-visit measurements too.

August 8, 2012
Today was the exit interview with the audit today. David mostly went through verification of data and I was able to help a little just by directing him on terms that are used in our studies that he was not familiar with. Unfortunately, there have been some mishaps through this process that he was able to share with me. He also took the time to introduced to me Tara Weaver, the research nurse that works in our department as well. Her job title is a research nurse, but she is actually the research coordinator for one of the other doctors here.

August 9, 2012
I met with Tara this afternoon to follow-up with our brief meeting yesterday. She was incredibly helpful and even agreed to take a brief tour of what I've done so far here at the clinic. I also found out that she is highly interested in having someone work with her at her clinic. I discussed with her about my internship and that she can also see if UNTHSC would like to add another site to their CRM program. I told her that more than likely, my advisor would be happy to speak with her about the opportunity. I asked her how she basically organizes her space and what her responsibilities are with the doctor she works for. I noticed a lot of overlap, except that she is far and beyond the process of clinical research coordinating work than we are in now.

August 10, 2012

I came in today to organize all my stuff and started writing some of the things I've learned during the audit visit. I take the audit as an addition to my practicum gatherings. A lot of the auditors findings were strikingly similar to mine. I also advanced invited David to my defense sometime mid-November. He said he would like to make it.

August 13, 2012

This morning, I was fairly upset after Google searching the study that I have worked on the first and a half years at UNTHSC. I printed out the article, seek the advice of Craig and left it at that. I was worried about this last week, but probably even more today. The rest of the day consisted of making more copies of study consent forms and preparing already prepared patient study files to make it easier on us. Then, I had a meeting today at 2 pm with career services at my school to discuss issues on my resume and CV.

August 14, 2012

The day was busy consisting of a number of follow-up subjects in the UCL and ACL studies. I made sure that all collection points were completed and that no discrepancies are obvious. Taking the time to input the data and organize them in their right places took most of my day. Craig and I had a meeting today to discuss research updates and the continuing review. Unfortunately, we have not been able to discuss a new study that he is interested in pursuing. However, the topic of possibly requiring a research coordinator in the future was touched on.

August 15, 2012

I was excused early today. I just made sure that the schedule was clear of any patients that needed data collection or new patients. I remember one subject needed their data collection sheet filled-out so I reminded Craig to get that done.

August 16, 2012

I started the day going upstairs to check with Billie. I know she is very busy, but somewhere in the process of screening, she forgets to inform me that eligible patients need to be sent downstairs. Knowingly this is not her fault, I mention the problem to Craig informing him that if there was any way that we did the pre-screen, rather than impede the responsibility on other staff, we would probably not be having the problem of missing patients. Luckily, the patient was local and all he needed to do was come back to get measured. The rest of the day included editing the protocols for the UCL and ACL studies to prepare for amendment submissions, data collecting on two patients, and preparing paperwork for the control group we are measuring on Monday.

August 17, 2012

Today I finished up working on the preparation paperwork for gathering data on the UCL controls for Monday. Being invited to come, I wanted to make sure that all of the necessary paperwork be completed. I highlighted all areas where every person needs to fill things out,

including signatures of PI. I printed informed consent process sheets and data collection sheets, so that Craig is ready to write down measurements right after the consenting process. I'm hoping that Monday goes smoothly.

August 20, 2012
Today, we headed off to TCU to measure normal controls. Being there, I tried my best to make sure all aspects of the informed consent were touched. We were there for about 2.5 hours and in my opinion, thought it was generally appropriate. Craig was present in case any questions needed to be answered. Returning back to the clinic, I started organizing the paperwork.

August 21, 2012
I had a busy day of paperwork. I encountered some problems with the UCL study control screening and enrollment, as it was not reflected in the protocol of *how* these subjects were going to be screened as a "normal." While this is a conflict in paperwork, I know I did not want to add on another task to the study. Ideally, the eligibility and informed consent process should show proper screening. It looks like I need to do a little extra work to show proof of proper screen now. I'm feeling satisfied with the amount of work there is to do to "fix" the regulatory matters of the studies here, but at the same time, I feel like I lack resources on who to contact when I have a question on regulatory affairs. The struggle of communication within our IRB has been immensely difficult.

August 22, 2012
I started organizing the UCL data check into a spreadsheet indicating which data points were missing from subjects. I did it for the initial visit data collection points. Then, I highlighted areas where there seemed to have a pattern where possibly a patient was not present, but was invited to participate later. While that was an assumption, again, it was not documented. A way needed to be figured out on how to handle these situations.

August 23, 2012
I prepared some UCL data measures today. I also emailed Billie to discuss meeting with weekly about the new scheduling program done in their office. Unfortunately, it's going to be a harder process figuring out when new UCL patients come in to clinic. Later during the day, I attended the SoCRA meeting that was hosted in our hospital.

August 24, 2012
This Friday, I stayed a little longer. I was actively attempting to find good reasoning on why it's good to have an author of a paper have research education certification. There was only a couple of sentences in the policy and procedures that explained this, but it wasn't good enough. When I told Craig, he doubted it was needed. I decided to let the issue go since Craig thought it may put some burden on the busy staff. He was right, but at the same time, I thought that in the future,

something had to be done about this. Lastly, as I was looking through the policies, I stumbled across a letter on the IRB website that explained the need to put a billing code in each patient charges even if it's standard of care. I emailed the person responsible for the email to make sure we had to do this.

August 27, 2012
Data checking the UCL study continued again today as I did the 6 weeks collection group. I made it aware that the missing data points in the database look too hectic. Meaning, there were more than what I thought was acceptable in missing data. I brought up the issue to Craig and he said he will work with me to verify the reasoning of why there were missing data points. Eventually, I have to create an NTF and protocol deviations. It's a lengthy task, but I feel like it needs to be done in case another audit ever comes through. I submitted the UCL amendment no. 4 today as well. I am hoping that goes through fast.

August 28, 2012
I data checked the 3-4.5 months collection in the database and found that much more were missing than the 6 weeks. There is still a lot of work to be done in regards to verifying the data of each patient. During lunch, I went to the THREI Informed Consent class that was led by an IRB coordinator. She guided us how to appropriately fill-out the informed consent template and other information towards a good informed consent process. Later, I had a meeting at school to discuss the issue I had about co-authorship in a research study.

August 29, 2012
I started my day by reading an email from the compliance officer about the ACL Retro study. She plans on finalizing this week, so she wants to take the appropriate measures and tasks. However, the questions she was asking in the email were confusing. Before I called her, I met with Tara to discuss how she does her retrospective studies.

August 30, 2012
I left early today to help one of the residents out with car troubles. I completed some data checking before helping however.

August 31, 2012
Unfortunately, I missed consenting one new patient yesterday. Since Craig had to pull up the consent forms from elsewhere, the demographics page was missing. I have to come up with a way for him to easily retrieve all needed forms. Then, I prepared the needed documents for data collection for Monday follow-up patients. I also emailed Mike to set-up a meeting to talk about a plan of action for the ACL retro study. I hope he responds well to these changes. I ended my day by planning for next week. I plan on doing a majority of data verifying and maybe writing up deviations and NTFs.

September 3, 2012
This week I started off with immediate action in summarizing the Data Check for the UCL study. I have found numerous points of fault in the data that need to be addressed for Wednesday's meeting with Craig. Today, I started creating a large excel file for each data set. I finished with the Initial measurements. Afterwards, I highlighted missing data points. In a perfect situation, the highlight missed points would have documentation of why they were missed. Nevertheless, the data points are going to become protocol deviations.

September 4, 2012
I had a few subjects to prepare patient files for follow-up measurements. The whole rest of the day, I continued with Data Check. It took all day.

September 5, 2012
I had a meeting today with Craig to discuss the Data Check. I appreciated the time that he took to go back into some patient charts to figure out the reasoning behind the missing information. Luckily, he has a good memory and remembers the patients well. Afterwards, we discussed other matters such as submission of a

September 6, 2012
Today was the Education Meeting that was held at our clinic for all the physical therapists. Since I was welcomed to join, I stopped by a little bit this morning to check out what they were learning about. After some time, I decided to leave early because I wasn't able to take parts of the activities they were all doing (which were sample exercises that required comfortable clothing). I started working on the protocol deviation sheet. I also started thinking about my Defense date and when I should be scheduling. I immediately emailed all my committee members to figure out best times and dates for all of them.

September 7, 2012
It looks like setting my defense date is harder than I thought. I'm hoping to hear back from my committee for a better date than November 20th. Today, I spent time reading requirements for my thesis practicum. I made a timeline to make sure all my data from my project is finalized by October, and I'm writing actively at that time period before presenting. I also plan to start writing the background portion of my thesis.

September 10, 2012
I visited Billie to get the schedule from her. Unfortunately, there hasn't been a flow of new patients lately. We are thinking it's because it's back-to-school month. There wasn't much to do today except working on the pre-review changes that was received for the ACL Retro study. I

have a feeling this study is getting closer to approval. I organized the binder for this study to match all the correspondences that has been happening lately.

September 11, 2012
I started the day making sure that the schedule had any new UCL patients. We have at least 3 follow-ups today. Follow-up visits are getting SO much easier with this system that I've created. Creation of a visit log, then making sure patient files are completed accordingly make data collection and recording faster. What used to take Craig a few hours to days to complete, are now done in 20-30 minutes. Today, I also called the IRB at UNTHSC on assistance for understanding HIPAA. I decided calling them was a good option because I would get an immediate response, especially being a student. After explaining briefly what I'm going through, the person was able to explain to me how the waiver of HIPAA works under federal guidelines. The rest of the day, I continued the report of protocol deviations and headed to the library for thesis writing.

September 12, 2012
Today I continued figuring out how to get in touch with the Compliance Director and the THR Privacy Officer. I have read and understood the Privacy Rule yesterday in great detail. Now, I think the next step is to get consultation from the Privacy Officer. Getting this retrospective study has forced me to understand federal regulations and HIPAA. The rest of the day, I had no patients so I just worked on thesis writing.

September 13, 2012
There were a few number of UCL follow-up patients today. In the morning, I was able to finally get in touch with the Privacy Officer of THR. She informed me that we will need HIPAA when we decide to mail the questionnaires to the patients. She explained that the first part of the study is a waiver for preparatory to research, and then the second part, in where we actually contact the patients, will need permission from patients if we can view PHI even further in the study. Now, all I have to do is wait for the Compliance Director, in which she is also standing as an IRB Coordinator with the shortness of staff, to accept/reject this response and decide what to go forth in this study. At around 2:30, I asked for permission for early leave as I had to really focus on writing. Craig let me have off tomorrow to concentrate working on my thesis.

September 14, 2012
Excused absence.

September 17, 2012
Today started with data inputting. Not only did I input data into the appropriate UCL data collection sheet, but I updated protocol deviations. Fortunately, I finished listing all past deviations, which makes it easier for me to add deviations presently. There are deviations

because the amendment hasn't been approved yet. Once approved, I'm hoping fewer deviations will be listed. I gave Mike the synopsis of what the Privacy Officer told me last week. Since we haven't heard from the Compliance Director yet, I suggested to him that he can pursue further communication. The rest of the day compromised of reading articles.

September 18, 2012
After some UCL follow-up measurements today, I just focused on thesis writing. Instead of heading home, I thought that staying in the clinic today would be more beneficial in case any other new subjects or unexpected follow-ups occur.

September 19, 2012
Today, I worked a little bit on some thesis article reading and writing. I'm assuming that I will have a draft finished by the second week of October. I also began the process of organizing the UCL data chart. After about 3 long hours, the chart signified actual duties that needed to be performed. It is complete and missed data points are explained in the protocol deviation chart. I'm positive that if there was a scheduled research audit to take place with this study, all resources will be presented in an organized fashion. It took me about 2 months to complete. Also today, we finally had a new ACL subject after a few weeks without having any new subjects. One goal that I think should be organized with the ACL study is patient recruitment.

September 20, 2012
I continued with what work I had left from yesterday as far as inputting data from follow-up and new patients. There were also a few follow-ups today that I was able to input data into the newly revised UCL data chart. I am really hoping to get the amendment back soon so that the deviations on the protocol doesn't seem so hectic anymore. Also, Craig also reminded me of another change that needed to take place with the protocol. I'm afraid that the more and more I make these changes, the IRB will further delay our response. I'm desperately thinking of just doing it afterwards or setting up a meeting to go through the details of the procedures of the study. Craig also mentioned to me he is getting ready for a submission of a UCL study manuscript. I have to start keeping track of all these publications so that I keep them in the binder. It will show the progression of the study.

September 21, 2012
After finishing the UCL Data Study collection excel sheet, I went ahead and wrote the initial date seen for each conservative patient. This will help track them better. In the future, documentation of why these conservative patients end the study much earlier than expected should be done. I also met with Billie today to discuss usual scheduling of UCL follow-up patients.

September 24, 2012

Today was a pretty slow day, but I had responses from the IRB about both the amendment and the ACL retro study. The amendment just needed a little tweaking, which I was glad to hear about. I sent the edits right away to the new IRB coordinator. Then, I started reading the pre-review correspondence sent for the ACL retro study, and it was terribly lengthy. Unfortunately, I wasn't able to understand it and decided I needed to communicate with the IRB on what specifically what to do. Throughout the day, I worked on trying to communicate with the IRB, and then the rest of the day working on my thesis.

September 25, 2012

I went upstairs to check the schedule. There was only 1 follow-up and possibly 2 new subjects. As the day progressed, the new subjects never came down to clinic. In a way, even if assuming that the screening are getting done right, I do wish I had the chance of observing how the screening was done. Maybe one day in the future.

September 26, 2012

The day consisted of mostly IRB activities. I had a phone meeting with the Compliance Director, Tanya Poe, to discuss the ACL retro project. I spent most of the day editing and re-wording the protocol and all study documents. I hope this project can get started soon. My time here as an intern is running out and I might not see the project much longer, but at least I started a Reg. Binder for them to hopefully continue using.

September 27, 2012

I haven't heard much from the IRB today except that our amendment is finally going through expedited review. It took nearly a month to get this amendment done, but at least I had thought ahead of time and turned it in early. Next step is the continuing review. We had a few UCL follow-ups. I also helped the residents with their data mining today.

September 28, 2012

I met with Billie again today to discuss next week's schedule. There were no patient follow-ups today and since Friday's are short-days, I worked in my office for the remainder of the time. It's important I finish my outline so I can ask my committee members to review it.

October 1, 2012

I spent the day reading and writing a detailed outline for my thesis. It is coming along really well and I think that it would be beneficial to have when writing the actual thesis report. Craig gave me an article that discussed EBP in the Sports Therapy spectrum. It is dated October 2012, so I'm definitely using it as one of my sources.

October 2, 2012

I dropped by Dr. Conway's office today and met Fay, the new assistant nurse for Billie. I introduced myself and went ahead to look at today's schedule to mark any follow-ups. Today, I organized the UCL binder. It's been awhile since I looked at the binders, but because I'm preparing for my thesis, editing SOPs, and waiting for an amendment to get approved, I decided today was a good day. Also, I wanted the binder to look good in case Craig needed to see it for his research meeting tomorrow.

October 3, 2012

After a long wait, the amendment for the UCL study has been approved! We are one step closer to making our studies up-to-date and current. I got started working on the continuing review right away. I developed the timeline for 4 months of research activities just for Craig. I think it's immensely helpful because it portrays points in time where Craig should start planning things, submit applications, and create amendments.

October 4, 2012

I decided to revamp my regulatory binder. It wasn't such a difficult task. All I did was combine the some sections of the patient binder into the regulatory binder. The reasoning behind this was because it was more sensible to organize it this way instead of having 2 separate binders. I spoke to Tara to get advice on this. She said it's best to get everything in as less space as possible. With that said, this binder can placed in the same box as all study subjects once study closure occurs in the future. Today, I mainly worked on the presentation of my binders and SOPs. We had a few follow-ups today as well, as well as a new subject enrollment. Follow-ups and enrollment have been incredibly easy lately.

October 5, 2012

Today consisted of playing a little bit of catch-up. I made sure all study subjects had a visit schedule and that I get confirmation subject visits for the next two weeks from Billie. Next, I read Tanya's email, printed it, made notes, and decided that I was going to work on her suggestions first thing Monday morning. Then, I finalized my outline for my thesis.

October 8, 2012

We enrolled 2 conservative group UCL patients today. I worked on the edits to the ACL retro study today but was concerned because so many edits have been placed already. I emailed Tanya discussing that Mike requests that he be the person of contact next time there are edits.

October 9, 2012

I worked on finalizing the UCL continuing review today. There was supposed to be a follow-up patient today, but they didn't show up. Unfortunately, that's going to be a missed data point. After documenting that they missed their appointment, I worked on my paper.

October 10, 2012
I noticed that after I left yesterday, Craig enrolled an ACL patient. He left the informed consent forms on my desk and while it was complete, no other study sheets were included (e.g., the informed consent checklist, tracking form, data collection sheet). So, I spent the morning preparing packets that included all study documents. Next time a patient comes in and I'm not around, the packets will be available so that the rest of the study staff has everything they need. After the staff lunch meeting today, I worked on finalizing my specific aims for my dissertation report. Afterwards, I had a long phone meeting with Tanya discussing real-time edits to the ACL retro study. It was successful. We are hoping to have approval by this Friday.

October 11, 2012
I spent most of my morning preparing the patient files that will be seen today. I realized that the organization that I implemented in the beginning isn't the best anymore. In fact, it worked in the beginning because it me organize the Master Log and data check. So today I decided I'm going to organize all the patient files in one box and leaving a section in the drawer with extra space for other things. Where the boxes will be places, not so sure, but at least it will all be in one place!

October 12, 2012
Mike and I met today to discuss details about the ACL Retro study. While it's not technically called "retrospective" anymore, we are still calling it that just as a short name. The meeting consisted of planning for the future. Unfortunately, the study calls for time commitment and I won't be around to help anymore.

October 15, 2012
I was given permission to leave early today because I unfortunately lost my flash drive and could not find a back up of my paper.

October 16, 2012
I stopped by upstairs and did the daily check of schedule for any new patients or follow-ups. I also made an appointment with Billie for next Wednesday. We found out today that Dr. Conway needs to renew his HCCS training. I have to work with her to discuss how this will occur during his busy schedule.

October 17, 2012
I wrote most of the day. After a few ACL follow-ups, I made a note to myself that an amendment still needs to be written for that study. Reason being is to reflect everything that's on the protocol correctly. I plan on submitting the amendment when we decide that it's time to remove me from the study near the end of my internship.

October 18, 2012
The day consisted of writing. I was focused on the results section of my paper that not much else was done. A few follow-ups were collected for data today.

October 19, 2012
I met with Mike again today to discuss more information about the ACL retro study.

October 22, 2012
Today I worked on my paper mostly. We had one ACL follow-up today, but nothing else research related. Tanya also emailed Mike and I today that we are not receiving our approval letter yet due to technical issues.

October 23, 2012
I heavily finished my rough draft of my paper today by adding in references and the bibliography. It took nearly all day and was lucky that I didn't have much happening in the clinic. There were a few follow-up patients, but it went smoothly with the residents taking over.

October 24, 2012
Today was a busy day that consisted of a lot of communication and action on getting Dr. Conway's human subject research training certification. I worked with the necessary people to make sure this was finished. I also simultaneously had to enroll 2 new patients.

October 25, 2012
I turned-in my rough draft today. I started working on the ACL protocol amendment and scheduled an appointment with Craig to discuss it specifically. Next week I have to fully edit my paper and get started on my powerpoint. I also asked Tara to take a look at my paper for any suggestions she might have.

October 26, 2012
I tracked follow-up patients for the next upcoming weeks. I also got to meet one of Craig's colleagues who he used to work with in the research foundation. It was a good conversation about experiences of having a research coordinator. I finished the day with finalizing this week's tasks to be ready for next week.

October 29, 2012
We had 1 follow-up today. We at last received the final approval for the ACL Retro study today. I printed out the approval letter, all other documents, and immediately added it to the regulatory binder.

October 30, 2012

This seemed like a slow week because there are no scheduled new UCL patients or follow-ups. By Friday, I'd have to check what is going on with the follow-ups.

October 31, 2012
Craig and I had our research meeting and thesis mentor meeting. After going over what changes must be made to the ACL study, he heavily went over my dissertation. The rest of the day, I worked on editing.

November 1, 2012
I received Dr. Gwirtz peer-review edit on my dissertation today, therefore Craig let me work on editing all day. There were no follow-ups or any other research duties to do.

November 2, 2012
After meeting with Billie and finding out there has been a lack of follow-ups lately, I finalized my rough draft #2. I am hoping to get input from Craig and Dr. Gwirtz again before turning in the final next week. Craig and I settled on another research meeting next week to discuss adding new changes to the UCL study protocol