

12-1-2014

Improvement of Data Quality through Source Data Verification in Physical Therapy Research

Kalyssa M. Pollard

University of North Texas Health Science Center at Fort Worth, kmp0176@live.unthsc.edu

Follow this and additional works at: <http://digitalcommons.hsc.unt.edu/theses>



Part of the [Medical Sciences Commons](#)

Recommended Citation

Pollard, K. M. , "Improvement of Data Quality through Source Data Verification in Physical Therapy Research" Fort Worth, Tx: University of North Texas Health Science Center; (2014).
<http://digitalcommons.hsc.unt.edu/theses/808>

This Internship Practicum Report is brought to you for free and open access by UNTHSC Scholarly Repository. It has been accepted for inclusion in Theses and Dissertations by an authorized administrator of UNTHSC Scholarly Repository. For more information, please contact Tom.Lyons@unthsc.edu.

Pollard, Kalyssa M., Improvement of Data Quality through Source Data Verification in Physical Therapy Research. Master of Science (Clinical Research Management), November, 2014, 61 pp., 2 tables, 7 figures, bibliography, 9 titles.

It is imperative to minimize errors in essential data to achieve maximum reliability in a research study. The primary objectives of this practicum were to identify the advantages and disadvantages of using clinical trial management software in physical therapy research studies and to determine the ability of that software to improve data quality and therefore research validity. Using source data verification within three research studies at the site, 480 data points were verified retrospectively and 428 were verified prospectively. Following the use of the software, there was a significant reduction in multiple types of data errors at each subject research visit, with an overall error reduction of 86%. The largest limitation of the clinical trial management software is the time requirement for implementation and continuation in each enrolling research study at the site. Alternate electronic management systems should be evaluated for feasibility and improved data quality at the research site.

IMPROVEMENT OF DATA QUALITY THROUGH SOURCE DATA
VERIFICATION IN PHYSICAL THERAPY RESEARCH

Kalyssa M. Pollard

APPROVED:

Dr. Robert Mallet, Major Professor

Dr. Peter Raven, Committee Member

Dr. Craig Garrison, Committee Member

Tara Craig, Committee Member

Dr. Patricia Gwartz, Graduate Advisor

Dr. Meharvan Singh, Dept. Chair & Dean, Graduate School of Biomedical Sciences

IMPROVEMENT OF DATA QUALITY THROUGH SOURCE DATA
VERIFICATION IN PHYSICAL THERAPY RESEARCH

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate School of Biomedical Sciences

University of North Texas Health Science Center

In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

Kalyssa M. Pollard

Fort Worth, Texas

November 2014

ACKNOWLEDGEMENTS

I sincerely thank all members of my internship practicum committee for their support and guidance throughout the time of my graduate program and internship. Dr. Patricia Gwartz, my graduate advisor, was a wonderful mentor during all my classes, taking time out of her busy schedule to answer any questions and reassure me throughout the process. She was extremely helpful in assisting me with selection of an internship site and offered immense guidance through the last few months. I also thank my major professor Dr. Robert Mallet and committee member Dr. Peter Raven for their invaluable assistance with my research proposal and thesis writing and for making themselves available whenever I needed direction during my internship. My fellow students and friends in the Clinical Research Management and Medical Science programs deserve thanks as well; due to their hard work and dedication they were my inspiration during study sessions and throughout my Master's education.

I especially thank Dr. Craig Garrison, my internship site mentor, for teaching me the ins and outs of clinical research every day of my internship. He allowed me to take on immense responsibilities at the research site that allowed me to learn so much more than I would have by simply observing operations at the site. He also guided me in my search for a job following graduation and was a great support in that aspect as well. I also send thanks to clinical research coordinator Racella de Guzman who was my initial internship site mentor for the first half of my internship. She taught me aspects of clinical research management that I did not learn in school and reinforced what I had learned by giving me responsibilities at the site and guiding me towards a career in the field. Everyone at Ben Hogan Sports Medicine deserves big thanks as well, for accepting me as part of their

team, allowing me to learn more about physical therapy and sports medicine and to foster an interest in staying in sports medicine research. Clinical research coordinators Tara Craig and Nathan Fisch also deserve thanks for being wonderful supporters during this time. Tara was there for support by offering advice and suggestions in my day-to-day tasks and Nathan helped with the entire start-up process in my project and with my thesis. I also thank Institutional Review Board (IRB) analyst Erik Soliz for his guidance and direction in my study coordinator tasks at the site and for taking time to assist me in my first IRB correspondences.

Completion of this program would have never been possible without the constant support of my family. I extend immense thanks to my mom and dad who made a Master's degree a possibility for me. I would not be where I am today without their support. I also thank my significant other, Kristopher, for his encouragement every single day. His motivation pushed me to work my hardest and strive to be the best I could be and he continues to be my constant support.

LIST OF TABLES AND FIGURES

<i>Table 1:</i> Results of Retrospective Source Data Verification.....	20
<i>Table 2:</i> Results of Prospective Source Data Verification.....	21
<i>Figure 1:</i> Types of errors discovered in pCRF source data verification	21
<i>Figure 2:</i> Error rate by week discovered in pCRF source data verification.....	22
<i>Figure 3:</i> Types of errors discovered in eCRF source data verification	22
<i>Figure 4:</i> Error rate by week discovered in eCRF source data verification.....	23
<i>Figure 5:</i> Comparison of error rate between pCRF and eCRF formats	23
<i>Figure 6:</i> Comparison of the total number of errors by type of error	24
<i>Figure 7:</i> Comparison of error rate by type of visit.....	24

TABLE OF CONTENTS

ACKNOWLEDGEMENTS.....	iv
LIST OF TABLES AND FIGURES.....	vi
CHAPTER I:.....	1
Introduction:.....	1
CHAPTER II:.....	3
Background and Literature Review.....	3
Specific Aims.....	6
Significance.....	7
Materials and Methods.....	10
Results and Discussion.....	14
Summary and Conclusions.....	25
CHAPTER III:.....	29
Internship Site and Experience.....	29
Journal Summary.....	31
APPENDICES:.....	32
Appendix A: Online Random Number Generator.....	32
Appendix B: Source Data Verification Checklist.....	33
Appendix C: Data Entry Log.....	34
Appendix D: Study Audit Log.....	35
Appendix E: Daily Internship Journal.....	36
REFERENCES.....	61

CHAPTER I:

Introduction:

The quality of the research data retained within a research site is a direct indication of research integrity at that particular site. The validity of the research findings may be questionable if the retained data is not accurate and complete. A reputable research site desires the highest quality data to ensure reliability of its research findings. At most clinical research sites, the research data is captured on individual subject case report forms, with primary data originating from source documents such as patient medical records. Different types of data management within a clinical research study can have an impact on the quality of the study database. Previous research shows that switching from a paper-based data management system to an electronic system improves data quality.^{6,7} However, research in the field of physical therapy is relatively new and electronic data management systems are not common in this field.

The primary objective of this practicum report is to identify the advantages and disadvantages of using clinical trial management software in physical therapy research studies. By addressing the following specific aims, this practicum will determine if the software has the ability to improve data quality and therefore research validity at the research sites:

1. Evaluate the feasibility and advantages of an electronic data management system using source data verification to compare the number of errors between the electronic and paper systems.

2. Evaluate data capturing methods related to the reduction of errors during initial data collection which might improve the ease of data analysis.
3. Incorporate a single data management system to allow controlled access to research data and create a time-stamped audit trail to ensure secure, correct data.

This practicum report will begin by providing background information regarding research data and the methods available for collection and retention of that data. Previous literature will be presented to establish what is known about improvement of data quality through electronic data management and to identify persistent gaps in this knowledge. The specific aims and significance of the practicum will be explained in greater detail before the methods of the practicum are presented. Finally, the practicum report will describe the results obtained and discuss how those results affect research at the site and in the field of physical therapy.

CHAPTER II:

Background and Literature Review

The Federal Acquisition Regulations, which governs most federal research contracts, define data as “recorded information, regardless of form or the media on which it may be recorded.”¹² Data management is one of the most crucial aspects of clinical research because it is a pivotal way to ensure research integrity. Improper data management may lead to intense scrutiny of the validity of the research findings. A reanalysis of the research data may prevent invalidation of a clinical research study; however, availability of the primary or source data is essential to ensure the data is not compromised. Typically, clinical trial data are closely monitored to ensure subjects’ safety (i.e. tracking adverse events), but it is also important to monitor the data to ensure the reliability of the accumulated study data. Data acquisition, one of the most crucial aspects of data management, should be practiced with attention to detail and the data recorded in a way that allows it to be continuously analyzed and reviewed.⁴ If the research data is error-free and is readily available for analysis as it accrues, the integrity of the research will be high and the researchers involved in the study may defend its integrity with confidence.

In all medical fields, including clinical research, paper documentation is being replaced with electronic records. In regards to research, it is important that electronic source documentation meet the same quality requirements that paper records must meet. Data collected in a research study, whether on paper or electronic, must be “attributable, legible, contemporaneous, original, and accurate.”³ Such data monitoring, as outlined in

the Good Clinical Practice defined by the International Conference on Harmonization (ICH E6 5.5), ensures high-quality data capture.

Studies have shown that the transition from paper case report forms (pCRFs) to electronic case report forms (eCRFs) reduces the time and effort of organizing paper documents and allows for more complete and valid data.^{6,7} Electronic case report forms are not an entirely new concept in the field of clinical research – they have been used since the mid-1980s and are reported to have increased data quality and completeness through a number of characteristics which pCRFs lack. With an eCRF, there is a possibility for use of automatic completions and reminders for required fields of data.⁶ All electronic data included in a software system and its eCRFs must comply with the rules and regulations laid out in Title 21, Part 11 of the U.S. Food and Drug Administration’s Code of Federal Regulations (CFR).¹ This section of the code describes all specific guidelines which electronic records must fulfill to be considered reliable.

There are many types of software designed specifically for clinical trial management. A research site may use this software in order to keep all essential documents organized in one place and to improve overall efficiency of its research studies. One such software system, OpenClinica (Isovera, Inc., Waltham, MA), is used to capture and manage data. The system allows the user to enter and validate clinical data for enrolled patients. It includes tools for data management and extraction of desired data to run reports and statistical analyses. The use of an electronic data capture software system complies with Title 21 CFR Part 11 Subpart B by providing the protection of patients’ protected health information and allowing patients to be de-identified, as well as requiring a secure login to access the database. OpenClinica is the software system being

evaluated for potential use by the research site for multiple physical therapy research studies.

Source data verification (SDV) is an essential part of quality data management. It is defined as “an evaluation of the conformity of the data presented in CRFs with source data”.⁵ During the process of source data verification, the information included on the CRF is compared with the source documents to ensure that all data on the CRF is complete, accurate and valid. Source documents are original records where the information is initially captured. If source data verification is completed in the early stages of a clinical trial rather than near the end, problems that are encountered can be repaired before the validity of the data is affected. The results of source data verification within a clinical research study will determine if the data documentation is sufficient.⁵

Clinical research within the field of physical therapy is designed to improve patient care by increasing the effectiveness of therapy procedures. Presently, physical therapy research, specifically related to sports medicine physical therapy, seems to be limited. Many physical therapists and institutions accept modern procedures as effective and are not concerned in advancing their techniques; however, it has been shown that implementing research at a physical therapy institution not only raises recognition of the institution, but also increases the value of therapists who work there by teaching them problem-solving skills which can be incorporated into their patient care.⁸ Since research in sports medicine is relatively new, it could be argued that effective data management is even more crucial. Data monitoring in newly implemented research ensures that data integrity and patient safety are not overlooked by the institution or its physical therapists conducting the research.²

Specific Aims

The research project will determine whether an electronic system for data management should be implemented for all research studies at Ben Hogan Sports Medicine Fort Worth. The project will introduce an online clinical trial software system, OpenClinica, to manage all research data within three anterior cruciate ligament (ACL) studies. Within the software system, electronic case report forms (eCRFs) will be created. Source data verification will be applied using a checklist to count the number of errors that occur when transcribing data. This source data verification will also be completed on previously recorded paper case report forms (pCRFs) for the research studies. Finally, the number of errors discovered in the old and new techniques as well as the feasibility of implementation and ease of use will be compared to determine whether the new data management system should be implemented within the research site at Ben Hogan Sports Medicine.

A major concern of the research staff at the Ben Hogan Sports Medicine Center is that the collected data are not readily analyzed in a convenient or organized way. Currently, data are collected on the pCRF and then transcribed into a Microsoft Excel database. From there, when research personnel want to conduct statistical analysis, they must select the groups of data to be analyzed and transcribe them into statistical software called a Statistical Package for the Social Sciences (SPSS). This process is time-consuming, work-intensive and cumbersome, with risk of error in transcribing the data. There is a need for improving data capturing methods so that mistakes can be found immediately after data collection instead of when attempting to analyze the data, when it is more difficult to identify and correct errors.

Another problem with the current data capture system is poorly controlled user access to the research data. There are multiple physical therapy residents and other study staff that have access to the database, and currently there are no means of tracking changes to the database made by the staff. There is a lack of a secure, time-stamped audit trail for all electronic modifications. Problems of uniformity have been reported, and the lack of a single data management system leads to confusion as to which database is the most up-to-date. In summary, this project addressed three specific aims:

1. To evaluate the feasibility and advantages of an electronic data management system by using source data verification to compare the number of errors when using pCRFs and when using eCRFs.
2. To critically evaluate data capturing methods related to eliminating errors upon initial data collection in order to simplify data analysis.
3. To incorporate a single data management system to allow controlled access to research data and to create a time-stamped audit trail to ensure secure, correct data.

Significance

According to Pfizer's quality management team, "quality must be integrated into the entire clinical study process, not just through testing or oversight during the course of the trial."¹⁰ In other words, it is important to capture correct data in its entirety, beginning with the initial collection and point of entry, to ensure the highest data quality.

Implementing a system of data collection and entry that minimizes human error should improve the quality of the research. One way to minimize data errors is to collect only

essential data, including data that is relevant and critical to the safety and endpoint of the research study. This essential data should be limited to numbers and possibly a few descriptive words in order to decrease the potential for discrepancies among data points. It is also important to avoid recording a single data point on duplicate occasions (on separate data collection sheets, for instance), as this also leaves room for human error.¹³ Keeping all source documents and case report forms clear and concise helps to minimize these types of errors. By implementing a clinical trial software system, data from the source documents will be entered directly into an eCRF, which allows reports to be pulled and data to be analyzed immediately, reducing the number of steps within data management and expediting these processes. By setting limitations on the data that can be entered on the CRF, the software also has the capability of improving data quality. Every guideline for electronic records outlined in 21 CFR 11 will be fulfilled by the use of OpenClinica.

Another advantage of using a designated data management software program is the specificity that can be easily maintained or altered by the data manager. When one uses what is known as a “flat file” such as a Microsoft Excel spreadsheet, it is easy to enter any information that the user considers relevant, and to update or change any previously updated information.⁹ With a large amount of data, these spreadsheets can grow to hundreds of pages, with numbers arranged in a tabular format. Not only are these numbers difficult to view and analyze, the spreadsheets can become very broad and may contain a vast amount of irrelevant data. A software system such as OpenClinica enables the designer to specify only the specific data points that are relevant to the study, and no other data points may be entered into the database. OpenClinica also allows for reports

pulled during analysis to limit the data being presented, making analysis of specific comparable variables easier. The ease of data entry is equivalent among the software system or “relational database” and a well-designed flat file, but the possibilities for sort and filter functions and statistical analysis are superior in the software system.⁹

A relational database contains tables of data comparable to a flat file, but the tables are combined in an advantageous way. It has been shown that a relational database will contain fewer errors. If the user enters a data point indicated by text into a spreadsheet every time that data point is collected, it is likely to be misspelled at one time or another. Then, when analysis is run using that particular data point, it is likely to be skewed due to multiple entry types that should have been the same. A relational database includes the option to select that data point from a drop-down menu, eliminating the chance of a spelling error and improving outcomes upon analysis. Relational database users have also found that updating information is easier than when using a flat file such as a spreadsheet. In the relational database, when a particular data point is changed that is present in multiple areas, it will automatically change all affected data points, while in the spreadsheet the user must usually change each data point individually.⁹

When a relational database is able to be accessed online or through a shared computerized network, it can be beneficial for a team who conducts research at multiple sites. The software allows data to be separated by site, but the data may also be analyzed as a whole among sites if necessary for the study. Data access can be limited so that users at a particular research site can only edit or manage data pertaining to subjects at that site. While only one user is allowed to edit a flat file at a particular time, the use of a

relational database allows for multiple users to make changes simultaneously to keep the database as updated as possible.

Materials and Methods

The internship project involved multiple steps in order to determine whether a clinical trial management software system was feasible for use by the clinic and whether it actually reduced errors and proved beneficial for research use. First, the clinical research coordinator was designated as data manager and was trained to use the software used to build electronic case report forms (eCRFs) for the three research studies that would be used in the project. The eCRFs were designed according to the format of the paper case report forms (pCRFs) currently used at the research site. Then, as data was collected during subject visits in those studies, a specified data entry user took the measurements collected on the paper source document and entered them into their respective studies in the system. During this time, paper charts containing data collected in the past were randomly selected for retrospective source data verification. Following completion of prospective data entry into the system, prospective source data verification was completed in the same fashion as for retrospective data.

To begin the experiment, the clinical trial management software OpenClinica was implemented as part of three anterior cruciate ligament (ACL) studies that were ongoing at Ben Hogan Sports Medicine. Following training of the online software system, each study had to be built and eCRFs for each study had to be created *de novo*. To build the study, a series of questions about the study were answered and a plan devised to determine when eCRFs would be used for each research subject. An organizational

Microsoft Excel template for creating an eCRF, provided by OpenClinica, was used to design the layout for the interface, which included each data point and associated rules for every research visit a subject might encounter. Creating the eCRF involved entering labels for each data point; determining whether the data point could be entered as text, a specific selection, an integer or real number, or a calculation; and specifying the layout of the data points on the eCRF. There were also limits set for each kind of data point by setting predetermined parameters for numeric values entered in the eCRF. If the data point involved a calculation, a specific formula was entered into the template so that a calculation would be done automatically when the corresponding data points were entered into the eCRF.

Retrospective source data verification was divided equally among five subject visits made during the research study. There were 105 patients who had completed a Week 1 research visit for the ACL study. A list was made that included the subject IDs of those 105 patients, and each ID was assigned a consecutive number between 1 and 105. An online random number generator (Appendix A) was then used to randomize the subject files to be used for Week 1 source data verification. This online generator produced a table of 105 random numbers between 1 and 105 without using duplicate numbers. The 105 random integers listed were used to allow the corresponding ACL subject research files to be pulled at random. The ACL subject research files were pulled in groups of five, starting from the beginning of the generated list.

Chart randomization and retrospective source data verification were then completed on subject research visits for Weeks 1, 4, 8 and 12, and the Return-to-Sport visit. The methods mentioned previously were used to randomize subject files for all

visits. There were a total of 98 subjects who completed a Week 4 visit, 9 subjects for Week 8, 7 subjects for Week 12, and 57 subjects for the Return-to-Sport visit. Source data verification was completed on five subjects for each of the research visits, so that a total of 25 visits were retrospectively verified. Each subject research visit contained a different number of data points, depending on what data was collected at the time of that visit. In Weeks 1 and 4, 8 data points were collected at each visit. Week 8 contained 20 data points, Week 12 had 26, and the Return-to-Sport visit contained 34 data points. Since 5 visits were verified for each week, there were a total of 480 data points considered for retrospective source data verification (Table 1). To complete this source data verification, the paper chart (or source document) was compared to the Excel spreadsheet (or pCRF). Each data point collected on that visit was compared between the two documents, and if any mistakes or discrepancies were discovered, they were indicated on the “Source Data Verification Checklist” (Appendix B) by marking the type of error discovered. The Source Data Verification Checklist was composed by listing all data points collected at each research visit and applying the knowledge of possible errors that might occur during data collection and transcription.

There were six types of errors which were considered during source data verification. If a data point had been recorded on the CRF but was not written on a source document included in the subject chart, the error was marked as “no source document.” This error included instances where a copy had been made of the original source and the copy placed in the subject’s research folder. An error was excused if there was a “note-to-file” contained in the research folder explaining that the original data could be found in the subject’s medical file. The next type of error, documented as “mismatched

source/CRF,” indicated that there were different numbers recorded for the same data point on the source document and the corresponding case report form. In an instance where the data point had been recorded on the source document but was never transcribed onto the case report form, the error was documented as “missing CRF data.” Another error that was taken into account during source data verification was when the data point had been written multiple times on the source document or on multiple sources. This error was documented as “multiple source copies.” If the hand-written data point found on the source document was illegible, it was counted as an error and marked as “illegible writing.” The final type of error that was accounted for was “strike-out/rewrite”, which occurred when the data recorder wrote an initial data point, crossed it out, and rewrote the number without an initial by the data recorder. The total number of errors was counted for each visit and the total percentage of errors was calculated by dividing the number of errors by the total number of data points for that visit and multiplying by 100.

Prospective source data verification was completed using the same techniques as the retrospective source data verification. Beginning on July 1st, 2014, a data entry log was kept for all ACL patients who came in for a research visit (Appendix C). The data collected on that visit was entered into OpenClinica. There were two Week 1 visits, four Week 4 visits, four Week 8 visits, five Week 12 visits, and five Return-to-Sport visits for a total of twenty visits available for prospective source data verification. This resulted in a total of 428 data points which were considered for prospective source data verification (Table 2). When the source data verification occurred, the data on the subject’s paper chart (source document) was compared to the eCRF in OpenClinica. The “Source Data

Verification Checklist” was completed for each visit, and the total number of errors counted and the percentage of errors calculated as before.

Results and Discussion

Retrospective source data verification revealed that among 480 total data points, 49 errors were discovered including data points with no source document available, a mismatch between the source documents and the pCRF, missing pCRF data, and data points that were crossed out on the source document and rewritten with no initial or date to document the change. Data points with no recorded source document were the most prevalent among retrospective charts at 32 errors, comprising 65.3% of the total errors. A total of 9 mismatched data points made up 18.4%, struck out and rewritten data points made up 6 errors or 12.2%, and 2 errors consisting of missing pCRF data made up 4.1% of the errors accounted for retrospectively (*Figure 1*). No errors were discovered in which there were multiple sources for the same data point or the writing of the data point was illegible (*Table 1*). It was noted during retrospective verification that the research charts completed earlier in the year had fewer source documents contained in the subjects’ research files. As the study continued and a research coordinator was hired, the number of missing source documents decreased due to an understanding of the problem of missing source documents and an active effort to reduce this error. The responsibilities of this research coordinator included improvement of data capture by ensuring only one member of the study staff was collecting and recording data in a single database using consistent methods for each study.

Errors discovered in retrospective source data verification were also evaluated by the subject visit in which they occurred. Error rate was calculated by dividing the number of errors discovered by the total data points verified among all charts for that visit and multiplying by 100. It was discovered that the highest error rate (40%) occurred in the Week 1 visit. Five percent of errors occurred in Week 4, 6% in Week 8, 13.1% in Week 12, and 4.7% at the Return-to-Sport visit (*Figure 2*).

Prospectively, only 6 errors were discovered upon evaluation of 428 data points that were entered in the eCRF format. It is interesting to note that no data points were found to be missing in the eCRFs (*Table 2*). This can be attributed to the fact that OpenClinica required all data points for each visit to be entered, or required an explanation of why the data point(s) were omitted, before the eCRF data could be saved in the system. These requirements leave no room for error in regards to missing data when transcribing from the source document to the eCRF. There were also no errors involving multiple source documents or illegible writing (*Table 2*). Three errors (or 50%) were attributed to no available source document. Mismatched source document and eCRF data accounted for 16.7% of the errors, and two data points were found to be struck out and rewritten, accounting for 33.3% of the errors in prospective source data verification (*Figure 3*). The “no source document” and “strikeout/rewrite” errors are considered to be associated only to the source document and not the eCRF. These errors occur during data collection when they are hand-written on the source document, and therefore might not reflect on the error-reducing capacity of the eCRF compared to the pCRF. A mismatched data point simply occurs by human error during transcription of the data from the source document over to the eCRF.

The error rate was also evaluated by visit number within prospective source data verification. The error rate across visits revealed a downward trend in which errors appeared to decrease at each subsequent subject research visit. Week 1 had an error rate of 6.3%, the Week 4 error rate was 3.1%, Week 8 was 2.5%, and Week 12 was 1.5%. There were no errors discovered in the Return-to Sport visits prospectively (*Figure 4*).

When evaluating the overall error rates in the retrospective and prospective formats, a significant reduction in error was obtained when the eCRF format was used. Retrospectively, there were 49 errors out of 480 possible data points, displaying an overall pCRF error rate of 10.2%. Prospectively, there were only 6 errors out of 428 possible data points, displaying an overall eCRF error rate of 1.4% (*Figure 5*). When the eCRF was used in place of the pCRF in the study, there was an 86% decrease in errors made during data collection and transcription, demonstrating the ability of a software system such as OpenClinica to increase reliability of data in a research study. A χ^2 analysis with Yates' correction for continuity was completed to compare the error rates discovered in the retrospective and prospective formats. Taking into account 1 degree of freedom and a χ^2 value of 29.308, the analysis resulted in a p-value of <0.001, demonstrating a statistically significant decrease in total errors in data points following the use of an electronic data management system.

Figure 6 shows a direct comparison between the types of errors made in the pCRF and eCRF formats. There was a decrease in twenty-nine data points with no source documentation among errors made when the eCRF format was used. There was also a slight decrease in the number of data points (eight) whose source documentation did not match the CRF documentation among errors made when the eCRF was used. Another

decrease in error was demonstrated with missing CRF data, in which there were two errors in pCRFs from missing pCRF data, while no eCRF data was found to be missing. There was also a decrease in the number of data points that were crossed out and rewritten once the eCRF format was implemented, regressing from six to two errors.

Finally, error rates sorted by visits were directly compared (*Figure 7*). Consistent findings showed that the error rate decreased with use of an eCRF in each research visit. Data analyzed in weeks 1 and 12 of these ACL research studies in particular seem to be the most important in predicting how well a patient will do in his or her return-to-sport test. If the data at these crucial visits are incorrect or missing, the physical therapist might misinterpret the patient's readiness for return-to-sport. This practicum project actually showed that use of an eCRF system has the potential to reduce errors, particularly at the Week 1 and Week 12 visits. In Week 1, errors decreased from 40% to 6.3% with the use of an eCRF ($\chi^2 = 4.664, v = 1, \alpha < 0.05$). Week 12 showed a decrease in error rate from 13.1% to 1.5% ($\chi^2 = 11.13, v = 1, \alpha < 0.001$).

Aside from a measurement of error reduction when using eCRFs, this practicum report was designed to subjectively measure the feasibility of the electronic data management software, the possibility of multiple data capturing methods, and the accuracy of an audit trail and limited data access. While OpenClinica did demonstrate a reduction in the number of data errors and an increase in data quality, its feasibility and ease of use were lower than expected. The software required no installation as it is web-based, which facilitated installation and accessibility on any computer throughout the research site. Building each of the studies within the online system did not take much time to complete (around one working hour), and there was a step-by-step question and

answer portion about each study that allowed the software to custom-format each study to meet the needs of the research team. Construction of the eCRFs within OpenClinica seemed to be the most challenging task. From start to finish, it took around 24 working hours to complete a CRF with 428 data points. Following completion of the eCRF and its implementation in the correct portion of the research study in OpenClinica, it took around 8 working hours to edit the eCRF and fix any problems that were not discovered at the time of construction. For this practicum, two eCRFs were created to fit the needs of the three research studies evaluated, totaling around 66 working hours on building the studies and eCRFs before data entry could even begin. The research site currently has five more actively enrolling studies, which would take an additional 165 working hours before data entry could begin.

It is important to note that some of the errors accounted for in source data verification are associated only with human error during data collection on the source document, while some are associated with human error during transcription of the data from the source document to the pCRF or eCRF. The “no source document”, “multiple sources”, “illegible writing”, and “strikeout/rewrite” errors can be attributed solely to human error during data collection and the error rate should be consistent regardless of the type of CRF used. The “mismatch and missing CRF data” errors occur during data transcription onto the CRF, and should be reduced by the use of an eCRF, which requires all data points to be entered and has regulations on a range of values that can be entered for each data point. So while the use of OpenClinica still included errors in data collection and transcription, the method of data collection appeared to be the prime source of errors. A solution to this problem would be to use an electronic tablet with

OpenClinica capabilities for data collection. This approach would eliminate the use of a paper source document entirely, and the source document and CRF are essentially the same. In this format, the data entry user would enter the ACL measurements in the CRF during data collection in the physical therapy clinic. The eCRF would require all relevant data points to the patient visit to be entered at the time of data entry, so no measurements could be inadvertently missed. No transcription of the data points would occur because all patient data will have already been entered into OpenClinica. This aspect would considerably reduce human error including the lack of a source document, mismatched data points, missing CRF data, multiple sources, strike-outs or illegible writing. Implementation of electronic tablets is not yet feasible at the site for financial reasons, but could be considered for application in multiple studies in the future.

OpenClinica did result in a much better system for decreased user access to data and creation of a time-stamped audit trail in comparison to the previously used methods. Currently, the data for all studies at the research site is contained on a network drive that can be accessed by multiple users in the physical therapy department. Although there are regulations governing which folders may be accessed by specific users, these folders are not password protected, raising the possibility of security breaches. Anyone from the research team is allowed to view the data from the research studies to which they are assigned, and they can open the Microsoft Excel database, make changes to the data, and overwrite the old database without any audit trail of the changes or the research team member who made them. In OpenClinica, all research databases are password protected, and the data manager has the capability to assign roles in the system to each member of the research team depending on their level of activity in the study. Some users can only

view the data, while others can add new subjects or data or make changes to existing data. When these changes are made, OpenClinica keeps a time-stamped audit trail called a “Study Audit Log” for each research study and each subject folder documenting all changes (Appendix D). This study audit log tracks when a user creates a subject, when data is added, edited, or deleted, and any other actions made to the subject’s chart. If data is edited or deleted, the audit log shows what previous data was entered in case it needs to be changed back to the original number. This system holds research staff accountable for all changes made to the database, an element that is non-existent in the current procedures at the research site.

Table 1: Results of Retrospective Source Data Verification

RETROSPECTIVE	Week 1	Week 4	Week 8	Week 12	RTS	Total Errors	% Errors
No Source Doc.	10	1	2	15	4	32	65.3
Mismatch	6	1			2	9	18.4
Missing CRF Data				2		2	4.1
Multiple Sources						0	0
Illegible Writing						0	0
Strikeout/Rewrite			4		2	6	12.2
Total Errors	16	2	6	17	8	49	100
Data Points	40	40	100	130	170	480	
% Errors	40	5	6	13	4.7	10.2	

Table 2: Results of Prospective Source Data Verification

PROSPECTIVE	Week 1	Week 4	Week 8	Week 12	RTS	Total Errors	% Errors
No Source Doc.	1			2		3	50
Mismatch			1			1	16.7
Missing CRF Data						0	0
Multiple Sources						0	0
Illegible Writing						0	0
Strikeout/Rewrite		1	1			2	33.3
Totals	1	1	2	2	0	6	100
Data Points	16	32	80	130	170	428	
% Errors	6.3	3.1	2.5	1.5	0	1.4	

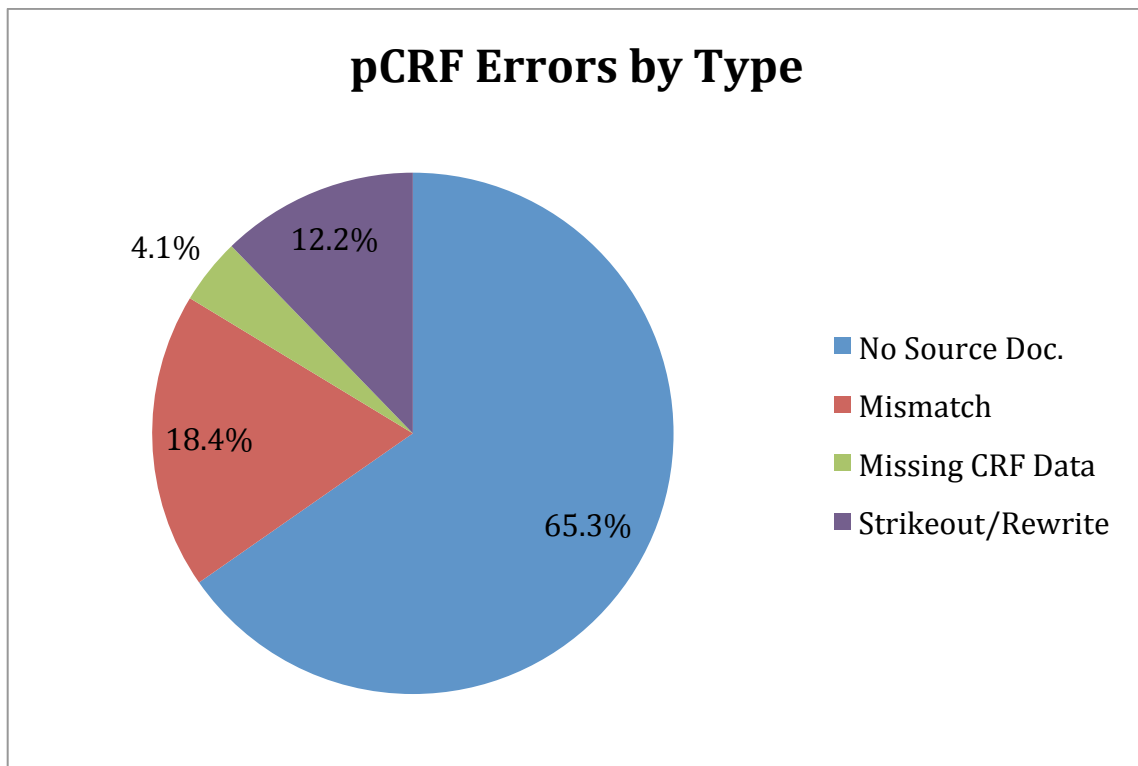


Figure 1: Types of errors discovered in pCRF source data verification

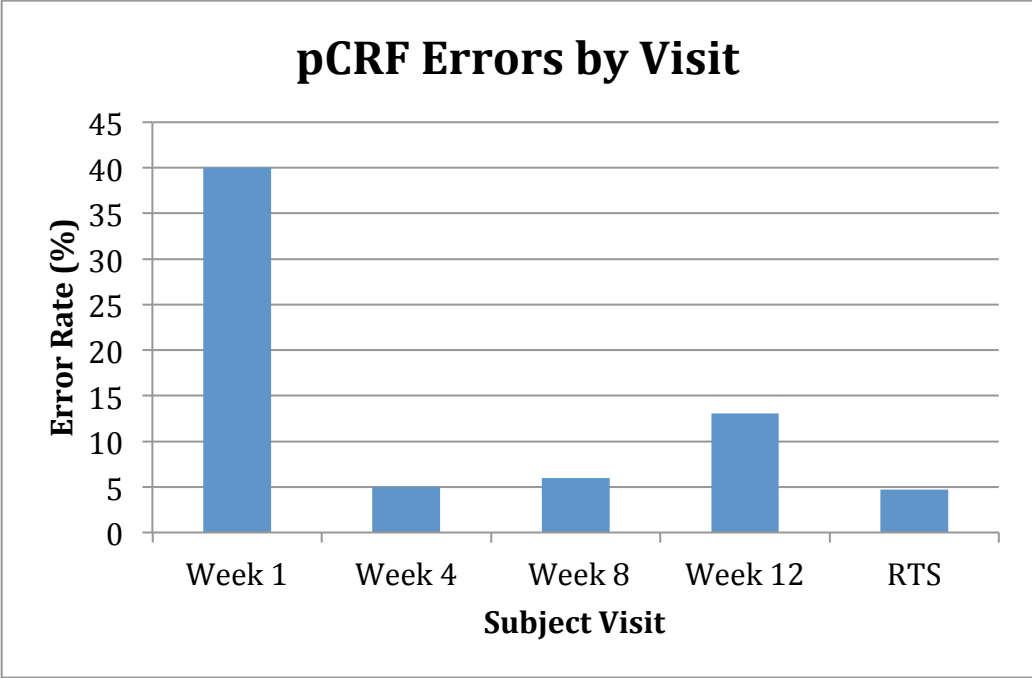


Figure 2: Error rate by week discovered in pCRF source data verification

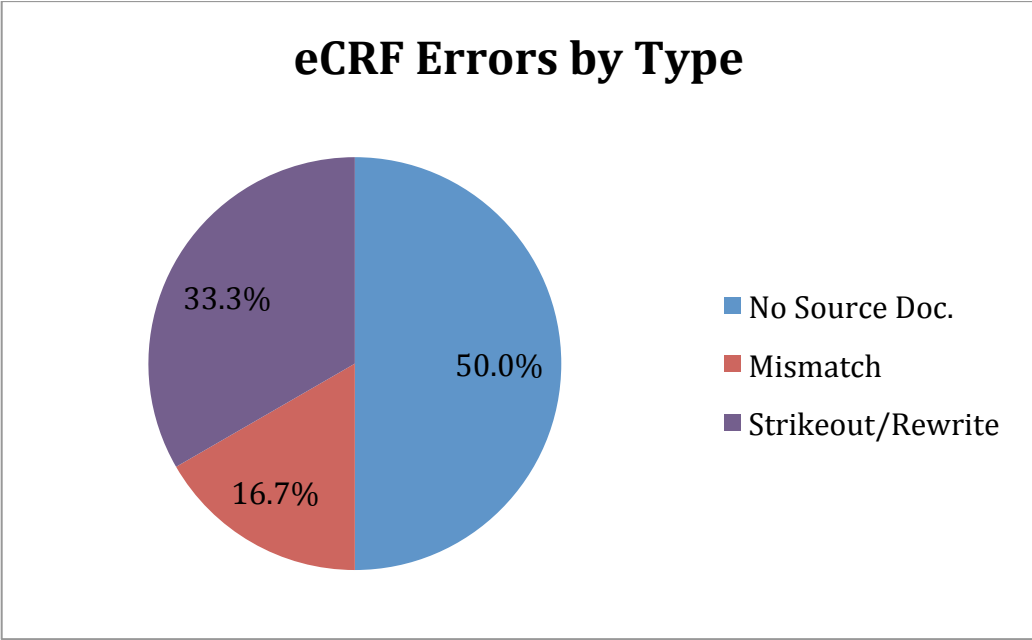


Figure 3: Types of errors discovered in eCRF source data verification

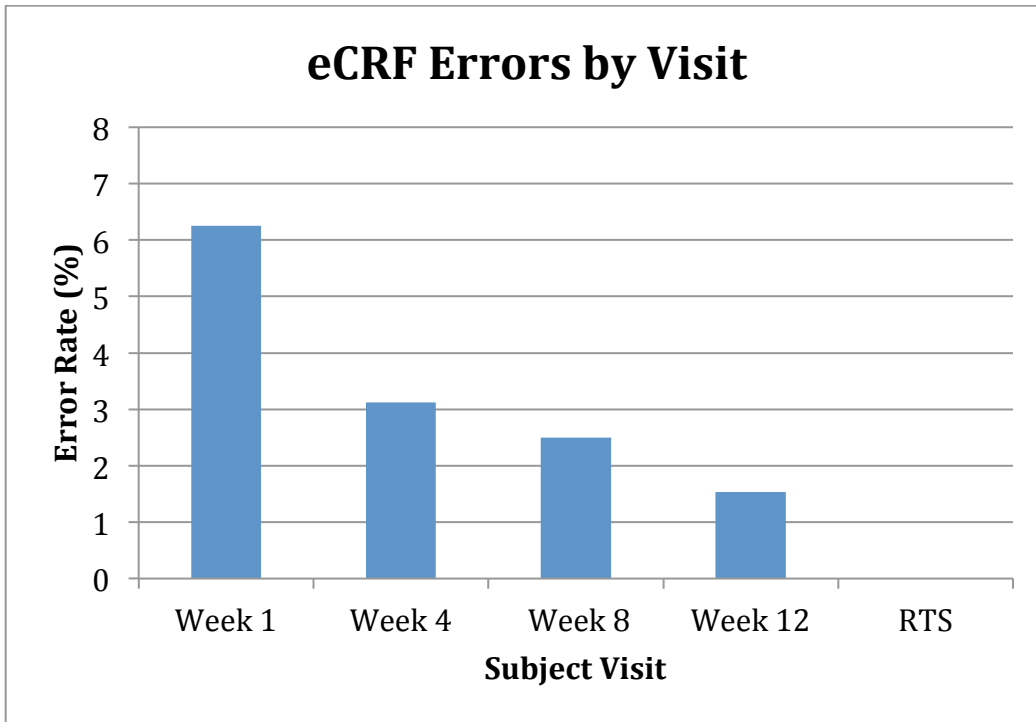


Figure 4: Error rate by week discovered in eCRF source data verification

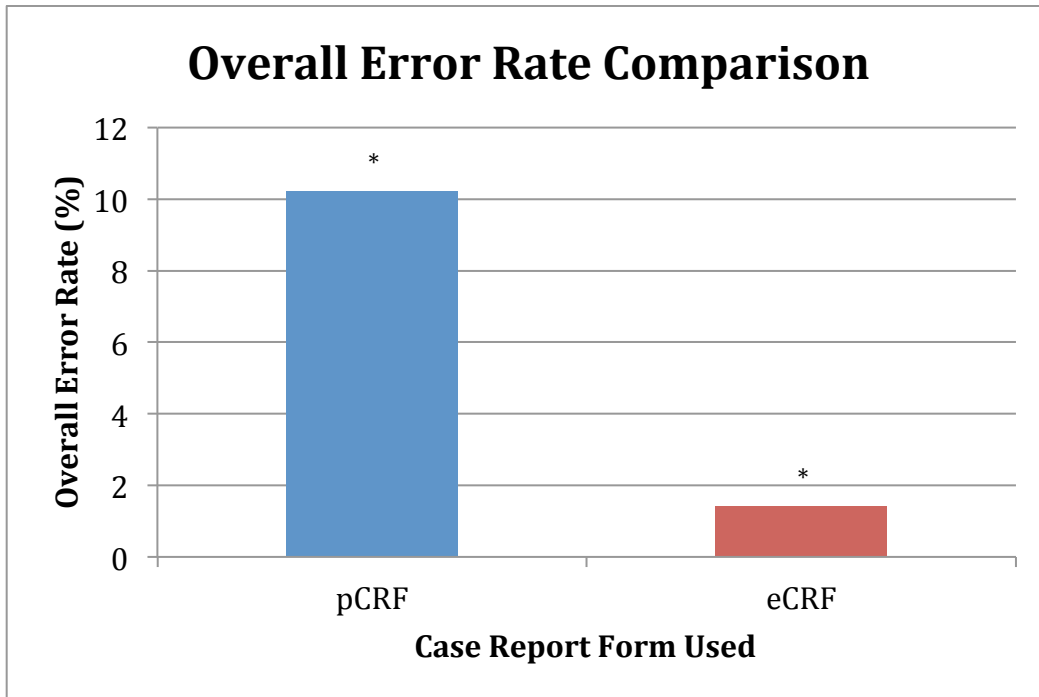


Figure 5: Comparison of error rate between pCRF and eCRF formats
 $(\chi^2 = 29.308, v = 1, \alpha < 0.001)$

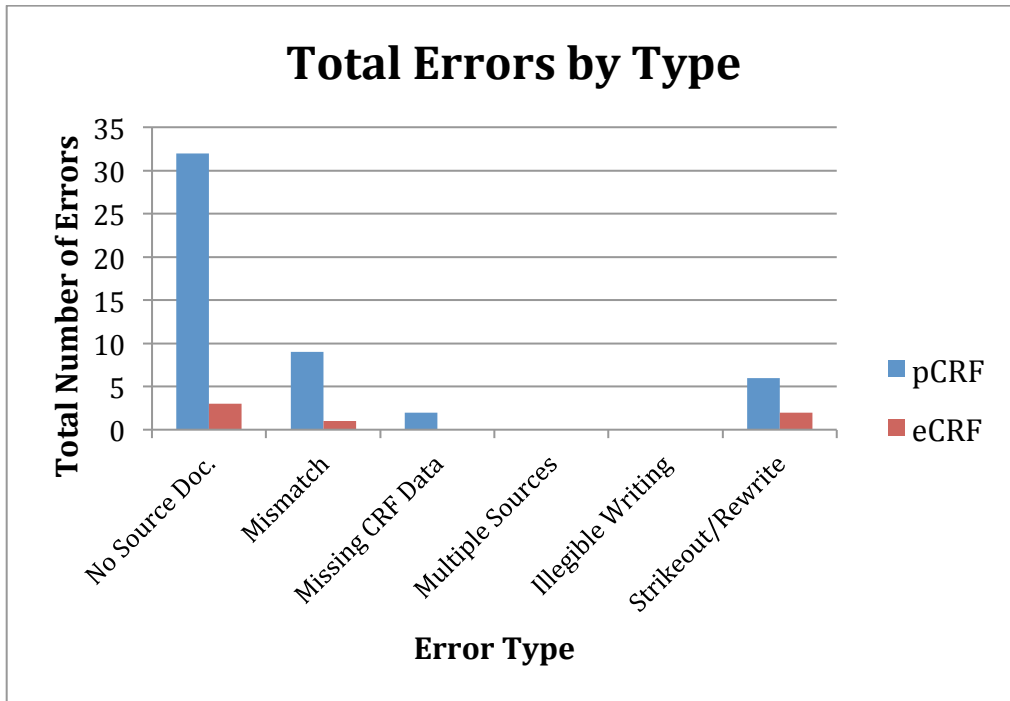


Figure 6: Comparison of the total number of errors by type of error

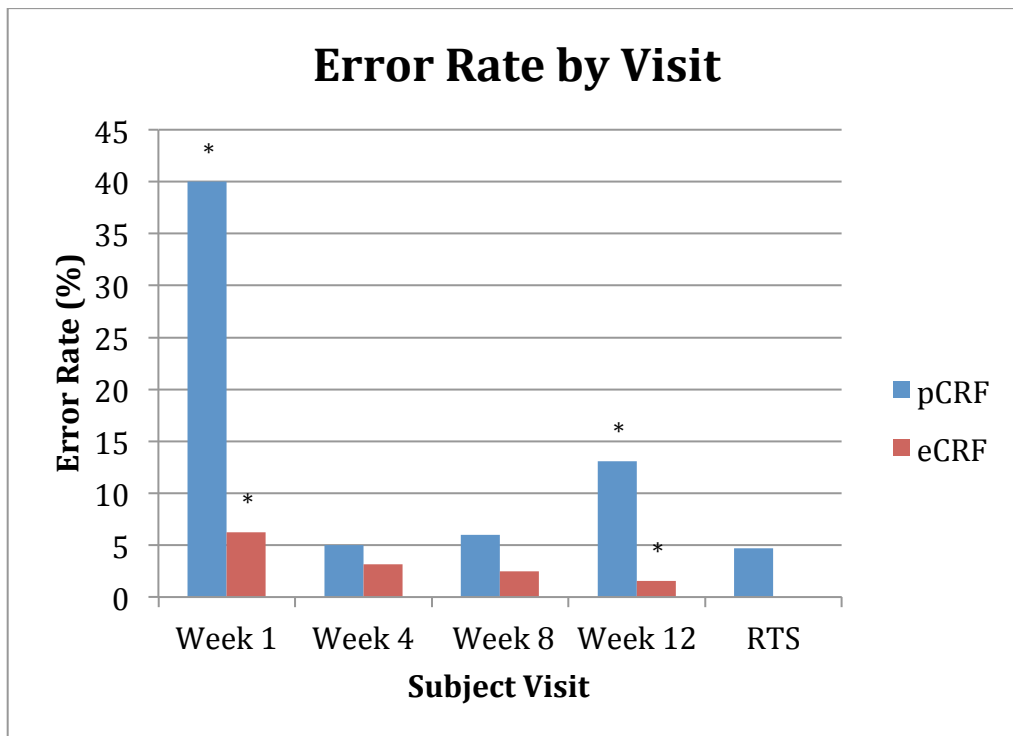


Figure 7: Comparison of error rate by type of visit

Week 1: ($\chi^2 = 4.664, v = 1, \alpha < 0.05$)

Week 12: ($\chi^2 = 11.13, v = 1, \alpha < 0.001$)

Summary and Conclusions

Data quality is an essential indicator of reliability within research studies. In clinical research studies, there is always the chance for human error to occur within data acquisition and transcription, allowing the possibility of impairment of data quality. In this practicum, use of an electronic case report form within clinical trial management software has been shown to decrease the likelihood of human error in the essential data management aspects of a clinical research study.

The practicum began with implementation of an electronic data management system, OpenClinica, in three clinical research studies at the research site. Upon the initiation of the practicum, each research subject's data was entered into an eCRF for the study in OpenClinica. Source data verification was used to count the number of errors in data acquisition and transcription that occurred when using OpenClinica and that had occurred previously using the pCRF system. The practicum addressed three specific aims designed to determine whether or not OpenClinica should be implemented in all research studies at the site.

This practicum was designed to evaluate the feasibility and advantages of an electronic data management system by measuring data quality within three similar research studies by comparing the number of errors occurring during data collection and transcription when using pCRFs and eCRFs. The error rate among eCRFs was decreased compared to pCRFs in every subject visit for the studies. Every type of error evaluated except for the "strikeout/rewrite" error was also decreased with use of an eCRF compared to a pCRF. These results along with an 86% reduction in errors when using the eCRF method over the pCRF method demonstrates that there are apparent advantages in data

quality improvement when using the electronic data management system. If OpenClinica were to be implemented in all research studies at the site, there is the possibility of increasing data quality and therefore research integrity in every study. The time required to create and edit each eCRF; however, is burdensome and limits the feasibility of eCRF implementation at the research site. Implementing OpenClinica in every research study at the site would require the effort of a data manager who could dedicate 165 working hours to build the studies and eCRFs for the actively enrolling studies, and 33 hours for each additional research study that is added on in the future. At this time, there is no such position at the research site and it is not feasible for the research coordinator to complete these tasks.

The practicum analyzed data capturing methods and their ability to eliminate errors upon initial data collection in order to improve ease of data analysis. The current method used by the site, in which data is collected by hand on a paper source document and later transcribed to the pCRF, carries substantial risk of human error in collection and transcription of data to the pCRF. The use of OpenClinica demonstrated complete elimination of transcription errors, but there were still data acquisition errors that were not eliminated, but reduced appreciably, by the use of the eCRFs. In order to eliminate the data collection errors, an electronic tablet could be used in place of the paper source document. Electronic tablets are currently not financially feasible for the research site; however, they may be considered for application in multiple studies in the future.

Finally, the practicum was designed to allow controlled access to research data and create a time-stamped audit trail to ensure secure, correct data. The “Study Audit Log” in OpenClinica proved to be a very detailed and reliable audit trail that would be

beneficial for the research site. Previously when a database was updated, which data points were changed or who changed them were unclear; with OpenClinica, the Study Audit Log allowed the data manager to view any changes made to the data and to identify the user who made those changes. Implementing OpenClinica and using the “Study Audit Log” would hold the entire research team accountable for data quality, strengthening study integrity across all research studies at the site.

In conclusion, the implementation of OpenClinica into all studies at the research site is not currently feasible. The time required to employ the software in all current and future studies and to build multiple eCRFs for each study cannot currently be fulfilled by any member of the research team; however, the use of a software system significantly improved overall data quality in the research studies in which it was implemented, demonstrating the possibility of overall improvement of research integrity at the site. It is recommended that the site implement clinical trial management software other than OpenClinica which would allow for increased data quality without sacrificing the increased time to implement and run the software in all research studies. There are over a dozen clinical trial management software programs which contain the same data management characteristics as OpenClinica and also offer compliance with 21 CFR Part 11. Future research studies could identify the feasibility of implementation of multiple types of software that still improve data quality in physical therapy research.

One major limitation of this study was the number of charts that were available for prospective source data verification. The practicum was implemented starting in July 2014, at a time when the number of new ACL patients in the clinic was low. The new ACL study was not approved by the hospital’s IRB in the timeline anticipated by the

practicum, creating another limitation that lowered subject enrollment numbers. From the time the practicum was implemented, a total of only 20 research visits were made across the three ACL studies. To closely match the number of prospective visits, 25 retrospective visits were verified. Although the number of patient charts available for source data verification was limited, an ample number of data points could be verified from these visits (480 and 428), which allowed the researcher to gather sufficient data to evaluate the benefits of implementing OpenClinica.

CHAPTER III:

Internship Site and Experience

The Texas Health Ben Hogan Sports Medicine center in Fort Worth, TX is affiliated with Texas Health Resources Harris Methodist Hospital. Ben Hogan Sports Medicine is an institute designed to improve the health of athletes across North Texas. It includes a highly qualified team of professionals including orthopedic physicians, physical therapists and athletic trainers. The specialties of Ben Hogan Sports Medicine include injury prevention, physical therapy and rehabilitation, sports nutrition and psychology, and clinical research. The site offers post-professional residency programs for athletic trainers and physical therapists preparing for a career in sports medicine. One of the major goals of the residency program is to implement evidence-based research into clinical practice. The athletic training and physical therapy residents are encouraged to create and implement their own research studies as well as participate in the ongoing research studies under the principal investigator, Craig Garrison, PhD, PT, ATC, SCS.

The mission of the research team at Ben Hogan Sports Medicine is “To become a regional and national leader in clinical research of the prevention and rehabilitation of shoulder, elbow, and knee injuries in athletes.”¹¹ Ongoing research studies at the site include:

1. Measure of humeral torsion and injuries at the shoulder and elbow
2. Mobility of the hip and shoulder in overhead athletes with injuries at the shoulder and elbow
3. Study of factors that lead to osteochondral defects (OCD) and determination of return to sports in the gymnastics and baseball athlete
4. Do pre-operative measures influence post-operative outcomes in anterior cruciate ligament (ACL) injuries?

5. Factors that affect return to sport after ACL reconstruction
6. Hip Strengthening after ACL reconstruction
7. ACL reconstruction rehabilitation outcomes within Texas Health Resources
8. The validity of Vail Sport Test as a measure of performance after lower extremity injury
9. Retrospective case-analysis of concussions in athletes

The clinical research internship was completed under the supervision of Dr. Craig Garrison, director of physical therapy research, and partly by Racella de Guzman, MS, clinical research coordinator. The responsibilities held during the internship included most of the tasks that are encountered by a clinical research coordinator during the management of clinical trials. My responsibilities also included the screening and recruitment of potential subjects for the research studies. I participated in the process of informed consent and child assent during subject enrollment in the studies. I assisted in data collection, recording the measurements taken in the clinic that were collected by the physical therapists and residents. Data monitoring and verification was also a large part of the internship, which was enhanced by the work in my internship project. I was also involved in a number of regulatory operations, including all communication with the IRB and writing and editing protocols, consent forms, case report forms and other study documents. Maintenance of essential documents for each of the studies was also a large responsibility that I held. I maintained communication between the principal investigators, co-investigators, and the rest of the study staff to ensure each research study ran smoothly for the duration of the internship. This internship allowed me to be a part of the day-to-day activities of the research team that gave me incredible insight into the activities of a research coordinator.

During my internship, I was also provided the opportunity to work with one of the physical therapy residents to initiate a research study for approval through the IRB. I worked with her to write the protocol and consent forms, and I filled out the application for the study in the online IRB system. I communicated with the IRB analysts and reviewers to make alterations to the study to pass it on to approval. This was an excellent learning experience during the internship. Ben Hogan Sports Medicine was an ideal internship site for my interests in clinical research management. With the support of an amazing research team and all the other staff at Ben Hogan, I was able to take on these responsibilities while also learning about the field and working on my own project at the same time.

Journal Summary

(Refer to Appendix E for complete day-to-day log of activities)

APPENDICES:

Appendix A: Online Random Number Generator

This online random number generator was found at:
<http://stattrek.com/statistics/random-number-generator.aspx>. It was used to randomize the visit numbers which would undergo source data verification retrospectively.

123 Random Numbers

021 094 057 046 019 068 045 023 056 081 040 039 009 099 041 123 034 113 032 121
008 069 035 064 111 098 112 102 007 015 050 100 104 003 026 014 084 042 090 012
122 097 049 070 071 067 079 044 027 116 024 022 060 075 115 028 010 096 053 058
107 051 062 095 119 078 048 080 073 029 037 047 108 074 103 118 109 013 088 016
110 065 004 006 018 038 106 066 083 063 061 114 031 011 092 101 085 117 054 036
043 086 033 020 025 052 120 077 001 089 105 055 017 093 082 002 030 072 059 091
087 005 076

Specs: This table of 123 random numbers was produced according to the following specifications:
Numbers were randomly selected from within the range of 1 to 123. Duplicate numbers were not allowed. This table was generated on 7/25/2014.

Appendix B: Source Data Verification Checklist

The Source Data Verification Checklist was used to verify the number of errors in data collection or transcription in 25 retrospective visits and 20 prospective visits. The checklist accounts for the number of errors discovered during verification as well as the type of error discovered and comments regarding the error. The research study protocol number and subject ID number(s) are included on the checklist for ease of access to the data.

Source Data Verification Checklist

Week 12 Follow-Up

SDV Information

Name of Data Verifier: Kalyssa Pollard
 Date of SDV: 9/10/2014
 Protocol: 2212/5018
 Subject ID: 97123/9704

Required Fields

Error **Comments**

Visit Date	0	
IKDC Score	1	IKDC form not included in chart; no NTF
VAS Score	1	"
Range of Motion:		
Involved Flexion	1	Range of motion measurements not written on source doc.
Involved Extension	1	"
Uninvolved Flexion	1	"
Uninvolved Extension	1	"
Other: _____	0	
Y-Balance		
Leg Length	1	Y-Balance measurements not written on source doc.
Involved Ant	1	"
Involved PM	1	"
Involved PL	1	"
Uninvolved Ant	1	"
Uninvolved PM	1	"
Uninvolved PL	1	"
Other: _____	0	
Hip Strengthening (Pro5018)		
Involved Hip Abduction	0	
Involved Hip Extension	0	
Involved Hip External Rotation	0	
Uninvolved Hip Abduction	0	
Uninvolved Hip Extension	0	
Uninvolved Hip External Rotation	0	
Involved Knee Flexion	0	
Involved Knee Extension	0	
Uninvolved Knee Flexion	0	
Uninvolved Knee Extension	0	
Involved Single Leg Squat	0	
Uninvolved Single Leg Squat	0	
Other: _____	0	
Total		
Total Number of Errors	13	

Additional Notes or Comments

Source document containing written measurements not found in subject chart. Subject chart needs to include source document or a "note-to-file" explaining where to find the data in the subject's medical file.

Error Key

1 = no source document 4 = multiple source copies 0 = no error
 2 = mismatched source/CRF 5 = illegible writing
 3 = missing CRF data 6 = strike-out/rewrite

Appendix C: Data Entry Log

This Data Entry Log was used to track when a patient who was enrolled in one of three anterior cruciate ligament (ACL) studies underwent research procedures. When it was indicated that data collection had occurred, the data entry user would transfer the data written on the source document over to the electronic case report form (eCRF) in OpenClinica. The Data Entry Log allowed tracking of which data had been entered in the system and when it had undergone source data verification by the data manager.

Date of Entry	Protocol	Subject No.	Date of Collection	Visit No.
7/1/14	2212/5018	98118	6/26/14	8 week
7/2/14	2212/5018	97119	7/1/14	8 week
7/2/14	2212	97123	7/2/14	RTS
7/2/14	2212	01124	7/2/14	1 week
7/7/14	2212/5018	98116	7/3/14	12 week
7/9/14	2212	93120	7/8/14	4 week
7/14/14	2212	98122	7/14/14	4 week
7/15/14	2212	97106	7/14/14	RTS
7/24/14	2212/5018	99117	7/22/14	12 week
7/30/14	2212/5018	97119	7/29/14	12 week
7/30/14	2212	01124	7/30/14	4 week
8/7/14	2212	98113	8/4/14	RTS
8/7/14	2212/5018	93120	8/7/14	8 week
9/3/14	2212/5018	01124	9/1/14	8 week
9/3/14	2212/5018	93120	9/2/14	12 week
9/3/14	2212/5018	98122	9/2/14	12 week
9/8/14	5219	9801	9/3/14	Pre-op
9/11/14	2212	98116	9/10/14	RTS
10/2/14	2212	99117	9/30/14	RTS
10/2/14	5219	9702	10/1/14	4 Week

Appendix D: Study Audit Log

The following is an example of a “Study Audit Log” for a patient in one of the research studies in OpenClinica. This audit log keeps track of who creates the patient, who enters patient data, and who edits the data. If there is any deleted data, it also tracks what was deleted, the day and time, and the user who completed the deletion.

9604 Audit Logs

Study Subject ID	Secondary Subject ID	Date of Birth	Person ID	Created By	Status
9604		21-Dec-1996		pollaka	available

Audit Event	Date/Time of Server	User	Value Type	Old	New
Study subject created	02-Oct-2014 19:03:30	pollaka			
Subject created	02-Oct-2014 19:03:30	pollaka			
Subject Group Assignment	02-Oct-2014 19:03:30	pollaka	Status		Surgery

Study Events	Location	Date	Occurrence Number
ACL Data Collection		01-Oct-2014	1

Name	ACL Data Collection				
Location					
Start Date	01-Oct-2014				
Status	data entry started				
Occurrence Number	1				
Audit Event	Date/Time of Server	User	Value Type	Old	New
Study Event data entry started	02-Oct-2014 19:03:33	pollaka	Status	scheduled	data_entry_started
Audit Event	Date/Time of Server	User	Value Type	Old	New
Item data value updated	02-Oct-2014 19:05:18	pollaka	EXT_DIFF_V2 (1)		-6.0
Item data value updated	02-Oct-2014 19:05:18	pollaka	FLEX_DIFF_V2 (1)		-100.0
Item data value updated	02-Oct-2014 19:05:18	pollaka	EXT_UNV_V2 (1)		1
Item data value updated	02-Oct-2014 19:05:18	pollaka	FLEX_UNV_V2 (1)		130

Appendix E: Daily Internship Journal

Monday, June 2 – Today was the first day of my internship at the Ben Hogan Sports Medicine Facility. Most of today was spent becoming more familiar with the facility and the research being done there. Racella, my mentor, was very helpful and spent the day answering all of my questions. I learned a lot about entering collected patient data into a spreadsheet, and we talked about what some of my options could be for a research project. I attended a meeting at Texas Orthopedic Specialists in Bedford about a symposium for athletic trainers that will take place in the spring. I also learned what some of my daily tasks will be during the internship.

Tuesday, June 3 – Today was another day of learning about the facility and research. I have decided that my research proposal will include implementing new database software called OpenClinica into this clinic, along with creating case report forms to use within the software. I completed the research privacy training for THR (Texas Health Resources) and the training for the IRB at the hospital. I observed Racella writing a protocol for a new research study on shoulder instability. I also got to see her submit an application for a new ACL study to the IRB. Finally, I got to help collect the data for a patient in the elbow OCD study. I also worked a little more on entry of data into the spreadsheet.

Wednesday, June 4 – This morning I worked alone (with help with my questions, of course) on a project for the first time. I took the spreadsheet of data from the ACL study and looked for missing information that I could pull from previous patient charts and put into the spreadsheet. This proved to be rather time-consuming as I'm not very familiar with where to find all the data yet. But working on this helped me learn a lot more and to find out what I need to research on my own as well. I also went with Racella to talk with someone about implementing the OpenClinica software in the Ben Hogan center. This is going to be what my research project is over – I am just waiting to become more familiar with the software's components before I set the details for my proposal. I went through Volunteer Orientation today and received my volunteer badge. At the end of the day I worked on the morning project some more.

Thursday, June 5 – This morning was spent writing up a Data Sharing Agreement between Ben Hogan Sports Medicine and UNT. BHSM will send some of the data collected from their concussion study to the Psychology Department at UNT, where they will do data/statistical analysis. The purpose of the Data Sharing Agreement is to allow UNT to use the data but to make sure that BHSM has access to all analysis and that the PI is allowed authorship on all papers submitted by UNT that uses that data. The agreement also describes in detail that confidential patient information must maintain confidentiality. I was also able to observe my first informed consent process today. After the doctor finished his appointment with one of the OCD patients, we went into the exam room with the patient to complete the screening, consent, and enrollment process for the patient. The OCD study is looking at gymnasts and baseball players who have osteochondral defects caused by trauma in their sports. The study tracks the patients before their surgery and for 6 months following their surgery, tracking their progression and how soon they are able to return to their sport. After the informed consent process

was complete, we brought the patient downstairs to the PT clinic where his measurements were taken and recorded. Some of the measurements included shoulder range of motion, wrist range of motion, and grip strength. I'll enter the collected data from this patient into the spreadsheet tomorrow. I also assisted on a project sending out questionnaires to previous ACL patients asking them to complete them for another research study.

Friday, June 6 – This morning was spent helping the physical therapist with his research study about recovery of Texas Health ACL patients. We worked on getting the questionnaire packets together to send to the potential study patients. These packets include a cover letter describing what the study entails, a 10-question questionnaire for the patient to fill out, and an authorization form to use or disclose protected health information. I also helped check the schedule for the current participants in each of the studies. At the end of each week we have to check upcoming appointments for each of the patients so that we can make sure we know when we can collect measurements from them for the study. I also observed another informed consent today, this time for a study being conducted by a different area of the hospital. The study is titled: AT&T Heart Failure Telemanagement Pilot Study and its purpose is to reduce the number of readmissions of heart failure patients. This informed consent was slightly different than the consent I observed Thursday, as it was conducted at the patient's bedside the day before they were discharged from the cardiac wing of the hospital. After the coordinator explained all aspects of the study to the patient and after the patient agreed to be in the study, paperwork was filled out and then we had to put the patient's information into the software system connected with the study. The patients in this study take home a tablet, bathroom scale, and heart rate/O₂ monitor and after the consent process was complete the coordinator showed the patient how to use these. For the study, the patient will use this technology at home daily and the data will be sent to the coordinator so he can monitor the patient's health and a nurse can call the patient with health advice accordingly.

Monday, June 9 – The morning started by assembling a binder for each of the studies that are awaiting approval by the IRB. These regulatory binders contain all pertinent information regarding each study, including the protocol, IRB documents, consent forms, data collection tools, and adverse events. Then we had a late morning meeting with Craig Garrison, the principal investigator for most of the studies at Ben Hogan Sports Medicine. There is a meeting with Craig each Monday to discuss what was completed the week before, what needs to be completed in the current week, and gives an opportunity to ask him questions. Today we discussed the patients that were seen last week and the measurements that were taken, which new studies were submitted to the IRB, and I spoke to him about my research proposal. I observed another informed consent process today, this time for a patient that was then enrolled in the UCL/Humeral Torsion study. Then I was able to record the measurements taken by physical therapists Craig and Megan, and later I entered the data into the spreadsheet. I also worked on entering data from previous patients' charts into the ACL data spreadsheet.

Tuesday, June 10 – Today I began working on some research training modules that were required by the hospital that I did not take with my CITI training course while in school. I also worked on editing the protocol for a future study on shoulder injuries in baseball and

softball players. The patient schedule was busy today, and ultimately we ended up seeing a UCL patient who was being released back to pitching, a new UCL patient, and a new ACL patient. The new patients were consented, and data was collected on all three. I'll input the data into the database tomorrow. I got to observe my first humeral torsion test using the ultrasound machine today, which was very interesting to me. I am getting more familiar with different physical therapy terms regarding the measurements that are taken for the studies.

Wednesday, June 11 – For the first few hours of work this morning I entered the data from Tuesday's patients into the spreadsheet. From 10am to 5pm today I went through OpenClinica training with another clinical research coordinator within the hospital. He uses the software for his study, and is the "super-user" for the software, so he took the day to train Racella and I on how to use the software. We began by building a study in the "test" interface of the system. This allows us to make as many alterations as we need without putting it into "production" mode, or the mode that will be used when we actually use the software for a study. After the study was built, it was time to start making a case report form, or CRF, for the study. I started making the CRF that contains all data collection throughout the entire study. This includes demographics, information about the patient's injury, and the measurements that are taken at each physical therapy visit. Racella was working on making a questionnaire CRF that will also be used in the study. We are scheduled to have another research training next Wednesday where we will test each other's CRFs by putting a fake patient's data into the CRF and seeing if it contains everything we'll need for the study.

Thursday, June 12 – Today, a member of the hospital's IRB returned the stipulations for a study. We had to take their comments on the protocol, consent forms and eIRB application and fix the mistakes in order to re-submit the study for approval. It was very time-consuming, but it was interesting to see what a pre-review actually looks like. We didn't finish making revisions, so that will probably be completed next week. We also worked on a new organizational system for the studies, where we can see what currently needs to be worked on for each study. There was a new UCL patient today, so we went through the informed consent and data collection processes again. There were a few other patients that came through the clinic for data collection as well. This evening I attended my first SOGRA chapter meeting. The topic was "Implementation of Targeted Source Document Verification," and the four speakers were employees of Alcon. The objectives of this lecture were: to describe a case study for implementing a targeted source document verification model, to describe metrics established for measuring the impact of targeted source documentation, and to describe the enhancement of remote monitoring to support targeted source document verification. The lectures didn't directly apply to much of the PI-initiated research that I've observed thus far, but some of it did apply to the software and eCRF's that I'll be implementing at the site.

Friday, June 13 – This morning we worked on assembly of regulatory binders for some of the unapproved studies. These regulatory binders include all information regarding the study, including everything submitted to and received from the IRB. These include the protocol, study application, correspondence, consent forms, and data collection tools,

among others. Each binder is updated whenever a protocol is approved, whenever an amendment is made, when a continuing review is done, when correspondence is made, and when the study is closed. It is a way to make sure all documents are kept securely in one place and all information about the study is organized. This afternoon I had the first meeting with my committee from UNTHSC. Dr. Garrison told Dr. Gwartz, Dr. Raven and Dr. Mallet about the site and about the current studies. We then discussed my research project where I will implement the clinical trial software system for one of the projects at the site. Drs. Raven and Mallet suggested adding a quantifiable measure into my study in order to show its effectiveness. I may try to compare the time saved by using the new system, or I might try to compare the errors in data collection between the old system and the new system.

Monday, June 16 – I spent some time today working on updating the ACL database. When I do this, I take the chart of a patient who was previously enrolled in the study and I compare all the data points from the research chart with the data that was entered on the spreadsheet. Sometimes all of the data points are entered correctly and sometimes there are missing or incorrect data points that I change in the database. Some of these include the range of motion measurements, balance measurements, or measurements from the strength tests that are taken before the patient is released to return to their sport. We had our research meeting with Dr. Garrison this morning to fill him in on the status of all the studies. I told him about what I had found while going through the ACL database and we also talked a little bit about my research project. At the end of the day there was a new patient who had just had surgery on their ACL and they were consented and enrolled in the study and measurements were taken.

Tuesday, June 17 – Today I spent a lot of time working on my research project. For this project, I am trying to implement OpenClinica, a clinical trial software system, into the Outcomes Following ACL Injury Study. Part of this process includes creating all case report forms, or CRFs, that will be used in the study. Normally, these CRFs are papers that the therapists use to collect the data that is then put in the Excel database by the coordinator. If this system can be implemented, the data will be able to be entered into these electronic CRFs after collection, and from there it can be directly analyzed or grouped however the coordinator or PI would like. I finished building the first CRF for the study – the data collection tool. This required downloading an Excel template from the OpenClinica website and then entering formulas for each of the items that I wanted to be on the CRF. When the Excel sheet is uploaded into the website, it converts it into a form where each data point can be entered. I also worked on updating the protocol and informed consent forms that the IRB had sent back with stipulations. At the end of the day there was a patient that was already enrolled in the ACL study but was eligible to enter the hip strength study since she was 8 weeks into her physical therapy treatment so she was consented and enrolled in the hip strength study.

Wednesday, June 18 – This morning I continued to work on editing the stipulations for the new ACL study for the IRB. Most of the day I spent in training with the super-user for OpenClinica. Today I learned how to put validations within the CRF, meaning that when a data point is entered, it will not be allowed to be submitted unless it fits into a

certain range of values. This will hopefully eliminate errors in data entry. I also learned how to use calculations within the CRF. These calculations are completed automatically when the page is saved after data points are entered. This will save time because the data entry user will not have to do the calculations by hand and then put them into the CRF, and those numbers will be immediately available for use if needed. For example, if you enter knee flexion and extension measurements for the injured and uninjured sides, it will automatically calculate the differences between these measurements which helps the therapist understand where the patient stands in his/her therapy.

Thursday, June 19 – This morning I helped finish amending the stipulations for the Outcomes Following ACL Injury study. All edits were made for the protocol, the informed consent forms, and the eIRB application. Then we completed a Word document summarizing the changes made, and submitted the forms and that document to the eIRB for them to review again. We also made a few changes to the protocol and IRB application for the ACL Prevention study. The rest of the day was spent helping Dr. Blueitt with his research training. During this time I also completed another draft of the data collection eCRF for the Outcomes Following ACL Surgery. It is uploaded into OpenClinica and ready for testing to see if it contains all the components needed to collect all data points for the subjects in the study. After Racella and I go through it we will present it to Dr. Garrison to see if there are any changes he'd like.

Friday, June 20 – Today we submitted Dr. Blueitt's research training documents to the hospital so they would have it on record. I also checked the schedules of the study participants to see when their upcoming appointments were with the doctors and therapists so that I could update the research schedule. We look at this research schedule to know when to expect the patients' follow up appointments. Then the schedule for next week was emailed to the physical therapy residents who help with all the measurements for the research studies. I also edited one of the questionnaires for the UCL/Humeral Torsion study for Dr. Conway to look over for approval.

Monday, June 23 – This morning I spent a lot of time going over previous subject research charts for the ACL study and updating them in the database. One of the physical therapists is going to use the data in a manuscript so we are trying to have it completely updated by the end of the week to be sent to her. We also checked Dr. Conway's schedule for tomorrow to see what time his follow-up patients are coming in so that we can get their appropriate measurements and to see if there will be any new patients that can be screened for enrollment. I also had a meeting with Racella to talk about my research project. She helped me brainstorm ideas for my methods and a plan is finally coming together. I worked on my research proposal for a while today, and I am going to start collecting data for my research project when the next ACL patient comes in for measurements.

Tuesday, June 24 – Today the IRB reviewer responded to our stipulations document with the final changes that need to be made to the protocol and consent forms before the study can be approved. We will need to take some time in the next few days to make those changes and submit them back to the IRB. There was a patient who had been

enrolled in the UCL study previously and was returning to see Dr. Conway due to pain in his elbow. Since he was back on site, we were able to screen and enroll him after consent in the Humeral Torsion study. After his appointment, we met him downstairs in the physical therapy clinic to collect measurements. We also figured out how to collect CPT (current procedural terminology) codes for patients for an upcoming retrospective concussion study. We needed to find the correct CPT code in order to find the records of previous patients of Dr. Blueitt who had a concussion at some point.

Wednesday, June 25 – Today there was a junior volunteer in the office to help with administrative work, so in the morning Racella and I helped explain the ACL questionnaire study to her and then showed her how to stuff the envelopes to be sent to the patients. Most of the day I attended another OpenClinica training. Today I learned how to create “rules” within the system, which means that you can make the system pop up a message or create something new whenever a certain data point is entered a certain way. It took a while to learn the programming for the rules, and I ended up making three rules for the study I was building. The rest of the day was spent helping the junior volunteer to make copies and file papers away in the regulatory binders.

Thursday, June 26 – Today was a very busy day as we had a total of 7 patients come in to the clinic that were either enrolled in a study or that could be enrolled in one of the studies. There was a new OCD patient that was consented and we collected measurements on. I was able to screen a patient for the Hip Strength study and another patient for the Humeral Torsion study. The other four patients were in the physical therapy clinic for appointments and we collected their measurements as well. I made some final revisions to the eCRFs for the old and new ACL studies and uploaded them into the study I built on the OpenClinica site.

Monday, June 30 – Throughout the day today I worked on the stipulations written to us by the IRB in their pre-review for the ACL Prevention study. I made changes to the study’s protocol and the adult, child, and parent informed consent forms. I also edited the corresponding questions in the eIRB application for the study. After all necessary changes were made, I submitted everything back to the IRB to wait for their approval or for them to send back more required changes. There was also a new patient in the UCL/Humeral Torsion study who was screened, enrolled, and taken downstairs for measurements. These measurements included shoulder, elbow and hip range of motion, scapular dyskinesis, neural tension, rotator cuff strength, balance, and a humeral torsion measurement done by ultrasound.

Tuesday, July 1 – Today while Racella worked on some edits for the informed consents for IRB approval, I worked on editing the eCRFs for two of the ACL studies. I had to add in hip strength measurements that I forgot to add previously. I also entered the first set of data that will be used in my research project from a patient in the ACL study into OpenClinica. Later I will use my source data verification checklist to count the number of errors made when transcribing the source document into the eCRF. Today I also entered data that was collected from multiple patients on June 26 and June 30 into their respective spreadsheets. I worked on the methods section of my research proposal and I

made a proposed timeline for my research project. At the end of the day we recorded data on a returning ACL patient.

Wednesday, July 2 – Today there was a new UCL/Humeral Torsion patient enrolled in the study and two new ACL patients enrolled as well. All three of these patients had measurements collected and recorded for their respective visits, including a return-to-sport test that I had not observed before. I was able to enter three more ACL patients into OpenClinica, and while doing this I realized that the eCRFs for the ACL studies have changes that need to be made. I began working on changing the CRFs but will need to continue to work on those over the next few days. I also decided I'm going to keep track of each patient that I enter into the system, so I made a log for that as well. I also entered the data for today and yesterday's patients into the normal Excel database and made a few changes to the protocol for the upcoming shoulder study.

Thursday, July 3 – Today there were three patients seen for research studies. One was a new UCL patient who was screened and enrolled. There were also two follow-up ACL patients and measurements were taken on them. One of the patients has moved therapy locations, from the Ben Hogan Sports Medicine at Texas Health Fort Worth to the Ben Hogan location at Texas Health Southwest. I was able to tour the Ben Hogan facility there after collecting measurements on the ACL patient. The rest of the day was spent entering data in OpenClinica for my project, in the Excel spreadsheet for the study, and doing different regulatory activities for several of the research studies.

Monday, July 7 – Today I worked on finalizing details for my research project and I worked on more sections of my proposal. It is difficult to determine how the source data verification checklists are going to be implemented for the different studies and how errors will be counted. I also did a few things to work on the amendment to the Humeral Torsion protocol. We also looked at patient schedules to determine who had follow-up appointments coming up and when they could be seen by one of the physical therapists for measurements.

Tuesday, July 8 – There was a new patient today who was screened and enrolled in the Humeral Torsion study and measurements were collected and recorded. There were also two follow-up ACL patients that came in for measurements in the physical therapy clinic. Their measurements were also collected and recorded. All measurements were entered into the respective Excel databases. I also had Racella to enter the data from the ACL patients into OpenClinica.

Wednesday, July 9 – The morning was spent finalizing and submitting the amendment to the Humeral Torsion protocol. We had to meet with Dr. Garrison to discuss the changes we had made to the protocol, and then I finished editing the document and submitted the entire amendment to the IRB for approval. During the meeting with Dr. Garrison, we also discussed the status of the other research projects and set up a few future meetings. We also started working on compiling elements for research training for the physical therapy/athletic training residents that will be coming in August. I worked on a document explaining how to write their manuscripts for their projects.

Thursday, July 10 – Today we continued working on planning the research training for the residents. I worked on a document explaining the step-by-step process of how to do HCCS training and how the residents should submit their conflict of interest forms to the eIRB for each of the studies they are assigned to. I also formulated a document about expectations of residents for data capturing. I continued to research how to count errors for my source data verification for my project. I am now seeking help from different monitors or people within clinical research who have more knowledge about the monitoring process.

Friday, July 11 – I continued to work on compiling the research training handbook for the residents today and also worked on my research proposal. We checked the schedule to see which research patients would be seen next week and updated the calendar.

Monday, July 14 – This morning was spent preparing for the research meeting with Dr. Garrison. In the meeting, we discussed my research proposal and what he thought of the overall project. We also talked about the research patients that were seen last week and the patients that will be seen this week. We discussed future meeting dates and what would occur at those meetings. We also showed Dr. Garrison the research training manual we have been working on to get his opinion on that. He told us what would be expected at that research training and what days each event of the training would occur. There was an ACL patient who came in today for a 4 week follow-up, so Racella recorded range of motion and straight leg raise measurements on the patient and then documented those measurements in the Excel database and in OpenClinica. There was also an ACL patient who took their return-to-sport test and those measurements were recorded as well. The rest of the day was spent working on my project and creating standard operating procedures for data collection for some of the studies.

Tuesday, July 15 – Today I learned quite a bit about the standard-of-care vs. the research related procedures that are done in the studies. These two types of procedures must be differentiated between for many purposes. I collaborated with Racella to come up with a plan to present to Dr. Conway, Dr. Garrison and others on the research team to discuss details about these procedures within the Humeral Torsion study. One of the Humeral Torsion patients was in the PT clinic today and we were going to take the humeral torsion measurement since we were not able to the last time the patient was in, however the ultrasound machine was being used and we were not able to take that measurement.

Wednesday, July 16 – Today I made more edits to my research proposal to be submitted to my research committee. I met with my major professor and my advisor to discuss how my internship is going and to update them on the progress of my research project. I also worked on typing up Standard Operating Procedures that will be included in the handbook to be given to the upcoming residents.

Thursday, July 17 – This morning we went to Dr. Conway's clinic to check the schedule for which patients would be coming in today. Then I began working on typing up the document for the Standard Operating Procedures for data collection in the Humeral

Torsion study. This document explains in great detail every step that occurs when data is collected for that study. All members of the research team must sign that they have read the document and that they understand all of the procedures. Dr. Conway then called us over to his clinic to discuss a new study that he would be interested in starting that would look at elbow injuries in all the gymnasts that he sees. I responded to an IRB correspondence about the ACL Prevention in Female Soccer Players study. I made changes to the protocol for the study and updated it in the eIRB application, then submitted that protocol along with my correspondence back to the eIRB. I also updated some instructions for the upcoming residents about how to submit a conflict of interest form for each of the studies they will be involved in. There was a new patient who was screened and enrolled in the Humeral Torsion study and two 6-week follow-up patients in the Humeral Torsion study as well.

Friday, July 18 – This morning I made final edits to my proposal to be turned in. I entered the data from yesterday's UCL patients into the Excel database. I also checked the patient schedules to see when they will be coming in for their next follow-up appointments. We created an agenda for the research meeting to be held next Monday morning with Dr. Bothwell. I also did some research about data repositories for research since Dr. Conway might want to use one for his new study of elbows in gymnasts.

Monday, July 21 – We had an 8am research meeting today. In attendance were Dr. Bothwell, Dr. Garrison, Joe Hannon, Racella and I. In the meeting we discussed what will be done in research this upcoming year regarding Dr. Bothwell's patient population. Dr. Bothwell had many great ideas about what data points he would like to look at and what type of papers he would like to write about the research. Dr. Garrison and Racella updated Dr. Bothwell on the progress of the studies that are currently under IRB review and they discussed possible start dates and the implications. There is a meeting scheduled a month from now to update Dr. Bothwell on our progress with the current and upcoming research studies. Following the meeting, there were two new UCL patients that took up the remainder of the day. Each of the patients was screened and enrolled in the study, and we collected their pre-operative measurements including humeral torsion.

Tuesday, July 22 – I spent this morning editing my electronic case report forms in OpenClinica. I had to revise the CRFs for both of the ACL studies because there were some things I had left out when I made the last edits that I did not realize were missing until data was entered. I also changed some of the data points around within the CRFs so that it followed more along the lines of the paper data collection tool. This will make it easier for the data entry person to find the data points that are to be put into the eCRF. We had a short meeting with Dr. Garrison to tell him about the progress we've made in determining how to differentiate standard-of-care vs. research-related procedures in the UCL study and what needs to be done in regards to that. We also discussed the control subjects who will be coming in on Saturday for measurements. Next, I made changes to the data collection tools for the UCL study and the upcoming ACL study. There were a few things on each of those documents that needed changes so I edited those documents and then made the same changes on the eCRFs as well. I completed the standard operating procedures for data management for the Humeral Torsion study and submitted

it to Racella. This afternoon, we worked on collecting retrospective data for the concussion study. We planned a meeting for tomorrow with Dr. Blueitt's team to discuss a plan for this study.

Wednesday, July 23 – This morning we went to the mailroom in the hospital to mail out all the envelopes from Mike Macko's ACL research study. We mailed out questionnaires to all previous patients with ACL injuries that they can send back for the data to be used for a research study. The envelopes contain a consent form, a HIPAA authorization form, the questionnaire, and a return envelope. There are around 670 patients who will receive these questionnaires. Next, I began researching random sampling techniques. I need a technique to choose which paper charts will be reviewed through source data verification. I discovered a formula on Microsoft Excel which allows you to put in a range of numbers and it will then produce a random number from that range through its own random sampling. I will start with 25 random chart numbers, since I don't know the number of electronic files I will be comparing them to quite yet. At 10am I had a meeting with Nathan Fisch. He helped me move the studies I had built in OpenClinica from the "test" environment over to the "production" environment. I had built my studies in test mode so that I could practice using the system and get the CRFs built the way that I needed them. Then I can move it over to production mode when everything is clean. All the ACL patient data that we've entered will have to be re-entered in OpenClinica. After lunch we had a meeting with Dr. Blueitt's team to discuss the organization of data for the concussion study. We also explained the requirements for their research training. Next I made changes to the consent forms for the Humeral Torsion study that were requested by the IRB. The consent forms needed to match the changes that were made to the study protocol when the amendment was submitted.

Thursday, July 24 – We continued working on getting the amendment for the humeral torsion study approved. There are going to be control subjects coming in on Saturday and we'd like to have the amendment approved before then so we can use the correct consent forms and data collections sheets.

Friday, July 25 – Today I worked on my research project. I tried to figure out how to randomize which visits I will complete source data verification on from the paper charts. I also had a meeting with David Chen and Elizabeth McDonald from Texas Health Research and Education. I told them about my project and asked for their advice about source data verification and how to complete it. I wanted to get a monitor's perspective so that I could see if my project is something that is really going to benefit the research site.

Tuesday, July 29 – This morning was very busy with patients. Before lunch we had two new UCL patients to be screened, enrolled and measured and also two follow-up UCL patients to gather measurements on. In the afternoon there was another follow-up UCL patient and a follow-up ACL patient to take measurements on. We entered all the patient data into the Excel database. I completed the randomization of visits that I will be doing source data verification on retrospectively.

Wednesday, July 30 – This morning I wrote part of the methods section for my thesis. I explained the randomization process for the retrospective SDV. Then I began my first source data verification on some previous patient visits. There was a new UCL patient who was screened and enrolled before we took measurements on him. He was having surgery this morning so we took his pre-op measurements right before his surgery. I had to meet with Craig to ask him about some missing data from the ACL database. He showed me where the data could be found on another document. The rest of the day was spent collecting data for the concussion study. We went back to the charts of all previous concussion patients to pull out their date of birth, gender, age at injury, mechanism of injury, and date of return-to-play. I also gathered measurements on a 4-week ACL follow-up.

Thursday, July 31 – There were two new UCL patients this morning who were screened and enrolled in the study. We were able to take all the pre-operative measurements on one of the patients, but the other one had to leave for an MRI and EMG and came back in the afternoon to complete his measurements. I had to make copies of the new packets for the UCL study since the amendment was approved and the documents changed. The packet includes a screening form, a parent/child or adult consent form packet, data collection sheet, and two questionnaires. I also continued working on collecting data for the concussion study today.

Friday, August 1 – Today Racella and I finished looking through all the patient charts for the Spring 2013 concussion patients. We filled in the Excel spreadsheet with the patients' date of birth, age of injury, mechanism of injury, and date of return-to-play. The next step for this concussion project is to go through the electronic files of the patients who came in the clinic in the Fall 2013 season to the present. We also have to collaborate with Tiffany from the concussion clinic to get the Fall 2012 data that she collected from paper charts. Once all the data has been consolidated, Dr. Blueitt's research team will analyze the data and start writing their paper.

Tuesday, August 5 – This morning I completed retrospective source data verification on five Week 1 visits and five Week 4 visits. I began writing the methods section of my Internship Practicum Report by explaining how chart randomization and retrospective source data verification were completed. There were two 6-week follow-up UCL patients and one 6-month follow-up UCL patient. We took measurements on all three of them downstairs in the PT clinic and then I put all their measurements in the Excel database. I had to re-calculate the number of visits which I could SDV for weeks 8 and 12. Since the Hip Strength (5018) study started well after the main ACL study, there are not as many patients who we have hip strength measurements on at 8 and 12 weeks. Therefore, I will not have as many charts to SDV for those two weeks. I recounted and randomized those charts and began SDV on those weeks as well.

Wednesday, August 6 – This morning I had to create amendments for 4 of the research studies here at Ben Hogan. I added myself as a research coordinator to these four studies because I had not been added before. In each study I had to create the amendment, explaining what changes I was making to the study. Then I had to go into the eIRB

application and add myself as a member of the study staff. Then I had to complete a conflict of interest form and submit it. Finally, I notified the principal investigator of each study that the amendment had been created and was ready for them to submit to the IRB. I also had a short meeting with Craig and asked him for signatures on a few forms. I gathered some data collection sheets from previous control subjects from the humeral torsion study that were in his office and added them to the subjects' research folders. Later in the afternoon, I went to the medical records office in our building to locate the paper charts I needed for the concussion study that I had not been able to find downstairs in the concussion center. I located these charts and recorded the information I needed from them in the concussion research Excel database. The next step for that study will be to consolidate the data collected by Dr. Blueitt's team and then have Dr. Garrison run data analysis so they can begin writing.

Thursday, August 7 – First thing this morning, there was a new UCL patient in to see Dr. Conway. He was screened and enrolled into the study; however we were unable to collect measurements due to a conflict in the patient's schedule. This worked out for us, however, because the therapists were then able to get measurements on a follow-up UCL patient who was there at the same time. I was able to put his measurements in the database and check the schedule for his next follow-up appointment. Racella and I went to Arlington to the THR Corporate Office for an IRB meeting to discuss the new eIRB that will be implemented soon. Once we were back in Fort Worth we finalized the resident research training handbook and began working on the PowerPoint presentation that will accompany it. There was another new UCL patient who was screened and enrolled but measurements could not be collected due to conflicts with the patient's schedule. I'll keep track of his future appointments and his MRI results so we can gather the baseline measurements. There was a follow-up ACL patient as well and measurements were collected.

Friday, August 8 – This morning I updated the subject schedule for follow-up appointments. I called two patients to schedule appointments for research measurements and updated the calendar. I made a few updates to all the databases as well and filled in missing patient information. Then I worked on Dr. Macko's ACL research study by entering IKDC scores that were mailed back to us into the database. I compiled the concussion data from two spreadsheets that had been sent to us from Dr. Blueitt's team.

Monday, August 11 – I compiled the rest of the concussion data from Dr. Blueitt's team into one finalized spreadsheet. I attended a meeting with Dr. Conway, Dr. Garrison, Racella, and Dr. Conway's nurse, Heather. For most of the meeting, we discussed how to differentiate between standard-of-care and research-related procedures and how those visits are to be billed. We finalized a plan of what to do for all visits for every UCL patient who is enrolled in the UCL study. I met briefly with the new residents about how to sign up in the eIRB so that they can do their HCCS training when we meet with them on Wednesday.

Tuesday, August 12 – Today I worked on updating the subject follow-up schedule and entering subject data that I had missed from last week. Then I worked on updating the

data collection sheet for the new ACL study, which has been approved and will start this week. I downloaded all the IRB-approved documents for that study to the shared network so that one of the physical therapists at Ben Hogan Southwest, Joe, would be able to access them if he screens any patients for the study. I spoke to Joe on the phone about what the plan is going to be for enrollment and data collection for that study at the Southwest location. Then I typed up the minutes for the research meeting with Dr. Conway yesterday. I entered the data from the control UCL subjects into the database and updated the subject ID numbers. Finally, we collected follow-up measurements on a UCL subject.

Wednesday, August 13 – This morning I updated the subject follow-up schedule. I also updated the database for the new ACL study that will be used when patients are enrolled. I had the junior volunteer, Melinda, to scan in the data sheets for the UCL controls we had collected on July 26th. These will be sent to the parents of the subjects. Then I helped her collect all the new consent forms and other forms needed for the new ACL study that we will be using here at Ben Hogan and also at the Southwest location. I submitted a protocol deviation to the IRB for the humeral torsion study stating that rotator cuff measurements were taken on the control subjects. I finished typing up the minutes for Dr. Conway's meeting and changed up the data collection sheet for the new ACL study, and then submitted it to the IRB as well. Finally, we had our research meeting with the PT and AT residents. We explained our expectations for research for them throughout the year and told them about what we do in research here at Ben Hogan. We then showed them how to do their HCCS training and explained the required documents required before they can participate in research.

Thursday, August 14 – This morning we worked with the PT and AT residents who started on their reliability training for research measurements. We had them practice shoulder range of motion, elbow range of motion, and Y-balance measurements. We will compare their numbers to test their reliability to see if they need more practice before beginning taking measurements for the research studies. There were two follow-up patients today – a UCL and an OCD. In the afternoon I worked on separating the data within the concussion database so that it is easier to put into SPSS for analysis.

Friday, August 15 – This morning we completed reliability training with the residents after a short meeting with one of the PI's, Mike Macko. I attended a staff meeting over lunch. Then I entered yesterday's patients into their respective databases and updated the follow-up sheet. I called our only follow-up patient for next week to confirm his appointment and to ask him to come in for measurements. I gathered all the required research training documents from the residents and put copies in the study staff binder. I will send electronic copies to the IRB when I have them all. I continued working on separating the concussion database for analysis. I sent Mike Macko the updates on his ACL study, and finished writing up the minutes from Dr. Conway's meeting earlier this week.

Monday, August 18 – This morning began with a research meeting between Dr. Bothwell, Dr. Garrison, Racella and I. We gave Dr. Bothwell updates on the ACL

research and finalized the plan for enrolling new ACL patients at Southwest now that the study is approved. We also discussed their future meetings with physicians and therapists in multiple locations for a multi-site collaborative study. The budget was also discussed, and Drs. Bothwell and Garrison decided where grant funds would be allocated. After this first meeting, Racella and I worked on finalizing a few of the concussion databases to be analyzed before we went to our weekly meeting with Dr. Garrison. At this meeting, Dr. Garrison ran the numbers from the concussion data through SPSS (the statistical software program) and we decided which data points had statistical significance that Dr. Blueitt and his research team could use when writing their papers. We also discussed the concussion collaborations between the UNT Sports Psychology program and the possible UTSW collaboration. We also discussed these topics in our afternoon meeting with Dr. Blueitt. In this meeting, we also talked with the UNT PhD student, Thomas, who will be looking at retrospective and prospective data from the concussion center for analysis and to assist in writing. In the afternoon, I also met with the residents to answer questions they had about starting up their own research projects and showed them where to find the databases for all our current research studies. They will be planning their research over the next few months.

Tuesday, August 19 – This morning there was a new UCL patient who was screened and enrolled in the humeral torsion study. I recorded his measurements in the physical therapy clinic after his MRI appointment. I put his data into the Excel spreadsheet and put together his subject research folder. I also prepared materials for consenting the TCU soccer players in the future for the ACL Prevention study. I got a few regulatory documents organized for the study binders and recorded measurements for a 6 month UCL follow-up.

Wednesday, August 20 – Today was Racella's last day at Ben Hogan Sports Medicine. I worked on switching all my documents over to her computer since I will be using it now. I won't be in the office tomorrow so I got the subjects' research folders together who will be coming in tomorrow for follow-ups. I will give these folders to Craig so he can collect and record their data tomorrow. I also updated the ACL data collection sheet to include hip strength measurements at 8 and 12 weeks and knee strength measurements at 12 weeks. Then I updated the regulatory binder for the ACL prevention program study by printing all the IRB-approved documents and consent forms and placing them in the binder. I did the same for the new ACL study since it had not been done yet. I prepared a Research Training Log for the residents to sign saying that they have been trained in the research procedures for our studies. I will have them sign the logs on a day when they are all in clinic.

Friday, August 22 – This morning I met with Dana Westcott from Texas Health Research and Education. I gave her the service agreements between BHSM and UNT for the concussion study to be handed out for signatures and returned to UNT's contract office. I began writing amendments in the eIRB to add the residents to the studies they will be helping with, and replacing Racella with myself as the research coordinator for the studies. I had a meeting with Dr. Garrison to discuss gaining computer access as research coordinator for the studies. He also told me about yesterday's patients and gave

me their measurements and consent forms, which I entered in the database and filed. He also told me the plan to collect humeral torsion control subjects at TCU next week, so I got the supplies ready for that. The rest of the day was spent checking up the follow-up schedule and updating it with new information. I called the patients who have appointments next week to confirm with them that they need to come in for research measurements.

Monday, August 25 – This morning I got together all the materials we will need this afternoon when we go to TCU to collect control measurements from the baseball players. I prepared for my meeting with Dr. Garrison and I filed recent correspondences in the respective studies' regulatory binders. In the meeting with Dr. Garrison we spoke about the control data collection today, this week's follow-up patients and a patient who had to be dropped from the humeral torsion study because he did not have a true UCL injury. After the meeting, I phoned the parents of the un-enrolled subject to let them know the consents and data collection that had occurred on their first visit would be shredded and that the subject would no longer be enrolled in the study. I scanned in the data sheets and consent forms from the previous humeral torsion controls so that Dr. Garrison can send them to the parents to have a copy. We collected shoulder and hip range of motion and Y-Balance measurements from the control subjects at TCU.

Wednesday, August 27 – Today I sent consent forms to Dr. Garrison to forward to parents of the UCL controls and met with him about what happened yesterday when I was gone. I organized the consent forms and data sheets from the TCU controls we took on Monday, and prepared materials to get the rest of the controls this Friday. I checked up on patients MRI results who had been enrolled in the study but had not yet had a diagnosis. I also worked on the retrospective ACL study by entering in IKDC scores and the envelopes that were not able to be sent to the patients.

Thursday, August 28 – Today there was a new UCL patient who was screened and enrolled in the study and measurements were taken. There was also a UCL patient who was 10 days out from surgery who we had missed before surgery. He was enrolled in the study but no measurements were taken. The rest of the day was spent working on organizing materials for the regulatory binders and in the eIRB.

Tuesday, September 2 – This morning I responded to the emails I had missed on my days out Friday and Monday. I set up research meetings and planned to send materials for signatures for the concussion study agreement with UNT. I checked the schedule for possible new patients and checked the follow-up schedule as well, letting Dr. Garrison and the residents know when to expect patients for measurements. I then finished writing the amendments for 7 of the current studies in the eIRB and changing the corresponding applications. I will wait for the residents to submit their conflict of interest for each study they have been assigned to and then I will submit those amendments for review. I entered all the data collected from the TCU controls for the humeral torsion study into an Excel database. I assigned each of the new subjects an ID number and organized their consent forms and data sheets. I delivered the Business Associate Agreement with UNT to the IRB office after Craig had signed it. There was a young gymnast who was screened and

enrolled into the OCD study and we took measurements. We also took measurements on two follow-up ACL patients who were 12 weeks out of surgery.

Wednesday, September 3 – This morning I put in the data from yesterday’s three patients into their respective Excel databases. I continued organizing the consent forms from the UCL control patients from TCU. I also worked on my own research project, organizing patient charts within OpenClinica. In the afternoon I met with one of the physical therapy residents about her ideas for a research project. She wants to assist in the writing portion of the retrospective concussion study and she wants to look at learning disabilities within the concussion data as well. At the end of the day I traveled to the Ben Hogan Southwest location where a pre-operative ACL patient was screened and enrolled in the study and pre-operative measurements were recorded.

Thursday, September 4 – This morning I entered the data from the new ACL patient into the database and organized his chart. I spoke to the mother of a new UCL patient who is having surgery next week and scheduled a time to do the pre-op UCL measurements. Next, I checked all the current research patients to see if they have any follow-up appointments scheduled and updated the follow-up list. Tomorrow I will call the patients who are scheduled for next week to remind them to come in for research measurements. I checked up on the ACL patients who are still doing physical therapy to see when they might be doing their return-to-sport tests when we need to get our final measurements on them. I got in touch with each of their physical therapists to get an idea of when those tests might be. Then, I began doing retrospective SDV for my project. I met with another physical therapy resident about her research project. We have started working on a protocol for a prospective research study looking at balance and risk of injury in female volleyball players at the collegiate level. In our meeting, we talked about how the recruitment and consent processes would go and how to contact the teams’ representatives and get started on protocol and consent form writing. There was a new pre-op UCL patient who came in. He was screened and enrolled but was scheduled for an immediate MRI so we will have to get measurements on him the morning of his surgery.

Friday, September 5 – I composed the continuing review for the retrospective ACL study this morning. The continuing review is due to the eIRB next Friday, and I have a meeting with the PI Mike Macko on Monday to discuss it before submission. I had to fill out the entire continuing review application and I also drafted timesheets for the research staff who participate in the study to submit to the grants committee of Texas Health Research and Education. Later in the morning I had a meeting with Tiffany, the AT from Dr. Blueitt’s concussion team, and Sarah Stone, one of the physical therapy residents. Sarah is interested in participating in the concussion research and starting her own research project involving concussions, so I wanted her to meet Tiffany so she could tell her about all the work they do in the concussion clinic. We set timelines for Sarah to start working on writing for the publication for the current concussion study, and where she can find the data she needs from the patient charts for her research study. I also spent part of the morning looking at the edits Christy had made to the protocol, consents, and recruitment ad for the volleyball study she wants to start up. I made edits to the documents and sent them back to her. We are going to present the project to Craig on

Monday. In the afternoon there was a 3 month follow-up UCL patient who we took measurements on.

Monday, September 8 – When I got to the site this morning I prepared for my 10:00 research meeting with Craig. We discussed what had happened while he was out last week, patients that would have follow-ups this week, upcoming research projects, and other research-related topics. In the afternoon I had a research meeting with Mike Macko, the PI for the retrospective ACL study. I am submitting the continuing review for that study this week so we met to discuss the review and what the next steps for that study will be. I am going to look up the names of all the people whose envelopes were sent back as “Unable to forward” and I will try to find an updated address for them so we can send the IKDC form to them. The amendments for all the current studies were submitted today and there was a 3 month follow-up UCL patient that we took measurements on downstairs.

Tuesday, September 9 – This morning I followed up with different people at Ben Hogan and Texas Health Resources regarding questions about different research studies. I prompted Craig and Mike to submit their conflict of interest for the retrospective ACL study in the eIRB so that I can submit the continuing review. I organized a few patients’ charts that had forms that needed to be filed. I submitted the time sheets for the retrospective ACL study to the grants committee in the hospital and updated the IKDC scores for some envelopes we’ve received. I also added all the strength measurements to the data collection sheet for the new ACL study. I began working on the continuing review for the OCD study with is due next Tuesday the 16th. In the afternoon there were 2 new UCL patients who were screened and enrolled into the study and measurements were taken. I also brought the handheld dynamometer to the Ben Hogan Southwest location to be used on two ACL patients there today and tomorrow.

Wednesday, September 10 – Today I continued working on changing the addresses for the envelopes that were returned to us from the retrospective ACL study. I also entered all the patient data for two UCL patients and one ACL patient. I put the data from the two ACL patients that are enrolled in the new study into OpenClinica. Then I worked on retrospective source data verification for my research project. I had to complete some online courses for the hospital which took up a lot of the day. I traveled to the Southwest location for a return-to-sport follow-up on an ACL patient.

Thursday, September 11 – When I got to the site this morning I went over to Dr. Conway’s clinic and got a copy of his patient schedule for today. I saw that we had four follow-up UCL patients coming in, and two possible new UCL patients. I informed Craig and the residents of these patients so they would know when to expect us to come down for measurements. I also scheduled a new UCL patient to be consented on Monday. I put the data into the database from the return-to-sport ACL measurements yesterday. I also put that data into OpenClinica. I gathered all the materials that will be needed for enrolling new patients and seeing follow-up patients today, because they were all scheduled to come in around the same time and I wouldn’t have had time to run back and forth to my office. I am still waiting on all my amendments to be approved so that I can

submit the continuing reviews that are due tomorrow and next week. Between patients, I worked on addressing the envelopes to be sent out to the retrospective ACL patients. There were four follow-up UCL patients that we took measurements on. All of the amendments I submitted were approved by the IRB, so I printed off the amendment information and the approval letter for each study and placed them in the regulatory binders. I also received a call from one of the IRB analyst who had a suggestion on some changes to one of the continuing reviews before I submit it, so I made those changes as well.

Friday, September 12 – This morning I checked and updated the follow-up schedule for the research patients. I also looked at the studies in the eIRB to see who has submitted their conflict of interests for the OCD study so that I can submit the continuing review. I also typed up two protocol deviations for the UCL study and prepared a document for Craig to sign in regards to a previous adverse event in one of the ACL studies. Then I worked on return-to-sport source data verification retrospectively.

Monday, September 15 – This morning I prepared for my weekly meeting with Craig and began writing my thesis. The IRB analyst that reviewed the amendment for the humeral torsion study sent back changes to be made to the application, so I made those changes and submitted them back to the analyst for review. As always, I printed out these correspondences to be put in the regulatory binder for the study. The new UCL study patient we were expecting did not show up. I worked on editing the new protocol and consent forms for the volleyball study that Christy wants to start up soon.

Tuesday, September 16 – There was a new UCL patient this morning and two 3 month follow-up UCL patients in the afternoon. After seeing the follow-up patients, I talked with Craig, one of the residents and a physical therapist about the measurements we got for their shoulder range of motion and their humeral torsion, how those numbers added up and what they meant for the patient. We re-measured humeral torsion on one of the patients to be sure that the measurements we took initially were correct. We also learned that one of the subject's younger brothers is a 13 year old baseball player who might be interested in enrolling in the study as a control. He is going to come in with the subject and their mother the next time they come in for research measurements, and we will see if we can enroll him as a control subject. I also created my first study in the eIRB today – the volleyball study that one of the residents wants to start for her project. I filled out the application in the eIRB for the study and attached the protocols, consent forms, and recruitment ad that we had worked together to create. I also had to fill out a “Bill One” form to submit along with the study. I am very excited to hear back from the IRB analyst, since this is my first time submitting a new study and I did it almost all on my own.

Wednesday, September 17 – Today I prepared the regulatory binder for the new study that was submitted. I was also interested in how we can increase subject recruitment here at the site, so I researched different possibilities for that. I will present my ideas to Craig at our next meeting. I got in touch with a patient who wanted to come in as a new subject in the UCL study and he was enrolled today.

Thursday, September 18 – I came in early this morning to get measurements on a 3 month follow-up UCL patient who had an appointment with Dr. Conway at 7:45. Measurements were taken on that patient and recorded in the database. I spent some time catching up on updating the regulatory binders for the studies – putting the appropriate correspondences and entries for the eIRB into each study’s binder. Then I worked on source data verification for the prospective data that was put into OpenClinica. I decided to create a separate spreadsheet for this data.

Friday, September 19 – I updated the follow-up schedule this morning and paid special attention to patients who had follow-up appointments next week. If they did not have an appointment with a physical therapist at Ben Hogan, I called them to make sure they knew to come in for research measurements either before or after their appointment with Dr. Conway. There were a few ACL patients at other Ben Hogan locations that were due for research measurements so I took some time to figure out how those measurements could be collected. The rest of the day I continued working on prospective source data verification for my project and worked on writing my thesis.

Monday, September 22 – When I got to my office this morning I prepared for my weekly meeting with Craig to update him on the research. I checked the eIRB to see if the amendment had been approved for the humeral torsion study yet. The continuing review for that study is due next Friday, and the amendment has to be approved before I am able to submit that continuing review. The new volleyball balance study is now under IRB staff review, so I am just waiting to hear if there are any changes that need to be made to the application, protocol or consent forms. I’ll need to make those changes as soon as possible to get the study approved quickly. We will be taking balance measurements on some of the TCU volleyball team’s opponents when they visit TCU for games, and since the volleyball season has already started, we want to take measurements on as many teams as possible. Christy, the PT resident and co-investigator for that study, is also trying to get in contact with local high school-level club volleyball teams to see if they would be willing to participate as well. In my meeting with Craig, we discussed this week’s research patients as well as updating the website for research at BHSM. We also talked about doing an 18-24 month follow-up on UCL patients. The rest of the day I worked on gathering data for feasibility of the UCL follow-ups and typing updates for the website. I also worked on writing my thesis. At the end of the day there was a new UCL patient who was consented and enrolled into the study.

Tuesday, September 23 – This morning was a busy patient day in Dr. Conway’s clinic. There were two new UCL patients who were screened and enrolled and then I recorded the measurements that two of the residents collected. Then there was a 6 week follow-up UCL patient who we got measurements on as well. In the afternoon, there was a 6 week follow-up OCD patient and another new UCL patient who was enrolled.

Wednesday, September 24 – This morning I put in the data from yesterday’s OCD patient which I didn’t get around to doing yesterday. I also worked with Craig and Joe to figure out why we have been missing pre-operative ACL patients at Southwest. I met with Craig and we talked to Dr. Bothwell’s practice manager to straighten things out and

come up with a definitive plan for these patients. I also talked to Craig and Joe about the humeral torsion data since Joe will be presenting on it in a few weeks. I compiled a new database with only the data points and calculations they wanted to look at in order to make it easier for them to put into SPSS and analyze. The rest of my day was spent on thesis writing.

Thursday, September 25 – This morning I prepared the materials we would need for the seven possible new and follow-up research patients for the day. Then I checked the eIRB for updates on the amendment for the humeral torsion study and the application for the volleyball study. I entered some information from some envelopes that were returned for the retrospective ACL study. Some of the new patients we were expecting turned out to have an alternate diagnosis and one of our follow-ups did not show up, so during the afternoon I worked on thesis writing. At the end of the day, we had a 4 month follow-up OCD patient and a 3 month follow-up UCL patient who we took measurements on and recorded. Later, there was a 6 week follow-up OCD that we took measurements on. Her twin sister was actually seeing Dr. Conway for the same injury and to schedule surgery, so she was enrolled in the study as well and we got her measurements also.

Friday, September 26 – Today I checked the schedule for follow-up patients and tried to contact them by phone to remind them about their research measurements. I also entered a few patients' data into the database and updated their follow-ups. I also received an email from Dr. Bothwell's surgery scheduler about potential research patients for the ACL study, so I tried getting in contact with them to set up a time to speak with them before surgery.

Tuesday, September 30 – This morning there was a UCL patient who came in for his 6 week follow-up measurements. I also spent time printing out correspondences with the IRB as two of the continuing reviews I submitted were approved and the reviewer responded in regards to changes that need to be made to the new study. I worked on making those changes to the application, protocol, and consent forms. I also entered some data that was collected last week into the database and updated the follow-up schedule. I received an email from Dr. Bothwell's surgery scheduler about potential research patients, one of which has Spanish-speaking parents. I spoke with Craig about how to get an interpreter for the consent process for this patient. I also created a tracking form in Excel for these ACL patients who are eligible for recruitment in the study, so that I can track which patients I have spoken with and which might be interested in participation. There was a follow-up OCD patient who we took measurements on in the afternoon. I put those numbers in the database afterwards. I printed out the newly approved consent forms for the OCD study and replaced them for the old ones. I also did some filing in the regulatory binders after I completed all the edits for the new study. One of the ACL patients also did her return-to-sport test today and I recorded the measurements for that.

Wednesday, October 1 – Today was very busy working on IRB submissions. I completed all changes to the application, protocol, and consent forms for the new volleyball study and submitted them to the IRB. I also began working on the continuing review for the humeral torsion study which is due this Friday. I am still waiting on the

previous amendment to be approved before I will be able to submit the study, so I will have to call someone to be sure that is finished tomorrow. I met with Craig to talk about one section of the continuing review which asks about preliminary results and findings of the study. One problem I encountered while drafting the continuing review was the number of subjects which have been withdrawn from the study since its start. There have been seven subjects withdrawn; however protocol deviations were only filed on two of them that I had submitted last month. I spoke with Tara and Craig about how to go about submitting those to the IRB with the continuing review. In the afternoon I was scheduled to go to Ben Hogan at Southwest to enroll a new pre-op ACL patient in the study and to pick up some measurements that had been taken there this week. The new patient did not show up for his appointment so I was unable to enroll him, however there just happened to be another patient in the clinic who was eligible for the study so he was enrolled post-operatively. Then I headed back downtown to meet with Craig to go to the Jim McLean location to gather measurements for a 12 week follow-up patient there. We went to Jim McLean and then that patient didn't show up for her appointment, either.

Thursday, October 2 – Today there were three follow-up UCL patients who we took measurements on. I also worked some more on the continuing review and figured out what to do regarding the withdrawn subjects with no protocol deviations filed. I entered lots of data into the Excel databases and also into OpenClinica for my project. I had to complete a few forms for school and interacted with members of my committee regarding my dissertation and defense.

Friday, October 3 – Today I completed everything in the continuing review, had all the study staff submit their conflicts of interest, and submitted the review to the IRB. I also did my weekly subject follow-up, seeing when upcoming appointments are and calling subjects to remind them they need to have research measurements done when they come in to see Dr. Conway. This is also a good time for me to let the therapists know when their patients are due for measurements and how they are progressing in the study. Next I worked on prospective source data verification for my project.

Monday, October 6 – This morning we had our monthly research meeting with Dr. Bothwell. Mike and Craig were in attendance and we discussed topics involving the research and clinic. Immediately after, I met with Craig to get some signatures from him and to discuss a few things that occurred last week and what will be happening this week. I did a lot of filing that I was behind on and typed up the minutes from this morning's meeting. Mike had another envelope from the retrospective ACL study come in so I put the IKDC score into the database. In the afternoon I had an interview with Craig for the clinical research coordinator position here at Ben Hogan. There was a follow-up UCL patient and a return-to-sport ACL patient who we took measurements on and recorded for the studies. Today I also did some calculations of the errors I found while doing source data verification for my project.

Tuesday, October 7 – I communicated with the residents early this morning about who would be able to come in for research measurements since there were two possible new study patients seeing Dr. Conway. I entered yesterday's ACL return-to-sport data into the

Excel database. I continued working on my project and evaluating the results I've found regarding errors in data collection/transcription. There ended up being only one new study patient, and the follow-up patient who was scheduled cancelled his appointment with Dr. Conway so we will see him next week. The rest of the day I spent writing my dissertation.

Wednesday, October 8 – Since I was caught up on all regulatory tasks and there were no research patients today, I spent the entire day writing and editing my dissertation. I am beginning to analyze results and make conclusions at this point.

Thursday, October 9 – The IRB sent a correspondence late last night that I worked on responding to this morning. Daniel, the IRB analyst assigned to my humeral torsion continuing review, had a few questions regarding my continuing review submission that I had to answer. I did not have to change any part of my continuing review application, I just had to clear a few things up for him. There were a few patients in Dr. Conway's clinic that were not study patients but that needed physical therapy consultations, and since Craig was out of the office teaching a class at TCU, I collaborated with Dr. Conway's office and Ben Hogan Sports Medicine to get those patients set up with what they needed. I continued working on my dissertation in the afternoon, and there was a 3 month follow-up UCL patients whom measurements were taken on.

Friday, October 10 – This morning started with my weekly patient follow-up updating. I check the follow-up lists for patients who are scheduled for research measurements in the next two weeks. Then I go to each of their medical files to check when their appointment with their physician will be. If their appointment is in the upcoming week and they do not have an appointment for PT here at Ben Hogan, I call the patient or patient's parents to be sure they are aware of the research measurements. They have the option of coming in for research measurements either before or after their appointment with their doctor. Then, I update my follow-up list and the calendar with the upcoming research visits. I also continued to work on the results section of my dissertation today. I am meeting with Craig on Monday to discuss the results I've found and to get input from him about the project and update him on my progress.

Monday, October 13 – This morning I had my weekly research meeting with Craig. We started the meeting a little earlier today so I could discuss my research findings with him. He was pleased with the results I've found, so I spent a lot of the day putting my tables and charts into words for my dissertation. We also prepared for our afternoon research meeting with Dr. Conway, in which we discussed how to avoid protocol deviations in the UCL study, the new shoulder study we want to start up, and submission of abstracts for AOSSM (American Orthopedic Society for Sports Medicine) this year. I also put together a spreadsheet for Craig containing humeral torsion and shoulder range of motion data so he could begin writing an abstract for AOSSM. The new volleyball study was approved today, so I printed the approval letter and all essential documents for the study to be put in the binder.

Tuesday, October 14 – I continued working on thesis writing this morning. In the afternoon there were two follow-up UCL patients that came in for measurements at the same time, so I had to coordinate with Craig and one of the residents to get both of their measurements done at the same time.

Wednesday, October 15 – Last night, the IRB analyst for the humeral torsion study responded to the continuing review with more changes that were necessary. This morning I read his correspondence and began making the necessary changes. This included writing four protocol deviations that Racella had not submitted to the IRB when they had occurred. Writing these deviations took me a while since she is no longer employed here and I was not here at the time they occurred. I submitted those four protocol deviations and changed the numbers of subject enrollment in the continuing review application. I noted these changes in a Word document and submitted it with my response to the IRB. Then I had to enter the data from yesterday's patients in the Excel database and update their future follow-ups. One was a 6 month patient so he will most likely not be coming back for any research measurements in the future.

Thursday, October 16 – Thesis writing continued today as well as a few follow-up UCL patients. I reorganized some of the humeral torsion data and sent it to Craig for analysis. There was a new UCL patient in the morning that was enrolled and measurements taken. One of the follow-up patient's measurements didn't seem to make sense – so we spent a while evaluating those to see if maybe we missed something. I also met with Christy, the PT resident who is doing the volleyball study. She has a few teams that are interested in participating so I went over some things with her and told her I would get packets of consent forms together for her.

Friday, October 17 – When I got to work this morning, I had received an email from Dr. Bothwell's surgery scheduler about some upcoming ACL surgeries that Dr. Bothwell will be doing in late October and November. I put those patients on my own follow-up list so that I can contact them about the research study before they have surgery. Bobby, one of the PT residents, also informed me of a post-op research patient she had scheduled for two weeks from now, so I contacted the patient and set up an appointment for consent and enrollment before the patient has surgery. After that, I did my usual Friday follow-up for all the upcoming research patients and continued to work on my thesis.

Monday, October 20 – This morning I prepared for my weekly research meeting with Craig. We talked about the ACL study and why we haven't been getting many subjects enrolled and how to possibly increase enrollment numbers. He also helped clarify what he wanted to look at for the case control study data for humeral torsion. I spent most of the rest of the day compiling the data he needed into a new spreadsheet for analysis.

Tuesday, October 21 – I received an email from Dr. Bothwell's surgery scheduler about possible research patients and added them to my follow-up lists. I called the patients who had surgeries scheduled for this week and next week to determine their interest in the research study. I emailed the PT and AT residents with the

research worksheet they have due in two weeks. Between patients, I worked on writing my thesis. We had a three month UCL follow-up and a new pre-op ACL patient.

Wednesday, October 22 – This morning I met with one of the applicants for the research coordinator position at Ben Hogan Sports Medicine Southwest. Craig wanted her to get a chance to see what some of her daily tasks would be if she took the job. I explained to her what I do and explained the research studies to her. I got all the consent form packets together for Christy's volleyball study since she has some teams coming to town soon that are interested in participating in the study. I also drafted a cover letter to include with some consent forms we will be mailing to some of the teams.

Thursday, October 23 – I will be out of the office tomorrow, so I did my usual weekly follow-ups a day early. I checked the schedule for upcoming patients in all enrolling studies to be sure I would be prepared to take research measurements on them whenever they were scheduled to come in. I also updated Dr. Bothwell's upcoming ACL surgery list. There was one new UCL patient who was enrolled in the study and one six week follow-up UCL patient. I spoke with Joe at Southwest about the follow-up ACL patients that have been coming in over there and how I could get those measurements from him. I also assembled the regulatory binder for the Y-Balance Volleyball Study and got envelopes together for sending the consent forms out for the study. I got started on another protocol deviation for the humeral torsion study – we had enrolled another patient who did not end up having a UCL tear included in his diagnosis after the MRI. I also called the IRB analyst to figure out when to submit that protocol deviation as the continuing review for that study is already with the reviewer.

Monday, October 27 – Today I worked on different aspects of the volleyball study for most of the day. Christy had collected data on some club volleyball players over the weekend, so I helped her consolidate the data and get all the consent forms in order. She had also gotten more information about teams that are interested in participating, so I helped her get all the consent forms and materials prepared for those. Tomorrow we will go to TCU to collect data on the West Virginia volleyball girls. I also prepared consent forms to mail out to another collegiate volleyball team. I also prepared an amendment for the study, expanding the age range of subjects from 15-25 to 13-25 and adding weight as a data point to collect. I received some follow-up measurements on ACL patients from Joe at Southwest so I added them to the database and updated their follow-up dates.

Tuesday, October 28 – With last night's new ACL patient, I forgot to get Dr. Conway's schedule for today, so I went to the site early to make sure there weren't any possible new patients with early appointments that I would have to get physical therapists or residents for. There were no possible new study patients on the schedule. There was supposed to be an OCD follow-up patient coming in for measurements after her appointment with Dr. Conway. She was a little over 2

months into conservative treatment, and Dr. Conway decided to schedule surgery, so we did not take measurements. We will actually restart her in the study by taking post-operative measurements until she returns to gymnastics. During this time, I checked the eIRB for the studies to see where the continuing reviews, etc. stood. I also sent a notification to Craig to submit the amendment I created for the volleyball study yesterday. I entered the measurements we took on the ACL patient last night and created his research folder. Throughout the day between patients I also continued working on my thesis. I also called upcoming ACL surgery patients to ask about their interest in participation in the research study and to set up enrollment times if necessary. One of the UCL patients came in for a follow-up and we collected Y-Balance on him since we had missed that measurement at the last research appointment. We also had a 2.5 month follow-up OCD patient and a 3 month follow-up UCL patient. In the evening I went with Craig, Christy, Casey and Sarah to TCU to take balance measurements on the West Virginia volleyball team.

Wednesday, October 29 – The continuing review for the humeral torsion study was approved today, so I printed all new stamped approved essential documents and placed them in the regulatory binder. I also replaced all the old consent forms with the new, stamped approved ones. I compiled the consent forms and data from the volleyball balance measurements we collected last night. I also made changes to my thesis and began composing the PowerPoint for my defense. I left at 4:30 to go to Southwest to help with enrollment of a new pre-operative ACL patient. However, the patient had fallen the previous day and her knee was inflamed and painful, so we were unable to take pre-op measurements. She is not having surgery for two weeks, so we hope to collect pre-op measurements next week.

Thursday, October 30 – This morning I finished compiling the volleyball balance data and consent forms in the database. I also did a write-up about last night's ACL patient and entered some IKDC scores into the retrospective ACL database. There were no UCL patients in Dr. Conway's clinic today, so I continued to work on my presentation for my defense and traveled to Southwest to collect 8 week research measurements on a follow-up ACL patient.

REFERENCES

1. "Electronic Records; Electronic Signatures." 21 CFR 11. U.S. Food and Drug Administration. 1 April 2013.
2. Fitzgerald, G Kelley, and Anthony Delitto. "Considerations for Planning and Conducting Clinic-Based Research in Physical Therapy." *Journal of the American Physical Therapy Association* 81: 1446-1454. August 2001. Web. Accessed 6 July 2014.
3. "Guidance for Industry - Computerized Systems Used in Clinical Investigations." U.S. Food and Drug Administration, May 2007. Web. Accessed 21 June 2014.
4. "Guidelines for the Conduct of Research in the Intramural Research Programs at NIH." National Institutes of Health. Web. Accessed 25 September 2014.
5. Khosla, R., D.D. Verma, A. Kapur, and S. Khosla. "Efficient Source Data Verification." *Indian Journal of Pharmacology*: 180-186. 21 Feb 2000. Web. Accessed 23 June 2014.
6. Le Jeannic, A., C. Quelen, C. Alberti, and I. Durand-Zaleski. "Comparison of Two Data Collection Processes in Clinical Studies: Electronic and Paper Case Report Forms." *BMC Medical Research Methodology* 14:7 2014. Web. Accessed 21 June 2014.
7. Lu, Zhengwu, and Jing Su. "Clinical data management: Current status, challenges, and future directions from industry perspectives." *Open Access Journal of Clinical Trials*: 93-105. 19 June 2010. Web. Accessed 23 June 2014.
8. Morrissey, Matthew, Lynn Kanda, and Clive Brewster. "Development of a Clinical Physical Therapy Research Program." *Journal of the American Physical Therapy Association* 67: 1110-1114. July 1987. Web. Accessed 6 July 2014.
9. Orchard, John, and Blood, Greg. "How to Use Databases in Sports Medicine Research." *Evidence-Based Sports Medicine*. January 2002. Web. Accessed 25 September 2014.
10. Pfizer. "Quality Management in Clinical Trials." *Clinical Case Study Series*. April 2013. Web. Accessed 8 July 2014.
11. Texas Health Ben Hogan Sports Medicine. "Research Studies." Texas Health, 2014. Web. Accessed 16 July 2014.
12. Title 48, US Code of Federal Regulations, Part 27.401. Web. Accessed 25 September 2014.

13. Toth-Allen, J. "Building Quality into Clinical Trials – an FDA Perspective." *Protecting and Promoting Public Health*. May 2012. Web. Accessed 25 September 2014.