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GETTING LOST IN TRANSLATION: THE DANGERS IN LITERAL TRANSLATION

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GETTING LOST IN TRANSLATION: THE DANGERS IN LITERAL TRANSLATION

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CHAPTER I

INTRODUCTION

Informed Consent:

A core principle of ethical research is the concept of informed consent, as descried in the Nuremberg code and the Belmont Report. Contemporary ethics holds that voluntary consent and autonomy are fundamental rights of those participating in human subject research.[16] The Nuremberg Code drafted during the Nuremberg War Crime Trials defines voluntary consent as the right of an individual participating in research to "exercise free power of choice without intervention of any element of force, fraud, deceit or coercion." Further, the Belmont Report goes on to establish two moral convictions under the ethical principle of respect for persons, which state individuals should be treated as autonomous agents and be protected if their autonomy may possibly be jeopardized. An autonomous individual is capable of making a conscious decision regarding their personal goals and life.[16] Once violating the respect for an autonomous person by either rejecting a person's judgments, denying personal freedom or omitting information, the ethical foundation on which these regulations were built upon begins to crack.

The application of these fundamental rights resonates in the structure of the informed consent document by serving as an autonomous authorization to participate in research. The informed consent document contains the elements of information,

voluntariness and comprehension.[16] The disclosure of information is vital in protecting the autonomy of a subject. Under Federal Code of Regulations (CFR) 46.116 (a), the consent document must include these basic elements: the purpose, expected duration of the study, identify any procedures which are experimental, state all foreseeable risks, the benefits, any compensation, contact information, and a statement that the study involves research and participation is voluntary.[17]

Nevertheless, the information of the consent document does not have to limit itself to only these requirements. The consent document should adequately convey all the information needed for the subject to know that the procedure may be neither *beneficial* nor *detrimental* to their care. Though gaining direct benefit with their participation, the subject should be aware of the risks and recognize that their participation as voluntary. [16] Moreover, subject's voluntariness should come without coercion or undue influence. Inappropriate persuasion to participate in a research study does jeopardize the principle of autonomy and respect of individuals. [16]

Of the three elements of the informed consent document, it can be argued that comprehension is fundamental. Although information and voluntariness is necessary, a consent document even with the absence of coercion or undue influence and containing accurate and appropriate information does not hold any value without subject comprehension. Comprehension of the informed consent document ensures the autonomy of the subject. [16] The information may be complete and accurate, but if it is in a language or format that is not understandable to the participant then the purpose of the consent document becomes meaningless.

The intent of the *informed* consent process lies in respecting the autonomy of the human subject. However, without true comprehension of the informed consent, this automatically compromises the rights of the individual. The risk becomes even greater when translating the informed consent from English and Spanish. Therefore, the concept of translation becomes more than the act of simply providing language-appropriate information to the recipient. If this were the case, the Code of Federal Regulations would state that the informed consent "shall be *in the language* understandable."[17] However, the code of regulations explicitly state that informed consent must be *in language* understandable meaning the mere act of translating from English to Spanish is not enough. Moreover, getting lost in translation because of inaccurate translations jeopardizes subject comprehension and understandability of the informed consent.

Translation/Interpretation

In research and clinical practice, translators and interpreters are responsible for conveying essential information between the researcher/physician and the subject/patient. Any inaccuracy, error or bias on their part may jeopardize the rights and safety of the subject. Many interpreters/translators believe in remaining faithful to the original message to avoid inaccuracies.

Medical interpreters often use the Transmission Model in which information transfers from the sender to a receiver via the interpreter.[4] With this model, the interpreter remains the neutral party literally translating the physician's message to the patient.[4] One danger with this model lies in the determination of the interpreter to remain as neutral as possible by literally translating everything spoken or contained in the documents. The risk of

miscommunication occurs when certain words or concepts cannot be literally translated into the target language. Investigators, interpreters and translators may have good intentions when focusing on exact translations. However, the idea that a literal translation is the best method to ensure the rights and welfare (safety) of the subject may inadvertently cause inaccuracy and misunderstanding. For example, the literal translation of "clinical trial" in Spanish is *"juicio clínico."* However, the cultural meaning of the Spanish word "*juicio*" refers to a "court trial." Not only would this literal translation be inaccurate but also it may give the subject the idea that they may be involved in judicial trial. This may probably discourage the prospective subject from participating in the study. A better translation is "*ensayo clínico*" which is the equivalent phrase for the concept of a "clinical trial." Thus, an interpreter and/or translator should consider the dangers, potential pitfalls and traps in literally translating any word, phrase or concept.

Misunderstandings and interpretation inaccuracies tend to increase when a clinical or medical concept cannot translate into the target language. Investigators, in a study examining the accuracy of Spanish interpreters, found numerous divergences in the interpretation of the concept and understandability of the word "randomization". [11] This study reported that, one out of four interpreters strayed away from either describing or including the word "randomization" during consenting.[11] A study case example involved an interpreter pausing several times when translating the concept of randomization, ultimately conveying a vague understanding of the word. Instead of defining randomization as a method for removing bias from the study, the interpreter told the subject "in order to see the study well, the results would not be available right now."[11]

Clearly this is a wrong translation for defining "randomization." Most informed consent documents define "randomization" as an element of chance or a "flip of a coin." The National Cancer Institute defines "randomization" as a process in which research subjects are assigned to groups by chance (randomly). Overall, the explanation for randomization was frequently poorly phrased and misinterpreted in Spanish.[10] Thus, limiting the subject's understandability of the study.

Two other studies concluded that limited English proficient (LEP, speak little English) families were less likely to understand the concept of randomization. These studies also found LEP families understood less the difference between "randomized clinical trials" and "standard of care" more than English-speaking Caucasian families.[6,12] Therapeutic misconception occurs when there is an expectation for "treatment" effectiveness, usually involved in standard of care. However, the investigator/physician in randomized clinical trials cannot guarantee at any level complete or partial wellness thus causing some element of confusion for subjects.

Nevertheless, some interpreters who strictly follow the Transmission Model may view any addition to the original message as a violation of the "ideal" model and as a malpractice.[4] In theory, this sounds accurate and ethical. However, in practice special concessions for cultural context, accuracy of translation and general clarification of a concept or condition can avoid comprehension errors or limitations. A study noted by that an interpreter actually refused to give definitions of medical terms to the subject during the consent process.[4] The interpreter reasoned it was a waste of time and a violation to the neutrality factor. In addition, Transmission Model interpreters view defining a term,

when the patient/subject did not ask for it or the physician/investigator did not provide it, as "noise."[4] To Transmission Model interpreters, it does not matter if they understand the word or concept as long as they can translate it into the target language.[4] As seen in the example above, this idea of the Transmission Model not to interfere can cause misunderstandings. Clarification of terms may enhance the communication and understanding between the interpreter and subject.

The error in translation does not fall entirely onto the interpreter. The investigator showed also share in the blame for translation errors. The principal investigator must carefully define "randomization" in layman terms for the interpreter rather than explaining the purpose for randomization or assuming an easy translation exists for that word.[11,14] The interpreter should be able to understand and define the term in order to translate it accurately.

The Impact of Culture in Translation

Federal regulation, 45 CFR 46.116, clearly states that the information given in an informed consent must be *in language* understandable to the research subject.[17] Some investigators may assume this federal regulation only pertains to the clarity and readability of the documents. However, the "understandability" of an informed consent involves much more than writing the informed consent in simple terms. Since culture is a big part of language, as shown above, investigators and interpreters could enhance the understandability of the subject by incorporating colloquialisms and country specific words in the consent process. Further, even within the Spanish language many words or concepts reflect the different cultures and environment among each Latin American

country. Language is unique to each culture; therefore, it is reasonable to expect different colloquialisms and words within the Spanish language. This can be equivalent to the linguistic differences between Americans and the British. For a translation to be in the "language" of the subject, a principal investigator should consider which non-English speaking Hispanic population (i.e., Mexican, Puerto Rican, Salvadorian, or other Latin American country) would be more likely to enroll in their study. For example, "*guagua*" in Chile means "baby" while as in Puerto Rico, Cuba and the Dominican Republic it means "bus."[9] In Mexico, "*gau-guau*", which has similar pronunciation to the above example, is baby talk for dog. These different meanings for the same word demonstrate the cultural diversity found within the Spanish language.

To emphasize the significance of this concept even further, words in Spanish and their meanings can also differ depending on the Spanish-speaking country. Interpreters should be careful using the appropriate diction when translating. The variations in vocabulary, meanings and connotations could influence the degree of comprehension of the reader depending on their place of origin. An example of this, noted in a study examining the role of interpreters during the consent process was the usage of correct terms with the desired target meaning, but used in the wrong context.[6] The interpreter translated the terms "brain" and "neck" in Spanish to "*seso*" and "*pescuezo*", respectively.[6] If you do a back translation from Spanish into English, the target meaning would be "brain" and "neck," thus, misleading the investigators or Institutional Review Board members, who know little to no Spanish, into believing that the interpreter or translator had "successfully" translated the terms. However, within the Spanish language,

the context of these words is incorrect: the term *"seso"* and *"pescuezo"* are terms reserved to describe animal anatomy. These terms would never be used to describe the anatomy of a human being. *"Cerebro"* and *"cuello"* would be the correct terms. In English, there are no separate anatomical terms used specifically for animals or humans. The same term "neck" and "brain" can equally refer to a dog as well as for a human being. Thus, it is important for the investigator and the interpreter to be fully aware of the cultural context and correct usage of the terms during any translating interaction, including the consent process. A negative or disrespectful connotation of translated words, such as "animal brains", may cause some confusion for the subject.

In order to avoid any degree of confusion or mistrust, it is important for investigators and interpreters to consider the connotation of the words used in the consent process. The act of translating takes more than avoiding literal translations. Interpreters should consider the impact of the translated words on the subject's comprehension and perception. Some words in Spanish may hold a different connotation than they do in English. This problem usually occurs more often with English words that do not have a literal translation into Spanish. A study evaluated the connotation of the equivalent translation for "Institutional Review Board (IRB)."[9] Since there is no literal translation available for the word, their study hypothesized that *"junta"* was the best translation for "Board." However, after surveying a sample population of Hispanics, the study found that *"junta"* might be associated with a "military coup."[9] The study later concluded that the best positive translation involved the word *"comité"*.[9] A person reading an informed consent may not want to agree to be involved with any activity that may possibly include

the military. An Institutional Review Board (IRB) more than likely would not favor this connotation, as it is their responsibility to protect subjects, not endanger them.

In Mexico, rather than using the literal translation, *"comité de ética"* represents the equivalent translation for the IRB. This translation has a positive association by using the word "*comité*." Moreover, the translation simply alone, offers subjects a better explanation of the ethical role of the IRB. In this case, the non-literal translation can be better than the host language (English). Thus, cultural context and correct translation is vital for the subject's understanding of informed consent and other clinical research documents. Interpreters must be careful when providing a translation. Often literal translations or even equivalent translations, as in the cases above, can mislead the subject in a positive or negative direction.

Cultural differences also form part of the language barrier. The Semiotic Mode offers a solution for bridging language and culture when translating.[4] In this model, the interpreter acts as the cultural broker, working to fit the study to the culture of the subject.[4] This benefits the subject and the clinician who may not be aware of the cultural factors. As one study pointed out, the interpreter adjusted the meaning of "discipline" to fit the cultural context of the population.[11] Within the Latino community, discipline involves a spanking while in the American society discipline usually entails a time out or no television. If the interpreter would not have clarified the clinician's view of discipline, the parent would have deviated from the rules of the study and compromised the integrity of the data.[11]

However, here lies a potential risk of adding personal opinions or bias. A study showed where inexperience translators acting as the cultural link between the subject and the clinician would easily interject their opinion regarding a study procedure.[6] One case shows the clinic aide interpreting for the physician commented to the patient that the procedure was routinely done and nothing could go wrong.[6] Not only did the interpreter add her opinion about the procedure but during the consenting process it was never mentioned that the procedure was actually optional. Under federal regulations, it is necessary to include voluntariness in the informed consent.[17] The good intentions of the clinic aide interpreter to reassure the subject about the study more than likely coerced the subject into consenting. Therefore, enhancing the understandability of the subject may not lie solely in focusing on the technicality of translating the exact original message but also incorporating a cultural aspect to the translation.

Barriers in Comprehension of Translations

All these factors, literal translation, lack of equivalent words/concepts, differences within Spanish, connotations and cultural differences, contribute to make the language barrier stronger. Studies show that the rights of non-English subjects are more likely to be violated that English subjects during the informed consent process.[6,12] Key elements stated by federal regulations such as alternative procedures, voluntariness and acknowledgement of risk are often excluded from the informed consent process. [6,12,17] A leukemia clinical trial in children notes 57% of non-English parents did not receive clarification regarding randomization.[5] Eighty-even percent of parents in the English speaking groups were informed about their rights to withdraw from the study, whereas

only 43% of parents in non-English speaking group were similarly informed. Finally, in the same study, only 48% of non-English speaking parents received explanation of the structure, content, or accessibility of the consent document compared to English speaking parents. [5]

Another study concludes that the complexity of language interpretation, social status, and cultural norms contribute to the exclusion of critical information by the investigator and interpreter. These factors form barriers for minority recruitment in clinical research. It was reported that 90% of those enrolled between the years 2003 and 2005 were Caucasian compared to 6 % were only Hispanic. [18] The barrier of language is particularly influenced by the implications in which translation/interpretation entail, linguistic differences between English and Spanish, and the costs associated with translation/interpretation.[18] These barriers and factors allow for less clinical research opportunities for Spanish speaking only Hispanics.

This study will focus on the problems with translation errors, which influence the language barrier. The types of common translational errors include: literal (word for word), nonsensical, contextual, and cultural differences. However, the objective of this project is to enlighten the research community about the complexities in translation and the importance of minimizing translational errors in order to enhance subject comprehensibility and autonomy. This project examined how to minimize the confusion often found when textually translating documents into Spanish in the clinical research field by targeting crucial and complex words found in an informed consent form.

CHAPTER II

PART I: RESEARCH PURPOSE AND BACKGROUND

Problem/Specific Aims

In the United States, there are 32.2 million households (1 out of 8 U.S. homes) where Spanish is the primary language.[19] Of these households, over 13 million families do not speak any English.[19] Unfortunately, it is this group that clinical researchers often exclude from their protocol design because of language comprehension issues.[7] Several reasons involving language barriers such as comprehension issues, limited communication, cost of interpretation or translational services, cultural myths and socio-cultural issues account for principal investigators excluding ethnic minorities from clinical research studies.[7,14,18] If these reasons alone explain the exclusion of ethnic minorities, these same areas of concern are heighten even more when principal investigators debate the inclusion of *non-English speaking* Hispanic subjects.

Although these areas of concerns are valid, principal investigators should recognize the medical and ethical importance of including Hispanics in their clinical studies. Drug metabolism and diseases, influenced by genetic, cultural, and environmental factors, may differ within ethnic minorities.[7] However, for many years Caucasian males were the predominate subjects enrolled in clinical studies. The ethical principle of justice in the Belmont Report states that the benefits of research must be accessible to all.[16] An injustice occurs when the benefits of clinical research studies are unjustly denied to a person or population without good reason or because of additional

burden the population or person may impose on the study.[16] Principal investigators should not be readily dismissive of the need for more clinical research in the Hispanic community because of language and cultural barriers as well as for financial limitations in hiring interpreters.

Translators/interpreters ensure subjects remain autonomous agents by establishing a channel for communication between the principal investigator and subject throughout the informed consent process through their translations. Principal investigators should not consider them as an unnecessary expenditure simply because it represents another responsibility. A study reported that subjects, non-English speaking subject with no interpreter available to them, had only 38% comprehension of the procedures.[3] Interpreters/translators are the key component in bridging the gap between the investigator and the subject by adapting the process to meet the linguistic and cultural needs of the subjects.

However, this process of translation has show to have its flaws. Translators/interpreters can introduce bias, opinions and error causing misunderstanding and confusion for the subjects.[4,5,11] Interpreters/translators and investigators must recognize the significance of conveying fully and accurately the fundamental elements of the informed consent specified in the Belmont report: information, comprehension, and volutariness.[6,11,12,16] Studies have noted the frequency of excluding these important elements during the consenting of non-English speaking subjects more than in English speaking subjects.[6,11,12] This is mainly due to interpreter's translational errors or the investigator simply forgetting to mention these elements to the subjects. Other studies

have shown that the accuracy of translations depends on both the interpreter's and principal investigator's experience, training, cultural beliefs and values.[3,6] Therefore, the communication between the principal investigator and interpreter/translator is crucial for the subject's understanding of the clinical research study. If either party fails to communicate, the subject can make an ill-informed decision regarding the risks and safety issues involved in the study.

This project focused on one of the many complexities of translating by analyzing the effects of literal translation and non-literal translations. The purpose of this project was to determine whether literal translations are actually the best translations for key terms and concepts of an informed consent. Interpreters/translators often tend to resort to literal or textual translations when communicating with the subjects. Although there are not many studies indicating the direct problems with literal translations, other studies have shown low subject comprehension levels during the consent process of non-English speaking subjects because of translational inaccuracies.[4,11,12]

Specific Aim 1:

Identify if using literal translation, a textually translation from English to Spanish, is always accurate and comprehensible when conveying the essential points of an informed consent document.

Hypothesis:

Using literal translations will not correctly convey the original message, thus, confusing the reader of the true meaning of the document. Non-literal translations, conceptually and culturally modified translation, may offer better comprehension

to the subject than literal translations. For example, a few studies have shown the importance of culturally and linguistically adapting the informed consent process for non-English speaking subjects in clinical trials. The present study will analyze the relative effectiveness of literal and non-literal Spanish translated key terms commonly found in the informed consent process (i.e., subject, randomization).

Translating does not simply involve finding the equivalent word or phrase from English to Spanish but also involves giving the word that has the best comprehension. For this reason, there are certain concepts or common words used in clinical research that do not translate into Spanish easily or the translation given may instill confusion for the subject.

By determining which translation is the best (literal vs. non-literal) and the connotations of these translations, this information can be created in order to help IRBs, interpreters/translators, research personnel, and investigators during the informed consent process for optimal comprehensibility. The information could potentially improve the accuracy of the interpreters/translators, again enhancing true autonomy of non-English speaking subjects. It can also bring the clinical research field a step closer to increasing the number of non-English speaking Hispanics in clinical trials or research.

Specific Aim 2:

This project will analyze Spanish translations (literal and non-literal) of the key terms with the goal of finding the connotations associated with the translations in order to enhance the overall comprehension of the informed consent.

Hypothesis:

Target (Spanish) translations do not hold the same connotation or meaning as it does in the host (English) language, serving as a source of confusion for the subject. Offering translations with the appropriate connotation and meaning can improve the Spanish interpretation of the informed consent for the Spanish-speaking subject.

A past study analyzed the connotations of key terms and concepts found in an English informed consent.[1] This study discovered that the diction used in the informed consent did influence feelings of mistrust or therapeutic misconception in the subjects. A subject should not be intimidated, discouraged or confused as they read an informed consent. Very few studies have been conducted analyzing the common Spanish translations of key terms and concepts found in an informed consent.

Significance:

Hispanics currently are the fastest growing minority group in the United States. In 2006, Hispanics (Mexican, Puerto Rican, Cuban, Dominican Republic, Central American, South American and other Latino group) accounted for 15% (44.3 million) of the U.S population not including the 11.1 million unauthorized Hispanic immigrants not often considered.[19] These high numbers indicate the need for any clinical research study dealing with Hispanics to address the issues of language and culture, which arise during the informed consent process. Any translating error may cause a subject to misunderstand the objectives or risks involved in a clinical trial or research study leading to an uninformed decision that may result in an unwanted outcome. This not only violates the right of the individual to be truly autonomous but also can jeopardize the integrity of the study. But most of all, this may strengthen the barrier of fear and mistrust already present within the Hispanic community regarding physicians and the American health care system.[7]

CHAPTER II

PART 2: EXPERIMENTAL DESIGN/ METHODS FOR RESEARCH

Literature Review and Translation

This research study involved comparing the comprehension of literal and non-literal Spanish translations of key terms often found in the informed consent process (i.e. randomization, withdrawal, Institutional Review Board). This was be done by creating a Spanish informed consent about a hypothetical study and incorporating the translated key terms into the document.

The key terms chosen for the study were derived from a literature review (journal articles and informed consent document) and limited to 10 "target" terms. The search for journal articles was performed using PubMed, Academic Search Premiere and JSTOR databases. Internet searches were done for Spanish informed consent documents by selecting Spanish as a language preference and limiting the search for sites originating from Mexico. However, the final selection of the target terms was based on three criteria: 1) any issues found in journal articles regarding the mistranslations of a term, 2) common usage in the informed consent process, and 3) the ease to find a literal and non-literal Spanish translation for the English term.

The student investigator in this study is a native Spanish speaker and did the translation of the target terms as well as the study materials. In addition to the student investigator's fluency and academic background in Spanish, a Spanish-English dictionary was used as a reference, thus, providing assistance to the investigator. However, a second

translator verified the accuracy of the translations utilized in the research study. The second translator works as the senior clinical research coordinator (CRC) for the Primary Care Research Institute at the University of North Texas Health Science Center (UNTHSC). Moreover, the second translator has prior experience in doing translations for the clinical studies she coordinates.

The terms chosen for the study are listed as follows along with the literal and non-literal translation of the target term:

Target Terms	Literal	Non-Literal
1. Informed Consent	Consentimiento Informado	Documento de Información y Autorización
2. Randomization	Aleatorización	Al azar
3. Subject	Sujeto	Participación
4. Withdrawal	Salir	Retirar
5. Health Insurance Portability and Accountability Act	La ley federal de Portabilidad y Responsabilidad del Seguro Médico	La ley federal de Administración y Responsabilidad de Información Confidencial del Seguro Médico
6. Risk	Riesgo	Peligro
7. Compensation	Compensación	Indemnización
8. Institutional Review Board	Junta Institucional de Revisión	Comité de Ética
9. Placebo	Placebo	-
10. Double Blind	Doble-Ciego	-

It was important that the "target" translated terms be incorporated into the context of the informed consent. Therefore, there were two slightly different experimental informed consent documents used for the purposes of this study. One informed consent contained the literal translations (LT) of the key terms while another informed consent had the non-literal translations (NLT). Both informed consents were about an imaginary "Magic" patch that temporarily increases physical strength. The writing of the consent documents involved doing it in English and then translating it in Spanish (appendices A-D). As expected, the English version and the translated document have some discrepancies because of the linguistic differences between English and Spanish. Moreover, some of the back translations (from Spanish to English) of the literal translation (LT)/non-literal translation (NLT) target terms may be the same in English. For example, "aleatorización" (LT) and "al azar" (NLT) are both back translated to "randomization."

A point to address is that there were no non-literal translations available for the terms "placebo" and "double-blind." Since these two words form a critical part of the clinical research terminology, it was important to include these two words into the experimental consent documents. These two target terms were translated in the literal form ("placebo" and "doble-ciego") and were embedded into both consent documents (literal and non-literal).

Subject comprehension of these literal and non-literal translated words was tested using a comprehension questionnaire (appendix E). The format of this questionnaire consisted of "fill in the blank" and True/False questions about the concepts behind the translated key terms found in the informed consent document. The concepts dealt within

the questionnaire were further broken down into two different categories 1) Risk and Benefit/ Information and 2) Research Design. The idea behind the concept-based questions was to observe any trend of which translation (Literal or Non-Literal) offered the best comprehension via correct responses on the questionnaire. Therefore, as the number of correct answers and comprehension score increased, it would demonstrate not only that the subject understood the informed consent, but also the concepts that were translated.

Experimental Design and Recruitment

The study was divided into two main groups: Literal (LT) and Non-Literal (NLT) Translation groups. Within each of these two main groups, there were two subgroups comprised of Spanish speaking only SSO (i.e., Non-English speaking); and bilingual (BL) Hispanic subjects from the community. Each subgroup had a significant purpose in being included in the study. The following are the inclusion and exclusion criteria for subject recruitment:

Inclusion:

Spanish speaking and Bilingual Group:

- Only individuals who identify themselves as Hispanics could participate in the study
- Individuals who have not previously participated in any clinical or research study
- Individuals who are fluent in Spanish only (SSO) (read and write) could be in the study
- For the bilingual group (BL), subjects should be fluent in both English and Spanish (read and write)
- Ages 18 years and up

Exclusion:

Spanish speaking and Bilingual Group:

- Hispanics who did not speak or read Spanish could be included.
- Those you have participated in clinical or research study prior to this study.
- Those younger than 18 years of age

Because the study is about Spanish translations and the influence of the Hispanic culture on these translations, it was necessary for all subjects recruited to be Hispanic. For the purposes of this study, "Hispanic" was defined as those who were of Latin/Hispanic origin and fluent in Spanish. The second inclusion criterion was established in order to avoid any prior exposure and knowledge about the informed consent language, as it could become a confounder for the study data. A screening question regarding any prior participation in clinical/research study was asked to the subject to determine eligibility.

For the SSO group as well as the BL group, it was imperative that they knew how to speak and read Spanish fluently since all study material was in Spanish. It is important to note that by having the subject read the Spanish document and write in the answers to the open questions verified their fluency in Spanish. In addition, the BL group needed to be fluent (read at least at a 10^{th} grade level, and speak) in English. Subjects older than 18 years were included in the study because they should have sufficient cognitive skills for understanding a reading passage and determining its meaning.

The sample size of the subjects was initially targeted for a minimum of 15 individuals per subgroup (SSO and BL), totaling 30 subjects for each main group (literal

and non-literal). However, over the course of approximately two weeks of recruiting, the sample size grew to an endpoint of 25 per subgroup, totaling 50 subjects for each main group. Overall, 100 subjects were recruited to participate in this study.

The student investigator and senior clinical research coordinator of the Primary Care Research Institute at UNTHSC recruited subjects from within the Hispanic community that fit the inclusion criteria. The student investigator specifically recruited prospective subjects from a local Hispanic church, elementary school, the Patient Care Center Clinic (Family Medicine) at UNTHSC, and referrals from families/friends. However, a good source of the recruitment was through subject self-referral. Subjects who had completed the study would place the student investigator in contact with other prospective research subjects thus creating a network for recruitment. In addition, a recruitment advertisement was posted on the UNTHSC intranet in the research section of the daily news. It is important to note that the appropriate IRB approval and "site" permission was received for each site used in subject recruitment.

Research Methods

Once prospective subjects were recruited, either the student investigator, or the clinical research coordinator (CRC) from Primary Care Research Institute verbally consented the subjects. The Institutional Review Board (IRB) authorized a waiver of written informed consent. This was necessary because familiarizing the subject with the language of a genuine informed consent document prior to the study would alter their comprehension scores on the "target" consent form. However, a script giving a brief explanation of the general purpose and other pertinent information related to the study

guided the consent process in lieu of a written informed consent document (appendices F and G). This script was verbally presented to each prospective subject who fit the inclusion criteria. In addition, verification of subject eligibility to participate in this study was done only after giving consent via screening questions. The consenting and study procedures were done in either the waiting room of Family Medicine in the Patient Care Clinic (PCC) at UNTHSC, a classroom in the local Hispanic church, or a mutually agreed location.

The student investigator or the CRC decided subject assignment to the appropriate subgroup (BL or SSO) through a series of screening questions (appendices F and G). If the subject answered that they only spoke Spanish, they were placed in the SSO group. Those who stated they were fluent in both English and Spanish were asked to read aloud a non-related passage before placing them into the BL group. The passage came from an article entitled *"Is it Getting Too Warm for Penguins?"* found in the February, 2008 issue of Time Magazine (appendix H). The Flesch Kincaid Grade level was 10^{th} grade, which was determined by Microsoft Word 2003. Consequently, if the subject could successfully read the paragraph, it indicated that their fluency in English was at least at the reading level as most consent documents are written (8^{th} grade). If the subject had difficulty or could not read the passage, the subject was placed in the SSO group.

After determining subject assignment to the subgroup, the subjects were alternately assigned to the main group (LT or NLT). The first subject enrolled was therefore assigned to the NLT group while the second subject was in the LT group. A record log helped keep track of the alternate assignment to the main groups (appendix I).

In the record log, all the subjects enrolled in the NLT group had an odd number designated to them. Similarly, subjects in the LT group were assigned an even number to them.

The subject received the corresponding experimental informed consent document according to which main group (literal or non-literal) they were assigned. To facilitate the distribution, the literal and non-literal consent form along with the questionnaire were placed in color-coded envelopes. Color-coded labels on the envelope indicated the sub group (SSO and BL). This also served as a precautionary measure to ensure that the subject received the appropriate study documents (LT and NLT). The subject had sufficient time to read over the experimental consent form. However, subjects took about 10 minutes on average to read the experimental consent document.

Immediately after reading the experimental document, the subject received a questionnaire testing their comprehension about the hypothetical study entitled *"An Evaluation of the Effectiveness of the "Magic" Patch in Temporarily Increasing Physical Strength."* The subject was not able to use the sample consent document as a reference or "cheat sheet" to complete the questionnaire. Both literal and non-literal groups received the same questionnaire in order to have comparable results. Once again, the subject had sufficient time to respond to the questionnaire (about 20 minutes on average). However, the exercise was not expected to last more than an hour. No compensation was given to the subject for their time. However, bottled water was offered as a courtesy during the completion of the study visit.

The investigator annotated which main group and sub group the subject belong to at the bottom of the questionnaire for further record keeping. This ensured that the responses given were attributed to the correct main and sub group. The questionnaire was stored in their respective categories (main and sub group) in the student investigator's office to avoid misplacing or mixing up the questionnaires and results. The data collected were stored under lock in the student investigator's office. Computerized data including tabulations or data analysis were also kept in the student investigator's office computer.

Data Analysis and Monitoring

It was hypothesized that by having the translated (literal and non-literal) terms embedded in the informed consent, the comprehension of the informed consent document could correlate with the comprehension of the translation itself. The statistical analyses used for this study were done in SPSS 15.0 computer software. The variables entered into the database were: Subject (N=), Language (BL or SSO), Translation (LT/NLT), Questions 1-13, level of education, Country of origin, Age and Gender. The corresponding data/response to each variable was numbered according to order of appearance. For example, in the category of language, BL was assigned a "1" while SSO was "2." The answers to the True/False questions (1-6, 8-9, 11-13) were entered as "1" and "2," respectively. Although Question 7 and 10 were not True/False questions, the same numeration and coding was used. The answers were then recoded by using the command "recoding into different variables" in SPSS to reflect which subject answered correctly or incorrectly to the questions. From this, the comprehension score was determined, with 0 being the lowest possible score and 13 as the highest possible score. A

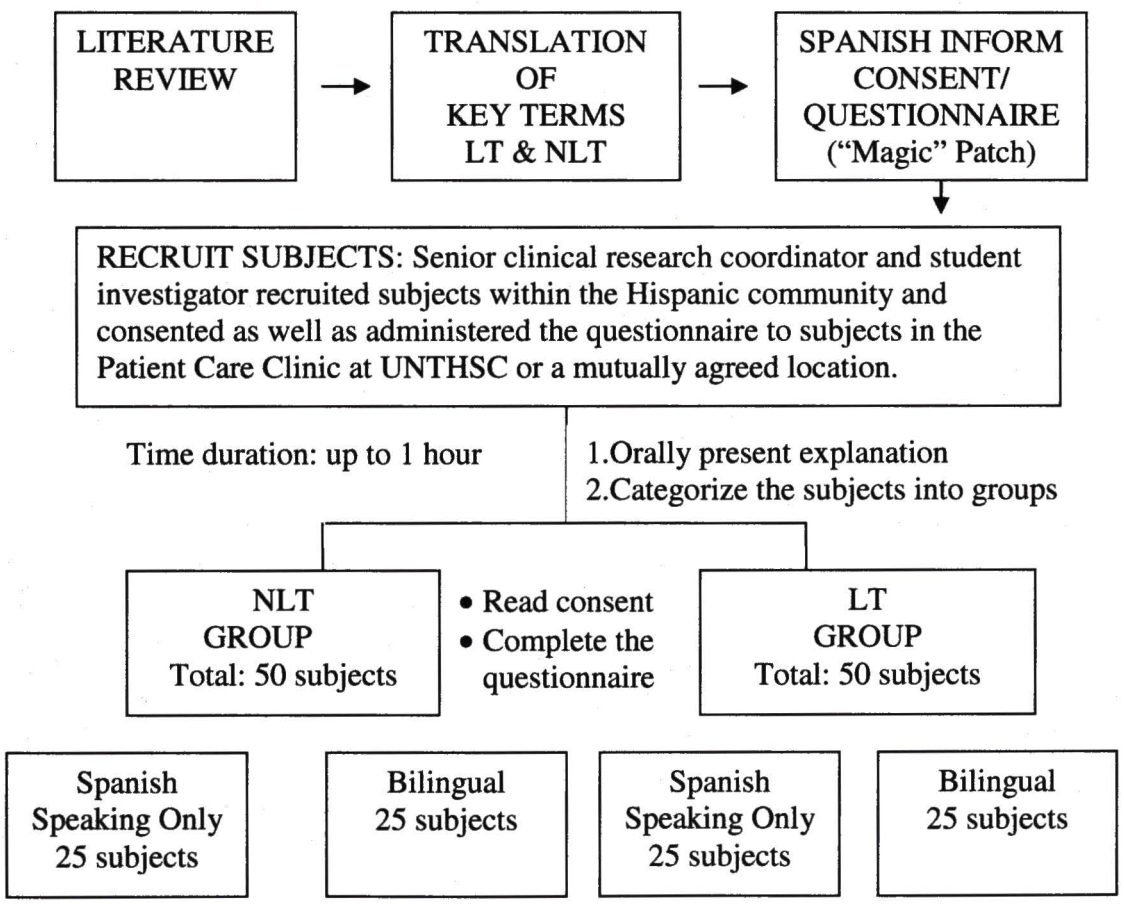
comprehension score for the questions regarding Risk/Benefit (i.e., Question numbers 3,4,5,9,10,11,13) and Design (i.e., Question numbers 1,2,6,8,12) categories was also determined. ANCOVA was used to determine any significance of translation and language on the level of subject comprehension of the experimental consent document (LT/NLT). Education was suspected to be a cofounding variable in this study. Thus, in order to control for it in the analysis, education was put in as a covariate in the ANCOVA analysis.

Each question was statistically analyzed by doing a 2x2 contingency table, chi-square and ANCOVA. The questions were analyzed by language and translation factors. In the ANCOVA, education was entered as a covariate. Separate demographic variables (Education, Country of origin, Age and Gender) were also examined for any correlation of inferences that these variables might have on comprehension for each experimental document by doing a chi-square analysis.

Risk/Benefit Assessment

The risks related to this study were minimal. All subject data were de-identified in order to minimize informational risk and enhance subject confidentiality. Since the visit with each subject was a one-time visit, there was no need to have subject identifiers upon entering the study. Phone numbers for contacting church members, family and friends were only used for the recruitment period. Moreover, there was no record linking contact information with the questionnaire. Any contact information that was used during the recruitment was destroyed after meeting with that subject.

The questions and answers were based on their comprehension of the sample informed consent document about the hypothetical patch called "Magic" patch. Therefore, there was a minimal probability of the subject being uneasy with any of the questions found in the questionnaire. The subject had the option to skip any question or stop at any time. Because there is minimal information regarding literal and non-literal translation, any knowledge about the differences in their comprehension would be beneficial. The results of this study could be a step toward improving the quality of understanding of the informed consent process for Spanish speaking subjects involved not only in clinical research but also in healthcare. The overall risk is minimal and is outweighed by anticipated benefits.



CHAPTER II

PART 3: RESULTS

Sample Characteristics

The endpoint of the sample size was 25 subjects per subgroup totaling 50 for each main group. Overall, 100 subjects were recruited to participate in this study. As shown in Table 1, the distribution of the subject sample population was determined to be comparable within each subgroup (BL/SSO) and main group (LT/NLT) through a chi-square analysis. Female representation was noticeable higher across all groups (total: N= 79 females vs. N= 20 males, respectively; one subject did not indicate gender). The age range of the subjects was diverse. However, the majority of the sample population was in the 31-40 year age range but with no significant difference in age across groups. [The questionnaire only had the subjects check a box indicating their age range; therefore, a more accurate mean could not be determined].

As suspected, the majority of the subjects (79%) reported that Mexico was their country of origin compared to any other Latin American country (Table 1). There was an evenly dispersed representation of other Latin American countries which included Central America, South America, Spain and the Caribbean (Puerto Rico and Cuba). Although the objective was to determine the country of origin of ancestry, several subjects identified themselves as Americans (N= 9). Overall, there were no significant differences of age, gender and country of origin across groups.

However, evaluation of the educational background of the sample population showed that a majority (88%) of the SSO had lower levels (elementary and high school) of education; while among the BL population approximately half of the sample had low education levels (N= 24). A key finding suggests that bilinguals in this study tended to be more highly educated than monolinguals (Table 1). In thus study, 25 bilingual subjects (compared with 6 Spanish Speaking only subjects) had a university or graduate level of education. The majority of bilingual subjects had university level of education, while a majority of the Spanish speaking only subjects had high school education. Two missing values, one for education and the other for gender were missing from the final total. [Note: These two missing values were accounted for and removed from any subsequent related analyses.]

Comprehension Score

A maximum score of 13 could be achieved on the quiz/questionnaire provided at the end of the experimental consent document (literal and non-literal translations). Those who had the NLT consent document received a higher mean score (M= 8.64) than the LT (M= 7.78; Table 2). Analyzing the comprehension scores between the bilinguals and Spanish speakers, the mean scores showed that the use of non-literal translation were better than the literal translation. Moreover in Table 3, within the bilinguals, the mean score of the NLT group (M= 9.60) was one point higher than the LT group (M= 8.60). The SSO group also an increase in their comprehension scores with the NLT (M= 7.68 vs. M= 6.96). Moreover in the bilingual group, 60% (N=15) who had the NLT received a comprehension score within the range of 10-13 while only 36% (N=9) of the LT scored

within that same range (Table 4). Thus, even for those who did not score the maximum (13), more subjects scored in "passing range" if they received the non-literal translation.

In addition, there was a noticeable difference between the bilinguals and the Spanish speakers. The bilinguals had significantly greater comprehension score compared to the Spanish speakers (M= 9.10 vs. M= 7.32, respectively), thus, proving bilinguals did better overall (Table 2). It was also interesting to note that bilinguals overall had scores closer to the maximum score possible.

These findings are supported by the ANCOVA, which demonstrated a strong language effect (p <0.001) and translation effect (p = 0.041) associated with the overall comprehension score (Table 3). Although the ANCOVA controlled for the education of the subjects, the language of the subjects (BL vs. SSO) continued to be significant, thus, indicating another unexpected variable influencing the comprehension of the consent document. Yet, the interaction between language (BL and SSO) and translation (NLT and LT) was not significant (p = 0.772) (Table 3).

The concepts dealt within the questionnaire were further broken down into two different categories: 1) Subject/Participant Information, and 2) Research Design. Questions with concepts relating to confidentiality (HIPAA), risk/benefit, compensation, protection of subject's rights (IRB), and voluntariness/information disclosure (informed consent) were grouped together (i.e., Questions 3,4,5,9,10,11,13) into the personal sub-score. These questions were analyzed separately to provide insight regarding the comprehension of subjects with concepts that directly deal with their welfare. Again by controlling for the education variable, the data demonstrate that there continued to be a

strong language effect (p <0.001) (Table 3). The mean for bilinguals was higher than the SSO group, thus supporting the ANCOVA results that show significance of languality. However, it is interesting to note that although there was not an interaction of both language and translation on comprehension; there was a marginal interaction (p = 0.051) on the personal sub-score (Table 3). Design element questions regarding the concepts of randomization and research (the design sub-score), showed no significance of language, translation or even an interaction effect on the comprehension of these elements (Table 3).

Question Breakdown

In Table 5, a chi-square analysis factoring language, translation for all individual questions yielded significant findings for two key concepts: "subject awareness" (Q7) and "risk" (Q11). *All* the SSO (Spanish speaking only) group who were in the NLT group answered correctly Question 7. This was the only question where SSO subjects scored better than those in the bilingual group. However, overall the NLT group performed better in answering Question 7 correctly. Conversely, the LT group did poorly on the "subject/participant" question. Only 8 bilingual subjects and 1 SSO subject who were in the LT group answered this item correctly. In Table 6, the ANCOVA on question 7 resulted in a strong translation effect (p <0.001). There was also an interaction of language and translation (p = .005) (Table 6). This suggests that both bilinguals and Spanish speakers, when given the option, will chose the non-literal translation ("participant") as opposed to the literal translation (subject). We will come back to this finding later.

An ANCOVA analysis showed Q11, which dealt with "risk", also had a significant language effect (p value= 0.038) (Table 7). More bilinguals in the NLT main group answered Question 11 correctly (N=23) compared to the bilinguals in the LT main group (N= 17). Conversely, the SSO subjects in the LT main group did better in answering Question 11 correctly (N= 19) compared to those in the NLT main group (N= 10). ANCOVA analysis show a significant interaction between translation and language (p = 0.001) suggesting that both factors influence the comprehension of the consent document (Table 7). Thus, there may be a difference in perception and/or comprehension of the literal and non-literal translations.

In the analysis of Questions 10 and 13, which deal with the concept of consent, only Question 13 had a language effect (p = 0.027) (Table 8). Other questions shown in Table 8 also revealed a significant language effect including Question 9 (withdrawal) (p = 0.045), Question 5 (compensation) (p = 0.005), and Question 8 (double blind) (p = 0.004). The rest of the items did not reveal any significant findings (Table 8). These included the concepts of confidentiality (HIPAA), randomization, placebo, research, and informed consent.

Although the results of Question 4 (IRB) did not show any significance, the open-ended part to the question can give a general idea of the participant's perception and understanding of the IRB. Table 9 shows the hand-written responses. Overall, the non-literal translation increased the level of understanding of the consent document, especially for the bilingual group. Although the Spanish speaking only group tended to do better with the non-literal translation in the mean total comprehension score, data

showed that literal translations worked best for concepts dealing with personal/subject issues. In addition, the language effect had a stronger significant value than the translation effect and tended to be the dominant effect in most of the items.

Table 1: Sample Population Characteristics

Sample Population Characteristics		Language			
		Bilingual		Spanish Speaking Only	
		Translation		Translation	
		LT (N=25)	NLT (N=25)	LT (N=25)	NLT (N=25)
Gender	Male	7	2	7	4
	Female	18	22	18	21
	Missing Value	-	1	-	-
Age (yrs)	18-25	4	7	4	4
	26-30	5	2	5	5
	31-40	7	6	9	8
	41-50	1	3	3	4
	51-60	4	3	0	2
	61-70	1	2	2	1
	71+	3	2	2	1
Country of Origin	Mexico	18	16	21	24
	Other Latin Origin	3	4	4	1
	USA (Hispanic Americans)	4	5	0	0
Other Latin Origin	Caribbean	1	1	0	0
	Central America	1	1	3	1
	South America	1	1	1	0
	Spain/Europe	0	1	0	0
	USA/Canada	4	5	0	0
Education Break-down	Elementary (EL)	0	1	13	8
	High School (HS)	11	12	8	15
	University (UNIV)	12	9	4	2
	Graduate (GRAD)	1	3	0	0
	Missing Value	1			
Education Level	Low (EL-HS)	11	13	21	23
	High (UNIV-GRAD)	13	12	4	2
	Missing Value	1	-	-	-

Abbreviations: LT: Literal Translation HS: High School NLT: Non-Literal Translation
UNIV: University EL: Elementary GRAD: Graduate

Table 2: Mean of Total Comprehension score by Translation and Language

Comprehension Score (CS)

Translation	Language	Mean
LT	BL	8.60
	SSO	6.96
	Total	7.78
NLT	BL	9.60
	SSO	7.68
	Total	8.64
Total	BL	9.10
	SSO	7.32
	Total	8.21

Abbreviations: BL: Bilingual SSO: Spanish Speaking Only
LT: Literal Translation NLT: Non-Literal Translation

Table 3: Means of Itemized Comprehension Score with ANCOVA analysis (control for education variable)

Comprehension Scores (CS)	Language				Analysis Of **Variance***
	Bilingual Translation		Spanish Speaking Only Translation		
	LT	NT	LT	NLT	
Total CS (Max= 13)	8.60	9.60	6.96	7.68	Language $p<0.001$ Translation $p = 0.041$ Interaction $p= 0.772$
Personal (Max= 7)	4.60	4.84	4.12	3.36	Language $p<0.001$ Interaction $p = 0.051$
Design (Max= 3)	2.20	2.28	1.92	2.24	No significant difference

Abbreviations LT: Literal Translation NLT: Non-Literal Translation
*ANCOVA (Control for Education)

Table 4: Itemized by Consent Concepts with the Breakdown of Subject's Scores

Itemized Scores (N= Subject's score to questionnaire)		Language			
		BL		SSO	
		Translation		Translation	
		LT N= 25	NLT N= 25	LT N= 25	NLT N= 25
Comprehension Score (CS)	2	0	1	0	0
	3	0	0	2	1
	4	0	0	2	1
	5	0	0	3	1
	6	3	1	5	3
	7	5	1	3	4
	8	5	2	2	5
	9	3	5	2	7
	10	5	8	6	2
	11	3	2	0	1
	12	1	3	0	0
	13	0	2	0	0
	Mean	8.60	9.60	6.96	7.68
Risk & Benefit CS	1	0	0	0	1
	2	1	1	1	6
	3	3	2	8	7
	4	9	6	6	6
	5	6	9	7	4
	6	4	5	3	1
	7	2	2	0	0
	Mean	4.60	4.84	4.12	3.36
Design CS	0	0	1	2	1
	1	2	3	5	3
	2	16	9	11	10
	3	7	12	7	11
	Mean	2.20	2.28	1.92	2.24
Randomization Questions	0	2	4	6	4
	1	14	9	11	7
	2	9	12	8	14
	Mean	1.28	1.32	1.08	1.40
Informed Consent Questions	0	2	4	7	10
	1	15	13	13	13
	2	8	8	5	2
	Mean	1.24	1.16	.92	.68

Abbreviations:

LT: Literal Translation NLT: Non-Literal Translation

Table 5: Pearson Chi-Square Tests for Questions 1-13

Questions		Language	
		Bilingual	Spanish Speaking Only
		Translation (LT / NLT)	Translation (LT / NLT)
Q1	Chi-square	.725	.802
	Sig.	.395	.370
Q2	Chi-square	.355	.000
	Sig.	.552(a)	1.000(a)
Q3	Chi-square	.104	1.754
	Sig.	.747	.185
Q4	Chi-square	.347	1.587
	Sig.	.556	.208
Q5	Chi-square	1.282	.439
	Sig.	.258	.508
Q6	Chi-square	1.471	.000
	Sig	.225	1.000
Q7	Chi-square	19.100	46.154
	Sig.	*.000(*)*	*.000(*)*
Q8	*Chi-square*	*.595*	*2.000*
	Sig.	.440(a)	.157
Q9	Chi-square	.136	.347
	Sig.	.713(a)	.556
Q10	Chi-square	.104	.333
	Sig.	.747	.564
Q11	Chi-square	4.500	6.650
	Sig.	*.034(*,a)*	*.010(*)*
Q12	Chi-square	.439	2.053
	Sig.	.508	.152
Q13	Chi-square	.081	2.000
	Sig.	.777	.157(a)

Results are based on nonempty rows and columns in each innermost subtable.
* The Chi-square statistic is significant at the 0.05 level.
a More than 20% of cells in this subtable have expected cell counts less than 5. Chi-square results may be invalid. d.f. = 1

Abbreviations:
LT: Literal Translation NLT: Non-Literal Translation

Table 6: Mean Score and ANCOVA of Subject/Participant Question 7

Question/ Concept	Bilingual		Spanish Speaking Only		Analysis of Variance
N= Correct	LT	NLT	LT	NLT	ANCOVA
Q7 Subject/ Participant	**8** "subject"	**23** **"participant"**	**1** "subject"	**25** **"participant"**	Translation p value<0.001 Language*Translation p value= 0.005

Abbreviations: LT: Literal Translation NLT: Non-Literal Translation

Table 7: Mean Score and ANCOVA for Risk Question (Q11)

Question Concept	Bilingual		Spanish Speaking Only		Analysis of Variance
N= Correct	LT	NLT	LT	NLT	ANCOVA
Q11 Risk	**17** **"riesgo"**	**23** **"peligro"**	**19** **"riesgo"**	**10** **"peligro"**	**Language** **p = 0.038** **Interaction** **p = 0.001**

Abbreviations: LT: Literal Translation NLT: Non-Literal Translation

Table 8: Questions and Concepts with ANCOVA (control for Education Variable)

	Language				Analysis of Variance
	Bilingual (BL)		Spanish Speaking Only (SSO)		
	Translation		Translation		
Question And Concept (N Correct)	LT N= 25	NLT N= 25	LT N=25	NLT N=25	ANCOVA
Q1 Rand	12	15	15	18	-
Q2 Research	23	24	21	21	-
Q3 HIPAA	19	18	21	17	-
Q4 IRB	17	15	20	16	-
Q5 Comp	11	15	5	7	Language $p = 0.005$
Q6 Placebo	15	19	12	12	-
Q7 Research	8	23	1	25	Translation $p < 0.001$ Lang*Trans $p = 0.005$
Q8 DB	22	20	10	15	Language $p = 0.004$
Q9 Withdrawal	20	21	15	17	Language $p = 0.045$
Q10 ICF	19	18	16	14	-
Q11 Risk	17	23	19	10	Language $p = 0.038$ Lang*Trans $p = .001$
Q12 Rand	20	18	12	17	-
Q13 ICF	12	11	7	3	Language $p = 0.027$

Abbreviations

LT: Literal Translation NLT: Non-Literal Translation Rand: Randomization

HIPAA: Health Insurance Portability and Accountability Act Comp: Compensation

IRB: Institutional Review Board DB: Double Blind ICF: Informed Consent

Lang: Language Trans: Translation

Table 9: Responses to the Question regarding the Role of the IRB by Language and Translation

	Bilinguals
Non-Literal Translation	1. *Rights* 2. Indemnify us in case of an accident 3. Help me investigate what went wrong in the study and how to resolve it 4. Help with questions 5. To answer any questions I have 6. To clarify 7. To answer any question I might have 8. *How to protect my rights* 9. Give information in case there are any doubts
Literal Translation	1. To answer any questions 2. If I decide to leave and no longer form part of the study 3. Help to clarify any doubt or answer any question that I may have during the study 4. To see if the Patch can help 5. To answer my questions 6. In nothing, this is help me prove that the "Magic Patch" works in order to help others
	Spanish Speaking Only
*Literal Translation_*	1. To solve... 2. To confirm the safety of the study 3. To find health benefits 4. To answer any question
Non-Literal Translation	1. Help in anything relating to the study 2. To clarify any doubt regarding the study 3. In case I have a question or doubt

CHAPTER II

PART 4: DISCUSSION AND CONCLUSION

Discussion

In the attempt to improve the quality of translation for optimal comprehension of the consent document, it became apparent that comprehension involved many other factors than the type of translation used. However, as originally hypothesized, the comprehension of the informed consent document improved with the use of non-literal translations. The means of the total comprehension score showed that the non-literal translation (the conceptually/culturally modified translation) offered a better understanding to both bilinguals and monolinguals (Spanish speakers). This finding agreed with other studies, which encourage interpreters to use culturally sensitive translations/interpretations to enhance the understanding of the consent document.[3,6,7,9] Just as the interpreter should be a cultural gatekeeper, so should the translator. [12]

To further this point, the results of Question 7 showed better understanding of the subject's role in the hypothetical research study with the non-literal translation (*"participante"*/"participant"). Alternatively, the data suggested that the literal translation of the term "subject" (*"sujeto"*) might be a cultural/connotation translation error, as many within the Literal group seemed confused on how to identify themselves. Because given the option, subjects seemed to rather be called a research "participant" than a research "subject." Reasons for this significant preference for the non-literal translation may be triggered by the connotation behind the word "subject."

The term "subject" may sound less personable and even subservient. Thus, the use of the term "subject" could deter prospective individuals from enrolling into a research study. This overall could effect the recruitment numbers for any study dealing with only Spanish speakers. Moreover, a translation that could allude to servitude and obligation to participate in a research study could be considered counterintuitive to the purpose of the consent document.

In addition, the term "sujeto" (literal translation from English to Spanish of the target term "subject") can be often used to refer to a criminal. This negative connotation could not only insult a prospective volunteer for research but also mislead or confuse them as to their role in the research study. Those in the Literal group could have thought that the word "sujeto" was not referring to them as participants in the research study but to another individual or a criminal. As hypothesized, literal translations may not always accurately convey the original message or *meaning*.

Conversely, the word "participant" may have lead people to perceive their involvement in the study as valuable and not as an act of servitude/obligation. Therefore, those who received the translation of "participant" (non-literal translation) were able to identify correctly their role in the study. If used more often in the consent document, instead of the term "subject," it could promote better understanding of the concepts, which directly effect the participant in research (i.e. risk, benefit). Thus, culture and connotation not only effect the comprehension of the consent document but also the manner in which the participants perceive himself/herself in clinical research.

Although translation proved to effect comprehension, the role of bilingualism was a stronger factor in the overall comprehension of the consent document. Because bilinguals were overall more highly educated than the monolinguals (Spanish-speaking only), it was suspected that education was an important factor influencing the increased comprehension of the bilinguals. However, even when controlling for the education variable, the effect of the language on the comprehension scores continued to be significant.

The social process of *acculturation* may explain this phenomenon. In the acquisition of the English language, an established familiarity with the "American way of life," may influence the way bilinguals comprehend, perceive and understand certain concepts. The exclusion criteria for subject recruitment and waiver of written consent were created to eliminate the confounding effects of prior exposure to clinical research (i.e. language and familiarity with the concepts). However, the bilingual participants seemed to understand and comprehend more the key consent concepts than did the monolinguals. Thus, familiarity may be a product of direct or more access to healthcare where most clinical research recruitment and the *informed consent process* really begin. Bilinguals may be exposed to the "research language" from just their environment given that recruitment advertisement (including media) is part of the informed consent process. Therefore, although a subject may not have participated in a clinical study it they may still be in tune with the clinical research/consent concepts which surround them.

In addition to this notion, the concepts of consent extend beyond the clinical research realm into the lager medical arena. Before any treatment or medical procedure is

performed, verbal or written consent is often necessary. Many of the subjects in this study could easily be acquainted with this form of procedure yet have never participated in a clinical or research study. Thus, "unintentional" awareness of the health care system could account for the overall better performance of the bilingual group compared to the Spanish speaking only.

At the same time, the Spanish speakers may have comprehended less the concepts of consent not only because of their lower levels of education but also because of their unfamiliarity with the United States medical/healthcare arena. Spanish speakers or LEPs (limited English proficiency) do not usually have easy direct access to medical care or may have poor quality of health care. [3] Consequently, they could have less access to clinical research opportunities and can be less familiar with general consent concepts.

In addition to this disparity, one study found that Spanish speakers were not always consented prior to performing a *medical treatment or procedure.* This means that even those Spanish speakers who could be exposed to the concepts of consent (as in when going to the emergency care room) are not given the opportunity to consent or again may receive a misinterpretation of the consent.[6] This creates a vicious cycle for the Spanish speaker. Monolinguals who are not yet acculturated to the American healthcare system or experience health care disparities because of other factors, may not receive the same exposure as bilinguals to these consent concepts.

Nonetheless, the Spanish speaking only subjects in this study tended to be less educated which may have played a role in the outcome of the study. Another study done by the Instituto Nacional de Cancerología in Mexico City found similar results regarding

monolinguals (Spanish speakers) and comprehension.[15] That study surveyed several individuals from a state-owned cancer center in order to gain insight regarding the comprehension of 10 *translated* informed consent processes. The subjects recruited were all patients who had advanced cancer and were participating in a Phase II clinical trial. After reading the consent documents, only 6% of the subjects understood the risk and benefits involved in the trial treatment.[15] These results mirror to an extent those of this study, which found a lower comprehension rate among monolinguals (Spanish only speakers) regarding risk/benefit and participant related concepts.

Future studies need to investigate the different perceptions of the target terms relating to risk and benefit, since even those subjects who have been exposed to the informed consent process continued to misunderstand these concepts. Nonetheless, the results of the Mexico City study validated the notion that limited education adds to the complexities of understanding the consent process.[15]

Overall, those who had the non-literal translation scored higher than the literal translation, perhaps because of the importance of culturally and linguistically adapting the informed consent process for Hispanic Spanish speaking subjects. However, other factors including educational background and the implications of acculturation also effected the comprehension of the consent concepts. Therefore, acculturation implies that acquisition of the English language, increased access to medical/health care and increased familiarity with the consent concepts found in the U.S healthcare system could also effect the comprehension of the consent process.

Limitations:

One limitation for this study involved the researcher doing most of the translations especially for phrases or words that do not have easy equivalent translations (i.e., HIPAA). In addition, the researcher/translator did not have any formal training in medical translation. This could have caused some discrepancies in the translations used for the target terms and study materials, which may have effected the outcome of the results. However, the design of the protocol attempted to address this issue by searching for translations commonly used in Spanish informed consent documents from Mexico, the use of a Spanish-English dictionary, and the review of a secondary translator who has experience as a clinical research coordinator.

Another limitation for this study was not having a large enough pool of Spanish speaking only subjects who had a higher education level (university and graduate). Although chi-square analyses demonstrated relatively good dispersion within the groups, the data analyzed could not be entirely comparable because of the offset of educational background. Although the education variable was controlled in the analyses, the language effect continued to be dominant. The study results may have been influenced because of a strong difference of education within the bilinguals and Spanish speaking only group. Better recruitment of subjects could be done to have comparable groups. This may mean traveling to Latin American countries in order to find more individuals who are monolingual and highly educated, or specifically seeking out such persons in the U.S.

The inclusion of target terms "placebo" and "double-blind" was also a limitation in this study. The target terms where embedded in both consent documents in the literal

form. Therefore, to an extent, the inclusion of these literal translations could have cross contaminated the results of the comprehension scores for the Non-literal group. Although the inclusion of these two words help confirmed that language has a great influence on the understanding of the informed consent process. The effect of language may be even more important than the effect of translation when reading a consent document. Better review and selection will need to be done for any future studies, such as setting up criteria for selecting target terms that are more stringent.

Finally, a major limitation for this study was in the design itself. The intention for not letting the participant have access to the experimental consent form during the completion of the questionnaire, was to avoid "guidance" to the participants when answering the questions. The experimental consent form was not to be used as a "cheat sheet." However, this created a situation where most individuals could not remember some of the elements of the consent document, when given the comprehension questionnaire. Some of the results in some subjects may have been compromised because of guessing. Any future studies will need to address the issue of memory retention by allowing subjects to have the experimental document for a longer period. In practice, the consent document will always be available to the participant and never denied as a resource. Having participants use the document may add to the significance of the translation effect.

Overall, these study results demonstrate that the type of translation (LT/NLT), cultural connotation, educational background and bilingualism play an important role in comprehending a translated document.

Conclusion

Previous studies have shown how inaccuracies in interpretation can lead to confusion and/or misunderstandings within the consent process. [3,5,6] The conclusions from those mentioned studies resulted in a call for awareness to investigators and interpreters regarding the importance of doing accurate and clear verbal "translation" (interpretation) of the consent process. [3-6,10,13] If problems currently exist with the act of *interpreting* the *consent process*, then more than likely there may be inaccuracies in *written* translations of the *informed consent document* itself. However, very few studies have ventured to show the importance of accurately translating the written consent document or have attempted to investigate the possible solutions in correcting errors in translation. These same issues with translations have been reported to create a language barrier for Hispanic recruitment in clinical research.[18] The present study attempted to address some of these issues with translating the informed consent document from English to Spanish.

The results of this study show that translation is key and effects comprehension. Having conceptually/culturally adapted translations (non-literal translation) may help increase the understanding of consent concepts over that of literal translations, which may not always accurately convey the original message. Therefore, translators should consider culture when translating a document instead of heavily focusing on the ""faithfulness" of the document via literal translations.[3] The perception of literal translations being "faithful" to the original message and thus ensuring autonomy may not be as accurate as many have thought.

However, further research needs to be done regarding non-literal and literal translations. Future studies should involve a deeper qualitative analysis regarding the subject's perceptions, connotations, meanings and comprehension of translated terms/concepts from clinical research. Examining the cultural distinction between ethnic groups can provide insight on the effects and differences in comprehension of the consent concepts. Moreover, the differences found between education and comprehension in relation to language (bilingual or monolingual) should be furthered investigated.

In addition, special independent awareness tools such as media, pamphlets, or any other form of additional information should be created in order to help familiarize non-English speaking individuals with certain concepts related to clinical research. By addressing the issues in translation and increasing the understanding of the importance of clinical research, this brings the Hispanic population one small step further in having broader representation in research.

However, the act of translating is complex, thus, making research studies relating to translations complex. Therefore, more research should be devoted to the translation of in the informed consent. The complexity of translations can be accurately captured by Don Miguel Cervantes, *author of Don Quixote de la Mancha*, who referred to translation as the back of a tapestry, a confusing version of a much clearer picture.[9]

Summary

Currently 16 million Hispanics in the U.S. do not speak any English making the need for Spanish translation apparent.[17] Within the clinical research realm, accurate translation is important for complete comprehension of the informed consent process, as it is the application of the ethical principle of respect for persons (autonomy). This study found that literal translations might not always be the best form of translation. Instead, non-literal translations may offer better comprehension of the consent process. However, the effect of being bilingual and attaining high education levels are significant factors influencing the comprehension of the informed consent document. Additionally these factors may actually facilitate the understanding of the consent form more than the literal and non literal translation. Lastly, the perception and meaning behind different translations can affect comprehension of consent concepts. Subjects preferred to be called participants showing that the two different translations can be hold different meanings.

CHAPTER III

INTERNSHIP ACTIVITIES AND EXPERIENCES

Internship site:

Office for the Protection of Human Subjects at the University of North Texas Health Science Center

The clinical research internship and practicum activities took place in the Office for the Protection of Human Subjects (OPHS), a unit within the Office of Research at the University of North Texas Health Science Center (UNTHSC). The Office for the Protection of Human Subjects (OPHS) in conjunction with the Institutional Review Board (IRB) is responsible for ensuring and protecting the welfare and rights of the individuals involved in human subject research. They carefully pre-review essential documents involved with the informed consent process; enforce the federal regulations under 45 CFR part 46, Belmont Report, Declaration of Helsinki and the Nuremberg Code; and uphold sound ethical and scientific research. The role of the IRB is to approve the biomedical or social behavioral research studies done on human subjects and assessing a study's risk level after careful scrutiny and discussion.

Dr. Brain Gladue serves as the director for OPHS and is the Chairman for the IRB at UNTHSC. He is assisted by a highly professional staff who pre-review research protocols and severe adverse event (SAE) reports, and work as a liaison between the principal investigator and the IRB. Dr. Gladue undertook the role of mentoring me during the course of my internship with the OPHS and research practicum. He provided

guidance, advice and instruction not only in the realm of intern activities but also in additional courses taken by the intern during the time of the internship. The OPHS staff also contributed to the instruction and was a source for encouragement. As Dr. Gladue has often put it, "it takes a village (OPHS) to raise an intern." The purpose of this chapter is to give an overview of the internship activities and the knowledge gained from the internship via narrative commentary.

Human Subject Research Training

As part of OPHS/IRB training, I took a course (BMSC 5400) taught by Dr. Gladue regarding intricacies involved when dealing with human subject research. This course explored the ethical principles (Justice, Beneficence, and Respect for Persons) based on the Nuremberg Code, Belmont Report, Declaration of Helsinki and the code of federal regulations; and its application to *human subject* research. The topics in class involved discussions about the federal regulations, IRB review, therapeutic misconception, investigator-subject relationship, the informed consent process and HIPAA, to name a few. This served as the foundation of my training while the application of this knowledge was in my actual internship.

The class concluded with a major project in which we were expected to write and defend a research protocol of our own to a "mock IRB". The experience of writing your own protocol and defending it front of an IRB really showed me the detail that should be put in when designing a protocol. Most important, it showed me that ensuring the welfare of the subject begins from the moment of designing the protocol to the execution of the study procedure and even after the conclusion of a study. Thus, thoughtful consideration

regarding the safety of the subject must be done at every step of the way. The experience helped me in the writing of my own thesis proposal "Getting Lost in Translation: the Dangers of Literal Translation" for submission to the actual UNTHSC IRB for approval.

Moreover, that course "Regulation of Human Subject Research," BMSC 5400 is considered a substitution for Collaborative Institutional Training Initiative (CITI), which is necessary to complete before initiating human subject research. In general, CITI is an 8 hour training course highlighting the key issues of clinical research and protecting the welfare of human subjects in research. However, Dr. Gladue's course offered an extensive view of the different aspects in protecting human subjects right's and allowed for discussion based learning, which cannot come from a computer training course. Therefore, CITI training was not a necessary requirement to fulfill when I submitted my protocol to the IRB for approval, as I had successful completed the human subject research course offered by UNTHSC Graduate School (BMSC 5400).

IRB Review

The policies of the Code of Federal Regulations (45 Part 46) apply to research dealing with *only* human subjects. Furthermore, the regulations require protocol submission to the IRB for review and approval prior to starting the research in order to protect the rights and welfare of subjects participating in research. The Code of Federal Regulations provide some guidance as to the application of these principles. The federal regulations define *research* as:

> "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[17]

Therefore, the knowledge from research must be of scientific value to the community and data must be reproducible because of the value of the "testing subject". Furthermore, the regulations define *human subject* as:

> "Living individual(s) about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with individual, or 2) identifiable private information." [17]

Knowing the definition of "human subject" and "research" creates a preliminary screening basis for IRB review. If the research project does not fit the elements of these definitions, then it does not require IRB submission. However, those that do fall under human subject research can have four of the following types of IRB review:

- *Exempt Review:* A research study with "exempt" status does not mean it is exempt from IRB review. It means that the research protocol fits within the set criteria outlined by the federal regulation 45 Part 46. 101 to be exempt from the federal regulations. Moreover, it is considered no more than minimal risk. The federal regulations define *minimal risk* as: "the probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [17]

  Thus, an exempt category study is only exempt from IRB review. At UNTHSC OPHS staff and the IRB chair, not the investigator, does the final determination regarding the exempt status of a protocol. At UNTHSC, an exempt study is reviewed by both the assigned OPHS compliance coordinator and the

chair of the IRB. Exempt review receives final approval by the chair. Unless any changes to the protocol are made, further IRB surveillance is no longer necessary. My research protocol falls under this exempt category, specifically under 45 Part 46.101(b) (2) which deals with research involving educational tests, survey procedures, interview procedures or observation of public behavior.

- *Expedited Review*: Human subject research that involves no more than minimal risk and fits the criteria of the federal expedited review category (45 Part 46.101) qualifies for this review. At UNTHSC, an OPHS compliance coordinator and Chairman of the IRB do the expedited review. The chair gives final approval of the expedited study.
- *Full Board Review*: This type of review applies to all other protocols that do not fall under exempt and expedited. Those research protocols that involve greater than minimal risk are brought to the entire Board for review and approval. The inclusion of vulnerable populations (children, minorities, prisoners and pregnant women) or studies in which information may have to be reported (i.e., child abuse) can cause a protocol to become full board. Once the IRB approves the protocol, the study will continue to be under review until the study is officially closed by the IRB.
- *Continuing review*: Expedited and Full board protocols are approved for not more than one year. Annual or 6 months review cycles depend on the risk level of the protocol and thereby continue protecting the welfare of the subjects.

- *Amendments*: Although this is not a type of review, any changes in the protocol or consent form must be reviewed and approved by the IRB before being implemented. This is especially crucial for any exempt or expedited category research protocol, because any modifications can make it a full board protocol.

Although I did not review any protocols for the IRB meetings, the majority of my training came from evaluating old protocols and determining the type of IRB review it would receive. In addition, Dr. Gladue's course in human subject research gave me further instruction in the types of review through example-based learning. I also would compare good and bad informed consent documents in order to learn how to do a proper review of the study material. On occasion, I also had the opportunity to review any consent document or advertisement that was in Spanish. Because the basis of my research project dealt with the importance of accurate translations for comprehension, I would verify if the translations given were accurate and correct.

OPHS and the IRB

At UNTHSC, the OPHS receives all the protocols that deal with human subject research and does a pre-review for IRB members (and investigators). Each research protocol is assigned to and exclusively reviewed by the appropriate OPHS compliance coordinator. Each OPHS coordinator acts as a liaison for a specific department, college or principal investigator affiliated with UNTHSC's IRB.

New full board and continuing review protocols are submitted two weeks prior to the IRB meeting for an OPHS pre-review. For full board IRB review, the principal investigators must submit an IRB packet including the following:

- Protocol synopsis and IRB review form application
- Informed consent documents
- All study material (i.e. questionnaire)
- Recruitment ads
- Investigator's brochure
- Clinical trial protocol
- Any correspondence between the sponsor of the clinical trial and the principal investigator
- Investigator's curriculum vitae
- Conflict of Interest Disclosure
- CITI training certificate for each key personnel listed on the protocol

In the pre-review, the OPHS coordinator examines the protocol for any special findings that may be an issue regarding the subject's welfare or concern for the IRB. However, a week prior to the IRB protocol submission deadline, the principal investigator can submit their protocol synopsis and study materials for a "courtesy review" done by the OPHS coordinator. This courtesy review can help investigators identify and address any potential problems the IRB might have with the protocol. Unfortunately, most investigators do not take advantage of this unique feature offered by the UNTHSC's OPHS.

Once the OPHS coordinators finish the formal pre-review, they type up a brief synopsis and any special findings associated with the research protocol. This is sent to the IRB members as an additional resource when reviewing the research protocol packets scheduled for the upcoming meeting. In addition, the Chair's Report and the Minutes from the previous meeting are also sent. The Chair's Report includes a brief synopsis and Chairman's deliberation regarding the expedited and exempt category studies as well as information about SAEs, amendments, etc. Although it is the IRB chair who determines the status of an exempt or expedited study, IRB members can raise concern or request a reconsideration of any item in the Chair's Report during the convened meeting.

The OPHS staff prepare for the upcoming IRB meeting with a pre-meeting. The purpose of this meeting is to discuss any areas of concern relating to human subject safety for the scheduled research protocols. The input of the staff gives Dr. Gladue, who is not only the director of the OPHS but also the Chairman of the IRB, an idea on how to coordinate/schedule the meeting agenda. In these meetings, I would take notes and consider how the IRB would deliberate on such areas of concern dealing with risk. I also learned how much work the staff and Dr. Gladue do to thoroughly review a protocol with the purpose to protect subject's rights and safety.

IRB Meetings

Attending the IRB meetings, which are held every first Tuesday of the month, helped me apply the concepts, ideas, and regulations taught in my human subject research class and from the OPHS. The IRB meetings served to educate me regarding the issues in protecting human subjects in research by giving me real case scenarios. It also gave me

the opportunity to analyze critically the issues and come up with my own thoughts and concerns, as human subject research is never a black and white issue. Overall, these meetings were one of the most insightful experiences of my internship.

The meetings begin once Dr. Gladue confirms quorum. The Board currently has 15 members. Therefore, at least 8 members must in attendance to call the meeting to order. (The regulations require that there be a majority of members to discuss and vote on the protocols on the agenda.) The agenda first addresses any issues with the Minutes from the previous meeting. The Minutes should be an accurate portrayal of the discussion, issues, and the votes that occurred in the last IRB meeting. The Minutes are then voted on if there were no issues found by the Board members. Members also vote to approve or disapprove the Chair's Report. The IRB then goes on to review new and continuing review protocols as well as any amendments.

In the discussion of each research protocol, IRB members must assess several elements and deliberate based on the ethical principles of the Belmont Report (Respect for Persons, Beneficence and Justice) before approving a protocol. Some of these considerations include:

- Risk-Benefit Assessment: The risks of the protocol must not outweigh the benefits. The possible risks in a study do not always involve physical harm but can be also psychological, informational or socio-economic harm. Therefore, the IRB members must not only assess the anticipated risks but also consider any other form of risk that the principal investigator may have not addressed in their protocol regarding subject safety. In addition, IRB members must deliberate the

risk level for new full board protocols. Depending on the level of risk associated with the protocol, the Board will determine how soon the protocol must be brought back to the IRB for reassessment (12 or 6 months).

- Evaluating Informed Consent: Board members must evaluate the clarity and language of the consent document as it is the ethical foundation of autonomy. IRB members review for complete disclosure of the information (i.e., compensation, risks, benefits, and inclusion/exclusion criteria). Community Board members are often the best advocate for the subjects when dealing with issues relating to the informed consent process. Their familiarity with the local community allows them to be in the "mind set" of the subject. A community member can readily point out any need for clarification regarding the exclusion criteria or the language of the consent document.
- Privacy and Confidentiality: This is an important issue for Board members to consider as the loss of privacy /confidentiality can be a form of risk. Special safeguards must be in placed by the investigator to protect the privacy of the subject. It is the job of the IRB to make sure this element is addressed.
- Scientific Merit: This is key. The Board assesses the scientific validity of the study by how the scientific design effects the welfare of the subject. A study may hold great scientific value but if the appropriate safeguards are not set in place to protect the welfare and rights of the subjects then it becomes an issue for the Board. The converse is also true. The study may have the appropriate safeguards to protect the subject, but if there is no scientific merit, then Board members

must consider if it is worth exposing the subject to an unnecessary risk. The relationship between risk-benefit and scientific merit must be balanced.

- Compensation: The Board must also consider if compensation given to the subject is a cause for coercion or undue influence. The ethical conviction of voluntary participation as part of the informed consent process becomes compromised once the amount of money passes the line from compensation to coercion. A subject should not be pressured to be in a study. However, compensation alone is not in itself a cause of concern, especially if the protocol is considered "approvable." Compensation becomes an issue once the element of risk is introduced.

My function during the IRB meetings involved writing down the highlights of the discussion between Board members regarding the research protocols for the minutes. From the discussions during the Board meetings, I learned the main driving force of the IRB. The design and different elements of a research protocol must be reviewed in relation to *risk to the subject*. It is the task of the IRB to determine the risk involved in participating in a research study and ensure the proper safeguards are in place to protect the subject. However, reviewing human subject research in relation to risk is not a black and white issue. Therefore, guidance for review must come from the ethical principles derived from the Belmont Report and Nuremberg Code (Justice, Beneficence and Respect for Persons) and the ambiguity of the federal regulations.

After discussing the review and receiving additional input from the principal investigators, OPHS staff or Dr. Gladue, the Chair calls for a motion for either approval

as submitted, approved with modifications, or deferred for major revision. The majority vote decides the status of the protocol. If any Board member has a protocol up for review, they are recused from the vote because of conflict of interest. OPHS staff later informs the principal investigators through Board Actions regarding the deliberation made by the IRB as well as indicate any modifications needed for approval.

Office of Human Research Protection (OHRP) Conference in New Orleans

The Office of Human Research Protection, a federal agency within the Department of Health and Human Services, in conjunction with Oschner Health System organized a regional conference in New Orleans, Louisiana from April 3-4. The main objective of the conference was to address the different issue in protecting human subjects in light of the expanding and innovative research studies involving human subjects. The target audience for this forum was institutional officials, IRB Chairs, principal investigators, research staff, compliance officers/staff, legal staff and patient advocates. Therefore, it was a rare opportunity for an intern to be included with the rest of the UNTHSC OPHS staff, who also attended the conference. Moreover, to add to the privilege of going to the conference, all my expenses were paid by the OPHS and UNTHSC.

The conference gave me some insight as to the different aspects involving the protection of human subjects in research. The most interesting seminar for me was about the importance of risk-benefit analysis. The responsibility of the IRB is to minimize risk to the point where the risk benefit ratio remains acceptable. To assure the risk-benefit ratio remains balance, a continuous review must be done. Therefore, the more time and

attention to detail is needed for the review of already approved protocols. It was also interesting to hear and learn from one of the commissioners of the Belmont Report, Dr. Albert Jonsen, who explained the journey and thought processes which lead to the creation of that report. Although the concepts of beneficence, respect for persons, and justice were not novel at the time, the commissioners faced the challenge of creating a contemporary ethical statement regarding subject protection. The end result came to be the incorporation of these ethical principles with the main conviction in risk-benefit evaluation in relation to the subject in order to protect their rights.

Clinical Experiences

My internship site dealt with another aspect of clinical research- the ethics side of research. However, I did receive some clinical research management experiences by attending the clinical coordinator's meeting and visiting with a clinical research coordinator. The coordinator's meetings are held monthly to discuss difference aspects and challenges present within each coordinator's field. These meetings gave me some insight as to the different challenges facing the management of clinical trials. Among the issues discussed involved challenges in getting enough dry ice (for sample storage), budget development, and the creation of policies and guidelines for the Office of Clinical Trials. The meetings gave coordinators an opportunity to share concerns and experiences regarding the management of their studies.

I also spent some time in the Texas Pulmonary site with clinical research coordinator Kathy Kwaak. I attended two monitor visits in which I gained some exposure to case report forms and regulatory binders. My experience also included observing an

informed consent process and study visits. It was a great to see the actual/practical application of the ethical principles and efforts of an IRB to make sure the informed consent is understandable to the subject.

Overall, the experience gained from my internship has given me a broader perspective of clinical research (the clinical and the ethical). Moreover, I learned the importance of protecting the welfare of human subjects in research through ethically and scientifically-sound research. The knowledge gained from my internship will make me a better investigator or clinical research coordinator, whichever I decide to be in the future.

APPENDICES

APPENDIX A

DOCUMENT OF INFORMED CONSENT AND AUTHORIZATION TO PARTICIPATE IN A RESEARCH PROJECT

Title of Research: *An Evaluation of the Effectiveness of the "Magic" Patch in temporarily increasing Physical Strength*

Principal Investigator: Juan Pérez, Ph.D.

Purpose of the Study:

This is an invitation to be a participant in this research study. It is important for you to read carefully the following explanation and procedures before deciding to be in this study.

The purpose of this study is to find out if an experimental patch called the "Magic" patch can temporarily increase physical strength in healthy adults.

Because the study will only involve healthy adults, we will ask you to give some information about your health. Your vital signs (pulse, blood pressure and respiratory rate) will also be taken.

What will happen in this Study?

The following mentions the procedure that the participant can expect:

- Your vital signs and health information will be recorded.
- If the vital signs are in a normal range, then you will be randomly assigned (like flipping a coin). A group of participants will receive the "Magic" patch, which temporarily increases the physical strength. Another group will receive a placebo patch that gives no temporary increased strength.
- This study is a double-blind study. This means neither you nor the investigator will know which patch (the "Magic" patch or the placebo) you received.
- Your initial physical strength, before putting on the patch will be measured by how hard you hit a small platform with a hammer. The bang of the hammer will cause a small marble to jump. A ruler will measure the jump. The highest point on the meter has a bell. Hitting the bell indicates you have reached the maximum point of strength measured by the ruler. This instrument is the same game used in fairs and carnivals.
- After measuring your strength without the patch, the investigator will put the patch on either arm. You will be asked to wait an hour with the patch on.
- The strength test will be repeated to see if there is any improvement in your strength.

What are some dangers associated with this Study?

- There exists some danger that you may be hurt while using the hammer. This may include pulling a muscle or hitting yourself with the hammer.
- Another danger is the possibility of being allergic to the adhesive on the patch.
- There is a danger that your information will not be kept confidential. However, the researchers involved in this study will take every precaution necessary to ensure that your privacy is protected. All information pertaining to your participation in this research will be kept in a locked file cabinet in investigator's office. The danger of losing your privacy is minimal. Authorization to use your health information is also necessary (vital signs etc.).

Is there any Indemnification for Injury?

It is unlikely that you will be injured as a result of taking part in this study. However, if you are, there are no funds set aside to indemnify you in case you are injured.

What are the alternatives to taking part in this Study?

There is no alternative treatment for this research. You can choose not to participate in this study.

What are the benefits for participating in this Study?

You might not receive any direct benefit for participating in this study. However, the information from this research can possibly help other individuals with debilitating diseases in order to build their strength.

Can I Withdraw from the Research Study?

You can withdraw from the study at any time. Refusing to participate or withdrawing from this study will involve no consequences or loss of benefits to which you are otherwise entitled.

Is there any Indemnification to participate in this Study?

All participants will receive a $10 Starbucks gift card as indemnification for participating in the study.

Whom do I call if I have questions?

If you have any questions at any time about the study, you can contact Dr. Juan Perez at 555-555-555. If you have questions regarding rights as a research participant, you can contact Dr. Brian Gladue, Chairman of the Institutional Review Board at 555-666-9999.

Authorization

I voluntarily agree to participate in this study. I have had the chance to ask the study investigators any questions I have regarding this study.

ADDENDUM TO THE DOCUMENT OF INFORMED CONSENT AND AUTHORIZATION TO PARTICIPATE IN A RESEARCH PROJECT

The Federal Law HIPAA
For the use of Protected Health Information in Research

Purpose of this Form:

The document of informed consent and authorization to participate in a research project, which you have read describes your participation in this study. This section of the document is an addendum required by the federal law "Health Insurance Administration and Responsibility Act" (HIPAA). The purpose of this addendum is to get your permission (authorization) to use health information about you that is used in connection with the research.

APPENDIX B

INFORMED CONSENT
AUTHORIZATION TO PARTICIPATE IN A RESEARCH PROJECT

Title of Research: *An Evaluation of the Effectiveness of the "Magic" Patch in temporarily increasing Physical Strength*

Principal Investigator: Juan Pérez, Ph.D.

Purpose of the Study:

This is an invitation to be a subject in this research study. It is important for you to read carefully the following explanation and procedures before deciding to be in this study.

The purpose of this study is to find out if an experimental drug called the "Magic" patch can temporarily increase physical strength in healthy adults.

Because the study will only involve healthy adults, we will ask you to give some information about your health. Your vital signs (pulse, blood pressure and respiratory rate) will also be taken.

What will happen in this Study?

The following mentions the procedure that the subject can expect:

- Your vital signs and health information will be recorded.
- If the vital signs are in a normal range, then you will be randomly assigned (like flipping a coin). A group of subjects will receive the "Magic" patch, which temporarily increases the physical strength. Another group will receive a placebo patch that gives no temporary increased strength.
- This study is a double-blind study. This means neither you nor the investigator will know which patch (the "Magic" patch or the placebo) you received.
- Your initial physical strength, before putting on the patch will be measured by how hard you hit a small platform with a hammer. The bang of the hammer will cause a small marble to jump. A ruler will measure the jump. The highest point on the meter has a bell. Hitting the bell indicates you have reached the maximum point of strength measured by the ruler. This instrument is the same game used in fairs and carnivals.
- After measuring your strength without the patch, the investigator will put the patch on either arm. You will be asked to wait an hour with the patch on.
- The strength test will be repeated to see if there is any improvement in your strength.

What are some risks associated with this Study?

- There is some risk that you may be hurt while using the hammer. This may include pulling a muscle or hitting yourself with the hammer.
- Another risk is the possibility of being allergic to the adhesive on the patch.
- There is a risk that your information will not be kept confidential. However, the researchers involved in this study will take every precaution necessary to ensure that your privacy is protected. All information pertaining to your participation in this study will be kept in a locked file cabinet in investigator's office. The risk of losing your privacy is minimal. Authorization to use your health information is also necessary (vital signs etc.).

Is there any Compensation for Injury?

It is unlikely that you will be injured as a result of taking part in this study. However, if you are, there are no funds set aside to compensate you in case you are injured.

What are the alternatives to taking part in this Study?

There is no alternative treatment for this research. You can choose not to participate in this study.

What are the benefits for participating in this Study?

You might not receive any direct benefit for participating in this study. However, the information from this research can possibly help other individuals with debilitating diseases in order to build their strength.

Can I Withdraw from the Research Study?

You can withdraw from the study at any time. Refusing to participate or withdrawing from this study will involve no consequences or loss of benefits to which you are otherwise entitled.

Is there any Compensation to participate in this Study?

All subjects will receive a $10 Starbucks gift card as compensation for participating in the study.

Whom do I call if I have questions?

If you have any questions at any time about the study, you can contact Dr. Juan Perez at 555-555-555. If you have questions regarding rights as a research subject, you can contact Dr. Brian Gladue, Chairman of the Institutional Review Board at 555-666-9999.

Consent

I voluntarily agree to participate in this study. I have had the chance to ask the study investigators any questions I have regarding this study.

ADDENDUM TO THE INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A RESEARCH PROJECT

The Federal Law HIPAA For the use of Protected Health Information in Research

Purpose of this Form:

The informed consent for this study, which you have read describes your participation in this study. This section of the document is an addendum required by the federal law "Health Insurance Portability and Accountability Act" (HIPAA). The purpose of this addendum is to get your permission (authorization) to use health information about you that is used in connection with the research.

APPENDIX C

DOCUMENTO DE INFORMACIÓN Y AUTORIZACIÓN PARA PARTICIPAR EN UN PROYECTO DE INVESTIGACIÓN

Titulo: *Una Evaluación de la Efectividad del Parche "Mágico" en Aumentar Temporalmente la Fuerza Física*

Investigador Principal: Juan Pérez, Ph.D.

Propósito del Estudio:

Esta es una invitación para ser un participante en este estudio de investigación. Es muy importante que lea cuidadosamente las siguientes explicaciones y procedimientos antes de tomar su decisión de participar en esta investigación.

El propósito de este estudio es investigar si un parche experimental llamado el parche "Mágico" puede incrementar temporalmente la fuerza física en adultos.

A raíz de que este estudio involucra únicamente adultos sanos, le pediremos información sobre su salud. También sus signos vitales (su pulso, presión y ritmo respiratorio) serán tomados.

¿Qué sucederá en este Estudio?

A continuación se menciona el procedimiento que el participante puede esperar:

- Se anotarán sus signos vitales e información de salud.
- Si los signos vitales están en un rango normal, usted formará parte de uno de dos grupos de participantes que serán distribuidos en una forma al azar (como el lanzamiento de una moneda al aire). Esto significa que un grupo de participantes recibirá el parche "Mágico" el cual incrementa temporalmente la fuerza física. Mientras otro grupo recibiera un parche placebo el cual no incrementa la fuerza temporal.
- El estudio es de "doble-ciego". Esto significa que ni usted ni el investigador sabrán cual parche (el "Mágico" ó el placebo) recibió.
- Su fuerza física inicial, antes de ponerse el parche, será medida por la fuerza con la cual usted golpea una pequeña plataforma con un martillo. El golpe del martillo causará que una pequeña canica brinque. Una regla medirá el brinco de la canica. El punto más alto de la regla tiene una campana. Pegándole a la campana indica que ha alcanzado el punto de máxima fuerza medido por la regla. Este instrumento es el mismo juego usado en las ferias y carnavales.

- Después de medir su fuerza sin el parche, el investigador le pondrá el parche en cualquier hombro y le pedirá que espere una hora con el parche puesto.
- El examen de fuerza será repetido para ver si hay algún mejoramiento en su fuerza.

¿Cuáles son los peligros asociados con este Estudio?

- Existe el peligro de lastimarse mientras esta usando el martillo. Esto incluye lastimadura de músculos ó golpeándose con el martillo.
- Otro peligro probable es el ser alérgico al adhesivo del parche.
- Existe el peligro de que su información no se mantenga confidencial. Sin embargo, el investigador tomará todas las precauciones necesarias para asegurar su privacidad. Toda la información que es relacionada con su participación en esta investigación se guardará bajo llave en un gabinete en la oficina del investigador. El peligro de perder su privacidad es mínima. También es necesario su autorización para usar su información de salud (signos vitales etc.).

¿Hay algún Indemnización en caso de Daños?

Es probable que usted no resulte lastimado por participar en este estudio. Sin embargo, si lo es, no hay ningún fondo apartado para indemnizarle en caso que usted se lesione.

¿Cuáles son las otras alternativas para participar en este Estudio?

No hay ninguna alternativa de tratamiento para esta investigación. Usted puede escoger no participar en este estudio.

¿Cuáles son los beneficios de participar en este Estudio?

Quizá no reciba ningún beneficio directo al participar en este estudio. Sin embargo, la información de esta investigación puede determinar la efectividad del parche para así ayudar a personas con enfermedades debilitantes.

¿Puedo Retirarme de la Investigación?

Usted puede retirarse del estudio en cualquier momento. Negándose a participar ó retirándose de la investigación no involucra ninguna consecuencia ó pérdida de los beneficios que le corresponden.

¿Habrá alguna Indemnización por participar en este Estudio?

Todos los participantes recibirán una tarjeta de regalo de $10 para Starbucks como indemnización por participar en el estudio.

¿A quien llamo si tengo preguntas?

Si tiene preguntas acerca del estudio, puede llamar a Dr. Juan Pérez al número 555-555-5555. Si su pregunta es sobre sus derechos como participante en la investigación, usted podrá contactar al Dr. Brian Gladue, Presidente del Comité de Ética, al numero 555-666-9999.

Autorización

Acuerdo voluntariamente participar en este estudio. He tenido la oportunidad de preguntar a los investigadores del estudio sobre cualquier duda que pudiera tener con referencia a este estudio.

APÉNDICE DEL DOCUMENTO DE INFORMACIÓN Y AUTORIZACIÓN PARA PARTICIPAR EN UN PROYECTO DE INVESTIGACIÓN

La ley Federal HIPAA
Para el uso de Información Protegida de Salud en la Investigación

El propósito de esta Forma

El documento de información y autorización para participar en un proyecto de investigación que ha leído describe su participación en este estudio. Esta sección del documento es una adición por la ley federal "Administración y Responsabilidad de Información Confidencial del Seguro Médico" (HIPAA). El propósito de esta adición es de obtener su permiso (autorización) para usar su información de salud que fue obtenida durante la investigación.

APPENDIX D

CONSENTIMIENTO INFORMADO AUTORIZACIÓN PARA PARTICIPAR EN UN PROYECTO DE INVESTIGACIÓN

Titulo: *Una Evaluación de la Efectividad del Parche "Mágico" en Aumentar Temporalmente la Fuerza Física*

Investigador Principal: Juan Pérez, Ph.D.

Propósito del Estudio:

Esta es una invitación para ser un sujeto en el estudio de investigación. Es muy importante que lea cuidadosamente las siguientes explicaciones y procedimientos antes de tomar su decisión de participar en esta investigación.

El propósito de este estudio es investigar si un parche experimental llamado el parche "Mágico" puede incrementar temporalmente la fuerza física en adultos.

A raíz de que este estudio involucra únicamente adultos sanos, le pediremos información sobre su salud. También sus signos vitales (su pulso, presión y ritmo respiratorio) serán tomados.

¿Qué sucederá en este Estudio?

A continuación se menciona el procedimiento que el sujeto puede esperar:

- Se anotaran sus signos vitales e información de salud.
- Si los signos vitales están en un rango normal, usted formará parte de uno de dos grupos de sujetos que serán distribuidos en forma aleatoria (como el lanzamiento de una moneda al aire). Esto significa que un grupo de sujetos recibirá el parche "Mágico" el cual incrementa temporalmente la fuerza física. Mientras otro grupo recibirá un parche placebo el cual no incrementa la fuerza temporal.
- El estudio es de "doble-ciego". Esto significa que ni usted ni el investigador sabrán cual parche (el "Mágico" ó el placebo) recibió.
- Su fuerza física inicial, antes de ponerse el parche, será medida por la fuerza con la cual usted golpea una pequeña plataforma con un martillo. El golpe del martillo causará que una pequeña canica brinque. Una regla medirá el brinco de la canica. El punto más alto de la regla tiene una campana. Pegándole a la campana indica que ha alcanzado el punto de máxima fuerza medido por la regla. Este instrumento es el mismo juego usado en ferias y carnavales.
- Después de medir su fuerza sin el parche, el investigador le pondrá el parche en cualquier hombro y le pedirá que espere una hora con el parche puesto.

- El examen de fuerza será repetido para ver si hay algún mejoramiento en su fuerza.

¿Cuáles son los riesgos asociados con este Estudio?

- Existe el riesgo de lastimarse mientras esta usando el martillo. Esto incluye lastimadura de músculos ó golpeándose con el martillo.
- Otro riesgo probable es el ser alérgico al adhesivo del parche.
- Existe el riesgo de que su información no se mantenga confidencial. Sin embargo, el investigador tomará todas las precauciones necesarias para asegurar su privacidad. Toda la información que es relacionada con su participación en esta investigación se guardará bajo llave en un gabinete en la oficina del investigador. El riesgo de perder su privacidad es mínima. También es necesario su autorización para usar su información de salud (signos vitales etc.).

¿Hay alguna Compensación en caso de Daños?

Es probable que usted no resulte lastimado por participar en este estudio. Sin embargo, si lo es, no hay ningún fondo apartado para compensarle en caso que usted se lesione.

¿Cuáles son las otras alternativas para participar en este Estudio?

No hay ninguna alternativa de tratamiento para esta investigación. Usted puede escoger no participar en este estudio.

¿Cuáles son los beneficios de participar en este Estudio?

Quizá no reciba ningún beneficio directo al participar en este estudio. Sin embargo, la información de esta investigación puede determinar la efectividad del parche para así ayudar a personas con enfermedades debilitantes.

¿Puedo Salirme de la Investigación?

Usted puede salirse del estudio en cualquier momento. Negándose a participar ó saliéndose de la investigación no involucra ninguna consecuencia ó pérdida de los beneficios que le corresponden.

¿Habrá alguna Compensación por participar en este Estudio?

Todos los sujetos recibirán una tarjeta de regalo de $10 para Starbucks como compensación por participar en el estudio.

¿A quien llamo si tengo preguntas?

Si tiene preguntas acerca del estudio, puede llamar a Dr. Juan Pérez al numero 555-555-5555. Si su pregunta es sobre sus derechos como un sujeto en la investigación, usted podrá contactar al Dr. Brian Gladue, Presidente del la Junta Institucional de Revisión, al numero 555-666-9999.

Consentimiento

Acuerdo voluntariamente participar en este estudio. He tenido la oportunidad de preguntar a los investigadores del estudio sobre cualquier duda que pudiera tener con referencia a este estudio.

APÉNDICE DEL CONSENTIMIENTO INFORMADO AUTORIZACIÓN PARA PARTICIPAR EN UN PROYECTO DE INVESTIGACION

La Ley Federal HIPAA
Para el uso de Información Protegida de Salud en la Investigación

El propósito de esta Forma

El consentimiento informado que ha leído describe su participación en este estudio. Esta sección del documento es una adición por la ley federal de "Portabilidad y Responsabilidad del Seguro Médico" (HIPAA). El propósito de esta adición es de obtener su permiso (autorización) para usar su información de salud que fue obtenida durante la investigación.

APPENDIX E

Complete this questionnaire to the best of your ability. Take as much time as you need. Please answer all questions to the best of your abilities.

R: 1. The investigator in the study is the one who decides if you get the "Magic" patch or the "fake" patch.

True or False

S: 2. Your participation will help the researchers find out if the "Magic" patch effectively increases your physical strength True or False

H: 3. The federal law previously mentioned in the document allows the researchers to use your health information without your permission. True or False

I: 4. There is a group you can call in case the researcher did something wrong in the study. True or False

How does this group help you? Ex: This group protects the rights of the participants

C: 5. You will be given ten dollars to participate in the study.
True or False

P: 6. Some might get a patch that contains inactive ingredient which will cause no effect on your physical strength. True or False

S: 7. In the document, you are called a research subject / participant.

☐ Subject ☐ Participant ☐ Other name

Do you like to be referred as this? Yes or No

DB: 8. Both the investigator and you will know which patch you received (the "Magic" one or "fake" one). True or False

W: 9. You must stay in the study until it is completed, even if you want to quit. True or False

IC: 10. What is the general purpose of the document you read? (Circle the best possible answer)

A. Explain why you have to participate in this "Magic" patch study
B. Explain the purpose of the "Magic" patch study
C. Explain the purpose of and ask your permission to be in the "Magic" patch study

Ri: 11. The document describes some side effects that you may incur during the study. True or False

R: 12. Of the two patches being tested in this study, you can choose the one you want. True or False

IC: 13. The document that you read only contains information about the procedure of the study. True or False

Please fill out some information about yourself. This information will be kept confidential.

What is your level of education? (Mark all that apply)

☐ Elementary ☐ High School ☐ University ☐ Postgraduate

Please indicate your country of origin.

☐ Mexican ☐ Cuban ☐ Venezuelan ☐ Salvador ☐ Puerto Rican
☐ Colombia ☐ Nicaragua ☐ Honduras ☐ Argentina ☐ Bolivia
☐ Other: _____

Check which age group you belong?

☐ 18-25 ☐ 26-30 ☐ 31-40 ☐ 41-50 ☐ 51-60 ☐ 61- 70 ☐ 71+

What is you gender? (Circle one) Male or Female

The letters indicate the concepts being tested for:

R = Randomization
P = Placebo
S = Subject
IC = Informed Consent
C = Compensation
DB = Double Blind
H = HIPAA
W = Withdrawal
Ri = Risk

Filled out by Investigators:
☐ **Spanish Speaking Only**
☐ **Bilingual**
☐ **Non-Literal**
☐ **Literal**

APPENDIX F

Complete este cuestionario lo mejor que pueda. Tome todo el tiempo que sea necesario. Por favor, conteste todas las preguntas lo mejor que pueda.

1. El investigador del estudio es quien decide si usted recibirá el parche "Mágico" ó el parche "Postizo". Verdadero o Falso

2. Su participación ayudará a los investigadores a descubrir si el parche "Mágico" aumenta eficazmente su fuerza física. Verdadero o Falso

3. La ley federal mencionada en el documento permite al investigador usar su información de salud sin su permiso. Verdadero o Falso

4. Existe un grupo al que puede llamar en caso de que el investigador hiciera algo equivocado en el estudio. Verdadero o Falso

   ¿En que le ayudaría este grupo?

5. Usted recibirá diez dólares por participar en el estudio. Verdadero o Falso

6. Algunos recibirá un parche que contiene ingredientes inactivos que no causarán ningún efecto en su fuerza física Verdadero o Falso

7. En el documento, a usted se le conoce como un _____ en la investigación.

   ☐ Sujeto ☐ Participante ☐ Otro nombre

   ¿Le gusta ser referido así? Si o No

8. El investigador y Usted sabrán cual parche recibirá (el "Mágico" o el "Postizo"). Verdadero o Falso

9. Usted debe permanecer en el estudio hasta completarlo aun cuando se quiera ir. Verdadero o Falso

10. ¿Cuál es el propósito general del documento que leyó? (Circule la mejor respuesta)

    A. Explicar porque Usted debe de participar en este estudio del parche "Mágico"

    B. Explicarle el propósito del estudio del parche "Mágico"

    C. Explicarle el propósito del estudio y pedir su permiso para participar en dicho estudio

11. El documento describe algunas circunstancias que pueden ir mal en la investigación. Verdadero o Falso

12. De los dos parches que están siendo probados en el estudio, usted puede escoger el que desea. Verdadero o Falso

13. El documento que leyó solamente contiene información sobre los procedimientos del estudio. Verdadero o Falso

Por favor llene las siguientes preguntas sobre usted. Su información se mantendrá confidencial.

¿Cual es su nivel de educación? (Marque las cuadras que se le aplican)

☐ Primaría ☐ Preparatoria ☐ Universitaria ☐ Postgrado

Por favor indique cual es su país de origen.

☐ Mexicano ☐ Cubano ☐ Venezolano ☐ Salvadoreño

☐ Puertorriquense ☐ Boliviano ☐ Colombiano ☐ Nicaragüense

☐ Hondureño ☐ Argentino ☐ Otro: _____

¿Marque en el cuadro el grupo de edad a la que pertenece?

☐ 18-25 ☐ 26-30 ☐ 31-40 ☐ 41-50 ☐ 51-60 ☐ 61- 70 ☐ 71+

¿A que sexo pertenece? ☐ Masculino ☐ Femenino

Llenado por los Investigadores:

☐ **SSO** ☐ **BL**
☐ **NLT** ☐ **LT**

APPENDIX G

INFORMED CONSENT SCRIPT: FOR KEY PERSONNEL TO READ TO THE PROSPECTIVE SUBJECT

We are doing a research project on Spanish translations. Would you like to help us out?

☐ Yes (Continue)
☐ "No Thank you for your time"

The purpose of this study is to look at the quality of Spanish translations in research documents. If you agree to be in this study, we will give you a document that has fake information (not real). Once you have finished, we will ask you to complete a questionnaire about the document you just read. You can skip any question if you want. However, we would like you to answer as many questions as possible. You will have plenty of time to carefully read the document and answer the questions. Your answers may give us information on how to improve these research documents.

Are you interested in the study?

☐ Yes
"Great! Before continuing I have to ask you some questions..." (Go to screening questions)

☐ No
"Ok, we appreciate your time"

Screening Questions:

Have you **ever** been in a clinical or research study?

☐ Yes (Cannot be in the study)
"I am sorry but you cannot be in this study. We need volunteers who are not familiar with research documents. We do appreciate your time."

☐ No (Continue... can be in the study)

Are you **ONLY** fluent in **Spanish (You do NOT SPEAK ENGLISH)**?
☐ Yes (Spanish Speaking Only Group- SSO)

☐ No (Go to the next question)

Note: If the prospective subject/participant says they know a little English, ask them...

"Ok, just to check on your English ability, can you please read this page?" (See Attached paragraph)

☐ Can read it (Go to the next question)

☐ Have difficulty/cannot read it (They have not yet mastered English then in SSO)

Are you fluent in Spanish and English (You can speak, read & write in both languages)?

☐ Yes → Must read well the attached paragraph to belong in the Bilingual Group-BL ☐

If they do not read well the paragraph, they can be in the SSO ☐

☐ No "Which language are you **not** really fluent in"

☐ Spanish: "Sorry you cannot be in the study because all the study documents are in Spanish. Thank you for your time"

☐ English: Subject should be in SSO but before ruling out BL have subject read the paragraph.

APPENDIX H

INFORMED CONSENT SCRIPT: FOR KEY PERSONNEL TO READ TO THE PROSPECTIVE SUBJECT

Estamos haciendo un proyecto de investigación sobre traducciones. ¿Les gustaría ayudarnos?

☐ Sí (Continue)

☐ No "Gracias por su tiempo"

El propósito del estudio es evaluar la calidad de traducciones de documentos usados en estudios de investigación. Si acepta participar en dicho estudio, usted recibirá un documento que contiene información ficticia (no real). Cuando haya terminado de leerlo, nosotros les daremos un cuestionario sobre el documento que leyó. Puede saltarse cualquier pregunta, si así lo desea. Sin embargo, nos gustaría que contestara a todas las preguntas para apoyar esta investigación. Tendrá suficiente tiempo para leer cuidadosamente el documento y contestar el cuestionario. Sus repuestas nos darán información de cómo mejorar estos documentos que forman parte de los estudios de investigación.

¿Esta interesado en este estudio?

☐ Si

"¡Excelente! Antes de continuar con el estudio, le haré algunas preguntas." (Go to screening questions)

☐ No

"Esta bien, le agradecemos su tiempo."

Screening Questions:

¿**Alguna vez** ha **participado en** un estudio clínico o de investigación?

☐ Sí (Cannot be in the study)

"Lo siento pero no puede participar en este estudio. Necesitamos a voluntarios que no estén familiarizados con los documentos usados en este tipo de estudios. Agradecemos su tiempo."

☐ No (Continue… can be in the study)

¿Habla únicamente **español** (En otras palabras no domina aún el inglés)?

☐ Sí (In Spanish Speaking Group-SSO)

☐ No (Go to the next question)

Note: If the prospective subject/participant says they know a little English, ask them...

"Esta bien... ¿Para verificar su fluidez en Inglés, por favor podría leer esta pagina?" (See attached page)

☐ Can read it (Go to next question)

☐ Have difficulty/cannot read it (They have not yet mastered English therefore can be in the SSO)

¿Domina el **español e inglés** (Puede **hablar, leer y escribir las dos idiomas**)?

☐ Sí ⟶ Must read well the attached paragraph to belong in the Bilingual Group- BL ☐

If they do not read well the paragraph they can be in the SSO ☐

☐ No ¿"Cual idioma **no** domina muy bien?"

☐ Español: "Lo siento pero no puede participar en el estudio ya que los documentos están escritos solamente en español. Le agradecemos su tiempo."

☐ Inglés: (Subject should be in SSO but before ruling out BL have subject read attached paragraph.)

Is it Getting Too Warm for Penguins?

King penguins are supposed to be a wildlife success story. The flightless Antarctic bird — the second-biggest penguin after its movie-star emperor cousin — was hunted into near-extinction by sailors in the 19th century, who used their fat as cooking oil. When the slaughter ended — penguin fat no longer being the preferred way to simmer your cruise dinner — the penguin bounced back, and today numbers about 2 million. This is a healthy, robust species that sits near the top of the complex Antarctic food web. They may not stay that way much longer. A new report by French scientists in the *Proceedings of the Natural Academy of Sciences* finds that king penguins could be wiped out over the coming decades due to global warming.

Time Magazine

APPENDIX J

Spanish Speaking Only Group

Assignation Number

	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	
Non- Literal Group																					Total: 10 Subjects
Literal Group																					Total : 10 Subjects

Bilingual Group

Assignation Number

	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	
Non-Literal Group																					Total: 10 Subjects
Literal Group																					Total: 10 Subjects

APPENDIX K

Monday August 27, 2007

I discussed with Dr. Gladue the final idea for my thesis project. My first committee meeting concluded that I needed to narrow down the general problem found within translating an informed consent form. Prior to me starting as an intern, I had looked into several journal articles and with Dr. Agarwaal's guidance, I narrowed down my focus. In the articles, I began to see a trend in the poor quality and lack of information being given during an informed consent process involving non-English subjects. The problem lied among the interpreters not being able to convey all and accurately the informed consent. Yet, the responsibility does not lie entirely on the interpreters but also on the clinicians (PIs) who may not have trained the interpreters well in the policies, guidelines and medical terminology involved in an informed consent process. Dr. Gladue was interested in the subject matter. He helped me perfect the idea by suggesting I should create a list of common words and concepts that are difficult to translate literally into Spanish. For example, in on of my journal articles a common word that was hard for non-English subjects to understand was "randomization". The PI and the interpreter did a poor job in conveying and translating the word correctly leading to the subject's confusion. It may also be the fact that in the Spanish language it is hard to explain the clinical concept of "randomization" because there is not a good Spanish word that equates to the English meaning. Dr. Gladue allowed me to work on my list in the library (10-3pm). My task was to look up any information within journal articles or searching within English and Spanish informed consent forms available on line for any common words that were hard to translate. I wasn't too successful finding journal articles dealing with problems words in Spanish during an informed consent process. I did find a good journal article dealing with the negative connotations of the clinical words such as "experiment" to describe a clinical research study. In addition, words such as placebo and double blind were hard to explain to the subjects. Yet in this article, it did not specify the language or cultural background of the subject. In the afternoon, Sharon Tobola, an IRB compliance coordinator, gave me the assignment of reviewing the IRB new research protocol application and the protocol synopsis guideline. She wanted me to review the forms looking for any doubts, confusion or any suggestions I had with the purpose to improve the OPHS website. Most of my questions came from the IRB application. They were certain things I was not sure how to fill in if I was a newbie PI. By the end of the workday, I handed my comments and questions to Sharon who appreciated my input.

Tuesday August 28, 2007

Sharon Tobola, IRB compliance coordinator, gave me the assignment of reviewing more documents designed for the OPHS website. The documents were "How to submit a new proposal". I was to write down any questions, suggestions, and note any areas of confusion and compare it to other OPHS websites. The task took me the whole day but I wanted to be thorough. The instruction guideline included how to submit a packet to the

IRB, application for exempt review, the differences between full Board or expedited review, vulnerable populations and special circumstances, submitting for expedited review, preparing for full Board review, completing a protocol summary, confidentiality and use of protected health information, writing an informed consent, parental permission and assent forms for children, survey instruments/standardized tests, and recruitment material. All the points of an IRB application submission were pretty well covered. I did have some questions about certain terms such as "covered entity". I was also vague about the certificate of confidentiality and personal health information regulations. I also wondered if an expedited review did not require a protocol deadline did same principle apply to the progress report.

The instruction manual also helped me differentiate the differences between exempt, expedited and full Board review categories. The guidelines detailed the criteria for determining each review status. For example, a research study can become full Board when the PI is collecting systematically data from a medical record. However, the study can change to exempt review status if the PI collects only one data set of the record and erasing any identifier. Once the study is exempt, the study can be "free" of IRB monitoring only if there are no changes made in the protocol.

Wednesday August 29, 2007

Deb Ceron, IRB Compliance Coordinator thought it would be beneficial to review the IRB minutes complied during the last IRB meeting. I was actually present during the meeting on August the 6th. It was a very long document, which included the chair's report. It took me pretty much the whole day to review and digest everything the IRB minutes contained. It listed everything that occurred and what was said during the meeting. The report was very detailed. It included those who voted for or against as well as those who abstained. The minutes listed all the protocols reviewed including any special findings, deviations, violations, amendments, and severe adverse events. The chairman's report included all the minor amendments that were done to the protocol that did not require full Board review (an expedited case). After reviewing the IRB minutes, I got a general feel of all the work the office of protection of human subjects does in order to ensure that the subject's rights are being protected. I also noticed there were some SAEs that lead to the unblinding of a subject because of an emergency. I remember my CRM instructor indicating that the sponsor usually hated unblinding a subject and would avoid doing so at any cost. It was actually interesting to note how many sponsors did unblind a subject although it may have been a minor outcome at the end. The last two hours of the day Deb Ceron recommended me to look over the compliance oversight guidelines posted by the department of human and health services. The regulations seemed somewhat straightforward although I was confused regarding the section of exemption criteria in a clinical research study dealing with children. I know that there are cases where studies dealing with adults could be exempt as long as there are no identifiers and less than minimal risk. Therefore, I was confused about the vagueness of the regulations regarding children and exemption. I asked Sharon about this section and she explained everything to me. When it comes down to children, the laws are stricter

because they are a vulnerable population thus requiring more safeguards. A study involving a questionnaire in which the subject will fill out anonymously and only once can qualify as an exempt study. However, if the same study changes its target audience from adults to children, the study no longer qualifies as exempt. Once a protocol involves any type of survey, device, questionnaire or test for a child, the study automatically changes from exempt status because there is direct contact with the child. The study could even become full Board review at this point. Children have more protection under federal regulation so to speak, than healthy normal adults do.

Thursday August 30, 2007

Sharon gave me this morning the task of reviewing the progress report, the internal and external SAE forms. She wanted me to look for any areas of confusion. She also wanted me to go online and look at other formats of instruction manuals from different IRB websites. The OPHS office will use my input and research on line to set up a guideline for PIs as they are filling out these forms on their own website. I started with the progress report. I had remembered some of the points Sharon had made in her instruction manual about submitting a progress report but I still had some questions. I also had some suggestions for Sharon although I know more than likely; there will be no changes in the actual document. I thought it would be good in the instruction manual to have definitions for continuing and full Board review as well as the criteria for each status. It was the University of Miami I believe had a section for addressing continuing and full Board review. I then preceded with the SAEs reports. Sharon had told also to visit the University of South California IRB website since it was the website the OPHS office had liked. USC was a great source for SAE instructions. They had a really good template in which they wrote in exactly what was expected for each answer. After noting some of their instruction as references for our SAE instruction manual, I continued to look in other websites for more ideas. I found some good websites that had explained to PIs how to determine if an event is an adverse or unexpected occurrence, which needs to be reported. I think this would be great to have in our website as well yet I was not able to find another good SAE instruction manual. They all looked the same so I eventually ended the search. Later I decided I would type everything up for Sharon so it will be easier to read. I finished typing the Progress report and decided it will be good to type everything else up as well. Throughout the day, I took mini-breaks from looking for SAE and progress reports and looked at informed consents in Spanish available on-line. The templates that I found did not offer much. The informed consent would state the basic instruction line with easy words to translate but the difficult part they would just have an insert here translation. I am going to have to look harder for a good informed consent.

Friday August 31, 2007

I began the morning by transferring all my notes from the documents Sharon gave me to review into a word document. I thought it would be more user friendly especially with my handwriting for Sharon to have everything typed up. Yesterday, I had finished the

Progress report review and gave it back to Sharon. Therefore, I moved on to the typing the SAE report reviews. It was quite coincidental when Deb asked me to join her for a discussion about SAEs. She had just reviewed a batch of SAE reports and wanted to take me thru the process. She showed me some of the reports that had notable errors. For example, the CRM had noted the date of the SAE occurrence as 2004. Deb explained all AE/SAE must be notified within 10 working days to the IRB. Because the date was so overdue, she had to call the CRM to find out the reason for the late reporting. Deb stressed that documentation is crucial when reporting a SAE. There is no room for vagueness! She must review carefully not only the documentation of the SAE but also the SAE itself. It is important to pick up any recurring patterns of SAEs in a clinical study. If there is a habitual reporting of the same SAE to the IRB, it sends a red flag to Deb that something is going wrong in the study or the adverse event must be stated as a side effect or foreseeable risk in the informed consent. This allows subjects to be fully aware of the risks before signing on to a clinical study. This is one of the reasons she enjoys her job so much. By examining every detail, she ensures that the rights and safety of the subjects are being protected. I went on to ask her about the procedure taken during a death SAE report. She explained the death of a clinical subject must be notified to her via e-mail within 24 hours of the sponsor's or principle investigator's acknowledgement of the occurrence. The CRM must submit a detailed report of the reasons for the subject's death in order to determine any affiliation to the clinical study. She took me thru the SAE reports and clarified each section of the SAE report form. She also answered my question why off-site studies must submit a follow up report about the SAE while on-site studies do not. She explained UNTHSC faculty is pretty good about reporting everything. Many times off-site SAEs have cases where follow-ups are necessary to detect any chronic effects and many PIs are required by their sponsor to have a follow-up with the subject. The OPHS needs documentation of this follow-up. After Deb gave me other case scenarios of SAEs, we concluded our discussion. The rest of the day, I continued to transfer my notes of each document review into word documents. I completed SAEs (on-site and off-site) report forms, New Research Study Protocol Review Form and Protocol Synopsis for Research Project Involving Human subjects form.

Tuesday September 4, 2007

This morning I proofread all the documents I had typed up for Sharon. I wanted to make sure all my questions and suggestions made sense before printing them. Today I continued transferring my notes. I had saved the longest document for last-"How to submit a new proposal". I spent the whole day transferring my suggestions and questions about each step in submitting all the necessary documents for IRB approval. In my notes I had suggested adding some definitions about "research", "human subject", and "Non-human subject research (NHSR)" to name a few. I decided to go ahead and write in those definitions for Sharon. Therefore, I took the task of surfing different IRB websites and visiting the federal regulations website (45 CFR pt. 46) for clear definitions. I came across an excellent IRB website as a reference. Duke University had a detailed definition about "children" under vulnerable population. I would never have thought it would be

good to include a definition for children. It went on the detail all the applicable regulations regarding children enrollment in a clinical investigation. It also included definitions and requirements of parental permission and assent of a child. I thought all of these were good pointers for our own website and made a note of it. I also found a good definition for "existing data" by the NIH and Duke University. I remembered from my regulation of human subject class sometimes scientists have a hard time understanding the concept of existing data. Existing data is not data they have collected over the years in their lab regarding a study that has not been approved by the IRB. It must be published and established data. I thought it would be important to have apiece explaining this to the PIs who visit our website especially if Sharon used the term in a case scenario for exempt qualifications. I also thought it would be good to go ahead and type all the elements required for an informed consent form. I thought having all the basic and additional elements for an informed consent was essential to include especially for new PIs. The rest of the day I continued to look for good reference websites to improve my notes and suggestions for the "How to Submit a New Proposal" document. By the time the day was over, I had pretty much completed typing everything up. I also helped Mary in something today. I made some photocopies of a new protocol and protocol synopsis.

Wednesday September 5, 2007

Today I had a scheduled meeting with Dr. Gwirtz. Before attending the meeting, I finished proof reading my notes of "How to submit a new proposal". I also searched through the internet a little bit more trying to find other good websites to serve as references for Sharon. I found a really cool website from Vanderbilt University, which had a manual for recruitment advertisement. The manual actually had an advertisement template for PIs. I actually had a question about this, which I noted in my review. Does UNTHSC have any aesthetic guidelines for PIs as they are designing an ad or flyer? Wouldn't too much aesthetics or anything to flashy be a form of coercing a subject into a clinical research study? There are some marketing studies that proved people are attracted to flashy advertisement.

My meeting with Dr. Gwirtz went well. The purpose of the meeting was to have her also review the *new research study protocol form* and the *protocol synopsis for research project involving human subjects* for any questions or comments. She did bring up some points that I had not thought of myself such as how does a PI determine a document is at an 8th grade reading level. She was also amazed of how much paperwork and documentation it really requires for IRB approval of a new protocol. She equated it to writing another grant application. She did question whether or not the OPHS was considering electronic submission of all the documents. I did inform her that a PI does have to electronically submit the IRB application form, protocol summary, informed consent, parental permission and child assent form, recruitment material and ads, and any other material to be used or viewed by the subject. However, the PI still has to send in at least four hard copies for a full Board study and the conflict interest form with CITI training documents. She also asked if the IRB Board members had laptops so they could review all the protocols submitted or if the OPHS is considering the possibility. I

remembered that same point was brought up in the August 6 IRB meeting I attended. I guess the same principle applies now- where is the money going to come from to buy 15 laptops? I thought it was interesting she brought it up. After the meeting, I typed up all her notes into a word document for Sharon. Although Dr. Gwirtz's handwriting is very legible, I thought it would be a good idea to do the same as I did for my review notes. Sharon did appreciate the effort. The last hour of the day, I finished reading a journal article for my project. The journal article was titled "Groups potentially at risk for making poorly informed decisions about entry into clinical trials for childhood cancer." It was a really great journal article that included English-speaking minorities as a control group. The findings were similar to other articles I have read. Randomization was a hard concept to understand. Many clinicians forgot to mention during the informed consent process for many non-English speaking subjects about voluntariness and the distinction of clinical research from standard therapy. This article will be a great reference for my paper.

Thursday September 6, 2007

This morning I worked on my project since neither Sharon nor Mary had anything for me to do. I printed out some articles that I had downloaded this weekend that could help me form my list of difficult words. The first article that I read was "Translating from English to Spanish". It pointed out the importance of tailoring any translation tool into the right cultural context and sub-language. It went on to explain within Spanish there are several cultural differences in the language itself. A word that may acceptable in Chile may take on a completely different connotation in Mexico. There are colloquial differences in the Spanish language that PIs and interpreters must be made aware and acknowledge it. They found big area of issues for many non-English speaking or limited English proficiency (LEP) individuals were in vocabulary and the low reading levels. Another interesting point the journal article made was being careful about using words with negative connotations in the informed consent. For example, in the article they stated the word "junta" as the literal Spanish translation of "Board." Yet, toward was changed to "comité" which means committee because of the fear that the word "junta" would create I actually disagree with this point. I actually think "comité" is a better translation of the word "Board" rather than it being an appropriate word. I think the translation of "Board" to "junta" is a false translation. "junta" means "meeting' but "Board." I think it would be a good to include the words "junta" and "comité" in my word bank.

The second journal article "Bridging language barriers: How to work with an interpreter." The article was a great guideline for clinicians to train interpreters in the importance of conveying an accurate and complete informed consent. Medical interpreters must have understood the foals of the interview and the general topics to be discussed before starting the informed consent process. The clinician on other had must estimate the appropriate time for the informed consent process. Many times the article noted that extra time for translation was not included in the scheduling of an informed consent interview. Often the meetings with non-English subjects lasted the same as the

English-speaking subjects. The clinician must also consider that neither the interpreter nor the subject may be familiar with certain medical terms therefore the clinician must remember to put everything in layman terms and speak in short sentences.

The last article that I read was "The importance of cultural and linguistic issues in the emergency care of children." The article served to emphasize the importance of culture and language in pediatric emergencies. The failure of not understanding the cultural differences can lead to serious adverse events in the emergency room including difficulties with informed consent process, miscommunications that can ultimately lead to ethnic disparities.

In the afternoon, I had my first Board meeting I observed all the planning involved in orchestrating an IRB meeting. I gave a little report about what I have done so far as an OPHS intern. Deb was glad to see I had found a good recruitment advertisement template from an IRB website, which I emailed to her later. At the end of the meeting, my task was to email Dr. Gwirtz about arranging some OPHS staff members to accompany me to Dr. Burke's monitor visit on September 19th. She replied promptly to my email and informed me she would speak to Dr. Burke directly. The rest of the afternoon, I started working on my actual proposal. The deadline for submitting the first draft of the protocol proposal is next week. The proposal must have a background, summary, method, and literature. I definitely still have much to do!

Friday September 7, 3007

I pretty much worked on my proposal project. I looked into finding more journal articles about the interpreter's role in the informed consent process. Today I found mostly articles that discussed the actual method and format used by interpreters to convey fully the informed consent. It compared the transmission model to the semiotic model both terms, which I never heard. The transmission model is the most commonly used. According to this model, the interpreter communicates with the individual on a one-to-one basis. In other words, the information is being transferred thru a channel from a sender to a receiver. The semiotic model permits the interpreter to act more as the patient's advocate and culture broker. In clinical studies, it is essential that the interpreter and the clinician must consider the culture of the subject. Yet, it is fine line on which the interpreter walks as being the cultural broker. The only problem with this method is when the interpreter interjects their opinion. I believe a good solution for this problem is to have the PI adapt the informed consent within the linguistic and cultural context prior to the interpreter's opinions during the consent process. The other two articles "the impact of language as a barrier to effective health care in an underserved urban Hispanic community and the "exclusion of non-English speaking persons from research" discussed the under representation of Hispanics in clinical research studies. Both articles hand similar approaches for increasing the numbers of Hispanics in clinical trials: increase awareness among researchers of the prevalence of non-English speaking people. As well as, its impact on generalizability enforce a methodology which facilities any accommodations for NES, development and dissemination of valid instruments in various languages and have policies and finding practices among granting agencies that

encourage inclusion. Although, I thought these articles were interesting they did not really answer my thesis question so I left them as references. I am still looking for some more journal articles but I decided to stop and concentrate on my thesis introduction. I spent the afternoon rewriting my introduction.

Monday September 10, 2007

Sharon gave me an exercise activity today. She gave me three exempt review cases and had me overlook the application. I was supposed to determine whether or not the case really qualified as exempt status. I also had to write down any comments or questions regarding the case application. Before analyzing the review, Sharon gave me a brief discussion about the exempt criteria under the federal regulations. She directed me to the department of health and human services webpage for the complete breakdown of the exempt criteria. Sharon explained the importance of the "and", "or" and "unless" in the federal regulations. For example, a study involving educational testing or survey procedures can qualify as exempt. However, if the survey or testing requires identifiers and the questions involved may put the subject in civil or criminal liability then the study automatically becomes not exempt. If the study only has identifiers linking to the subjects without any risk of criminal or civil liability, then the study may continue being exempt. Both rules must apply. She also explained the requirements for the wavier of informed consent. She gave another case scenario where the investigator would have to debrief the subject after the procedure about the study in the case of a wavier of informed consent.

The first exempt application was pretty straightforward. It was a retrospective study regarding pancreatic injuries. This would qualify as exempt under the federal regulation 45 CFR pt. 46. 101 (b), category 4 which states studies involving the collection of existing data without the use of indirect or direct identifiers are exempt. The second case had more gray area. The study qualified for exemption under 45 CFR pt.46 101 (b), category 1 which states the research being conducted is in a common education setting involving instructional strategies or curricula are exempt. However, there were some issues with the case. There was not a clear definition or objective given about the study causing me to question the ethical basis of the study. The investigator would be retrieving sensitive information from student records without any consent for an investigational reason that plainly needed more clarification. In any case and above all other issues, the study did qualify as exempt under category 4. The other case that I looked at also qualified as exempt status although it was submitted thru a full Board application. The study fell under 45 CFR pt.46.101 (b), category 5. Although the investigator was going to be interviewing the participants, the information was not considered to be sensitive and results were going to be used to evaluate the service programs offered to senior citizens at the senior center. Overall, this was a great experience because I was able to use the federal regulations and my general knowledge about exempt review in order to analyze and determine actual studies. Great hands on assignment! Later in the day I reviewed, the pre-review notes that Dr. Gladue sent me as well as the progress reports of the new protocols that are going to be presented to the IRB meeting tomorrow

Tuesday September 11, 2007

Expedited review was on today's agenda. Sharon discussed with me the requirements for expedited review. The study cannot be more than minimal risk to qualify for expedited. She took a while to confer on the different forms of risk: physical, information/confidentiality, and emotional. We also had a lengthy conversation about vulnerable populations in expedited review. It really depends on the form of intervention when dealing with a vulnerable population whether or not the study is considered expedited. For example, a survey done in pregnant women asking general questions about illegal drug use 6 months ago would be considered full Board because the investigator is questioning their drug use activity when they recently became pregnant. This same case maybe considered expedited if the general questions were being made to non-pregnant women. There definitely a lot of gray area around expedited review. Sharon and I went over an old expedited case regarding a measuring device for measuring hot flashes. She went over systematically the reviewing of the case. She showed me her technical findings and explained the reasoning for notifying the investigator about these technical errors. We also reviewed Dr. McGill's notes regarding the device. The device had been customary made for the study and did not have FDA approval. This was a problem because the device although it would not be more than minimal risk it needed to have FDA approval.

Dr. McGill needed more clarification and details regarding the manufactures of the product before approving the study. Sharon wanted me to get the feel of some of the gray areas of classifying a study as expedited. We also talked about Dr. McGill's role as IRB chair as well as went systematically of receiving a new protocol. We actually concluded the discussion with something different. Sharon told me a little about her background as a clinical research coordinator. It was good to hear some of her experiences.

In the afternoon, we had the IRB meeting. Throughout the meeting, I filled in the required information in the pre-review notes that Dr. Gladue had sent everyone. Overall, it was an interesting meeting. The Board set the risk levels for new protocols and actually deferred one protocol because of its ambiguity. One thing I did observed was that some of the Board members had not fully over looked the informed consents and protocols. Although they must be very busy people, it is crucial that most members read the protocols and informed consents carefully in order to make an informed decision about the ethical basis of each study. Yet, some Board members did make some good points regarding a psychiatric study. However, as Dr. Gladue and Sharon pointed out it would be great to have more representation of the psychology expertise. My next task would be helping the OPHS look for a Hispanic woman who has expertise in psychology and works closely with prisoners. It's definitely going to be a challenge!

Wednesday September 12, 2007

This morning I talked with Deb about the making of the IRB notes. She explained some of her notes and why it was important to leave a detail paper trail of the all the discussion points. If by any chance, the FDA comes to review any of the paper work they will be able to find the dialogue that occurred for each study during the IRB meeting and

why the IRB deliberated certain decisions. The rest of the time I worked on a task that Mary gave me. I was on a scavenger hunt looking for a list of case studies. My assignment was to make copies of the IRB approved informed consent in which any form of compensation was given to the subject. It could be anything from a gift card to cash payment. The federal regulations under 45 CFR pt.46.116 states that any or lack of compensation must be included in the informed consent. Many would consider monetary compensation in a clinical study as a benefit but it really comes down to being a PERSONAL benefit rather than a benefit to society. Ethically speaking money should not be used to coerce an individual into a study but rather compensate or make up for any time and money a subject invests for being in the study. Therefore, money is not a benefit and should not be included in 45 CFR pt.46.116, category (a.3) which states a description of the benefits to the subject must be included.

Thursday September 13, 2007

I searched for advertisements regarding a research study, which Sharon asked me to do. My task was to verify if the advertisement stayed true to the IRB approved ad. I searched in the daily news starting from July up to today's date. All the ads were stated the same. The only catch was that the title posted on the daily news was different from the approved ad title. Sharon and I compared the titles. We saw the deviation of the title could imply something offensive and deceive individuals about the inclusion criteria. This was discussed in Dr. Gladue's class yesterday. PIs must be cautious in what is included in an ad. The words "free" or "win" cannot form part of the ad or mislead the individual in false expectation. This may include compensation, treatment/procedure of the study, and the inclusion criteria. You don't want people calling you up asking to be in the study to be later disappointed about not being allowed into the study because they do not meet the requirements. Sharon and I also discussed the informed consent process. I told her some of the things we discussed in Dr. Gladue's class. I did ask her about UNTHSC's policies and criteria for reviewing an informed consent in Spanish. This is something I would also like to ask Dr. Gladue as well. Wouldn't it be hard to review extensively a Spanish informed consent without any IRB member fluent in the language? In any case, she instructed me to look over an informed consent that was up for continuing review. My task was to evaluate and analyze the informed consent in both languages and compare it to the protocol synopsis. This was pretty interesting. I first reviewed the informed consent in English and highlighted each section, which detailed the basic and additional elements of the informed consent under federal regulation. In the informed consent, I found only two things that were maybe pertinent to add in the English informed consent 1) a statement regarding alternative methods and 2) the right of an investigator to withdraw a subject from a study. These elements may have not been included because the study's purpose had to do with improving adherence to treatment of a disease y interviewing subjects about their feelings regarding the treatment. However, it would still be good to include these points or better yet explain why they are not being included. I then reviewed the Spanish informed consent where I actually found some errors or discrepancies. In the confidentiality section, there was a sentence actually

omitted from the Spanish informed consent that was present in the English informed consent. There was also part where they had left out Dr. McGill's title as chairman of the IRB in the Spanish informed consent. Another error was grammatical and could be easily fixed. By looking at the Spanish informed consent, I got an idea for a word bank. For example, an explanation for randomization could be put in the cultural context of the subject. In Mexico, the expression "águilas o sol" is used for "heads or tails" which could be used to describe randomization. Or, instead of having the word "moneda" to describe "throw a coin in the air' the word "peso" could be used to fit the cultural context of the subject's language in Texas more than likely it will be Mexican Spanish. Some other word variations that I listed were "comité de revision institutional," "la mesa de revision institutional," "el comité de ética investigacional" to describe IRB. It would be good to see which translation has a better connotation or more understandable. Therefore, I'll continue to work on finding more variations of words or phrases.

Friday September 14, 2007

I reviewed the Spanish informed consent of another protocol, which recently underwent continuing review. It was a case-control study therefore, I had to review f our informed consent forms (case and control informed consents in Spanish and English). Again, I read thru the English informed consent, the case group first, and determined if any elements was missing from the informed consent. I merely did this as a training exercise. I highlighted each basic and additional element found under 45 CFR pt.46.116. There were some elements, which I found that might have been good to include in the informed consent. The consent could have stated the risks involved during the study. Although, the study dealt with a subject discussion regarding the role of liver disease in their adherence to the treatment of another acquired disease, it may be necessary to indicate no foreseeable risks or certain sensitive questions i.e. alcohol consumption may be asked.

Another point, which I found in both English informed consent, was missing information/detail. In the compensation for injury section of the Spanish informed consent, it detailed by signing the consent the subject was not giving up the responsibility of the CDC, the medical personnel in charge of the study, or UNTHSC in the case of any negligence events. Sharon Tobola came to the conclusion that they probably used an old UNTHSC informed consent template. In any case, this is one of the rare cases where the Spanish informed consent is better than the English is. I also found in the case informed consents there was never a clear indication that the subject was being asked to be a case study subject. The control informed consent actually had a sentence in the "How many people will take part in this study" section where it specified to the subject that they were being asked to be a control subject. This point should be made clear for the case informed consent. I then read thru the Spanish informed consent. I found fewer mistakes in this informed consent than the ones I reviewed yesterday. Yet, there were some small grammatical errors and there were some sentences, which needed to be rewritten in order to improve understandability. I also played around with various translations for the

Office of Protection of Human Subjects, which was included in the PHI section of the informed consent. For example:

1. Oficina de Protección de Investigación de Humanos
2. Oficina de Protección de sujetos Humanos
3. Oficina de Protección a los Humanos participando en Investigación

I personally like the first example yet it does have a lot of "de" in the phrase. The second is actually an example of a literal/direct translation. However, direct translations are not always the best. The word *sujeto* is often related to criminal or shady individual. The person reading the informed consent may relate the negative connotation with the OPHS and therefore may be discouraged from calling the office in case of any wrongdoing. The rest of the day, I continued to review the English and Spanish control-group informed consent. They had similar mistakes to the case group informed consent.

Monday September 17, 2007

Since I finished on Friday reviewing all the four informed consents of the case-control study, I began to type all my notes for the two assignments, which Sharon gave me. It took pretty much all day to type up the first English-Spanish informed consent and protocol synopsis review that I did on Thursday regarding the role of adherence to TB treatment. This informed consent had more errors and has not gone thru continuing review. Sharon Tobola, IRB compliance coordinator, had given it to me as a training exercise. I went ahead in wrote in my suggested translations for some sections and sentences, which needed clarification or improvement. Then I back translated it so Sharon would understand how I was translating the sentence so if she does not like how the sentence itself is worded then I can find another way to state it. I have learned that wording is crucial! Changing a word or phrase can alter the connotation, understanding or meaning of the sentence. By back translating, Sharon can ensure I am stating correctly the idea behind the sentence and the subject can completely comprehend the study. Dr. Gladue had previously explained the importance of back translation when reviewing Spanish informed consent for IRB approval. Of course, it did take longer to complete the document for Sharon but as stated previously it is necessary.

As previously mentioned in Thursday entry, the informed consent had left out a sentence, which was the only place where it indicated where the answers of their survey/interview were being stored. It also introduced the next sentence, which stated how the names were being linked to a numeric code for confidentiality purposes. Sharon thought it would be good to reword those two sentences in the confidentiality section in order to increase comprehensibility not only in Spanish but also in English about the concept of matching a name with a numeric code. I took Sharon's rewording and translated into *Usaremos una computadora para guardar sus respuestas. Su nombre será remplazado con un código numérico. El código numérico será usado para archivar sus respuestas en la computadora* which back translates into *We will use a computer to state your answer. Your name would be replaced with a numeric code. The code will be used to store/ (archive) your answer in the computer.* In Spanish, *archive* does not have the

same connotation/meaning as it does in the English language. If you think about the word *archives*, it brings to mind old history documents stored for future reference but *archivar* in Spanish does not have that same connotation/meaning. It is synonymous for *store*.

One important thing to note which has to do with both informed consents regards the omission of a basis element under 45 CFR pt.46.116. As I was reviewing the informed consent, I highlighted which elements were missing from the informed consent. I did find a basic element that was missing from the informed consent. It had to do with offering alternative treatments in the informed consent. The PI may have thought since this was an interview discussion about adherence issues it may have not been necessary to include in the informed consent. However as previously noted, it would be good idea to include this point by simply stating that there are no alternative treatments for this study or suggest counseling and support groups for patients that may help improve their adherence. In any case, I had merely presented the inclusion of this element as a suggestion but the short informed consent, which is often used for non-English speaking subjects, had listed alternative treatment as one of the points to cover during the informed consent process. Since it is mentioned in the informed consent, it *must* be included in the actual informed consent form.

Tuesday September 18, 2007

Today I began typing the case-control study notes. I finished typing the first assignment notes so I started with the other study, which has recently undergone continuing review. Just as previously stated there were fewer errors in these informed consents but there were some worth noting. Many of the errors were grammatical and there was one misspelling. Again, I wrote in my suggested translations for some sections and sentences, which needed clarification or improvement. I also back translated all my suggestions so Sharon may ensure that I am translating and conveying the correct message. This took more time to complete because it involved four informed consents. I worked on it all day and did not finish with it. Here are some following examples of what I found in the Spanish informed consent, which differed from the English informed consent.

One example I found in the Spanish informed consent that differed in the English informed consent was in the procedure section. It was minor detail but important to indicate. In English the informed consent, it indicated questions about *how much alcohol consumption* were going to be asked during the interview. Yet, the Spanish informed consent only indicated that the discussion involved general questions regarding alcohol. This may be an issue because some people might be ok with answering general questions about alcohol but will take offense once it is regarding on how much they drink. They might think the physician or medical personnel are judging them by answering this question. This impression was given on how and which words were used in the Spanish informed consent.

Another important point was the exclusion in the *compensation of injury* section in the Spanish informed consent regarding where the subjects may exactly receive medical care. In the English informed consent, the consent indicated that medical attention would be

given at the TB clinic yet the Spanish version only stated medical care would be provided. There was no indication or clarification for the subject regarding the location for medical attention. Although this study only involved an interview discussion, it did include the location where medical attention could be found in the English informed consent therefore this must also be included in the Spanish version. I also incorporated my notes regarding the protocol synopsis in the document.

Wednesday September 19, 2007

Today I went to observe a monitor visit at Dr. Burke's office. He currently has five chronic obstructive pulmonary disease (COPD) studies under Kathy Kwaak, clinical research coordinator. Depending on the study and how much information is collected by one subject determines how often a monitor from the sponsor visits the site. I was able to speak with the monitor. She was actually a CRO who contracts herself out to the sponsors so she has a pretty flexible schedule. She told me a little bit about her background and how she became a study monitor. She then explained the importance of her job an what she looks for during a study auditing. Monitors are responsible for making sure EVERYTHING is noted and reported. She looks at all the case report forms to make sure all notes and occurrences dealing with each individual subject are correctly noted in the forms. For example, the monitor saw that the CRC had noted the subject compliant but she was not filling out her journal. Kathy explained that the patient would come to the office religiously for the administration of the drug at 11am. Technically the drug administration called for an early time window as well. Monitor suggested to counsel with the subject and figure out a better plan for administrating the drug. She also made Kathy change the status of compliancy. Because no matter whether or not Kathy knew the subject took the drug, the subject had to write it in their journal to be considered fully compliant. The monitor also talked to me about the continuing role and obligation of the sponsor and the drug company has in monitoring a drug. It does not end once the trial is over. There are continuing studies being done regarding the effectiveness and most of all the safety of the drug in humans. She gave the example of Tylenol. Recent studies but most of all adverse event reports from doctors to the FDA have uncovered the side effects including problems in taking too many Tylenol pills. Of course, once a study is completed with an investigational drug it is no loner her job to monitor for safety but another department/division of the drug company. We also talked about the importance of SAE reporting. She also makes sure that the events are being reported with the proper information include in the form. Although, Kathy (CRC) writes down everything and probably has one of the best paper trails she still received many sticky notes that day asking for clarification or changing the measurements of the drug dosage. Most of her discrepancies came from the fact that the sponsors continue to change the administration or note taking of the drug. One example of this is the drug company changed the way the dial for the inhalation drug was being read. It was an ambiguous dial do in order to improve the reading they suggested another way to read it therefore Kathy and Jessica, CRM intern, had to redo everything.

I also have to see an informed consent process. This was pretty interesting. She gave the subject all the information about the study. At the end, she gave the subject the opportunity to read the informed consent. The patient didn't really want to and said she trusted Kathy but Kathy insisted she read the document herself. I see where it can be sometimes hard to get someone to read everything. I also see the importance of an ORAL informed consent process. The subject sometimes will only get what the PI, CRC, or clinician is telling them.

I also asked her what problems she faced as a CRC. She told me RECRUITMENT. She is the only one there overseeing, managing and doing the treatment procedure of five clinical trials. She does not have much time to recruit. There are currently looking for a more efficient method to recruit subjects that will be Jessica's, CRM intern, job.

Thursday September 20, 2007

In the morning, I worked on revising an advertisement for an integrative physiology study. It had to correct some minor issues. For starters, the document was written in *"tu"* form, which is an informal way to refer to someone. Usually the *"tu"* form is reserved for friends or people in your age group. If the study is going to be recruiting Hispanics with diabetes, most of them will be older in age. Within the Hispanic community, it is a sign of respect when referring to them in the "usted" form. In addition, it is always a sign of politeness to refer to someone you don't know in "usted" form especially at the professional level. Therefore, I changed the document to read in "usted" form. Another major issue was that they had left out the African American women from the list of participants needed. Granted maybe not a lot of African Americans will read the document in Spanish but any Hispanic reading the ad might have a friend who is a female African American and tell them about the study. It is important to include everything the English ad has in Spanish (the principle of justice). One last issue, which we later discussed about it in the meeting, was the politically incorrect way to refer to Caucasian in Spanish. The proper term is *Anglo-Sajón* and not *Blancos*. This is a good example where literal translation does not work at all. For starters, within the Mexican community, the word *"blanco"* would not be used to refer to a Caucasian person. Other colloquial sayings could be used but never that one. There were some other wording problems that I went ahead and corrected. I sent it to Sharon who emailed it back to the CRC from the study.

We also had a staff meeting today. I did mention a topic in which the IRB could be enlightened on during the next meeting. There is a good journal article regarding the ethical issues involved in IRB approval of an informed consent dealing with non-English subjects. It is important that IRB members are made aware of the importance of reviewing these consent forms but as Dr. Gladue pointed out there are dilemmas when demanding literal translation. There are lots and lots of issue with this. As I said it before and I will say it again, it is important to have, the consent fit the cultural context of the subject. This means there has to be a small deviation from the informed consent. Of course, we don't want a big deviation but there are certain things that could be worded differently in order to get the message across and increase comprehensibility. I need to

find more words and examples for the next Board meeting. In the meeting, I was also assigned to helping with the improvement of the website since I am starting to get a reputation for having a knack for pointing out errors. For clarification, most of my notes are recommended suggestions. Therefore, I need to begin surfing the web again.

Friday September 21, 2007

Tasks:

- Look for IRB websites in Mexico
- Try to find informed consent document templates in Spanish used in Mexico
- Find common words used in informed consent such as "randomization," "double-blind," and "placebo"

Learned

- I spent the whole day looking for web pages about similar institutions or committees to the IRB yet could not find much
- I looked specifically at FWA registered IRBs in Mexico as listed in the department of health and human services
- There was a list of FWA approved IRB's located in Mexico City.
- I looked at la Universidad Iberoamericana where my mom actually received her bachelor's degree.
- I tried using the IRB FWA number but that didn't work.
- I also tried la Universidad Iberoamericana and Guadalajara but didn't find any informed consent documents
- None of the Universities listed in the FWA list could I find the "IRB."
- Dr. Gladue helped me find a good article about local ethnic communities
- He also gave me some one to contact who is the catedra of ethics so I could contact him for some questions.

Monday September 24, 2007

Tasks:

- Looking for common words used in an informed consent in Mexico
- Also look for FWA IRBs in Mexico

Learned

- Finally found informed consent template in Hospital General in Mexico.
- They had instructions for investigators writing a protocol.
- Their IRB is called el "comité de ética." They are under the belt of la Secretaria de Salud and la Comisión de ética
- I found another informed consent template in el Grupo Medico Carrai in Mexico City.
- They actually had the best website. They listed the purpose and regulations the committee follows.
- Their IRB was composed of five people who were hired by the institution to review protocols and ensure patient subject
- I also tried to find the equivalent of the OPHS but could not find anything similar

- The structure in Mexico may be set up differently

Monday September 24, 2007
Task(s)
- Looking for common words used an informed consent in Mexico
- Also look for FWA IRBs in Mexico

Learned
- Finally found informed consent template in el Hospital General in Mexico.
- They also had instructions for investigators writing a protocol.
- Their IRB is called el comité de ética. They are under the belt of la Secretaria de Salud and la Comisión de ética.
- I found another in el Grupo Medico Carrai in Mexico City
- The actually had the best website. They listed the purpose and regulations the committee follows.
- Their IRB was composed of five people who were hired by the institution to review protocols and ensure subject safety
- I also tried to find the equivalent of the "OPHS/OHRP" but could not find anything similar
- The structure Mexico must be set up differently.

Tuesday September 25, 2007
Task(s)
- Follow around a clinical coordinator (CRC) and learned about her experiences
- Observe a monitor visit by the sponsor

Learned
- How to read a flow chart (results from a bronchodilator). This was really interesting! I had to remember some concepts from physiology (lung capacity) to understand how to read it.
- Inhalation, exhalation and lung capacity are marked by loops.
- The studies primarily done in the clinic are COPD studies. The bronchodilator shows a slower rate of exhalation than a normal person does.
- A normal person can exhale all the air inhaled within 6 sec yet a person with Chronic Obstructive Pulmonary Disease (COPD) can exhale all the air more than 15 sec because they have air accumulated within the alveoli.
- Notice the importance of CRC and subject relationship during the screening and study visits. Building trust is fundamental in the study. With trust, there comes into play the respect principle of the Belmont report.
- The monitor didn't come until 1:00pm so I wasn't able to spend much time with him
- He explained to me his position and purpose
- He looked at case report forms and verified all the information computed in the database.

- Jessica, the CRM intern, had showed me earlier that day how to compute the information taken by the CRC about the subject and their test results.
- The monitor found some problems with data accountability log
- We also talked about ICG/GCP and the ambiguity of certain forms in the federal regulations in which monitors must interpret and make clear when auditing a study.

Wednesday September 26
Task(s)
- Attend the clinical trial meeting
- Read and compare the informed consents downloaded (Mexico & Spain)
- Looked at the federal regulations from Mexico regarding human subject research
- Brainstorm activity for IRB meeting

Learned
- Heard some interesting points during the meeting abut advertisement
- They had mentioned in the future that clinical trials would like to see some advertisements of the different clinical trials on the website.
- Deb warned or cautioned about putting exact names of clinical trials on the web. It must go thru IRB approval.
- Also in the meeting, it was mentioned a specific phone line had been set up in the past years by clinical trials for prospective subjects soliciting information about a clinical trial.
- We later talked about the risks and ethical issues this may involve. Subjects should be able to talk directly to the clinical coordinator. A person answering the phone line will not be able to truly inform a subject thus jeopardizing the informed consent proves and true autonomy.
- Many CRCs may disagree regarding this "generic" phone line.
- Learned the organization of the clinical trials office
- Worked on comparing informed consents from Mexico and Spain
- There is not much difference between Spain's and Mexico's informed consents
- Found that the most common word used for "randomization" is "aleatorizacion" rather than "alzar".
- Found federal regulations of Mexico. It has definitions for minimal risk, more than minimal risk and less than minimal risk
- Most of the elements of an informed consent do translate over nicely (can have a literal translation).

Thursday September 27, 2007
Task(s)
- Make a list of about 20 words commonly found in an informed consent. Translate them (literal and non-literal translation)
- Show that in certain cases a literal translation is not the best
- Pre-IRB meeting

Learned

- Most of the words or key elements do transfer over nicely even the word subject in Spanish is used frequently in the federal regulations can be used in a literal context. However, I believe it still should not be used to describe the Office for the Protection of Human Subjects because it leaves room for some negative connotation.
- Peru, I found, had many literal translations of federal regulations. They actually had an OPHS called la "Oficina Federal para la Protección de la Investigación con Sujeto Humanos". Mexico so far, from my research, does not have a OPHS/OHRP but the actual Comité Ética (IRB) runs the operation.
- I ran into a problem in translating Health Insurance Portability & Accountability Act
- I did a literal translation and then a non-literal translation of HIPAA.
- The non-literal translation better explains the Act.
- I also looked at an old informed consent in Spanish from the Office in order to compare translations.
- I did this also with PHI (Protected Health Information)
- Overall, I learned that sometimes literal translations are good (like risk) but other times translation deviated from a literal context does a much better job in explaining the translated term (HIPAA).

Friday September 28, 2007

Task(s)

- Added more words to the list
- Made an excel document

Learned

- Mastered Excel
- Decided to include "flipping a coin" and "sugar pill" into the word bank because they are key points used to describe essential elements of the informed consent "flipping a coin" to "Un volado"; "placebo" to "pastille de azúcar"
- An interesting translation I found on-line from an IRB website in Mexico was the explanation for placebo. Instead of using "pastille de azúcar" (sugar pill) they used "pastille de talco" (baby powder). I thought that was an interesting way to explain placebo. Does that mean the placebo is white?
- Back translations are not always the best of may not convey the exact meaning that it has in the translated language (i.e. Spanish).
- Dr. Gladue asked me to translate "safe" and "security." In Spanish the translation for "safe" would be "seguro"

  Example: This procedure is safe

  Translation: "Este procedimiento es seguro"

  Back Translation" This procedure is secure
- The word "safe" is different from the word "secure." They are used in different context in English. In Spanish, there is not a real contextual difference between these two words. "Seguro" is a good and contextually correct translation for "safe."

  Example: The security of the documents was classified.

Translation: "La seguridad de los documentos era clasificado."
Back Translation: The security of the documents was classified.

- Here the back translation agrees with the original statement but just to state there is a different between "seguro" and "seguridad" in Spanish although the words seem similar to each other.
- I learned there are sometimes problems with back translations; therefore, it is important for the person reviewing a translated document to take into consideration the usage, meanings, and context of the translations. A reviewer cannot only be bogged done by literal translations but also by exact or literal back translations. This only shows the complexity of translating a document. Miguel Saavedra noted that translations were like the back of a tapestry- confusing version of a much clearer picture. This statement is very true.

Monday October 1, 2007

Task(s)

- Made last revisions of the English-Spanish word bank
- Made the Translation activity for the IRB meeting

Learned

- It took a while to find some really good examples where the literal translation does not always word that would be adequate for the Board to understand.
- I found a good way to set up the activity. I wanted it to be user friendly for those who didn't know or semi-know Spanish but at the same time a little bit challenging.
- My examples were based on the common mistakes beginners in Spanish make. I used to organize conversational tutorials for Spanish students in undergrad. The students would receive extra credit for going to the tutorial session.
- The best example is "bachillerato." It looks like bachelor's degree but it actually means high school. This may differ in other Latin American countries. So to be on the safe side when translating high school, it is best to say "preparatoria" (back translation: preparatory which is not often used in English to refer to "high school").
- Again, back translation may not always convey the meaning of the meaning of the foreign language to the host language.

Tuesday October 2, 2007

Task(s)

- Finished activity
- Finals revisions
- Highlighted informed consent templates use in Mexico for the IRB meeting
- IRB meeting

Learned

- IRB members must be knowledgeable about the procedures and the study before approving a protocol. A good IRB member would research the medical background and review the study in order to bring forth important issues so the population in the

protocol may be fully protected. It does not only involve reviewing protocols but also researching for answers and concerns.

- The meeting had a lovely conversation about exposing a vulnerable group to a routine procedure exam, which had been proven to show no risk within a healthy population.
- The protocol could have been approved as low risk in normal healthy individuals but by changing the target population (non-healthy individuals) additional health guards must be place to ensure the protection of the subjects. The study therefore was categorized as a moderate risk because of the population group.
- The expertise of the OPHS office also guides the Board in across that they might not know.
- In the Board meeting, I presented the list activity I was working on this past few days. It was a good experience because I need to practice more my public speaking abilities. It was a little nerve wrecking but I did learn the importance of being able to communicate with a big group especially of the academic elite. It is important that significant issues such as translation errors be made aware to the Board so they can continue to make knowledgeable decisions.

Wednesday October 3, 2007

Task(s)

- Review informed consent, demographics survey and vasomotor survey for Kimberly Brown

Learned

- The informed consent and other forms were about a hot flashes in menopause women.
- The translation for hot flashes is actually interesting. In Spanish, there is not literal translation for hot flashes. However, the equivalent word for "hot flashes" is "bochornos." "Bochornos" can also mean in Spanish something embarrassing. This word can be used in different context (must be careful with the back translation). It is interesting that in English, there is a specific word for it but in Spanish, another word is used to describe the condition.
- Again, cannot have a literal translation of hot flash (relámpago caliente; back translation: hot flash).
- Another term for hot flashes is "sofocos" (something that is suffocating). However, "bochornos," is the more popular term.
- I also reviewed the demographic survey. The survey had the literal translation of white ("Blanco") in the race/ethnic group section. This is another example where a literal translation is not correct or in this case politically correct.

Thursday October 4, 2007

Task(s)

- Typed my review notes for Kim Brown
- Send her a copy of the corrections
- Started translating the HIPAA Addendum form the OPHS website
- Put documents with private information in shred box

Learned

- So far, for each sentence I have 3 translated versions. After doing the entire document I will go back and analyze what sentences are better.
- I see I have to deviate from the document sometimes because if I follow the exact documents the translated version would not make sense. However, I have to be careful because I do not want to add anything that may distort the message; therefore, this is going to take some time.

Friday October 5, 2007

Task(s)

- Continued working on HIPAA addendum

Learned

- I am still working on the HIPAA translation. It is taking longer than expected because they are many ways to translate a sentence. However, you want the sentence to convey the same message as the original text.
- As discussed with Dr. Gladue, it is different once you are writing or creating a paper compared to just editing a paper.
- It is a good experience or more a good training exercise. It is different when translating everything from scratch especially a document like the HIPAA addendum than reviewing a pre-translated document. It has been some time I have translated a whole document from scratch.
- Of course, HIPAA was hard word to translate because there is no equivalent word in Mexico. Although I did not figure out what "la ley de Transferencia' actually entails. It is similar to the HIPAA addendum. It just has a different name. "Transferencia" means transfer so like HIPAA it deals with the portability and the handling of health information.

Monday October 8, 2007

Task(s)

- Reviewed my research proposal
- Typed up the bibliography section
- Finished the research proposal and send it

Learned

- I had mostly finished my paper during the weekend. I revised the paper throughout the day. I had missed some words and added some more sentences to clarify certain points.
- I also refreshed my memory on how to write bibliographies. I did not know how to site the Belmont Report or the federal regulations. I looked on line and followed the same format of my journal articles to site properly these items.
- I noticed near the end of the day I had missed a section and began to write it in order to send it to my committee members.

Tuesday October 9, 2007

Task(s)

- Revised take my section of General internship which forms part of my research proposal.
- Updated my journal article binder with all the articles used in my paper
- Reviewed the translation I did for Kim Brown

Learned

- I spent most of my day reviewing Kim Brown's informed consent (menopause) and some surveys
- I wanted to look carefully and analyze each translation.
- Kim Brown wants me to look over these translations one last time before sending them into Sharon.
- I did change some translations that were a little awkward (however, they were understandable).
  - Ex: "Marque una de las declaraciones siguientes que la describe mejor a Usted?"
    1. Tengo los periodos menstruales regulares.
       Back Translation: I have regular menstrual periods.
    2. Tengo las periodos irregulares pero tuve un periodo dentro de los últimos 3 meses.

    Back Translation: I have irregular periods but I had a period within the last 3 mon.
- Although the back translation remains true to the survey in Spanish, the translations seem a little off. It just doesn't seem right. The statement is understandable but the style in which it is written can be improved.
  - Changed to:
    1. Mis periodos menstruales se dan regularmente o son irregulares.
       Back translation: My menstrual periods come regularly or are regular.
- In English, the back translation may seem awkward now but in Spanish, it seems clearer.
    2. Mis periodos son irregulares pero tuve un periodo dentro de los últimos 3 meses.

    Back Translation: My periods are irregular but I ha done periods within the last 3 mon.

Wednesday October 10, 2007

Task(s)

- Meet with Dr. Gladue to go over my paper
- Started my revisions of my proposal

Learned

- I had a good session with Dr. Gladue regarding my paper. I learned now my thoughts and words could get lost in translation with the way I phrase certain things or my diction usage.

- Dr. Gladue made a good point about my writing I tend to over complicate things by the way I phrase things. I found this to be true as I was able to easily explain and express to him my thoughts behind the written statement better than the actual written phase.
- I think my best sentences were the ones I had in mind and did not over complicated them with a lot of concepts, thoughts or words.
- I also need to pay attention or analyze more what each sentence actually means (almost like a back translation). Words are powerful and each one can give a sentence a different spin if not used correctly.
- Of course, they were some technical findings that should have been resolved before handling in my paper.
- Another good point that Dr. Gladue made was providing definitions for the population I am describing about in the paper (project).
- I will be looking specifically at non-English speaking Hispanics. Many Hispanics do not know Spanish or they have been "acculturated." Therefore, it is good I define my population for my audience.

Thursday October 11, 2007
Task(s)
- Revised my proposal
- Took breaks from my paper to work on the HIPAA translation

Learned
- I do not know if it is a good thing or bad thing but I find myself implementing the same tactics I use when I am translating a document (English to Spanish).
- I write a sentence, read it, then "back translate" to see if it really stating my thought and re-read it.
- I also rewrite it and see if the sentence reads better.
- It is taking me more time to do my revisions by doing this process.

Friday October 12, 2007
Task(s)
- Revised my proposal
- I looked specifically at the problem/hypothesis section.
- I tried finding another good scientific article, which could strengthen my hypothesis/problem section.
- I was looking for a journal article showing clinicians/investigators are at fault for decreasing numbers of Hispanics in clinical trials.
- However, not much research is done in this area; therefore, could not find more journal articles to add to my problem section.

Monday October 15, 2007
Task(s)
- Worked on my problem/hypothesis and significance section

- Did the ethics tutorial/training that Dr. Kaman asked all UNTHSC employees to do

Learned

- I familiarized myself with the UNTHSC policies

Tuesday October 16, 2007

Task(s)

- Finished the problem/hypothesis section
- Revised Background/Literature review section

Tuesday October 17, 2007

Task(s)

- Continue working on my proposal
- Worked on HIPAA translation
- I surfed the internet looking for HIPAA Spanish translated forms

Learned

- Many institutions have different ways in translating HIPAA.
- One did a literal translation of "portability" to "portabilidad" which is really used in the context of computer software or transfer of fired arms.
- The best translation would be a non-literal translation
- Found different templates to compare

Thursday October 18, 2007

Task(s)

- Staff meeting
- Revised research protocol

Learned

- Top eleven things an IRB doesn't want to hear
- Modifications do not only include amendments but also survey revisions and changes.
- Found a better way to arrange my paragraphs for my background section so it can flow better (still more revisions are needed).
- During the meeting, I was asked to look at progress review reports from other IRBs.

Friday October 19, 2007

Task(s)

- Started to look for continuing review forms on line
- Attended the Inaugural ceremony for Dr. Ransom

Learned

- The first search hit was form Arizona State University that did not offer any tips for improving out continuing review for.
- I did ask Deb for clarification of what she was referring to in relation to the migration of subjects from one progress report to the next.

- The problem with current form is that the member of subjects who are migrating to other categories (undergoing research protocol go into the screening failure category) is not being tracked successfully.
- Deb showed me a progress report form Cynthia, clinical research coordinator. She had properly indicated the migration of the subject. However, it is a challenge for CRCs track of where the subjects migrate. Therefore, the purpose of my internet search is to find a report form that does capture subject migration.
- Many of the report forms I saw in the morning asked less information than UNTHSC-OPHS does.

Monday October 22, 2007

Task(s)

- Found a continuing review form
- Finished with the revising of my paper

Learned

- Duke University offers the best possible form for capturing the migration of the subjects. Instead of having a table of subject enrollment, Duke asks a series of questions where the investigator fills in the member of subjects for the past year and cumulative/total.
- I believe that asking a series of specific questions may help capture subject migration and minimize error or confusion the progress report form perhaps for some clinical research coordinators.
- I also downloaded continuing review forms from UT Southwestern and UConn Health Center.
- I also finished revising my proposal.
- I did notice my sentences would tend to run long. Therefore, I reviewed my paper for lengthy sentences.
- I also looked for passive voice sentences.

Tuesday October 23, 2007

Task(s)

- Although I had already changed and revised my problem/hypothesis section, I went back to add more to this section.
- Started working on research methodology by making a sample questionnaire for the study.

Learned

- I needed to make my problems/hypothesis clearer or more precise. The way my hypothesis/problem section read before it did not state a hypothesis. My core problem is finding if literal translations are actually the best translation. My hypothesis is that literal translations are not always the best translation. Instead, a non-literal translation should be used. Non-literal translation is defined as a conceptual/culturally translation.

Wednesday October 24, 2007

Task(s)

- Worked all day in creating a flow chart of all the points in the research procedures

Learned

- Dr. Gladue helped me directing focus on the important issues, which needed to be addressed in my methodology.
- I had a hard time trying to figure out how I would test the literal and non-literal translation. I had first thought to have an informed consent where I would have a selection of different translations. The subject would pick the best translation. This was not a good idea because the subject will not be able to pick the best translation if they did not know the context of the study.
- Yesterday, I had made a questionnaire with only a paragraph from an informed consent. Then I incorporated the translation into the context of that paragraph. I would do this for three translations (literal, non-literal and non-equivalent translations). However, this would be a long questionnaire, which will memorize the number of participants willing to fill it out.
- Dr. Gladue helped me "brainstorm" the best way to test out my hypothesis. I will have two informed consent documents with literal and non-literal translation. Although I would not be able to test all my translations because I realized I could not ask all the questions I want.
- I need to create a criterion as to how I will select my target terms.
- I spent the day try to fill in all the questions regarding my methodology. A flow chart did help organize my thoughts.

Thursday October 25, 2007

Task(s)

- Typed up my research/methodology section

Learned

- I spent the day writing my research methodology section. I erased my old section and started new.
- The outline that I made yesterday was helpful. Although I had to cut some things out because I was on a deadline, I wrote some general points.

Friday October 26, 2007

Task(s)

- Final revisions of my proposal
- Redid my degree plan in order to turn in my proposal
- Looked for more continuing review documents
- Compared continuing review documents that I had already downloaded

Learned

- I compared the downloaded revisions of progress reports from different institutions. The one I liked the least was University of Connecticut (which has AAHRP approval) and Oklahoma HSC. The University of Connecticut was a lengthy document (14 pgs)

which asked too detailed questions. Oklahoma HSC asks very simple questions and the set up was primitive. The best one is Duke and NYU School of Medicine. NYU had a similar set up to ours but had definitions for "screened" (subjects signed ICF) and "enrolled" (signed consent and has entered trial- not a screen failure). We should consider making definitions for out progress report. Duke University set up there subject enrollment section in form of questions. I think this would be a good option to consider. Duke University also had a statement which would be good to include and will help investigators working with Sharon. Duke defined subject enrollment as those who have signed a consent form or number of records reviewed in a retrospective study.

Monday October 29, 2007
Task(s)

- Class project: I worked on putting everything together for submission to the IRB. An IRB protocol packed consists of all the study materials, protocol synopsis and anything the subject may see during the informed consent process (ICF). This means since the time the subject is being recruited to the end/completion of the study. The packet also includes an IRB new protocol application. The packet also includes an IRB application, which asks straightforward questions regarding the study (i.e. finding, grade level of informed consent, use of certificate of confidentiality). The protocol synopsis, which details the background, objective methodology, subject recruitment, selection, risk/benefit assessment, and list of personnel, is turned in for review. The IRB carefully reviews this information in order to verify the ethical and scientific basis of research study. Therefore, the protocol synopsis should be very detailed regarding the execution of the study.
- I began working on my IRB protocol packet in order to turn in as a class project for my class. Therefore, I worked on my informed consent documents.
- For the purposes of my class project, some details of my research will changed to make it a full Board study. Currently my research projects can be classified as minimal risk because of the "low risk" questions and few identifiers.
- I used the sample ICFs given in class as a guide when making my informed consent document in English.

Tuesday October 30, 2007
Task(s)

- I spent the morning trying to decrease the reading level of the 3 informed consent documents. The reading level was at the reading level of 10.7. The grade level of an ICF should not be more than a 9^{th} grade reading level. It was hard to lower the reading level. I analyzed each sentence to lower the reading level. However, I noticed the sections that had 12^{th} grade reading level were the clauses of confidentiality or compensation of injury provided by UNTHSC.
- Translated the 3 informed consent documents into Spanish

- Since the UNTHSC "lingo" was increasing the reading level of the document. I made a note of it in the IRB application.
- I quickly found out that I might have bogged down in lowering the grade level in English as I began to translate the ICFs.
- Currently, Microsoft word is not equipped to verify the grade level of a document in Spanish. This means when I do my translations in Spanish there is no way (other than myself) to verify the simplicity of the document. The problem with this is when the back translation is done of the document. Since literal translations do not always work, other words are used to convey the message. However, if you do the back translation of the same message not only does the term changes but also can be a higher elevated term. In turn, this can increase the grade level of the document.
  - For example: The purpose of the research study is to *look* at literal translations.
    El propósito de esta *investigación* es averiguar una traducción literal.
    Back Translation: *Investigate*
- I realized that there are some problems in doing back translations.

Wednesday October 31, 2007

Task(s)

- Picked a sample ICF from the ones Dr. Gladue gave us in class to use for my questionnaire.
- Modified the sample ICF "Evaluation of a Hospital Emergency Decontamination" protocol to include the words "placebo" and "double-blind"
- Incorporated my translated terms (literal and non-literal) into the sample ICF
- Translated the sample ICF into Spanish

Learned

- I noticed there were some literal translations did not have a good non-literal translation (no equivalent word). Therefore, I had to settle with words that could have literal and non-literal translations.
- Benefit – Beneficios (literal)
- Same for: Riesgos- Risks; Peligro- Danger; Inseguridad- Insecurity
- "Riesgos" in Spanish has a strong connotation and needs to be used appropriately depending on the context of the situation.
- There were some discrepancies between the literal and non-literal sample ICF because the translated terms changed the structure of the document.

November 1, 2007

Task(s)

- Did IRB application
- Finished non-literal translation/back translation
- Started the questionnaire for the bilingual, Spanish-speaking only, interpreters group

Learned

- I started making the questionnaires for each group. I had to make some "risky" questions to make my study full Board for class purposes; therefore, I had to ask different questions to each group.
- After reading each sample ICF, I will give them a questionnaire. To minimize the member of questionnaires, I incorporated the "personal" and "risky" questions in the literal translation questionnaire. The first questions will be for comprehension while the other questions will ask there opinion/perception of certain words. The Spanish and bilinguals would be asked the same questions. The Interpreters will be asked a different set of "personal" and "risky" questions. However, to minimize the member of questionnaires, the interpreters will be asked the same questions for the non-literal translation section.
- Therefore, I will have literal translation questionnaire used for Spanish and Bilinguals. The non-literal questionnaire will be for Spanish, bilinguals, interpreters.

Friday November 2, 2007

Task(s)

- Finish protocol synopsis and proof read it
- Proof read the ICF in Spanish

Learned

- I also had some hard time assessing the risks/benefits of study since there is no direct gain/benefit for this study.
- I also had a hard time explaining the statistical analysis and method I would be using to determine this. This is mainly because I am still a little clueless of how I am going to statistically analyze my data or if I need statistical software to help me generate some results.
- As I am writing this journal entry, I also realize I missed mentioning certain details in my research synopsis regarding the methodology of the study.
- The "mock IRB" will help me get all the kinks out of my proposals as well as clarify certain points in this research. In particularly because this study may be a little confusing.

Monday November 5, 2007

Task(s)

- Finished writing in my journal.
- Reviewed a protocol for IRB approval for my HSR class
- As I was reviewing the protocol there were several points in which I was confused. The study was about observing interactions between caregivers of Alzheimer's or Dementia. The wording of the document first leads me to believe it was study with the Alzheimer's patients. So the subject was not properly identified in the protocol synopsis neither in the ICF.

- Another issue was with the recruitment of caregivers. The protocol synopsis stated the caregivers were to be recruited when they went to the doctor's office. If did not specify if the visit to the doctor would be his/her personal visit to the doctor.
- Another issue is what will happen to the patients while the caregivers are being consenting. A babysitting service needs to be set up. This introduces an element of risk.
- Another point lies in the structure of the discussion groups. In addition, the use of the PHI should only be used in case medical information is being collected. The use of it here seems unnecessary.

Tuesday November 6, 2007

Task(s)

- Reviewed another protocol for the "mock" IRB meeting

Learned

- This protocol had fewer issues than yesterday. However, I had some questions about the procedure.
- It was unclear the exact procedures being followed during the rehab program and the follow-up visit. What does Tuberculosis (TB) rehab entail? Is it better than standard care/treatment? If it is will there be an ethical issue, providing a "better" treatment than the standard of care? By not mentioning these procedures, the Board cannot address any of the possible risks associate with the study.
- Another confusing issue for me dealt with the recruitment and the initial visit of the subject. The subjects are supposed to be recruited after 20 weeks of TB treatment.
- Another issue: Is a Spirometry a routine test for these patients?

Wednesday November 7, 2007

Task(s)

- Look over my protocol for my regulation of human subject class
- Training for Word form design
- Typed up my notes for the OHPS staff

Learned

- The training was very interesting and informative.
- I was able to discover some interesting features, which Microsoft word offers to create a form. This will help me when working with the OPHS to enhance/improve out website.
- I typed these notes for reference.

Thursday November 8, 2007

Task(s)

- Wrote in my journal
- I went to a CRM student/thesis defense
- Looked in the internet for HIPAA forms

Learned

- The thesis defense was interesting. However, throughout the student's presentation, I could not help but think about the 11 things that an IRB does not want to hear regarding investigators and protocols. In any case, it was good to hear another perspective. However, the effectiveness of an IRB really does depend on the people. Our Board and staff is small compared to other institutions but they easily have the same amount of work load and still have a good turnover rate. This shows the quality of UNTHSC's OPHS/IRB.
- Another point from the defense also lies in the plausibility of having a central IRB.
- A decrease in PIs errors/speculations will also speed the IRB process.
- Dr. Gladue and I discussed that more time should be place in training IRB members, principal investigators, peer-review and clinical trials staff regarding writing, reviewing and the ethical/scientific importance of a protocol.
- UC Berkeley had a HIPAA form with a grade level of 9.3, which is one of the lowest grade levels for HIPAA documents (usually 13).

Friday November 9, 2007

Task(s)

- Look for more HIPAA forms
- Compared HIPAA forms collected by the internet search

Learned

- I searched for forms used by central/western IRB because of yesterday's thesis defense.
- The HIPAA form follows a question format. It has simple questions. Although I did not like the Western IRB HIPAA form, I did like the format of the form.
- By putting the HIPAA form into questions format, I think it may simplify the language and reading level of the form (more reading friendly).
- One of my favorite HIPAA forms is from the University of California. It offers more information is a simple and understandable language (reading level 9.3). The highest reading level of a HIPAA form has been 28!
- University of Southern California combines both question and statement format. This is probably a good way to set up our (UNTHSC) HIPAA form. The reading level is 13. Although this may be a high reading level but it is hard to lower the language used in HIPAA forms.

Monday November 12, 2007

Task(s)

- Reviewing a protocol/research study for regulation of Human subjects class

Learned

- The protocol was about finding the effectives of Directly observed therapy (DOT) over self-Supervised therapy (SST). However, the therapies were never defined nor the risks involved in each therapy.

- A better explanation of DOT as well as SST in the protocol synopsis and the informed consent is needed. A subject may not understand or know what a DOT or SST is by solely reading the consent. This also raises the question about what kind of procedure and risks are involved in each therapy. In the protocol synopsis, the procedure for the SST is never specifically addressed.
- This also raises another question if one therapy offers a better quality of care then other. By offering one therapy to a subject, there may be a possibility that the therapy can be beneficial or riskier compared to the other therapy. This may not be fair to the subject getting one therapy that is less beneficial than the other therapy.
- In the background information, it was mentioned that DOT is not well accepted in as a treatment for TB in Europe. This makes me wonder why the European medical community does not like to use DOT.

Tuesday November 13, 2007

Task(s)

- Review another study protocol for Wednesday IRB meeting
- Attend IRB meeting

Learned

- Reviewed a protocol for my HSR class regarding chest radiographies and pulmonary function test in detecting lung disability in TB
- There is a lack of information regarding the protocol synopsis and methodology.
- I was a little confused regarding the aim of the purpose.
- Although the investigator defines impairment and disability, the study protocol never specifies if the study will be testing for the lung impairment, disability or both.
- The investigator never specifies the use of pulmonary function test. It only mentions it but there needs to be an explanation for the subjects.
- In addition, how will the information from the study be interpreted. The study seems to be comparing chest radiographs and PTFs but the information that is expected from this comparison/analysis remains unexplained.
- The Board mock meeting provided some insight regarding the enormous responsibility that clinical research coordinates and principal investigators have when carrying out a study.
- It is important to plan for unexpected and random occurrences that may jeopardize the integrity of the study and safety of people. Also, have a plan to tackle these unexpected events when they do occur.

Wednesday November 14, 2007

Task(s)

- Reviewed the last protocol for IRB meeting
- Started on the assignment that Dr. Gladue gave me

Learned

- The last study I needed to review was about the causes of homosexuality and risk behavior in adults. Although the hypothesis of the study is not clear, the study seems

to questions the association between unwanted sexual abuse and leading toward homosexuality as well as risky behavior.

- One major issue is the actually scientific merit in asking subjects whether homosexuality is a result of sexual abuse. The emotional repercussion from the study may be too high. The argument of that by knowing if sexual abuse causes homosexuality then this can be prevented in the future and education programs can be set up. In addition, there is the argument that something else other than sexual abuse can cause homosexuality.
- The risk-benefit relationship is leaning more to risk without any good scientific validity for the unwavering balance.
- There is also a lack of definition of "risk behavior" in the protocol synopsis. This needs to be included in the informed consent process because there may be some confusion as to the subject regarding the term.
- More counseling must be offered to the subjects after the interview not only at the time of the discussion. A hotline should be set up. In addition, there were some issues with the questions. The progress of the questions seem not to get to the answering the core hypothesis.
- I worked on finding FWA approved IRBs in the Ft. Worth and Denton area.

Thursday November 15, 2007

Task(s)

- Worked and finished on the list of FWA approved IRBs in the Tarrant /Denton County

Learned

- As I was reviewing the list, (1050) FWA approved IRBs in Texas. I noticed many institutions were associated with one IRB. So I thought it would be good to arrange the institutions by their IRB; therefore, when looking at the color-coded list one can easily see the institution linked to the IRB.
- There are many IRBs in Houston, Dallas and San Antonio, which makes sense since the big hospitals, and medical schools are located there.
- Fort Worth had quite a few too but most of the institutions were affiliated with Central IRBs.

Friday November 16, 2007

Task(s)

- Worked another report for Dr. Gladue
- It involved noting the number of registered IRBs in the United States and its territories.

Learned

- It is hard to know actually the exact number of IRBs in the United States.
- IRBs only need to be registered with DHHS when their protocols are human subject research and the study is receiving money from the government. This means there is many IRBs in the U.S. that are not registered because not all studies receive

government funding. Those who are not registered with DHHS under OHRP may or may not follow closely 45 Part 46. Private funding does not have to follow federal regulations. Therefore, the government has no way to track the number of unregistered IRBs in the U.S.

- If they are currently 3,757 registered IRBs in the Texas, then there are approximately 5,000 total IRBs in Texas.
- They are always more FWA's than registered IRBs. Each institution doing HSR must have FWA. Several institution may belong to one IRB; therefore, this accounts for 20,903 (FWAs) compared to 3,728 registered IRBs.
- Texas ranks number three in most registered IRBs; therefore, one may conclude that Texas is currently doing the most human subject research with federal funding in the South.
- However, these members do include inactivated IRBs too.

Monday November 19, 2007

Task(s)

- Began updating the list I gave Dr. Gladue regarding the number of approved registered IRBs and approved FWA in the U.S.
- Put together new protocol packets to send to the Board. The packet includes protocol synopsis, informed consent, questionnaires and advertisements. I also made 20 copies for each protocol.
- Put together progress report with the appropriate additions (ICF and synopsis) for Sharon to send to the Board.

Comments

- I wanted to account for the deactivated IRBs and FWAs in the list I created for Dr. Gladue. I subtracted the deactivated accounts from the total to have the active IRBs/FWAs.

Tuesday November 20, 2007

Task(s)

- I continued to count the deactivate IRBs and FWAs in order to make the total number accurate.
- Put together packets for the IRB.
- I read the article "Ethics guidelines for research with the recently dead."

Comments

- There was an interesting quote in the reading describing the dead "Cadaver is none other than a human who has experienced morbidity and mortality." This is very true. Although human subject research is defined in the regulations as all living individuals; therefore, IRB does not get involved with deceased individuals, research ethics and review should be extended to the dead.
- The article details good points to apply for a protocol involving the dead. Many of the guidelines are drawn from regulations dealing with humans (i.e. scientific validity) and research procedures should be the similarly given to living human subjects.

- The body should be kept covered with minimal invasive procedures used. In addition, the investigator must consider the culture when dealing with the deceased individual out of respect of the person and the family. Different cultures have different beliefs when coming to handling the dead. The Hispanic community (in particularly Mexican culture) the dead must be handled with respect. Just to mention the vigil for a recently dead individual can extend a week. In some towns, the vigil is held at the person's house, which is then taken to the gravesite.
- The consenting of the nearly dead HSR can enhance the principle of respect for post-mortem research. However, special ethical guidelines should be following in order to ensure autonomy and respect not only for the individual but for the family as well. It will be interesting to see how the UNTHSC IRB will handle or what comments will arise as protocols dealing with the recently dead arrive.

Wednesday November 21, 2007
Task(s)
- Updated Mary's contact sheet with all personnel in the office of research
- Created an excel sheet with all numbers and contact information
- Continued to count deactivated FWAs for my list
- Answered the phones for OPHS

Monday November 26, 2007
Task(s)
- Finished updating the list of approved FWAs and IRBs
- Outlined possible arguments for justifying the need of Spanish translators
- Formulated a better methodology for my project
- Before my idea was to hand the subject one comprehension informed consent with literal translations and then hand them a questionnaire. After I would give the subjects another ICF with non-literal translations, then I would hand them a questionnaire regarding those translations. Dr. Gladue pointed out I run the risk of information contamination and collecting inaccurate perceptions and comprehension scores from the subjects. He proposed a less confusing and complex method for giving my comprehension questionnaire with their appropriate informed consent.
- Suggestion: two main groups (non-literal and literal translation) with three subgroups in each main group (Spanish speaking only, bilingual and interpreters). "Promotores" could be the interpreters for my study.
- I worked on my protocol synopsis and my hypothesis to include having the appropriate connotation of the translated term.

Tuesday November 27, 2007
Task(s)
- Started on my questionnaire for the non-literal translation
- I reviewed my target terms for translation. I needed to cut down from 22 words to about 10.

- Made an outline of the things to investigate for my report for Dr. Gladue regarding the need of Spanish translators in the IRB

Comments

- I eliminated words were the non-literal translations were very similar to the literal.
- Added IRB, Informed consent, subject, randomization, flipping coin, injury, HIPAA, risks, withdrawal, compensation, double blind, placebo, sugar pill, research study and research
- Although, placebo and double blind do not have non-literal translations, the words have literal translation in clinical research in Mexico.
- I started the questionnaire by coming up with two comprehension questions for each word. This was hard because I could not use the target-translated term in the questionnaire.
- Looked for articles expressing the need for Spanish translators in clinical research and how many translators are available in the biggest institutions

Wednesday November 28, 2007

Task(s)

- IRB pre-meeting
- Continued to work an questionnaire for my project

Learned

- Worked on questions for the concepts of subject, randomization and others from the list
- I began to think, since I would be doing literal and non-literal translation and the comprehension associated with each, it would be good to make the entire format of each informed consent literal and non-literal translation from the original English informed consent. At the end, I could test the subject for the overall comprehension of the study with the entire document being in one format (literal or non-literal) of translation as well as the comprehension of key translated terms. However, I need to have a comparable informed consent with only the target terms differ.

Friday November 30, 2007

Task(s)

- I found some articles from the Office of Minority of Health Research (OMH) from DHHS. The articles outlined the disparities of Hispanics in clinical research. The articles pointed out the Hispanics do want to participate but there are barriers such as language, which prohibit Hispanics from participating. Other barriers may include access and lack of understandable information.
- The OMH has also created an initiative (eliminating disparities in clinical trials-EDICT) that purposes to increase Hispanic participation in clinical trials. A long with CLAS (Culturally and Linguistically Appropriate Service in Health Care) are working on enhancing understandability of clinical research concepts via language.

- 5.6% Hispanics have participated in clinical research compared to 94.4% who were non-Hispanic. African Americans were the highest percentage of minority participation (8%).

Monday December 3, 2007

Task(s)

- I wrote in my journal about my past week activities
- I searched the we for more information regarding interpreters

Comments

- 33 million Spanish speakers in the U.S. Hispanics are the largest minority group exceeding in population growth compared to African Americans, Asian Americans and Native Americans
- In 2002, Mexican Americans constituted the majority of the Hispanics (66.9%)
- This boom has definitely has shown its impact on clinical research and medical care.
- 19% Hispanics in 2002 who were Spanish speaking receive no healthcare attention because of the lack of interpreters or translational services.
- In consenting process, translational errors and the language issues are great areas of concern for investigators and the IRB.
- In 2006, a study found that only 7% of the leading research institutions offered investigators translational guidance or services.
- UT Southwestern actually offers a full page of translational guidance. They also offer translational services for a fee.

Tuesday December 4, 2007

Task(s)

- Board meeting preparation
- Board meeting

Comments

- It was an interesting Board meeting. There was an interesting discussion about consenting the living before they pass away in order to use their tissues or body for research.
- The IRB in the U.S. does not deal with the decease as they do in Canada. However, because the investigator is consenting her subjects before they die, it does become an IRB issue. There are several risks and issues to consider when reviewing a protocol dealing with the recently dead. Our IRB members did an excellent job, I believe, in reviewing this protocol.
- Some areas to consider would be the state of mind the prospective subject may be in during the consenting process if the person is about to die there may be difficulty in assuring autonomy of the individual. Another would be the laws in Texas that refer the rights of the deceased.
- Although the IRB meeting was long and went past the scheduled time, I was impressed that none of the Board members seems to mind staying until all the

protocols were reviewed. They did not even cut shore the time of reviewing each protocol.

Wednesday December 5, 2007
Task(s)
- I revised my sample Spanish informed consent, which I will use to test my subjects for comprehension.
- Made changes to the back translation of the informed consent
- Studied for upcoming test for HSR class

Comments
- I found that I could polish the consent form a little bit more to enhance comprehensibility.
- I decided to eliminate PHI (protected health information) as one of my key terms because of the difficulty in creating a literal and non-literal translation. I decided to add adverse event to this list

Thursday December 6, 2007
Task(s)
- I finished the literal translation questionnaire in English.
- I began on working on the non-literal translation questionnaire, which is very similar to the literal translation questionnaire with only a few discrepancies of the words.
- Began translating to Spanish (questionnaire)

Monday December 10, 2007
Task(s)
- Continued to work on my thesis project
- I reviewed the literal questionnaire
- Finished the non-literal questionnaire

Tuesday December 11, 2007
Task(s)
- Continued to work on my thesis project
- Reviewed my informed consent documents for my subject population
- I specified in the protocol synopsis that there will be two main groups (literal and non-literal) and detailed the design for committee approval
- I made the changes in all the informed consents and did the translations to reflect the changes.
- Worked on special problems paper for Dr. Gwirtz regarding the OPHS internship

Wednesday December 12, 2007
Task(s)

- Dr. Gladue gave me an assignment to create a database with the names of the different departments, principal investigators, and the corresponding OPHS staff members.
- I made an Excel Sheet listing the department and the OPHS staff members that are in charge of reviewing protocols from those departments.
- I made several designs and formats of this database

Thursday December 13, 2007
Task(s)

- After making the Excel database, I wanted imported it to Access 2003.
- I spent the rest of the day trying to get the program to do what I wanted. However, I could not figure it out. I was able to separate the database into different tables and set up a query. Nevertheless, I did not know how to approach it after setting it up.
- Finished paper for Dr. Gwirtz regarding internship

Friday December 14, 2007
Task(s)

- Reviewed paper for Dr. Gwirtz and turned it in to her
- I had been collecting information these past two weeks regarding Hispanics, Spanish translation and the importance of offering a Spanish translation. I started to put the outline together. The information was divided up into statistics involving Hispanics in the US, Eliminating Health Disparities in Clinical Research for Hispanic, the importance of Spanish translations, Spanish translation and benefits of hiring a translator/interpreter. The information came from the Office of Minority Health (DHHD), Hispanic business, Census Bureau, UT Southwestern and Trusted Translation Company.
- I finished the outline.

Monday December 17, 2007
Task(s)

- Worked on my protocol synopsis, specifically looked at my background information and specific aims
- Looked over the questionnaires and changed some of the questions
- I also proctored a test for Dr. Gladue for his HSR class.

Tuesday December 18, 2007
Task(s)

- Continued to work on my protocol synopsis for IRB submission since my project deals with human subjects must turn in for review.
- Spent time working on the methodology and procedure section as well as the data analysis

- Proof read it
- Created a document that showed the objectives/concepts behind each question regarding the translated term

Wednesday December 19, 2007
Task(s)
- Made the packets for IRB Board members for the meeting
- I finished translating the questionnaires for the non-literal and literal groups

Thursday December 20, 2007
Task(s)
- I reviewed my entire packet for IRB submission in order to turn it to Dr. Gladue before I submit it to the Board.
- I did find some items that were incongruent with the rest of the information
- I made sure everything made sense for the subject's perspective and for IRB review.
- I modified the table of contents.
- I review the Spanish translator outline for Dr. Gladue

Friday December 21, 2007
Task(s)
- I wrote in my journal in order to catch up.
- I also found two protocols that Mary had asked me to highlight the compensation section in the protocol's informed consent, which I gave to the Office of Grants.
- Helped clean the kitchen for the Holidays for the Research department

Monday January 7, 2008
Task(s):
- In preparation for tomorrow's IRS meeting, I created new directional signs for IRS numbers and principal investigators, indicating the Boardroom and lobby area. Since the meeting has been moved to EAD, I went to scope out the area in order to make the appropriate signs.
- I also helped Mary with some copying in preparation for the Board meeting.
- I worked some time with Access 2003 in order to be prepared with some questions for the training session I have with ITS.
- After completing my signs, I went back to the 8th floor EAD and made sure they were visible enough for the PIs and IRB members to see.

Tuesday January 8, 2008
Task(s):
- Access 2003 training session with Suzanne Gravois and Gary Wilson from ITS decided the database I wanted to create was too complicated for an hour session.
- ITS will inform me once they have had a chance to look into the database more in depth.

- Help Mary set up for the IRB meeting.
- IRB meeting

Learned / Comments:

- The Board meeting was insightful in the sense that it reminded me of key points outlined as well as discussed in my Regulations HSR class.
- Mission creepiness, which usually does not occur often in this IRB, dominated the discussions regarding study protocols.
  (Mission creepiness involves one or more IRB Board member(s) discussing points or concerns not pertaining to the primary objective- the protection of human subject research). During IRB Board meetings, one member can lead the discussion away from the main purpose of an IRB and move toward analyzing the scientific merit as well as data analysis portion of each study protocol instead of human subject research safety. Although there may have been good intentions on behalf of the IRB member to demand scrutiny the scientific data analysis part of each study, Board members should realize the harm in being to o zealous scrutinizer especially if it is off topic. However, I am not saying Board members should be careful and meticulous when reviewing documents. Board members should judge which areas need special attention and discussion. This is definitely key because Board members have to balance the risks (of study) scientific merit and benefit when discussing and approving a study protocol. Although these judgment calls are hard, good IRBs can successfully do this.
  - One more note: I also learned a good rule of thumb from the chair of the IRB: as risk increases in a study so does the concern of the scientific merit/validity of the study.

Wednesday January 9, 2008

Task(s):

- Clinical Trail and Coordinator Meeting: The discussion involved dry ice, web page design, the distribution of Deb's Recruitment material guidelines, and the new database for clinical trial coordinators. The department is really starting to lift off.
- Learned with access 2003 database. Although ITS is still working on finding out the best way to set it up, they did give me some pointers on how to begin creating this database.
- With the help of Access 2003 for dummies, I began working on creating the database.
- I began working on creating the database.
- I also worked on looking for continuing review forms on line with particular emphasis on DSMB questions.
- My internet searches also included SAE report forms.

Comments:

- Preliminary observations find that most continuing research forms do not have detailed questionnaire regarding DSMB reports.

Thursday January 10, 2008
Task(s):

- Contribute training discussion session with ITS personnel.
- Securities training online in order to set up access to hamster contribute. This took some time and communication with the help desk because my online account request did not want to go through. However, ITS was able to fix everything by the afternoon in order to get access to Contribute software.
- Found more continuing review forms (John Hopkins, Duke, UConn, UPenn etc.) with DSMB questions.
- Also looked for SAE report forms

Comments:

- Along with the continuing review forms, I also searched for some journal articles which discussed the relationship and communication between the IRB and DSMB became more prevalent around the 1960s in randomized clinical trials, multicenter trials and single center clinical trials. DSMB focuses in the total safety experience of a trial as well as monitor the trial data. The DSMB in form should report to the IRB if any mishap occurs or flows within the trial data that may indicate harm to the subjects. However, the communication between the DSMB and IRB is often poor. This occurs because the lack of direct communication to the IRB. The DSMB usually communicates with the sponsor rather than the IRB. Therefore, the sponsor decides when the findings are significant enough to inform the investigator. The investigator in turn reports to the IRB. The IRB reviews the filtered findings of the DSMB, thereby making DSMB reporting more sponsor driven.

Friday January 11, 2008
Task(s)

- Did more SAE searches
- Wrote in my journal
- I also searched for some guidelines regarding SAE reporting.

Comments:

- Most of the SAE forms which I found were similar to ours. However, same like NYU and UMDJ asked a little more information for example the type of SAE included incarceration or events dealing with devices. Information also regarding the subjects is also solicited.

January 14, 2008
Task (s):

- I made an inventory of all the boxes in my office in order to be stored upstairs to avoid losing any files.
- I also organized and arrange lose files into other boxes so they too will not be lost during the moving.
- I attended an Office of Human Research Protection (OHRP) meeting at JPS.

- Searched for a journal article for my Feb. 4 presentation for scientific communication class

Comment(s):

- The first OHRP meeting gave me a nice overview (summary) of the foundation of the IRB and human subject research. However, the presentation itself could have been better. It could have been that I knew the material since last semester. The meeting could have been better if the presenter would not have read word for word from the power point. More and better examples could have been used to explain a point or even regulation. Each regulation was placed for an important reason. This same reason or purpose could be described to the audience this conveying the importance / need to adhere to these regulations.
- Another point: it would be nice if the OHRP presenters / representatives come prepared to present the laws set for the state in which they present (Texas). One of the presenters tried to define "children" by the regulations but mentioned it depended on each state's definition of the word "children". It would have been nice if she provided this information according to Texas law.
- Apart from this, the mini seminar did refresh my memory regarding wavier of informed (which I might do for my own project) and gave me a deeper view of neonate research.

Tuesday January 15, 2008

Task(s):

- I updated my journal entries.
- I also had a meeting with Dr. Gwirtz in order to discuss my proposal, grant writing, my class (scientific communications) and graduation. I spent the morning preparing her a packet of all my documents and journal articles used in this project to hand into her.
- I attended a journal club meeting (pharmacology department). I wanted to get a feel for how a journal article is analyzed & presented since I have not done this type of presentation.
- I was able to settle everything with Dr. Gwirtz regarding my thesis.
- The journal club was interesting. One person (student) within the department must present a pharmacology journal article in front of their peers and answer any questions regarding the study.

Comments

- The journal club was interesting. One person within the department must present a pharmacology-related journal article in front of their peers and answer any questions regarding the study. The setup of the presentation was good but the presentation itself could have been better. The presenter could not answer any of the questions regarding the study.
- The study was about cyclic GMP mechanism and how it inhibits platelet adhesion via inducing Nitric Oxide (NO) responses.
- I now have a general idea as to how to present a journal article.

Wednesday January 16, 2008

Task(s)

- Had meetings with Dr. Gladue, Dr. Gwirtz and Gary Wilson from the library (Access 2003 database)
- Using Dr. Gladue's input of my proposal; I started working on revising my project.
- Wrote in my journal

Comments

- Dr. Gladue had me think about the important points that should be addressed in my proposal. The current comprehension tool of the hypothetical informed consent may in fact scare the participants in my study. The participant may actually believe I may contaminate him/her with a product instead of thinking this tool is only being used for a fake study.
- There is a study design flaw in that two questionnaires are being used for the study. In order to have comparable data I would need to have one questionnaire, which I will give to all the groups. This is initially hard to do because I incorporated key translated words in the question. I would have to create two different sentences each with a non-literal and literal translation of the key word.
- Finally, a wavier of written informed consent will be necessary to avoid exposing the participant to the language of an informed consent process. There are four requirements for this wavier: 1) Research presents no more than minimal risk (my study will only be asking the subject's opinion regarding the terms); 2) The wavier will not adversely effect the rights and welfare of the subjects (all information will be addressed orally); 3) The research could not practicably be carried out without the wavier (the language of the ICF will exposed my subjects prior to starting the study. Therefore, I should probably ask if they have ever participated in a clinical research study prior in the past. This can eliminate bias); 4) The subjects will be provided pertinent information after they have participated in the study (I will have an IRB approved script that I will explain the study).
- I learned how to create forms and queries in Access 2003.
- By the end of the day, I had a new hypothetical study in mind for my consent tool.

Thursday January 17, 2008

Task(s)

- I worked all day writing an informed consent comprehension tool in English
- I also worked on Access 2003

Comments

- I am first writing the experimental informed consent in English then translating it to Spanish.
- I have to incorporate concepts of double-blind, placebo and HIPAA
- I have to make sure that all the requirements outlined in the federal regulations are covered in the ICF although it is about a hypothetical study.

Friday January 18, 2008
Task(s)

- Meeting with Dr. Vishwanatha regarding Scientific communications
- Had a meeting with new committee member
- Created some queries and reports in Access database for Dr. Gladue

Comments

- My meeting with my new committee member gave me a valuable learning experience. There are many factors a researcher must consider when setting up a study. Planning a research study does not only involve creating the ideal research study but also picking the right individuals to carry out and help with the research study. This is essential to the study's successfulness. A committee is just as a research team or any other team for that matter. There needs to be harmony and collaboration to build up, support and carry out the study.
- Take home message: Just because a person maybe well qualified and maybe even willing to help you with the study does no mean that individual is right for the job. The person's character and qualifications need to be considered.

Tuesday January 22, 2008
Task(s)

- Meeting with Dr. Gladue and Dr. Gwirtz regarding finding new committee member
- Worked on English informed consent sample
- Used informed consent lecture notes from BMSC 5400 as a reference
- Need to include all basic elements of an informed consent document detailed in 45 Part 46.116 in order to have the experimental document in the same context as the "authentic" ICF used in research studies

Wednesday January 23, 2008
Task(s)

- Meet with prospective committee member- Dr. Anna Espinoza
- Finished the non-literal translation experiment informed consent document and used as the template for the literal translation document in English.
- For this, I revised the list of key terms in order to make the document simpler and reduce the number of questions in the quiz.
- Eliminated terms where the non-literal translation was similar to the literal such as alternative treatment and protected health information.
- Began translating the non-literal translation

Thursday January 24, 2008
Task(s)

- Continued translating the NLT informed consent document
- Translation requires a lot of patience and finding the accurate way to structure sentences and select words to convey the original message.

- Started developing questionnaire for study in English during breaks of translating

Friday January 25, 2008
Task(s)
- Finished translating NLT and LT experimental informed consent document
- Minor wording discrepancies between both documents as the use of different translated key terms can alter the sentence structure. Therefore, it was necessary to translate both documents.
- Finished and translated questionnaire to send to Dr. Gladue and Dr. Espinoza for review.
- The questionnaire is needed in order to access the subject's comprehension of the concepts behind the translated key terms. It is important to have simple but challenging questions in order to make this assessment.
- Wording is important because this can effect the individual's answer and the comprehension score recorded.

Monday January 28, 2008
Task(s)
- Read over my protocol synopsis
- I started looking for a journal article for my class presentation for Scientific Communications. The article can be relatively short (5-6 data tables) in order to keep it to 15 minute time limit. I am taking Scientific Communications as an internship enhancing experience.
- Dr. Caffrey in class lectured on the breakdown and content of an abstract in preparation for our good and bad abstract presentation.

Tuesday January 29, 2008
Task(s)
- OPHS meeting about the upcoming IRB meeting
- Started writing my informed consent script document This is important because the subject should not be exposed to the language of an "authentic" informed consent document prior to this study. Already knowing the major concepts behind the translated terms can jeopardize the study. However, I need to be sure to disclose the proper information to ensure subject's rights.
- I also incorporated into the script a series of screening questions in order to determine eligibility and which group they belong to(bilingual or Spanish speaking only)

Wednesday January 30, 2008
Task(s)
- Meet with Dr. Espinoza regarding the corrections she made to my informed consent document and questionnaire. The major highlight was some Spanish grammar errors and key terms.

- We discussed the translations of the target terms. She also agreed with all the terms except the non-literal translation of informed consent "document informado y consentimiento." However, she suggested using her translation that she uses for her own consent documents ("autorización con conocimiento de circunstancia para participar en un proyecto de investigación.")
- There was also an issue with the non-literal translation of "flipping a coin" which is often used to describe "randomization." I had "volado" which is a colloquial way to say "heads or tails." She thought it might be too colloquial for those who do not come from Mexico. Therefore, maybe in this case a literal translation is better.
- Did the corrections, which Dr. Espinoza gave me. Further research was going to be done to determine which translation should be done for the explanation of randomization.

Thursday January 31, 2008
Task(s)

- Continue with correcting informed consent documents and questionnaire
- Read a journal article published in research compliance (vol.4). The article dealt with the transfer of material after a subject has withdrawn from the clinical trial. The basis of this report was the question who owned the consent after the subject withdraws from the study. The report explained the investigator must consult he property law in the state or draft the informed consent with this information included. For patients who donate their tissue, the informed consent document should include information about waving their right to their tissue and suggest having this as an inclusion criterion.
- Investigators can also clarify the right of ownership with the subject during the consent process. The investigator also needs to evaluate the institution's policy regarding research ownership.

Friday February 1, 2008
Task(s)

- Dr. Espinoza emailed me other words that could be incorporated into the experimental informed consent ("confidential," "researchers," "privacy" and "health").
- Although these words are essential in an informed consent document, there is not a good non-literal translation available for these words.
- Therefore, sometimes literal translations are the best and in some case the only form to translate the word.
- The inclusion of the words would alter the design of the study. May be these words can be used in another study investigating the comprehension behind these words.
- She did suggest changing the word "pago" (non-literal) to "compensacion." However, since that term is the literal translation for "compensation," I suggested using "indeminization" (indemnify) for the non-literal. She agreed with this translation.

- The English term "indemnify" maybe a complicated or more elevated word but in Spanish, it is commonly used to explain compensation. I have also seen it used in different informed consent documents used in Mexico.
- Worked on my power point presentation for my scientific communication
- I researched about the topic of discussion-lavender aromatherapy
- I looked some elements from the article (Doppler echocardiography, coronary flow velocity reserve)
- IRB appreciation night

Monday February 4, 2008
Task(s)

- Rehearsed power point presentation with OPHS staff
- They gave me really good/helpful criticism to improve my presentation
- Their questions and opinions made me think outside the box. This research study had some apparent flaws in it. The staff suggested I should include ways on how to improve this study. The study could have a baseline cortisol measurement taken at each study visit in order to better assess the effects of lavender aromatherapy on stress. In addition, the investigators cannot assume the subjects are stressed out from a regular workday. The staff suggested that I should incorporate my ideas on how to change these flaws
- Their guidance and critique really helped me prepare for my presentation. I learned the importance of using all your resources to prepare for a class.

Tuesday February 5, 2008
Task(s)

- Read the article "Oh Abigail, Abigail: the D.C. Circuit en Banc Decision in the Abigail Alliance Case" for the IRB meeting.
- The article was very interesting yet a saddening prospective of post-phase clinical trials. FDA's current policy limits the access to investigational drugs for the protection of the subjects/patients. The Abigail Alliance for Better Access to Development Drugs seeks to prohibit the FDA from continuing to enforce this mentioned policy in order to create better access to potentially life-saving post-phase I investigational drugs to terminally-ill patients. The author of the article makes three compelling arguments for this Alliance case. He argues patients in particularly terminally ill patients have the fundamental right to chose to continue with post-phase I drugs without FA approval just as women have the fundamental right to abort their un-borne child. This is a very powerful argument in my opinion. I personally don't see how its worse to permit access to terminally ill patients to off-label investigational drugs than abortion. Yes, there is potential for unknown toxic side effects but if a subject has responded successfully to the off-label treatment, there is a possibility that it will continue to do so. The FDA and drug companies can set up a follow up of these patients on off-label investigational drugs. However, the patient should sign a waiver of liability. This of course would be an ideal situation because this would cost

more government money to set up monitoring agencies and more. However, this nation was built on the phrase "Life, liberty and the pursuit of happiness." If off label/post-phase I investigational drugs may offer life and the pursuit of a better/happy liege, then the government should carefully analyze, discuss and weigh the importance of this case.

- The IRB meeting was also interesting. The main issue of the Board dealt with the availability of Spanish interpreters/translators for studies whose primary/only source of recruitment is within the Hispanic community. It is important especially if the study is geared toward the Hispanic population to have the tools necessary to work within the population. Asking the Board to remove the Spanish informed consent on the basis that there are no financial means to pay a translator/interpreter is not right. These things should be planned before time. It is not fair that only Spanish speaking individuals be excluded from a study because a research team is ill prepared to adjust to their needs. The investigator is also losing in potentially good data for their research project. Some investigators may see this as a burden but like in all research projects there are costs but there is also scientific benefit.

Wednesday February 6, 2008
Task(s)

- Completed the evaluation of my fellow peer's journal article presentation from scientific communication
- The evaluation consists of questions regarding style, clarity, overall understanding, and use of visual aids. Everybody did well. However, one did a journal article, which had no recent research since 1998. Therefore could not answer some questions. The other individual did a good job in explaining his topic but it was long (the basis of his thesis).
- Finished writing my informed consent script with screening question
- Started translating this script

Thursday February 7, 2008
Task(s)

- Answered the phones during my lunch hour
- Worked on translation a sentence for the Department of Integrative Physiology
- The sentence was to be inserted into the informed consent document regarding the interpretational services.
- "If a translator is not available at the time of your participation, a friend and/or family member, capable of providing competent assistance to you during your participation, will be allowed to be translated for you."
- "Si un traductor no esta disponible en el momento de su participación se permitirá a un familiar y/o amigo competente que le asista."
- Worked on ICF and questionnaire

Friday February 8, 2008 – Friday February 22, 2008
Task(s)

- Revising translations
- Correcting informed consent documents, questionnaires and protocol synopsis
- Search for Assessment too for English fluency in Time magazine
- Create advertisements for clinic and daily news (English and Spanish)
- Start getting all materials ready for IRB submission

Monday February 25, 2008 – Wednesday February 27, 2008
Task(s)

- Catch up on class evaluations for last class presentation
- Worked on updating my journal entries

Thursday February 28, 2008
Task(s)

- Began getting everything ready in order to start recruiting subjects once IRB has approved the study
- Made copies of the appropriate study documents once notified of the IRB approval.

Friday February 29, 2008
Task(s)

- Went to STARS Fellows lecture given by Dr. Gladue
- The lecture allowed/gave me the opportunity to learn from experience of the OPHS staff regarding the importance of study design, risk, and benefit in human subject research.
- Completed making study packets and meet with Dr. Espinoza
- Got IRB approval!

Learned

- Child assent with parental permission
- The use of HIPAA
- Vulnerable populations
- Risks in children research

The end of Journal Entries

March = Recruitment and Data Analysis
April = Write and present Thesis

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