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**Assessing the impact of culture and language barriers among Latino/a bone marrow transplant patients and their parent (s) : a descriptive study : a project based upon an investigation at Childrens Hospital Los Angeles, Los Angeles, California**

Lorena Mocorro  
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Lorena Mocerro  
(Childrens Hospital Los  
Angeles, Los Angeles, CA),  
Assessing the Impact of  
Culture and Language  
Barriers Among Latino/a  
Bone Marrow Transplant  
Patients and their Parent(s):  
A Descriptive Study

### ABSTRACT

This study examined correlations and the impact between culture, language barriers, medical adherence, post transplant recovery and quality of life among monolingual Spanish or bilingual English and Spanish female and male pediatric Latino/Hispanic transplant recipients between the ages of 13 to 21 who have undergone either an autologous or allogeneic blood stem cell (bone marrow) transplant and their parent(s)/caretakers. By definition, bone marrow transplant is the treatment of hematopoietic stem cell from bone marrow, cord blood or peripheral blood. An allogeneic bone marrow transplant is the infusion of healthy blood stem cells from a related or unrelated person, called a donor who is identified by bone marrow registries as genetically human leukocyte antigen (HLA) compatible with the transplant recipient. Donors in this case may be family members such as the transplant recipient's (patient's) sibling(s) or the donor may be someone who is outside of the family system who is genetically compatible with the patient. An autologous bone marrow transplant is the infusion of the patients' own blood stem cells.

The study design had two parts. Part I included the researcher's behavioral observations between the study participants and the participants health care providers, which included bone marrow transplant (BMT) doctors, nurses, social workers and medical interpreters. The behavioral observations were conducted at the BMT Outpatient Clinic located at Childrens Hospital Los Angeles (CHLA) Outpatient Tower. The BMT outpatient clinic visit interactions between the participants and transplant health care providers were observed, documented and audio taped during the participants routinely scheduled clinic visits. Although behavioral observations at CHLA's Walgreens pharmacy were included in the study design, the lack of participant pharmacy visits to this site led the researcher to remove Walgreens behavioral observations from the study. Therefore, the behavioral observations were completed at the BMT outpatient and not at CHLA Walgreen's Pharmacy. Part II of the study included Outpatient Focus Groups in which participants interacted with one another and the dialogue was guided by semi-structured open-ended study questions developed by the researcher. Eleven voluntary participants enrolled in this study. The researcher observed one outpatient medical clinic visit with transplant recipients, their parent(s)/caretakers and the transplant health care providers and participants participated in two post transplant outpatient focus groups that were audio recorded.

The findings from this study revealed that culture impacts medical adherence among Latino/Hispanic teenagers/young adults and their parent(s)/caretakers, and language, which is a cultural component unequivocally, impacts the process of medical adherence, post transplant recovery and long-term quality of life. Findings from this study suggest that effective communication patterns between health care providers,

transplant recipients and their parent(s)/caretakers and the distribution of educational information improves post transplant recovery and long-term quality of life. The study's findings also showed that culturally competent health care providers who are knowledgeable and skilled in cultural differences increase communication patterns and strategies that aid in bridging communication gaps between health care providers and Latino/Hispanic transplant recipients. Medically trained interpreters were also found to aid bridge communications gaps between health care providers and Latino medical transplant recipients. Findings also showed that when the transplant recipient teens/young adults served as interpreters, significant errors in interpretation and understanding were noted.



ASSESSING THE IMPACT OF CULTURE AND LANGUAGE BARRIERS AMONG  
LATINO/A BONE MARROW TRANSPLANT PATIENTS AND THEIR PARENT (S):  
A DESCRIPTIVE STUDY

A project based upon an investigation at Childrens  
Hospital Los Angeles, Los Angeles, California,  
submitted in partial fulfillment of the requirements  
for the degree of Master Social Work.

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## CHAPTER I

### INTRODUCTION

There are many barriers in healthcare that affect pediatric patients, parents, families, health care providers and social workers. In this study the researcher examined correlations between culture with particular emphasis on language barriers and medical adherence among Latino/Hispanic parent(s)/caretakers and transplant recipients that are female and male teenagers/young adults between the ages of 13 to 21. All teens/young adults in this study had undergone either an autologous or allogeneic hematopoietic stem cell transplant (bone marrow transplant) and were monolingual in Spanish or bilingual in English and Spanish. Eleven voluntary participants served as the sample population for this study.

Bone marrow transplants are used to treat patients with advanced stage and high-risk diseases that may not otherwise respond to other traditional treatments. Childrens Hospital Los Angeles (CHLA) is one of the nation's leading accredited pediatric centers for Hematopoietic Stem Cell Transplant (HSCT) and each year they perform an estimate of forty transplants for children diagnosed with leukemia, other blood affected malignancies, aplastic anemia, genetic diseases, marrow failure conditions and other life threatening immunodeficiencies. Autologous bone marrow transplants are used to treat medical conditions that do not affect the blood stem cell factory. Thus, the blood stem cells are from the patient and the healthy cells are given or are infused back after the completion of chemotherapy and/or radiation treatments. Non-Hodgkin's lymphoma,

neuroblastoma and brain cancer are a few of the autologous transplant treatable diseases. An allogeneic transplant is the infusion of healthy blood stem cells from a compatible related person, called a donor. A related donor may be a parent or sibling, or the donor may be an unrelated donor, someone outside of the family system who is identified by bone marrow registries as genetically compatible with the patient. Since 1983, Childrens Hospital Los Angeles (CHLA), Hematopoietic Stem Cell Transplant (HSCT) program has performed more than 900 transplants. There have been an estimated 58% of males, and 42% of female patients who have received transplants. The predominance of males transplanted has been related to x-linked disorders as well as males afflicted with childhood leukemia's. Per Dr. Ami Shah, Bone Marrow Transplant Division Head at Childrens Hospital Los Angeles, the ethnic diversity of the population reflects the local community of patients treated at CHLA; and shows an ethnic distribution of 45% Hispanics, 30% Caucasian, 10% African-American, 10% Asian and 5% other.

The current researcher found several studies that examined the implications of race and ethnicity on access to health care or other sociocultural barriers, but few studies specifically addressed the issue of language barriers in health care and there are even fewer studies on the impact of language barriers and medical adherence in pediatric bone marrow transplant recipients, their parent(s)/caretakers and families. This omission in existing research supported the need for the current study.

Medical adherence and compliance have been associated with medications, treatment regimens, acute and chronic care for children and medication administration. Differences are noted between compliance and medical adherence. Medical adherence is the patient's behavior of taking the medically recommended medication(s) as instructed

and for the length of time recommended. Non-adherence or the lack of compliance is noted in the increase in health care services, both in clinics and hospitalizations, and in the rising cost of health care; but more importantly, in failing at the treatment of medical conditions and illness (Butz, 2006). Therefore, for the purpose of this study the medical adherence term will be applied throughout the study.

The current research is relevant to the practice of clinical social work because medical and clinical social workers are in direct contact with transplant recipients and their families, many of whom are trying to cope with severe medical complications that at times result in fatal consequences. Social workers have to contend with the transplant recipients' and their parents' level of understanding, education, and language skills as well as their compliant behaviors when medical complications secondary to culture and language impact medical adherence. Social workers serve as important patient advocates and bridge the delicate balance between a sense of "personalismo" and the value of "familismo" in their worker-patient relationships.

Social workers are intrinsically involved when transplant recipients are readmitted to the hospital for side effects related to medical adherence issues. They are involved in the process of helping the patient and the patient's family re-adjusts to the hospital environment when readmission to the hospital is needed. Social workers help transplant recipients and their families adapt to the stressful impact of suffering a life-threatening illness and treatments, provide support, counseling, psychoeducation, referrals, and even help patients and families mobilize community resources for concrete needs such as housing, transportation, finances, school problems, and legal issues. Medical clinical social workers are the alliances and voices that provide support around the many complex



issues that relate to culture and language barriers and other sociocultural factors. How patients and families cope also impacts medical adherence and treatment outcomes. This study identified the impact that culture and language barriers have on already vulnerable populations that are impacted by a life-threatening medical condition, and who must adhere to medical recommendations to treatments and medications in order to survive. A second part of this research determined if culture and language barriers impacted patient communication and medical adherence to health care providers' medically recommended medications and treatments post blood stem cell (bone marrow) transplant, and was measured by the influence of culture and language barriers on post transplant recovery and long-term quality of life. The latter provided the researcher with insight to identify more effective patterns of communication that have potential to increase post transplant recovery and long-term post transplant outcomes among Latino/Hispanic Latino adolescents between the ages of 13-21, their parent(s)/caretakers, families and health care providers.

## CHAPTER II

### LITERATURE REVIEW

There are many variables that affect medical adherence among Latino/Hispanic children within the health care systems. Language barriers, however, consistently proves to be the primary variable in determining access to health care services for Latinos/Hispanics, and in their ability to effectively communicate with health care providers. Failure to effectively communicate or to understand medical personnel can lead to other negative consequences such as non-medical adherence, inappropriate use of medications or even death. This is especially true among minority groups and Latinos/Hispanics whose primary language is not English. Culture and language barriers are well-documented obstacles among many vulnerable populations; and when medical adherence is critical to long-term survival and quality of life, language communications may be the difference between life and death.

The correlation and the impact between culture, language barriers, medical adherence, post transplant recovery and long-term quality of life among Latino/Hispanic teenagers/young adult between the ages of 13 to 21, and their parents, was the focus of this study. Hence, the literature review is organized into four sections. In the first section of the review, the researcher provides information regarding the population of interest, Latino/Hispanic immigrants including statistical data regarding naturalized and undocumented immigrants in the United States. The second section of the review focuses on the Latino/Hispanic population accessing healthcare services. In the third section of

this review, the researcher provides information regarding language barriers in accessing health care by examining linguistics, acculturation, literacy and cultural competence factors. A discussion then follows regarding bone marrow transplants as a treatment for life-threatening medical conditions, which often are followed by acute or chronic side effects, and high risks of treatment and impediments to medical adherence. The final section of the literature review addresses social support stability and psychological variables that impact the quality of life of transplant recipients and their parent(s).

### *Latino Population*

Hoefner, Rytina & Baker (2009) reported in their yearly United States Department of Homeland Security report that Latino immigrants are the fastest growing population in the United States; and by the year 2040, the Latino population is estimated to be the “majority.” The report also indicated that up until 2007 the number of immigrants was 11.8 million, and in 2008 there was a slight drop to 11.6 million. The decline was attributed to the number of illegal immigrants entering the United States.

Lee & Rytina (2009) reported in a 2008 naturalization report, the historical trend of naturalized persons entering the US between the years of 1907 and 2008 was estimated at nearly 900,000 naturalizations, with an increase of 680,000 between 2000 and 2008. The rise in naturalization was partly due to the Immigration Reform and Control Act (IRCA) of 1986 that allowed undocumented immigrants eligibility for naturalization. The reliability and validity of both studies by Hofner, Rytina & Baker (2009) on undocumented immigrants and the report by Lee & Rytina, (2009) on naturalization of immigrants were not sufficiently established. Reliability problems were found in the

naturalized immigrants report as well as in the report of undocumented immigrants in that the number of naturalizations fluctuated from year-to year, which affected the annual average of persons naturalized. The undocumented immigrant report also had validity and reliability concerns in accuracy for year of entry reporting, and errors in administrative conversion of legal immigrant dates and year of entry dates.

### *Latinos and Health Care*

Immigrants like any other population need access to healthcare services. However, their access to healthcare often is affected by daily functions such as accessing jobs, education, healthcare services, transportation and other resources. The American Friend Service Committee (AFSC) (2009) provided a focus for the protection of human rights in relationship to policies that ensure Latino immigrants access to health care services. The AFSC used a qualitative method study to examine how immigrants accessed health care, and noted that language barriers was one of many factors that contributed to poor access to health care services. Although the AFSC provided effective qualitative data, the study provides little quantitative data.

As reflected by the immigration census, Latinos are the largest predominant minority group in the United States. Traditionally, Latino populations and communities migrated to states like California and Florida but as their populations increased, Latinos began moving to less traditional areas like the South. The National Council of La Raza (NCLA) (2004) reported that the Latino population faced growing challenges and disparities in accessing health care services. As such, the NCLR established a community base partnership with selected national organizations representing 16 agencies that

provided health care services to everyone, and five of these 16 agencies provided services in Spanish to the Latino population. The NCLR community partnership organized convenience focus groups whose participants' ages ranged from 18 and above and who identified Spanish as their primary language (98%), were mixed gender, and either married or living with a partner (75%). Findings from the Focus Groups suggested that barriers and communication issues were a primary factor in accessing health care services. Participants acknowledged that language barriers were an issue for them. The Focus Group participants reported understanding the federal law, and Title VI of the Civil Rights Act of 1964 that provides individuals the right to have language services. The focus group held in North Carolina reported a violation of the law due to lack of agency interpreters. Another recorded observation made was that the convenience focus groups did not amply represent Latino populations living in the south.

Significant findings of the 2004 NCLR qualitative study were that health care gaps in the population of Latinos contributed to such factors as un-insurance, immigration status, discrimination in the delivery of services, lack of knowledge regarding available resources, lack of trust in medical system, lack of transportation to health care agencies and lack of available interpreters. Language barriers, however, proved to be the primary variable in determining access to health care services for Latino participants, and in their ability to communicate with health care personnel.

This qualitative study conducted by the National Council of La Raza (2004) was an extensive study involving multiple agencies; however the agencies were selected based upon their direct involvement with NCLR. The study also allowed a fourth question to the already established focus group questions about discrimination of health

care services. This fourth question, however, was not uniform and was not asked of all participants. Instead this question only was asked of participants who reported discrimination. The omission of this question to all focus group participants led to reliability and validity errors.

There are an estimated 12.3 million Latino/Hispanic children under the age of 18 living in the United States (U.S Census, 2000). In the 1990 – 2040 State of California Department of Finance report, states that by the year 2010, half the children living in California will be of Latino heritage. Given this expected increase, Flores et al., (2002) reported that the needs of Latinos in relationship to child health and health care accessibility be examined by the Latino Consortium of the American Academy of Pediatrics Center for Child Health Research (CCHR).

The US Surgeon report by McCarthy (2001) reported that immigrants and minority groups endure various barriers to accessing culturally and linguistically appropriate health care services. One of the barriers is due to immigrants having limited English proficiency restricting their access to health care services. Furthermore, lack of health care access due to language and communication barriers presents ethical issues of quality of care as reported by the National Alliance for Hispanic Health ([www.hispanichealth.org](http://www.hispanichealth.org)).

The CCHR (Flores et al., 2002) identified Latino as “underrepresented” in research studies, health and health care access. The CCHR further explained that research practices and research methodologies that do not include or represent Latino children are not culturally or linguistically appropriate. Validity and reliability in

research outcomes are distorted when tools are not provided in Spanish to Spanish-speaking participants, which exclude or restrict their full participation in research studies.

### *Language Barriers*

Language and culture impact Latino children's health care access, health service, and quality of care (Flores et al., 2002). Some of the reported problems in medical compliance and adherence have been linked to medical errors, medication problems, informed consent issues, inadequate medical translations, and the use of dangerous home remedies. Although these problems continue to be significant, the lack of mandated cultural competency training to address some of the language and cultural challenges that impact Latino children and health care access is problematic.

The 2000 Census Report estimated that there are 17.5 million adults and 3.4 million school-aged children in the United States with limited English proficiencies. According to Leighton & Flores (2005) limited English proficient health care seekers (patients) are more likely to defer medical care and report being in good or fair health. For LEP patients who are able to get medical care, however, they are more likely to miss outpatient follow-up visit, leave hospital against medical advice and experience drug complications. Also patients who are LEP experience language barriers when seeking health care services and they are less likely to get health care services for their children. In this study language barriers have been identified through a survey conducted with Latino parents to have the greatest impact on health care access for children. The participants in the study reported the following factors contributed to language barriers in health care. Language was an access barrier, lack of interpreter and lack of providers who

do not speak Spanish. Additionally, Leighton & Flores (2005) noted that quality of patient care is compromised for patients who are LEP. Suggestions of having medically trained interpreters will reduce medical interpretation errors from non-medically trained interpreters or as referred in this study ad hoc interpreters and provide adequate to good care to LEP patients.

Although interpretation in some cases helps bridge communication between health care providers who are non-Spanish speaking and non-English speaking patients a study done by Flores et al., (2003) examines the clinical consequences of pediatric medical interpretation errors. The study reported 63 % of the documented errors had clinical implications with an average of 19 errors made per encounters. There were, however, an increase number of documented errors made by non-medical trained interpreters at 77% that had potential of clinical consequences. These potential clinical consequences may further be attributed to the overall medical and quality of care provided by medical providers. LEP within the immigrant and non-immigrant population of Latino/Hispanic living in the United States presents communication and language barriers in not only accessing health care services, but also impacts overall health care to adult and pediatric patients.

Accessing health care services for Latinos not only has been impacted by language and cultural challenges on the part of the health care providers and agencies, but has also been compounded by acculturation and health literacy levels. Acculturation is defined by Martinez-Schallmoser, Tellen & MacMullen (2003) as a cultural adjustment process where a person either adjusts or fails to adjust to customs, values, language and ethnicity, while trying to maintain one's own cultural values. Britigan, Murnan & Rojas-



Guyler (2009) conducted a qualitative study performed in Southwest Ohio that examined acculturation and health literacy level among a convenience sample of Latino community members aged 18 years and older who participated in semi-structured interviews coordinated by two trained interviewers, but only one interviewer was a native Spanish speaker. In this study, the researchers obtained demographic information on race, ethnicity, country of origin and number of years in the U.S. The researchers further measured acculturation using the Bidimensional Acculturation Scale for Hispanics (BAS). The findings showed that 52 of the mixed gender participants had a 36.5% English acculturation rate compared to a 94.2% Spanish acculturation rate. The study's literacy results were determined by the Short version of the Test of Functional Health Literacy in Adults (S-TOFHLA) which concluded that out of the 50 participants who completed the functional health literacy test, 8 participants who completed the forms in English were considered to have adequate health literacy; and from the remainder 42 participants who chose to complete the Spanish version of the S-TOFHLA test, 14% had low to marginal functional health literacy. Eighty-two percent had adequate functional health literacy in the Spanish language. Findings showed that participants chose to complete the functional health literacy test in their preferred language of choice, either English or Spanish.

Britigan, Murnan & Rojas-Guyler (2009) concluded that acculturation percentage rate for Spanish at 94.2% was similar to results from another study conducted on health information-seeking behavior by Rojas-Guyler et al., (2008), which was completed in the Midwest from a sample size of 204 Latinas. The results in this study were that 80% of the Latina participants had a low level of acculturation. In both of the studies conducted,

there were similar low acculturation rates. Britigan, Murnan & Rojas-Guyler (2009) in their study also found that the functional health literacy level measured as adequate and further determined that language related issues were the main problem in accessing health care information and in accessing health care services.

The study conducted by Britigan, Murnan & Rojas-Guyler (2009) represented a limited sample size and limited age group to 18 years of age and above. Interestingly however, was that the study was also conducted to determine health literacy level, but the study assumed that all participants were able to read and understand the study interview information, perhaps affecting the validity of the study.

Acculturation has not only been found to be a factor with immigrants accessing health care, but the stress of acculturating to a new country and culture has been found to impact immigrants loss of self identity and social support network, defined by Smart & Smart (1995) as acculturation stress. Acculturation stress has been further correlated to how immigrants adapt and acculturate to a new life because of barriers they experience related to the lack of English language competency, work, healthcare and education accessibility, family, and head of household role differentiation.

While language has been a dominant variable in not only accessing health care services but also in effective communication with health care providers, Dr. Yvone F. Bryan in Diamond & Reuland (2009) raised the issue that differences in the Spanish language based on geographical origin can impact access to health care. She explains that different Spanish speakers speak with different dialects influencing the significance or meaning of communication. Dr. Bryan in Diamond & Reuland (2009) indicated that

the dialect and cultural differences are correctable when both the patient and the other party (interpreter, clinician) are fluent in the same language, i.e., Spanish.

Other differences in the Spanish language as mentioned by Dr. Bryan are due to geographical locations. Historically individuals from Latin American countries are referred by their nationality and country of origin, such as Mexican, Salvadorian (Suarez-Orozco & Paez, 2002). Once in the United States, however, the identity of Spanish Speaking individuals is racialized by differentiating between Hispanics who are of Spanish European descent who speak Castellano and Latinos/as who on the other hand represent the greater Latin American countries, and speak Spanish. Although Latinos/Hispanics are geographically from different countries of origin, as Dr. Bryan indicates that communication is still obtainable and correctable if Latinos/Hispanics are fluent in Spanish.

A study conducted by Flores, Abreu & Tomany-Korman (2005) examined correlations between language barriers on children's health and health care by focusing on primary language spoken at home versus parental limited English proficiency (LEP). The U.S. Census Bureau (2000) reported a historical trend increase in the number of people in the U.S. who spoke a language other than English at home (p.2). This trend in the 1980's was estimated at 23.1 million (11% of the population); in the 1990's, the estimate was 31.8 million (14% of the population); and in 2000, 47 million people (18 %) of the total population from the age of 5 and over reported speaking a language other than English at home. Siegel, Martin & Bruno (2001) further reported that limited English not only affects immigrants, but also those born in the U.S. In 1990, 52% of the people living in the U.S. 5 years of age and older spoke a language at home other than English.

Thus, Flores, Abreu & Tomany-Korman (2005) determined in their 1,100 participants' study that limited English proficiency (LEP) better measured the impact of language barriers on children's health and health care compared to primary language spoken at home. The findings concluded that participants' self reported language spoken at home did not have a direct correlation to the status of children's' health. Rather, the most significant study findings were that lack of parental education, length of U.S residency, one parent employment status, and annual family combined income at below federal poverty level, all indicated correlation to LEP.

Although the study has examined multiple variables to determine if limited English proficiency (LEP) and primary language spoken at home contributed to children's health and access, the study does not account for error measurement in relationship to the participants self reported English proficiency.

Linguistics and culture are especially important and together they interlink with cultural competence. The NCLR (2004), Flores, Fuentes-Afflick, Barbot et al., (2002) and Gil & Drewes (2005) indicated that cultural competency provides increased knowledge among diverse populations. Providing culturally sensitive services to the Latino population provides identification of needs to the Latino community and also provides knowledge and awareness of how to communicate and deliver these needs.

Gil & Drewes (2005) further provided tools on how to develop cross-cultural competencies with diverse populations. They first indicated that clinicians must be aware of their own biases and values and build sensitivity between the interactions encountered between self and clients. Secondly, clinicians need to gather knowledge from clients responsibly, while maintaining awareness of power differentials between client and

clinicians and recognize their own limitations and are accountable. Lastly, Gil & Drewes (2005) reported that in order to develop active competence, clinicians needed to take action from knowledge acquired from interactions with clients and incorporate that knowledge into the development of an action plan.

Perhaps the development of cross-cultural competence among diverse populations are useful tools to clinicians; however if there are no mandated requirements to maintain the competence once it is achieved, then competence in knowledge is unlikely to be placed in to action. Furthermore, there will be no guarantee that cross-cultural competence will reach diverse clients.

The need to incorporate culturally competent practice in health care settings is important in addressing the various issues of disparities that Latinos experience in health care access, health services and quality of care that are intersectionally connected to language and culture (Flores et al., 2002; Gil & Drewes, 2005; National Council of La Raza, 2004). This is especially the case when health care services are too complex and technical for the average person without medical training or knowledge to understand.

Hence, it is more difficult when people who receive the medical care services are children; and when these children and families are faced with making potentially life and death decisions that involve very high risks treatments, which can acutely, threatened the life of the child, resulting in fatality. The elective treatment of bone marrow transplant, which is the focus of this study, is a potential life threatening treatment due to the intensive chemotherapy and radiation treatments that are involved.

### *Bone Marrow Transplant*

The treatment of blood stem cell (bone marrow) transplantation (BMT) has had an increased role in the treatment of childhood malignancies, genetic diseases, immune deficiencies and hematological diseases (Parkman, 1986). The treatment, however, imposes many associated medical complications and risks to the transplant recipient as well as psychological stressors related to life-threatening aspects of treatment.

The treatment regimen of BMT involves different phases, beginning with pre-transplant work-up phase where the recipient is medically cleared through a very in depth process of tests, and examinations to assure the recipient's condition is medically stable in order to be able to proceed through the second phase of pre-transplant conditioning. In this phase the patient is admitted to a highly restricted controlled (isolation) environment at a specific designated area of hospital where intensive intravenously chemotherapy, and at times radiation, is administered to attempt to destroy the recipient's immune system and create space within the recipient's bone marrow for engraftment from the new blood stem cells. The primary phase of transplant is the infusion of stem blood cells (bone marrow) that is (at times lab processed) and given to the recipient intravenously through a venous catheter that is often placed on the recipient's chest prior to the infusion of the blood stem cells. Engraftment is typically the last phase of the transplant process, in which the blood stem cells that have been infused begin to grow and develop mature, well functioning blood cells. The engraftment process varies in length from recipient to recipient, and the average time also varies on the type of transplantation (allogeneic or autologous) done from an average of 4-6 weeks (Parkman, 1986).

The most medically fragile time for the recipient undergoing transplantation is after chemotherapy and radiation (if used) because of the treatment's side effects and risks that can be acutely or chronically debilitating and life-threatening. Other very dangerous risks, however, are related to non-engraftment and relapse of recipient's disease. Because the treatment of BMT is the best available therapy of treatment for many patient's that suffer life-threatening conditions, it is of most importance that recipients and their families be provided with medical information that is language and culturally appropriate as a means of enhancing their knowledge and understanding of treatment and medication adherence.

Thus, medical adherence in pediatric bone marrow transplant is a relevant issue that will be discussed in this section of the paper. As previously described, the treatment of bone marrow transplant, although its acute and chronic high risks and side effects are high, provides in some cases the best available treatment for many patients (Parkman, 1986). The demands of medical and treatment adherence among BMT recipients are extensive. Phipps & Decuir-Whalley (1990) in a 3-year (1986 to 1988) medical record review and case summary study of 57 patients admitted to Childrens Hospital of Los Angeles Bone Marrow Transplant examined adherence related issues in pediatric inpatient bone marrow transplantation. The study population averaged an age of 9.1 years; and 29 out of the 57 patients were males. The primary diagnosis was identified as leukemia with 75% considered malignancies. The study identified two groups of participants: whites and Hispanics. Whites represented two thirds of the sample participants while Latinos/Hispanics represented one third. The researchers suggested

that based on the inpatient medical treatment demands and recipient's diagnosis, BMT recipients were considered to be a high-risk group for problems with medical adherence.

Phipps & Decuir-Whalley (1990) concluded that a recipient's chronic condition, the complexity of medications, the frequency of medications per day, length of hospitalization, the severity of the symptoms, delayed side-effects, and the recipient's negative perception related to the medications or treatments all have a relationship to an increase of non-adherence. Furthermore, the results indicated that 28 patients (52%) experienced significant adherence difficulties. The highest rate of adherence problem was found to be in preschool aged children and surprisingly the problem was intermediate in adolescents. These results, however, may have been related to what has been reported as subjective documentation on the part of clinical staff expecting to have less adolescent adherence. Additionally, the study placed all races other than Hispanics/Latinos under one category of group participants, which raised question about the study's reliability.

Rodrigue, Pearman & Moreb (2000) reported that patients' and families who were better informed about their illness had better psychological adjustments in survival of post bone marrow transplant. The authors also reported that there was a lack of empirical data on the role of social support and compliance on survival and health status following transplantation. The authors in this study do not provide information regarding the definition of "better informed" and how families were better informed. Were they better informed because information was provided to them in a language that could be understood, or were their other factors?



The study conducted by Falkenstein, Flynn, Kirkpatrick, Casa-Melley, & Dunn (2004) confirmed non-compliance in pediatric liver patients. A primary finding of the study determined that non-compliance to medications was linked to graft loss and morbidity post transplantation. Parental non-compliance also was found to compromise medical problems by increased liver dysfunction, graft loss and hospitalizations. Assessment of non-compliance in children post liver transplant was measured by conducting chart reviews. These chart reviews were performed from the time children were admitted to the hospital for transplant to the time the children were discharged and attended outpatient clinic for post transplant care and follow-ups. The chart reviews were conducted for the period beginning 1987 to 2002. A fifteen-year retrospective chart review determined that there had been a total of 266 liver transplants performed in 234 children. The findings of the study concluded that 40 children were documented to be non-compliant with mild to severe liver dysfunction. Non-compliance affected different age groups. Twenty-eight of the 40 children transplanted were reported to be younger than 10 years of age, while twelve of 40 children had one documented event of non-compliance. There were 26 of 40 children who had been documented to having multiple incidents of non-compliance varying from two to four incidents; and four children out of 40 were documented to having five or more non-compliance events.

Although the study provides chart reviews of liver enzyme abnormalities and family history as a method in which non-compliance was measured, the study lacks interpretation of non-compliance, which decreases the validity of the study. It is further unclear whether the total number of non-compliance results is inclusive of the total

number of transplants done in the 15-year time span of children who were status post transplantation or are the results inclusive of inpatient transplant non-compliance?

Hematopoietic stem cell (bone marrow) transplantation is an elective medical treatment that provides the option of cure in the case of malignancies and it may provide treatment to other life threatening conditions in both pediatric and adult patients. Although the treatment of transplantation may provide the likelihood of cure and treatment there are also significant high-risk factors that may be secondary to transplant treatment related complications and/or relapse of malignant diseases. Ullrich, Dussel, Hilden et al., (2010) conducted a study on end-of-life experiences of children who have undergone a blood stem cell transplant to examine communication patterns of prognosis between physicians and the transplant recipients parent(s)' understanding at the end-of-life phase. The study concluded that although the discussion of prognosis is a difficult one because it may diminish the family's hope, the medical information provided to families, however, might allow them to have an opportunity to emotionally prepare for their child's end-of-life-experience. The study further reports that the importance of maintaining communication between physicians and families is associated with parental ratings of high quality of care because they are provided with an opportunity to understand and be informed (Ullrich, Dussel, Hilden et al., 2010).

### *Summary*

This literature review has provided information regarding the multifaceted factors that impact Latino/Hispanic teenagers/young adults and their families in reference to medical adherence and compliance following transplants. These factors were reviewed in

the literature with emphasis on immigrant populations, healthcare accessibility, linguistics, acculturation, literacy, cultural competence, bone marrow transplantation and social and psychological factors. This literature review provides some evidence that language is the dominant barrier to Latinos/Hispanics accessing health care services. Even though there is an array of literature on medical adherence issues, health and health care access for Latinos/Hispanics, this investigator found no literature on the impact of language barriers on post bone marrow transplant teens and young adults. Almost all of the literature in its entirety provides information regarding language barriers in relationship to health and access to health care services or medical adherence. The two issues, although briefly mentioned in some of the literature, have not yet been studied in relationship to one another. Rather, literature suggests that language barriers make it difficult for Latinos/Hispanics to access healthcare services due to English proficiencies and inability to communicate with healthcare providers. The literature review does not specifically examine language as being a direct cause for lack of medical compliance and adherence, nor is there much literature available on language in relationship to pediatric bone marrow transplantation. The sum of this literature review helped the current researcher frame the foundation for this study.

CHAPTER III  
METHODOLOGY

*Formulation*

The purpose of this qualitative study was to determine whether there are correlations between culture and particularly language barriers and medical adherence among Latino parents and their adolescent/young adults ages 13 to 21 that undergo autologous and allogeneic bone marrow transplants, and post transplant long-term quality of life. The researcher hypothesized that enhancing cultural competent practices through knowledge, awareness, education, and training in health care settings will increase cultural competence and healthcare providers skilled in cultural sensitivity and proficient in responding to the needs of diverse populations. Additionally, the intersection between culture and language helped provide knowledge and awareness of communication that bridge gaps in health care access, health care services and quality of care between health care providers, health care systems, patients, patient outcomes and long-term quality of life. Furthermore, improved communication between health care providers and Latino/Hispanic teens/young adults and parent(s)/caretakers increases medical adherence that lead to fewer clinics visits, less number of hospitalizations and reductions in the cost of treatments, medications and medical supplies.

Based on the well-documented literature, there are many variables that affect medical adherence among Latino/Hispanic children within the health care system. Documented health care gaps in the population of Latinos/Hispanics has been attributed

to un-insured, immigration status, discrimination in the delivery of services, lack of knowledge regarding community available resources, lack of trust in medical system, lack of transportation to health care agencies, and lack of available interpreters.

However, language barriers among Latinos/Hispanics has proven to be the primary variable in determining access to health care services and in their ability to communicate with health care providers. Failure to effectively communicate or understand medical recommendations or treatments can lead to negative outcomes and lack of medical adherence. Particularly with minority and vulnerable populations whose primary language is not English. The impact of culture and language barriers among vulnerable populations, such as that of pediatric bone marrow transplant recipients and their parent(s)/caretakers can be critical to medical adherence and post transplant outcomes and quality of life. The difference between transplant recipients' life and death may be determined by cultural and language factors that weigh in on the effectiveness of communication and understanding.

Therefore, the research question undertaken in this study was to determine if culture and more specifically language barriers impact the medical adherence of Latino/Hispanic, Spanish monolingual or English and Spanish bilingual parents and their teenagers/young adults ages 13 to 21 who have undergone autologous and allogeneic bone marrow transplants; and finally to determine how medical adherence impacts post bone marrow transplant long-term quality of life.

The study design has two parts. Part I included behavioral observations that took place at the outpatient Bone Marrow Transplant (BMT) clinic and Part II included two

focus groups held at Childrens Hospital Los Angeles (CHLA) Smith Research Tower located away from the hospital.

The researcher's literature review helped consolidate information on language barriers and its impact on this study's population group. Additionally the literature review provided guidance to which type of qualitative, quantitative or mixed research approach was best suited for this study; and provided clarity and information on whether to use independent variables to examine cause and effect or dependent variables to determine if one variable impacted another.

Phipps & Decuir-Whalley (1990) conducted a quantitative study on pediatric bone marrow transplant recipients in an inpatient hospital setting, which differs significantly from an outpatient clinic setting. Phipps & Decuir-Walley's study was conducted by analyzing transplant recipient's medical records over the course of a three-year time frame. The conclusion of this study indicated validity errors in recipients' medical adherence caused by subjectivity of staff in documentation of the recipients' medical records by staff. Phipps & Decuir-Whalley also suggested exploration of other studies that used a prospective study design to gather objective data on actual adherence behavior, which affirms the current researcher's decision to complete a qualitative study.

The current study represents teens/young adults and their parent(s)/caretakers personal and real life experiences of maneuvering a complex health care system embedded with cultural, communication and language barriers among health care providers. This study allowed participants to share their experiences while data was collected in the form of behavioral observations between transplant recipients', their parent(s)/care takers and health care providers; and the outpatient post transplant focus

groups. The study researcher observed transplant recipients and their parent(s)/caretakers during outpatient clinic visit interactions with health care providers that included bone marrow transplant (BMT) doctors, nurses (Registered Nurse, R.N.) and Nurse Practitioner, NP), social workers and medical interpreters in attempt to gain first-hand knowledge about communication factors that included language use, medical adherence, transplant recovery and post transplant quality of life.

### *Population Sample*

The study population represented Latino/Hispanic teenagers/young adults who have undergone either allogeneic (the stem cells are from related or unrelated person, called a donor) or autologous (the stem cells are from the patient) bone marrow transplant (i.e. bone marrow, cord blood or peripheral blood) as treatment of the teenagers/young adults disease and their parent(s)/caretakers. The study participants had received and or were continuing to receive post transplant medical care services at Childrens Hospital Los Angeles, (CHLA). The adolescents/young adults and their parent(s)/caretakers were of Latino/Hispanic descend from Latin American countries that immigrated or were born in the United States; their primary language was Spanish; and they identified themselves as monolingual in Spanish or bilingual in English and Spanish. The study population reflected Latinos/Hispanics that lived in the central area of Los Angeles and represented Latinos/Hispanics who sought medical services at CHLA. The study participants included both males and females, and the transplant recipients were between the ages of 13-21. Although there was specific age range for transplant recipients', there was no age limit set for the transplant recipients' parent(s) and caretakers. The study sample included

four females and one male Latino adolescents/young adults who were status post autologous or allogeneic bone marrow transplant, five mothers, and one adult sibling caretaker. The teens/young adults' educational level was middle and high school education and the parent's/caretaker's education level varied from elementary to college education.

### *Sampling*

The sample population was non-probability purposive and quota sampling. Four characteristics for quota selection were utilized (1) the adolescent patient had undergone either an autologous or allogeneic transplant; (2) the adolescent patient was discharged from the hospital and was followed at CHLA BMT Outpatient Clinic for post transplant care; (3) the patient was medically stable when discharged from the hospital; and (4) all participants were voluntary study participants and there were medical indications of post-transplant secondary effects that included infections and a post transplant secondary condition known as Graft Versus Host Disease (GVHD). By definition GVHD is medically described as the new blood stem cells "attacking" the host (the transplant recipients) body resulting in mild, moderate or severe rash, abdominal, liver or pulmonary problems. The bone marrow transplant recipients' and their parent(s)/caretaker were identified to participate in the study by the co-faculty advisor, who is a transplant program attending physician and current acting Division Head and was familiar with the pool of patients who had undergone transplantation, and was aware of the recipients' health status condition and history of medical adherence. Additionally participants were identified by word-of-mouth and referrals from the bone marrow



transplant clinical team, which included doctors, nurses, social workers and other health care providers.

The majority of the patients at CHLA who have received hematopoietic stem cell transplant (bone marrow transplant) are children under the age of 18 years of age. The teens/young adults and parent(s)/caretakers study participants were fully informed of the purpose, risks and benefits of the study. The process of informed consent and assent were obtained at the start of the study. Potential study participants first were introduced to the study via telephone call and again the study was presented and explained in person during the participant's scheduled routine BMT outpatient clinic visits. The investigator ensured that the transplant recipients, parent(s)/caretakers had adequate time and opportunity throughout the consenting process to ask questions and to discuss their participation with family and friends. Furthermore the researcher ensured that all questions, when asked, were fully addressed and understood to the participants' satisfaction. When the participants needed additional time to consent and provide assent to the study, they were provided with additional time. The researcher wanted to ensure that potential language barriers did not exist. Study participants then were asked to sign and date the informed consent and assent forms. The consent and assent forms were obtained by the investigator from the transplant recipients parent(s)/caretakers. Legal mandates for identifying legally authorized representative and/or legal guardian for those unable to consent was obtained through informed assent. In addition to the parent(s)/caretaker's informed consent to participate in the study, assents from minors also were a requirement of the study. Minors who had medically identified cognitive problems had the study purpose and minimal risks explained to them by the study investigator and the

parent(s)/caretakers so that the minor was appropriately informed. The minors were provided with study Assents signed by them and their parent(s)/caretakers (see Appendix I), Experimental Bill of Rights (see Appendix N) HIPAA forms (see Appendices K). The parent(s)/caretaker's were provided study Consents (see Appendix J), Short Forms (describes study in a short form) (see Appendix M) Experimental Bill of Rights and HIPAA forms (see Attachments L and O) for copies of these forms. Individuals who were identified by the participants as friend, family or trusted advisors were permitted to be involved in the consent and assent process to assist in validating comprehension on behalf of the study participants. Copies of all signed forms were provided to study participants and the Experimental Bill of Rights, the study Short Forms and HIPAA forms were provided to participants in their identified native language of preference of Spanish or English. The study investigator also communicated with all participants in their preferred language of Spanish or English.

### *Data Collection*

Following an extensive three month IRB review and approval from Childrens Hospital Los Angeles and Human Subjects Review Board of the Smith College School for Social Work (see Attachments E and F), the study researcher began by providing Childrens Hospital Bone Marrow Transplant Staff, which included (three) clinical doctors, (three) nurses and (one) social worker with a study in-service to introduce the study, address questions, obtain verbal authorization to participate and audio record the outpatient transplant clinic and/or pharmacy visits. The BMT clinical staff and other health care providers were also provided with a study information letter requesting their

verbal authorization to participate and audio record the outpatient clinic visits (see Attachment D).

The design and methodology of the study included two parts. Part I of the study included behavioral observations where the study researcher observed one outpatient BMT post transplant clinic visit interaction and communication between the study participants and the participants' doctors, nurses, social workers and medical interpreters located at Childrens Hospital Los Angeles Outpatient Tower. The outpatient BMT clinic visits were observed by the researcher for the duration of the study participants' scheduled appointment and/or pharmacy visits ranging from 15 minutes to one hour. The study researcher prior to each outpatient clinic observation visits confirmed the participants' availability and the investigator met with the participants at their scheduled BMT doctor and nurse outpatient clinic visits.

Part II of the study design included focus groups. The study participants participated in two Saturday post bone marrow transplant outpatient focus groups held at Childrens Hospital Los Angeles (CHLA), Smith Research Tower. The two groups were held consecutively on two Saturday's when the majority of participants were available to participate. Each group meeting was held for the duration of the group's participation ranging in two hours per group meeting. At the start of the focus group meetings the participants were asked their preference of English or Spanish language to be used during the meetings and the consensus was Spanish, although the teenagers/young adults at times resorted to saying a few words in English. When this occurred the researcher provided translation to the monolingual Spanish group participants. The focus group dialogue was guided by semi-structured open-ended study questions developed by the

researcher as a means to gain unbiased knowledge about the correlations and impact culture, language barriers, medical adherence, post transplant recovery and quality of life had on bone marrow transplant recipients and their parent(s)/caretakers. The BMT clinic observation visits were documented by being audio recorded and by the clinic/pharmacy observation forms (see Attachment A). The focus group forms were not only used as a dialogue guide by the researcher, but the forms were also voluntarily completed by study participants (see Attachment B). The researcher provided additional time for the completion of the forms and allowed time for the participants to ask questions.

Both the behavioral observations at the BMT outpatient clinic and the data collected from the focus groups were audio recorded and documented to ensure study accuracy. The audio recordings were used for educational purposes and the participants' identity was protected and disguised. The data collected was anonymized with assigned unique protective number (UPN) codes to ensure identification protection, privacy and confidentiality and have adhered to mandated HIPAA and local, State and Federal privacy laws.

Participant's confidentiality and rights were fully protected throughout this research. Data collected from the behavioral observations was gathered during actual interactions and communication between study participants and health care providers and was audio recorded as interactions occurred during outpatient BMT clinic visits. The data collected from the focus groups was uncensored and participants were provided with a comfortable holding environment where participants had an open group dialogue and they shared personal and medical experiences related to transplantation. The focus group open-ended guided questions introduced by the study researcher provided the group with

semi-structure and educational information on methods of interventions that provided more effective communication between study participants and health care providers. For Part I of the behavioral observation BMT outpatient clinic visits, the study facility used were the BMT clinic examination rooms where transplant recipients and their parent(s) had privacy from public areas. Part II of the study included post transplant outpatient focus groups. The groups were held at the 4<sup>th</sup> floor Smith Research Tower, also part of CHLA. This facility provided participants with adequate room space as well as privacy from uncensored information discussed in each group meeting. The study was conducted in the participant's preferred language of either Spanish or English in order to maximize study validity and accuracy.

#### *Data Analysis*

The qualitative data was examined through analytic induction (observations) of both latent and manifest content of analysis, because both the individual behavioral observations and focus groups provided rich information concerning participants' personal and health care experiences semi-structured guided questions helped contain collected data to this study's thesis question. The two Saturday focus group meetings and the outpatient bone marrow transplant behavioral observation clinic visits conducted with each study transplant recipient and their parent(s)/caretakers were audio recorded and transcribed by the researcher in order to increase accuracy of verbal communication and data, including capturing participants' tone of voice, speech clarity and pace. In addition to the audio recordings this researcher maintained documentation of non-verbal communication among participants through field notes. Intra-transcript analysis was

used to maintain and coordinate study participants' topics and themes as well as to note commonalities and differences among participants.

### *Recruitment*

The recruitment of the purposive and quota sample population was done through the assistance of the study co-faculty advisor, who is the outpatient bone marrow transplant program-attending physician and acting Transplant Division Head. She was familiar with the pool of transplant recipients who had undergone either an allogeneic or autologous bone marrow transplant and she was aware of the transplant recipients' health status, condition and history of the patients' post transplant history of medical adherence. Additional study recruitment was through word-of-mouth and from the bone marrow transplant clinical team, which included the current acting Division Head for the Bone Marrow Transplant program, transplant attending physicians, nurses, social workers and other health care providers. BMT and other health care staff were provided with information and in-service regarding the study. The health care providers were given the opportunities needed to address any questions and/or concerns. After the participants had been identified the investigator telephoned them to introduce the study and if they agreed to participate they were provided with further in depth study information in their preferred language of English or Spanish during their routinely scheduled transplant clinic visit or before the start of the focus group meetings. The researcher explained the purpose, benefits and risks of the study while specifying that the study was voluntary and the participants' decision did not affect current or future medical care, services or benefits at Childrens Hospital Los Angeles (CHLA). Participants who wished to stop and

discontinue their participation and withdraw from the study were allowed to do so before April 30, 2010. The participants' rights to health care services and other services at CHLA were not compromised in any way if they decided to withdraw from the study. The researcher reserved the right to withdraw participants from the study in order to protect their health, emotional state or if other situations presented themselves that made it necessary to do so. The researcher was responsible for obtaining written informed consent from the parent(s)/legal guardian and a written assent from each child/minor (age dependent on local requirements) enrolled. The parent(s)/legal guardian and caretakers by signing the informed consent form, study Short Form, Experimental Bill of Rights (Declaracion De Los Derechos Del Sujeto Bajo Investigacion Para Estudios Sicosociales), Health Insurance Portability and Accountability Act (HIPAA) (Acta de Portabilidad y Responsabilidad de Seguros de Salud) confirmed their participation in the study. The teens/young adults by signing the assent and Experimental Bill of Rights and HIPAA confirmed their voluntary participation and their intent to follow the study protocol. The recruited parent(s)/caretaker and teens/young adults signed and dated consent, assent and Experimental Bill of Rights forms. Copies of the signed forms were provided to all of the study participants. Additionally, human subjects review from Childrens Hospital Los Angeles and Smith College School for Social Work were incorporated in the research as a measure of providing safeguards and ensuring ethical standards.

### *Study Benefits*

The anticipated benefits for the participants to take part in this study were that they had an opportunity to meet other teens/young adults and parent(s)/caretakers who as transplant recipients have gone through the intensive treatment of having a hematopoietic blood stem cell transplant (bone marrow transplant) or the parent(s)/caretakers have gone through the experience of having their teenager/young adult go through the process of transplantation. Study participants had the opportunity to learn more effective ways of communicating with health care providers, by learning to advocate their needs through the use of trained medical interpreters, and by education and training of learning how to communicate with health care providers. Other potential benefits of the study were to society. The collection of information from study participants contributed to a better understanding of culture, language and communication barriers. The information provided insight in methods of interventions that increased communication between the study participants and health care providers and in turn facilitated interventions that could improve the long-term recovery and quality of life of transplant recipients and their parent(s)/caretakers, while reducing the cost of health care. Finally, the information collected from the study will benefit future special non-English or limited English, culturally diverse populations and teens/young adults under the age of 21 years of age that undergo the process of allogeneic or autologous hematopoietic blood stem cell (bone marrow transplant).



### *Study Risks and Discomforts*

The study potential risks were that participants inadvertently would breach confidentiality by focus group participants. To reduce this potential risk, the study investigator at the start and end of each focus group session addressed the importance of maintaining privacy and confidentiality regarding information that was shared and discussed during the focus groups. A second minimal risk was that participants' level of emotional discomfort or stress varied in how they dealt with events in their life or when they talked about health care outcomes. To address these risks the researcher provided all participants with a referral list of free and low cost assistance for both Spanish and English speaking counseling (see Attachment C). The hospital assigned social worker was also contacted for collaboration of supportive services and counseling for the transplant recipients and their parent(s)/caretakers.

### *Study Limitations*

The most pronounced limitation of this study was the limited amount of data available on culture and language barriers between Latino/Hispanic and BMT. Although previous studies have been done on the impact of culture and language barriers in the health care profession, limited to no research is available on the impact of culture and language barriers on Latino/Hispanic bone marrow transplant recipients who have undergone either an autologous or allogeneic transplant and their parents/caretakers. The current small study sample from this study can only be generalized to the population studied and does not reflect the greater radius of Latino children and parents. Therefore, findings from this study cannot be translated to all Latinos/Hispanics. The study

presented a potential relational bias between this researchers' past work history with pediatric bone marrow transplant recipients. To address this potential limitation the researcher enrolled nine out of eleven study participants who were not known or familiar to the study researcher, and also maintained a log of her feeling and interactions, consulted with her research advisor, and maintained open dialogue with her field supervisor.

These limitations led to the strengths of this study. More knowledge and awareness was learned about the impacts of culture and language barriers upon medical adherence in a very high-risk pediatric bone marrow transplant population. This study also lends itself to recommendations for tool and strategies that helps provide greater communication and information related to the enhancement of medical treatments, medication and overall adherence for high risk populations. Lastly, this study is important because of its impact on social workers and other healthcare providers who work with medical adherence issues of providing insight into treatment options, and the inclusion of cultural sensitivity in working with this population of teens/young adults, parent(s)/caretakers and their families.

## CHAPTER IV

### FINDINGS

The purpose of the proposed study was to examine correlations between culture with specific emphasis on language barriers, and medical adherence among Latino/Hispanic descent parent(s) and pediatric transplant recipients that were females and males between the ages of 13 to 21, who had undergone either an autologous or allogeneic blood stem cell (bone marrow) transplant and were monolingual in Spanish or bilingual in English and Spanish. The study further investigated the correlations and impact of culture and language barriers on post transplant recovery and quality of life for the individuals involved in this study.

Although there has been previous research that investigates the impact of language barriers to Latinos accessing health care services and other research done on medical adherence issues, health and health care access to Latinos, there is currently no prior research specifically on the topic of how culture and language impacts bone marrow transplant teens/young adults and their parents post transplant medical adherence, recovery and long-term quality of life. Thus, this researcher acknowledged the importance of this ethically relevant issue as it impacts not only a fast growing population of Latino/Hispanics but also a specific population of Latino/Hispanic teens/young adults who have been diagnosed with life threatening conditions, their parent(s)/legal guardian(s), caretakers, families and medical providers.

This chapter contains the findings from Part I of the outpatient bone marrow transplant (BMT) clinic visits behavioral observations and Part II, the two outpatient post transplant focus groups. The study enrolled five teens/young adults, five transplant recipient parent(s) and one caretaker, who was the adult sibling of a transplant recipient. The behavioral observation visits were audio recorded and they took place at the BMT clinic where the transplant recipients and their parent(s)/caretakers received post transplant follow up medical care services from transplant trained doctors, nurses, social workers and medical interpreters. Behavioral observation visits between the transplant recipients and their parent(s)/caretaker were not followed at Walgreens pharmacy as originally planned due to the participant's lack of visits to the pharmacy. The two focus groups included the same participants from Part I of the study. The focus groups were guided by semi-structured open-ended questions that were developed and used in both groups by this researcher. The semi-structured guided questions were also voluntarily completed by all of the participants at the start of the first group and three of the eleven participants completed the study questions at a later time with the researcher's assistance.

The behavioral observation visits between the study participants and the health care providers were conducted as a means of gathering subjective data that assimilated actual interactions between transplant recipients, their parent(s)/caretakers, doctors, nurses, pharmacy providers and interpreters while allowing the researcher to observe if cultural and language barriers impacted transplant recipients and parent(s)/caretakers medical adherence, post-transplant recovery and long-term quality of life.

The focus group semi-structured guided questions were developed to elicit subjective information and responses from study participants based on their day-to day

experiences. Conducted at the two focus groups were semi-structured study guided questions that provided unfiltered insight to the participant's experiences, feelings, recollections and memories of transplantation related events while also providing further topics of interest relevant to the study.

The semi-structured questions pertained to the researcher's thesis question in determining if there were correlations between culture and language barriers impacting medical adherence, post transplant recovery and quality of life among teens/young adult bone marrow transplant recipients and their parent(s)/caretakers. This question was addressed through the collected data from Part I and Part II of the study and is presented in the following sequence: demographic data of teens/young adults and parent(s)/caretakers, self reported primary language of teens/young adults, parent(s)/caretakers and of health care providers, use of interpreters, communication patterns between teens/young adults, parent(s)/caretakers and health care providers, day-to-day personal and medical experiences with transplant health care providers, post-transplant medical complications, side-effects, restrictions, long-term quality of life and lastly participant recommendations.

### *Demographic Data*

#### *Teens/Young Adults Demographics*

The study enrolled a total of eleven participants. The demographics of the teens/young adults included four females and one male participant. The teens/young adults underwent either allogeneic or autologous blood stem cell (bone marrow) transplants (i.e. bone marrow, cord blood or peripheral) to treat life threatening conditions of leukemia (n=2), blood disorders (n=2) and blood disorder (n=1) that was at

a pre-leukemic disease stage. The number of months and years post transplant hospitalization discharge was from the minimum number of 5.7 months to the maximum of 6.8 years. An average number of post transplant hospital discharge for the transplant recipients was 9.38 months. The age range was between thirteen and sixteen. Three of the participants were sixteen and the average age range for this group of participants was 15.2. All five of the teens/young adults self-identified as being of Latinos/Hispanics descend and were born in the United States. Their education level reflected the enrolled grade level reported by the teens/young adults at the time of the study. The highest-grade level of education was eleventh and the lowest was eighth grade. The average grade of completion for the teens/young adult participants was a 9.6 (see Table 1.0 on the following page).

Table 1.0: Demographic Characteristics of Transplant Recipients

n=5	Age Range		13 n=1	15 n=1	16 n=3
Gender	Female		1	1	2
	Male		-	-	1
Diagnosis	Leukemia		-	-	2
	Blood Disorder		-	1	1
	Blood Disorder/Pre Leukemia		1	-	-
Average No. of Months/Years Post Transplant	5.7	Mo	1	-	-
	6.8	Yr	-	1	-
	4.5	Mo	-	-	1
	8.9	Mo	-	-	1
	6.6	Mo	-	-	1
Ethnicity	Latino/Hispanic		1	1	3
Country Born	United States		1	1	3
	Mexico		-	-	-
	Other		-	-	-
Education Level	11th Grade		-	-	1
	10th Grade		-	-	2
	9th Grade		-	1	-
	8th Grade		1	-	-

*Parent(s)/Caretakers Demographics*

There were six parent(s)/caretakers participants. Five of the six identified as the transplant recipients' mothers and the sixth participant was an adult female who

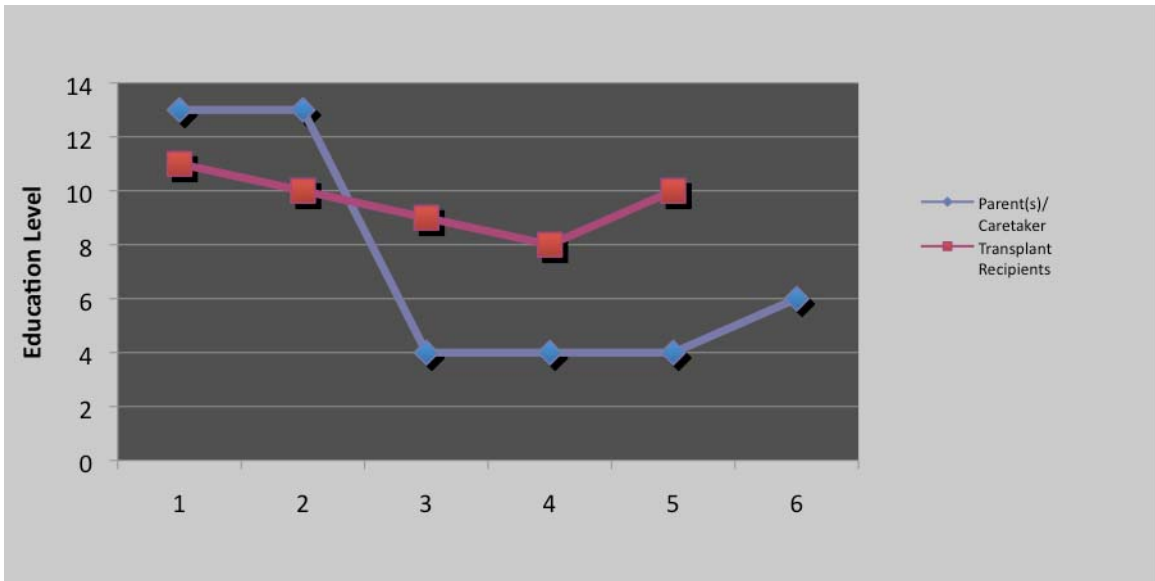
identified as the sibling and transplant donor to one of the transplant recipients. The participant's ages were from nineteen to 53 and the range was 43.3. The mothers and the caretaker identified as being of Latino/Hispanic descent born in either the United States or Mexico. Five were born in Mexico and one was born in the U.S. The participants who reported being born in Mexico immigrated to the U.S beginning in 1977 and the most recent immigration occurred in 1990. The highest education level completed was between 13 years to fourth grade. There were (n=2) participants with 13 years education level. Of these, one participant completed a technical degree at a Vocational School out of the United States and the second participant reported attending a local college as a freshman at the time of this study. There was one (n=1) participant with sixth grade education and four (n=4) participants with fourth grade. The average education level completed for this group of participants was 7.3 (See Tables 1.1 and 1.2 on the following pages).



Table 1.1: Demographic Characteristics of Parent(s)/Caretaker

n=6	Age Range	19 n=1	45 n=1	46 n=2	51 n=1	52 n=1
Participants Role in Study	Mother	-	1	2	1	1
	Caretaker	1	-	-	-	-
Gender	Female	1	1	2	1	1
	Male	-	-	-	-	-
Ethnicity	Latino/Hispanic	1	1	2	1	1
Country Born	United States	1	-	-	-	-
	Mexico	-	1	2	1	1
	Other	-	-	-	-	-
Year of Immigration to U.S.	1977	-	-	1		1
	1978	-	-	-	1	-
	1986	-	-	1	-	-
	1990	-	1	-	-	-
Education Level	13 (Vocational)	-	1	-	-	-
	13 (Freshman/College)	1	-	-	-	-
	6th Grade	-	-	1	-	-
	4th Grade	-	-	1	1	1

Table 1.2: Transplant Recipients vs. Parent(s)/Caretaker Education Levels



Parent(s)/Caretaker	Transplant Recipients
13	11
13	10
4	9
4	8
4	10
6	

Average Education Level for Parent(s)/Caretakers 7.3

Average Education Level for Transplant Recipients 9.6

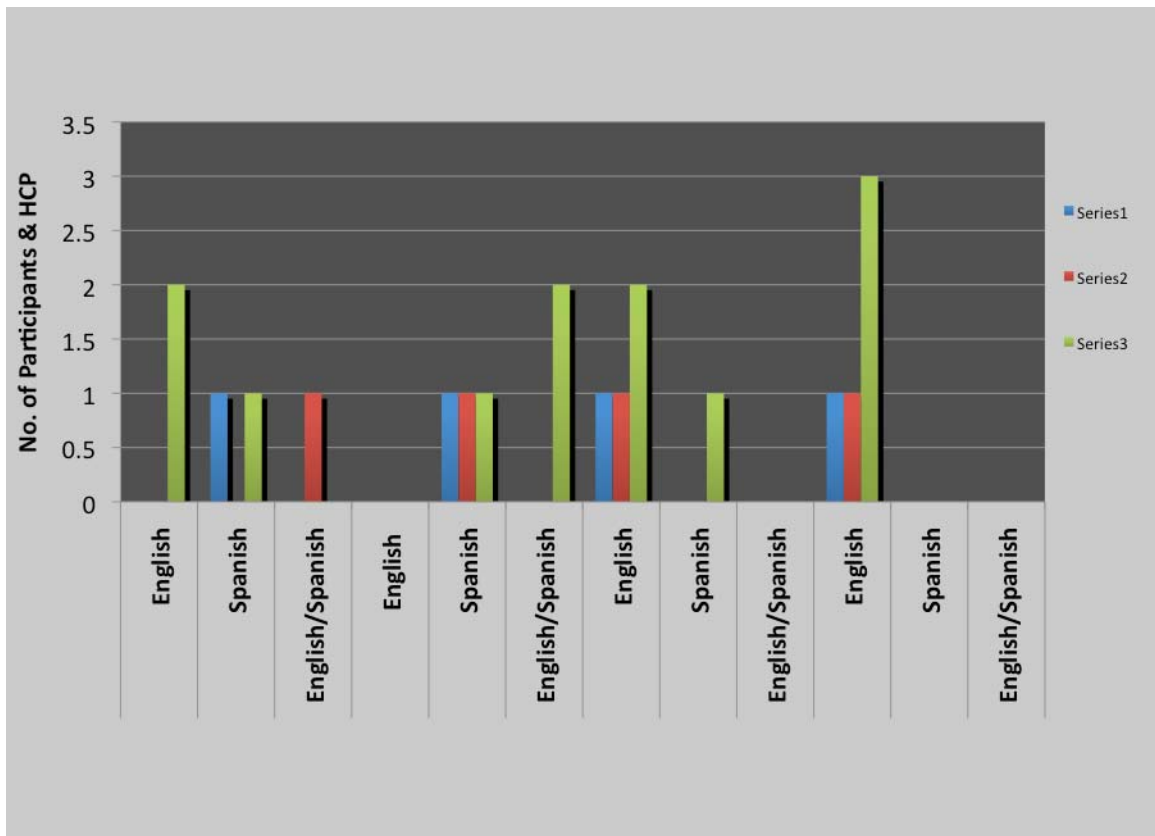
### *Language Demographics*

#### *Teens/Young Adults Language*

Primary self-identified language preferences were English, Spanish and English/Spanish. There were two (n=2) participants who self-identified as primary English speakers, two (n=2) self-identified as primary Spanish speakers and one (n=1)

participant who identified both English/Spanish as languages of preference. When participants were asked about primary language spoken at home, three (n=3) identified as speaking Spanish and two (n=2) identified both English/Spanish. One of the participants who reported speaking both English/Spanish at home indicated that despite her primary English language preference she spoke Spanish at home because of her parent(s) lack of English proficiency. Also the two participants who reported speaking both English/Spanish at home indicated they had siblings who spoke English at home and they in turn spoke English. Participants were asked what language(s) they spoke with health care providers during their outpatient BMT clinic visits and the majority of the responses were English (n=4) and one (n=1) participant reported Spanish. All five of the teens/young adult participants reported language spoken by the transplant health care team of doctors, nurses and social workers was English. When participants were asked if they requested medical interpreters for their BMT clinic visits, two (n=2) participants reported yes they did for their “mother’s” and three (n=3) reported no they did not request a medical interpreter. The participants were asked when medical interpreters were not available who interpreted for them. The response from all five (n=5) participants was that they interpreted for medical providers and parent(s)/mother’s. In determining communication patterns between participants and health care providers, five (n=5) of the participants were able to directly communicate in English with the transplant doctors, nurses, social workers and other health care providers (see Table 1.3).

Table 1.3: Transplant Recipients vs. Health Care Providers (HCP) Language Variances



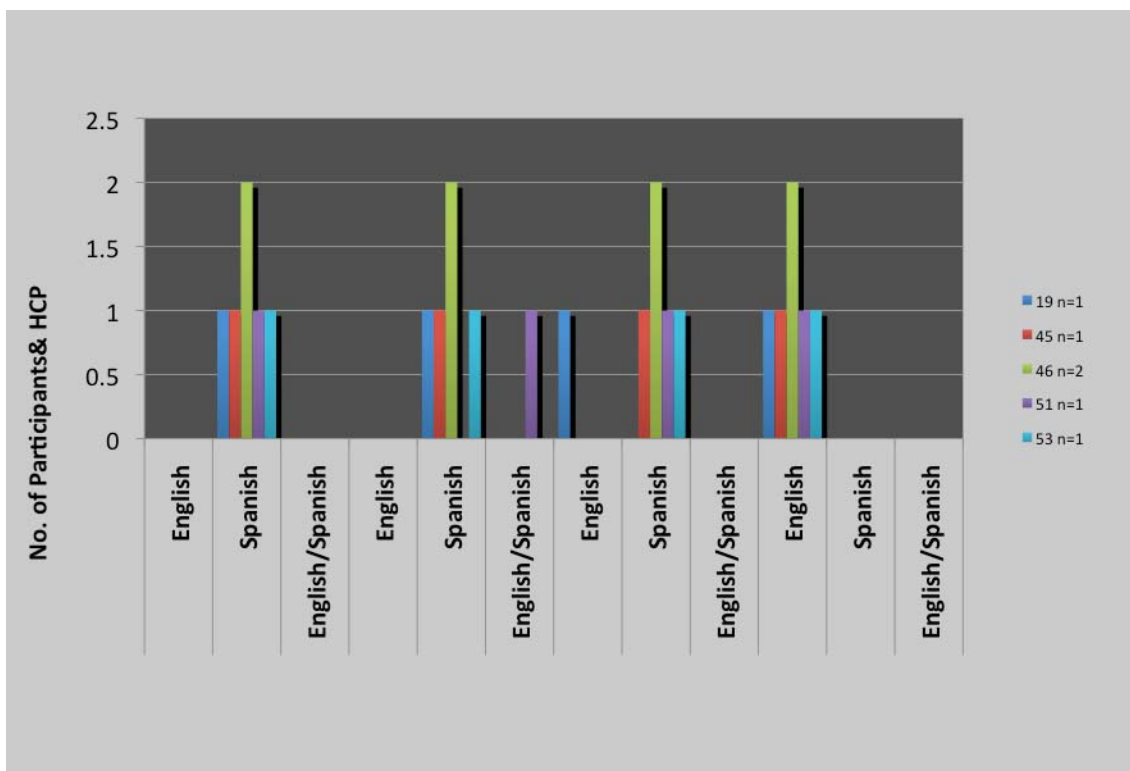
n=5	Age Range	13 n=1	15 n=1	16 n=3
Primary Language (Self Identified)	English	-	-	2
	Spanish	1	-	1
	English/Spanish	-	1	-
Primary Language Spoken at Home	English	-	-	-
	Spanish	1	1	1
	English/Spanish	-	-	2
Language Spoken with Health Care Providers	English	1	1	2
	Spanish	-	-	1
	English/Spanish	-	-	-
Participants Report of Language Spoken by Health Care Providers	English	1	1	3
	Spanish	-	-	-
	English/Spanish	-	-	-

### *Parent(s)/Caretaker Language*

Group participants were asked the same questions pertaining to language as the teens/young adult's participants. Six (n=6) participants self-identified Spanish as their primary language preference. There were five (n=5) who reported Spanish was the primary language spoken at home and one participant (n=1) who reported English/Spanish was spoken at home by her children. The parent(s)/caretaker were asked what language they speak with health care providers and their responses were five (n=5) spoke Spanish and one (n=1) participant spoke English. When asked what language the doctors, nurses, social workers and other outpatient transplant medical health providers spoke, six participants (n=6) responded English. The participants' response to the question of whether they requested a medical interpreter for BMT outpatient clinic visits showed that three (n=3) reported yes they did request an interpreter and three participants (n=3) stated they did not request an interpreter. When asked who interpreted when medical interpreters were not available for the clinic visits there were more than one response per participant. The majority participants (n=5) responded their teens/young adults (patients) provided interpretation for them and for the medical providers. Three additional responses for who provided interpretation when the medical interpreters were not available were a bilingual BMT secretary, a family member (daughter) and a mother who sought help from anyone who was bilingual in English and Spanish that was present during the time of need. The sixth participant responded she did not need interpretation because she was bilingual and she provided the interpretation for the medical providers and parent(s). The primary source of communication for this group of participants was through interpreters. One out of the six parent(s)/caretaker participants was able to

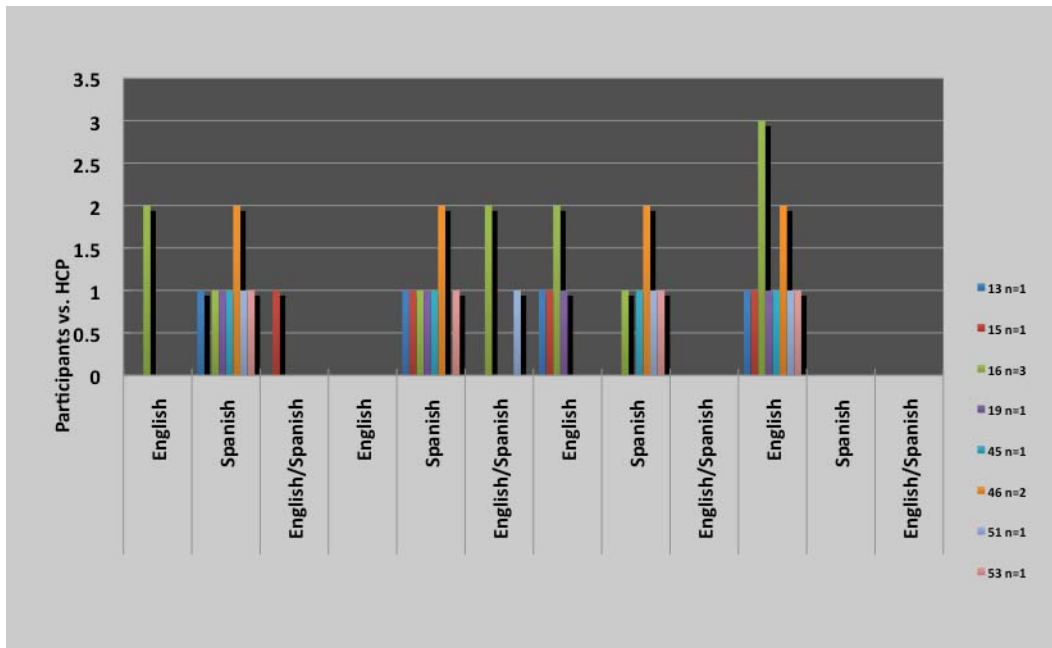
communicate directly in English and the remainder (n=5) communicated with health care providers through medical interpreters, transplant recipients (patients), other medical staff (secretary) and non-medical staff (transplant families/patients) (see Tables 1.4 and 1.5 below).

Table 1.4: Participants vs. Health Care Providers (HCP) Language Variances



n=6	Age Range	19 n=1	45 n=1	46 n=2	51 n=1	53 n=1
Primary Language (Self Identified)	English	-	-	-	-	-
	Spanish	1	1	2	1	1
	English/Spanish	-	-	-	-	-
Primary Language Spoken at Home	English	-	-	-	-	-
	Spanish	1	1	2	-	1
	English/Spanish	-	-	-	1	-
Language Spoken with Health Care Providers	English	1	-	-	-	-
	Spanish	-	1	2	1	1
	English/Spanish	-	-	-	-	-
Participants Report of Language Spoken by Health Care Providers	English	1	1	2	1	1
	Spanish	-	-	-	-	-
	English/Spanish	-	-	-	-	-

Table 1.5: Participants vs. Health Care Providers (HCP) Language Spoken Variances



n=11	Age Range	13 n=1	15 n=1	16 n=3	19 n=1	45 n=1	46 n=2	51 n=1	53 n=1
Primary Language (Self Reported)	English	-	-	2	-	-	-	-	-
	Spanish	1	-	1	1	1	2	1	1
	English/Spanish	-	1	-	-	-	-	-	-
Primary Language Spoken at Home	English	-	-	-	-	-	-	-	-
	Spanish	1	1	1	1	1	2		1
	English/Spanish	-	-	2	-	-	-	1	-
Language Spoken with Health Care Provider	English	1	1	2	1	-	-	-	-
	Spanish	-	-	1	-	1	2	1	1
	English/Spanish	-	-	-	-	-	-	-	-
Participants Report of Language Spoken by Health Care Providers	English	1	1	3	1	1	2	1	1
	Spanish	-	-	-	-	-	-	-	-
	English/Spanish	-	-	-	-	-	-	-	-

### *Communications*

There was a range of responses among the participants in determining communication patterns between them and the medical providers. The data collected is divided from Part I of the outpatient behavior observation clinic visits and Part II of the focus groups. The information is also presented in the following sub-sections: understanding, explanations, culture and language, compliance, post transplant complications and restrictions.

### *Understanding and Explanations*

Communication patterns observed at the BMT outpatient clinic revealed problems with confusion and misunderstandings primarily between the self-identified Spanish



speaking parent(s) (n=3) when there was not a medical interpreter available and also between teens/young adults and medical providers (n=3). See the following illustration:

According to this you were 64 kilos and now your 64.8, so it's up .8 kilos. The patient's mom asks, how much? Patient responds, eight kilos. I used to weigh 64 before, but now I weigh 64.8. The patient asks the nurse practitioner, is it 64.8? The nurse practitioner responds, no...yeah 64.8 today, and it says here that you were 64 last time. Do you remember what you weighed last time? The patient responds, yeah, one hundred and forty four. The nurse practitioner answers, I have to convert that, every kilo is 2.2 pounds. The patient states, no, I weighed one hundred and forty two..no, I weighed a hundred and forty eight. No, two, four. I weighed a 144.

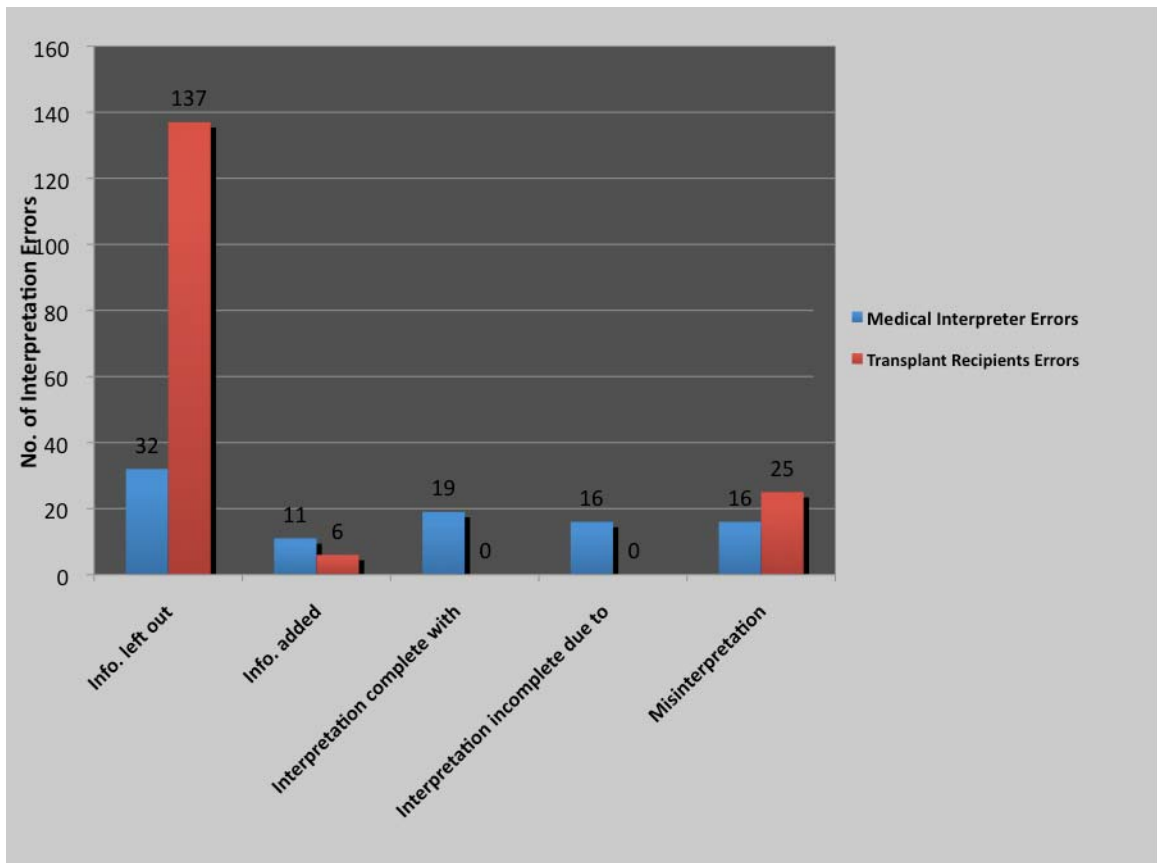
During the transplant recipients clinic visits the medical providers directly communicated with five (n=5) teens/young adults and limited their communications with the transplant recipients' parent(s) until either the patient, the medical interpreter or other interpretation means was provided. While waiting for medical interpreters there were three (n=3) teens/young adult (patients) who provided an estimated 30 minutes total of interpretation to medical providers and parent(s). The three (n=3) participants were observed by the researcher to not entirely interpret everything between medical providers and parent(s). There were 137 times documented when information was not interpreted and left out by the teens/young adults during interpretation. During one participant's visit the nurse practitioner communicated with the teen directly while waiting for the medical interpreter. The communication between the nurse practitioner and the teen included a specific blood pressure medication and dosage, as presented below:

Your blood pressure is a little low, it's okay, but it's a little low. We are going to decrease one of your blood pressure medications, but I need to know is the enalapril and your on 5 mg twice a day. Patient responds, I think so. The nurse practitioner asks, is it 5 mg tablets? The patient interprets to mom, they are 5 milligrams right...the enalapril. Yes, right? Patient interprets from English to English, from the blood pressure right?

The three (n=3) transplant teens/young adults who interpreted themselves while waiting for medical interpreters additionally committed 25 misinterpretation errors. There was also information that was added by the participants (n=3) six times. The total average interpretation errors made by participants (n=3) was at 33.6 in 30 minutes.

When one voluntary medical interpreter was available and provided interpretation to the parent(s) and the health care team there were observations of various interpretation interruptions. There were 35 interruptions made by medical providers, parent(s)/caretaker and transplant recipient when the medical interpreter provided interpretation to four of the five transplant recipient's parents. There were also medical interpretation interruptions observed when there was more than one topic or conversations discussed at a time. The medical interpreter was able to finish interpreting nineteen times after being interrupted. However, there were observations and documentation of sixteen medical interpreter interruptions when not able to complete interpretation. There was 32 times when information was left out by the medical interpreter and eleven times when information was added. Sixteen medical misinterpretation errors were made and one medical interpreter declined to participate in the study (see Table 1.6, page 54). During the participants' BMT outpatient clinic visits with medical providers there was an average of 18.8 medical interpreter errors in approximately two hours. The clinic visits also revealed communication difficulties resulting in confusion between the transplant recipients and the parent(s)/caregiver regarding a major transplant side effect called Graft Versus Host Disease (GVHD). The study participants referred to the medical condition as "infection." Following are two mothers talking about GVHD:

Table 1.6: Transplant Recipients vs. Medical Interpreter Interpretation Errors



n=5	Medical Interpreter Errors	Transplant Recipients Errors
Info. left out	32	137
Info. Added	11	6
Interpretation complete with interruption	19	0
Interpretation incomplete due to interruption	16	0
Misinterpretation	16	25
	18.8	33.6
	Average Errors	Average Errors

The first parent stated, the GVHD that affected, that affected him, and it attacked him very strongly. The second parent responds, and that GV...that infection was how long after transplant? The first parent, well, soon, soon, he started with a rash. More rash, and more rash, and then got better and then he would swell up

and it would come back. The second parent, the other day we had a visit. They checked her blood and it turned out that she has that infection, but the doctor told me, look we rate it with numbers and she is at one, and there is two, three and four and now she only has grade one, which is very little and she was given medicine.

At other times parents and patients demonstrated confusion related to medical terminology and laboratory results. One parent and transplant recipient's clinic visit revealed the following interaction with a nurse practitioner and medical interpreter:

What about the graft that she had an infection? I think that is VH what is it call, how do I say it.

Lastly there were observations of not all parent(s)/caretaker being able to learn medication names, doses, frequency without reference to a medication chart (provided by medical staff). One patient was observed having learned the names of the medications, the color and sizes so that communication could be maintained with parent. The following clinic observation was made between transplant recipient and nurse providing the following information:

Nurse: The meds you are on can cause some swelling. Did he come down on your Norvasc? Did he keep you down on it?

Patient: I don't know the blue one?

Nurse: I don't know what it looks like.

Patient: Ah..I still take it.

In part II of the study the focus group participants reported additional communication problems with transplant doctors and nurses. The focus group data continues with the same sequence reported in Part I of the study: understanding, explanations, culture and language, compliance, post transplant complications and restrictions.

### *Understanding and Explanations*

During the two focus group meetings the participants were asked two primary questions pertaining to communication patterns between them and the health care providers. Prior to the first question, however, the investigator openly informed participants of the study's purpose in determining if there was communication, cultural and language barriers with transplant health care providers, which impact the transplant recipients post transplant recovery and long-term quality of life. First question, what have your experiences been like when communicating with the medical team? Second, what have been your communication experiences with the transplant doctors and nurses regarding medical recommendations, medications, treatments and post transplant restrictions?

In discussing the first question there was agreement among the transplant recipients and their mothers/caretaker (n=11) that the communication with medical providers lacked clarity when talking about the many different aspects of transplantation.

A participant referenced her initial experience in the following manner:

At first we could not understand what was not a thing...a disease. Not the diseases, what they were, or what they meant. Little by little with time we have learned, but I don't think we have learned enough. Different things happen; the kids have different reactions, some, some good and others very bad. Like her, she has done well with the transplant everything is very good. There are small things like colds or something normal, but until now she is doing well. When we come to the doctor visits, we always have an interpreter, when there is none and I don't understand the secretary comes to help, we ask her to help. At times they get medications and we don't know how to give them. Something could happen, something more serious, a mistake or something.

The transplant recipients mothers (n=5) and the transplant recipients (n=2) reported having transplant understanding limitations related to what transplantation is,

transplant related medical conditions, prognosis and lack of medical explanation understanding. The question asked was, what have been your communication experiences at the outpatient clinic, the communication between you and the doctors? One of the participants responded by indicating the following:

The types of diseases that they would explain, the names, well I would say what is that, and they mapped out lots of circles and explained this means this and that means that, and I would say oh...what we don't even know or imagine. They used interpreters but it was difficult to understand. Yes, yes because we don't imagine that there are so many diseases. And, and with explanation and because of so much time, we have to...But there is still times that there are things that don't register.

A transplant recipient (n=1) reported having had good overall communication and experiences with the clinic visits and the medical team and the question was addressed in the following manner:

Well they do understand me every time I tell them what is happening they listen and then they send me to have my blood drawn and they explain what I have to and should do. There are times, that I don't understand them but I ask them to please explain more, so I can understand.

The majority of the mothers/caretaker (n=6) and the transplant recipients (n=2) reported explanations are a missing communication link. They further explained that the lack of time spent with them at the outpatient clinic was also interconnected to communication problems because they observed the doctors being "rushed." Participants shared that "evasiveness" and "lack of medical explanations" provided to them by the doctors caused increased "trust" problems, increased "anxiety", "fear" and "nerves." One of the eight participants who reported communication problems with medical explanations by doctors described it in the following manner:

Sort of evasive, everything is always fine according to the doctor. You want to ask questions, have them answer or have them tell you something about the diagnosis or what their plan is but..leaves.

Other responses related to communication patterns described by mothers/caretaker (n=4) as “lack of trust” from doctors and “lack of trust” towards both the inpatient and outpatient medical transplant health care providers (n=7). Seven (n=7) participants reported miscommunication and misunderstanding with medical providers regarding patient’s post transplant medical recommendations and restrictions. There were participant parent(s)/mothers (n=2) who communicated they experienced lack of parental validation and “disregard” when it came to expressing concerns about their teens/young adults diagnosis and medical conditions. This parent reported the following:

And the doctor never pays attention to when you say this and that is happening and you feel that if action is taken over the situation, maybe having an examination done, to see if it’s true or not.

The teen/young adult participants also shared “lack of trust” towards the medical providers by withholding information in reference to post transplant medical adherence to medications and restrictions. This is further addressed when answering the second question of what have been your experiences with the doctors and nurses regarding medical recommendation, medical treatments and post transplant restrictions.

### *Cultural and Language Barriers*

When the participants continued to share their experiences regarding communication with the transplant medical team they described the following common topics: race, cultural beliefs and language barriers. Two participants out of the total eleven participants reported feeling discriminated against because of their reported

“Hispanic” race. One of the participants reported, “I smile, and there is not even a look back.” From the eleven participants there were eight that did not respond and one reported the following:

“No, might not be very friendly perhaps, the person is very serious, but, but I get good vibes. Yes, she cares because the other day we were here all day and we got soup from her, ah..perhaps the manner she takes on, the physical.. I mean the way she is might give the wrong impression.

Two dominant themes emerged when participants were asked, what have your experiences been like when communicating with the transplant medical team? First, was culture and the second was language. One parent’s response was described as believing the medications the teens/young adults took post transplant affected the teens/young adults post transplant outcomes. During an interaction between two participants the first parent shared the devastating medical complications her son had experienced during and post transplantation and the second participant’s response was as follows: “well because of too many medications and because of the medications themselves.” Also shared by eight of the participants was the importance of demonstrating “affection” and “patience” to transplant recipients because their parent(s)/caretaker reported this action impacts the transplant recipients psychological and physical well-being. One of the participants described her post transplant experience with a transplant doctor who no longer worked at CHLA as “he used to make me smile and feel alive.” This participant explained that when she did not smile the doctor asked her why and expressed “affection” toward her and inquired about what may have been going on at that given time. A second participant shared a similar belief system and she described it as:



I feel that (refers to comment shared above) gives kids a will, will that helps you survive, and to feel better and to have your disease leave your body because you have a will.

The mothers and caretaker (n=6) of the transplant recipients explained their cultural role as primary caretakers to their families and even more to their teens/young adults who had been diagnosed with life-threatening conditions. Two of the participants expressed “pressure” from their spouses in providing around the clock support and supervision to the transplant recipients. One of the mothers described it in the following manner:

And I struggle a lot because my husband tells me did you do this, didn't you give him that. He pressures me, he pressures me, yes he does pressure me because he asks, didn't you give him...or didn't you insist or what?

The investigator observed at the outpatient BMT Clinic that although the participants were open and subjective to sharing their experiences without limitations during the two focus groups, all of the participants (n=11) were culturally appropriate in demonstrating respect and humbleness when communicating with medical providers. Although there were participants (n=5) who reported requesting interpreters during the clinic visits, the observation was that none of these participants were witnessed as requesting an interpreter. Culturally many Latino/Hispanic descendent will not actively seek assistance or make requests of perceived authoritarian figures. This brings up the last sub-topic of communication between the participants and the transplant medical team. The participants reported varied responses such as “doctors don't speak Spanish,” “interpreters are not always provided,” “the patients interpret” and “doctors ask patient's to interpret.” One of the participants reported requesting an interpreter after the doctor

asked the transplant recipient to interpret. She reports this information in the following manner:

When we have a clinic visit and the doctor begins, at times they request to have her interpret, or her (refers to caretaker) and I say no, I want to have an interpreter because she doesn't always tell me the truth, she only interprets what's convenient for her, so I ask..tell them that I need an interpreter and yes, they do bring one.

When the participant was asked if this occurs with only one specific doctor she responded by saying "almost with all of them." The transplant recipient agreed with her mother and she responded "with almost all of them." The participants were also asked if the medical interpreter is not available who interprets and five of the transplant recipients responded they provide their parent(s)/mothers and health care providers with interpretation. One (n=1) caretaker also responded that she provided the interpretation. All participants were asked two follow up questions regarding interpretation. First, when you are asked to interpret for your mothers do you interpret everything or are there things you are not able to interpret? There was one participant that indicated when interpreting for her parent(s)/mother's she experienced barriers interpreting everything. She reported the following, "I interpret what I can, because sometimes I don't know how to interpret some words." Another participant related she did not always interpret everything exactly as provided to her by the health care providers. This participant's response was as follows:

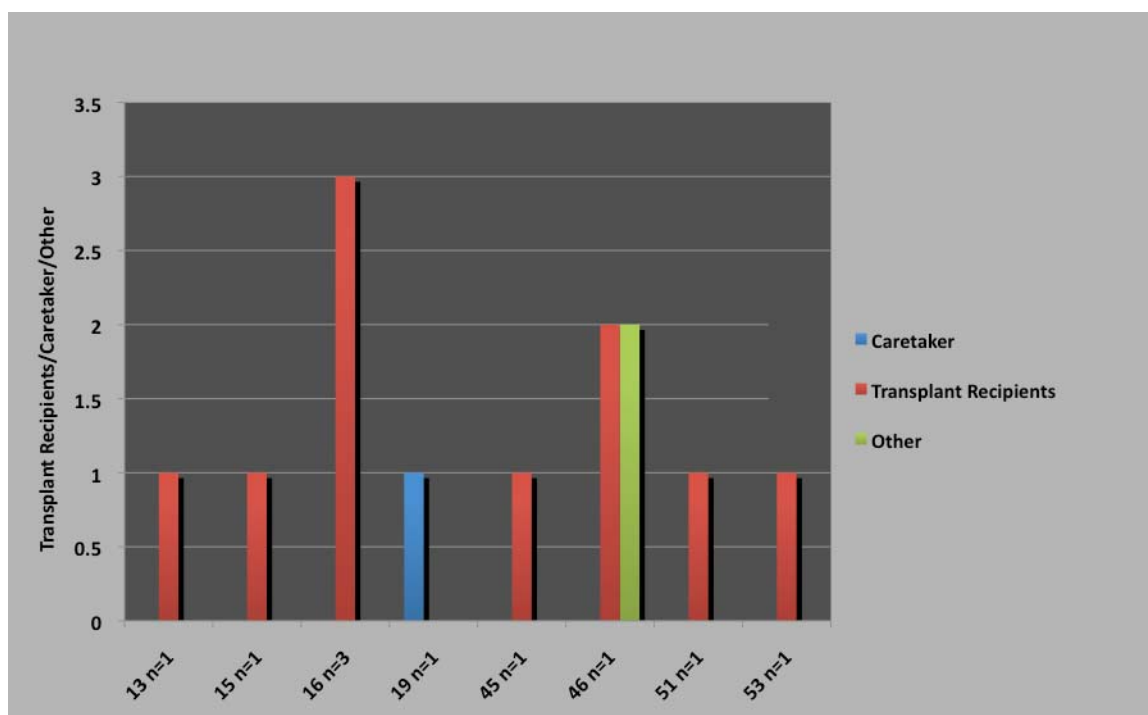
They used to tell me that I still couldn't eat that, because the lemons can't be washed well and back then we couldn't eat those kinds of things. So, I asked them can I eat lemons? They said not, not yet. When we went home I told my mom, I told her, yes I can have it but three drops to start with.

Second, how easy or difficult is it to interpret medication names or doses amount?

One participant responded, “my mom knows them by the size and color.” She is asked, when you are interpreting to the doctors about the medicines do you refer to them by name or how do you interpret that to your mom? The participant responded “the small one, or the color.” When participants were asked if nurses request interpreters when they give medical instructions their response was as follows:

Sometimes not always. I think they need more interpreter staffed, because it’s needed in all areas. They are in one area and we have to wait until they are done, and then they come (See Table 1.7).

Table 1.7: Transplant Recipients as Primary Interpreter



n=11	Age Range	13 n=1	15 n=1	16 n=3	19 n=1	45 n=1	46 n=1	51 n=1	53 n=1
When Interpreter is Not Available Who Interprets	Caretaker	-	-	-	1	-	-	-	-
	Transplant Recipients	1	1	3	-	1	2	1	1
	Other	-	-	-	-	-	2	-	-

\*More than one response per participant

Also shared by the mothers of the transplant recipients (n=5) was concern of not understanding medical providers transplant related information and instructions due to their self reported English proficiency limitations. One participant reported, “sometimes they get medications and you don’t know how to give them.”

Participants responses to communication patterns with health care providers pertains to the second question of what have been your experiences with the transplant doctors and nurses regarding medical recommendations, medical treatments and post transplant restrictions? The responses are presented in the following sub-sections: medications/compliance, post transplant complications and restrictions.

### *Medications/Compliance*

Four out of five of the transplant recipient participants reported at one time or another not adhering to medical recommendations made by transplant providers. They also reported not having taken post transplant oral medications and not following post transplant restrictions. The transplant teens/young adults (n=3) reported, “forgetting” to take medications because they are busy or “forget” to take them before leaving for school

or when in a “rush.” The teens/young adults responses to understanding the importance of taking medications was described by one participant’s inpatient and outpatient experience as follows:

Sometimes I didn’t take them; I used to cheat in taking them when I was in the hospital and when I came out. When I was hospitalized one of the nurses that was watching me, I told her that I was taking them and I would ask her to please turn so I would take the medicines, but I wouldn’t take them. I would hide them in my socks, and when I was home my mom crushed them so that I could take them but I would throw them in the sink. I would get bored and tired of taking them so much.”

The teens/young adults (n=4) reported not following medical recommendations regarding post transplant restrictions and one parent indicated she had allowed the transplant recipient to make her own decisions about whether to follow the medical recommendations provided by the transplant medical team. The parent further reported not telling the transplant team about her decision, but thought that the medical team was aware. The participant goes on to state the following:

She lives her live normal. She doesn’t have restrictions. She goes out, goes to the stores, she doesn’t have restrictions. She doesn’t look sick.

The parent is asked, how long after transplant did you allow her to live a normal life? She responded in the following manner:

After about five months, it wasn’t as open as to have her just go out, it was little by little, she would go out to the yard, she would go one block to visit a friend and little by little. I talk to my daughter and I maintain communication with her and I told her how..because as a mother you tell them don’t do this because of this reason, she has an entire life, how do you want to live your life, short and normal, or long with restrictions, and the decision is hers.

The parent(s)/caregiver were asked, what do you feel when the doctors ask you to implement restrictions? Do you feel guilty? One of the parents/caretaker participants responded, “I don’t feel that at all, I don’t feel guilty, in the contrary I feel that I’m

helping my daughter continue to make progress.” A second parent responded, “we as parents don’t understand, we want them to be all better the following month after transplantation.” The remainder (n=4) parents/caretaker did not respond.

The parent(s)/caretaker (n=5) communicated having difficulty with the teens/young adults following post transplant adherence. One parent recounted the following:

It’s very hard that they are teens. I don’t know if with the girls is easier, but for me it has been difficult because he is a male and sometimes he doesn’t want to understand and he doesn’t understand. I do struggle with him for instance to take water. I know if I insist too much he will not drink.” The more I insist I know that he will not drink.

The parent(s)/caretaker shared their personal struggles they experience with the teens/young adults following medical recommendations. They reported getting “angry” with them and trying to be “patient.” One parent reported the interaction her second child a seventeen year old had with the transplant recipient in attempt to get the teen to adhere to medical recommendations. The statement made was as follows, “why is it that you don’t understand, do you want to die, this is for your life, but you don’t want to understand.”

All teens/young adult participants were asked two follow up questions regarding their lack of medical adherence. First, what is the struggle in taking medications, eat and drink certain things your mothers and doctors ask you to? Second, what is difficult for you? One participant responded because of “stubbornness.” Four of the participants reported not taking medications because they “forget.” From the same four participants two also responded not taking medications because of nausea and vomiting. The fifth participant admitted always taking all of the medically recommended medications

regardless of her aversion to medications that cause her nausea and vomiting. One other participant also reported aversion to medication that at times caused nausea and vomiting.

Parent(s)/caretaker additionally communicated the teens/young adults medication schedule was frequent and there were many medications they had to take through out the day. The mothers reported this affected the teens/young adults' ability to adhere to taking oral medications. One parent reported it in the following way:

For instance she takes medicines at eight, nine, eleven, two, three, five, nine; I mean eight, nine and ten.

Another reported fact by the parent(s)/caretaker (n=3) was disclosed disagreement with transplant doctors' decision to medically release teen/young adults to return to school and one parent adamantly did not follow the doctors recommendations to send teen/young adult to (general public/private) school. The parent(s) (n=4) further expressed misunderstanding of medical explanations provided by doctors to release teens/young adults to school. Three of the parent(s) reported the doctors where "inconsistent and unclear" when providing medical recommendations pertaining to post transplant restrictions. The same three participants reported the doctors were also "unclear and inconsistent" with school medical release information, post transplant vaccines and other post transplant restrictions pertaining to food, visitor and no public contact.

### *Post Transplant Complications/Restrictions*

The transplant recipients reported having experienced or currently are experiencing more than one medical complication following transplantation. The teens/young adults (n=5) reported experiencing post transplant side-effects of immune

deficiency with high-risk of viral, bacterial or fungal infections and complications varying from chronic Graft Versus Host Disease (GVHD) with involvement of skin and abdominal organ effects (n=3). The same (n=3) participants also reported having had various types of infections requiring oral and/or intravenous medications and have in the past or currently reported suffering from nausea and vomiting. Two of the same three participants also suffered from additional problems. The first participant reported medical complications with medication induced (prednisone/steroid) diabetes requiring daily insulin injections and strict diet restriction. The second participant reported having growth hormone problems, significantly short stature, hypotension (low blood pressure) and recent need for oral/skin graft surgery. One of the two remaining participants also reported having had infections requiring oral medications. The second participant also reported having complications with medication-induced diabetes, which is currently treated with oral medications and strict diet restrictions. The last participant reported suffering from hypertension (high blood pressure), kidney dysfunction and lower extremities edema (fluid retention) leading to recent hospitalization for treatment of these symptoms.

Four of the five participants described having post transplant restrictions limiting public contact with any one who is not immediate family members to the patient and live in the same household because of immune deficiency and the high risk of infections. The participants (n=3) reported being home bound in isolation from extended family members, friends and the general public for an estimated time frame of seven months post transplantation. Four participants also indicated having dietary restrictions to only being allowed to eat meals prepared at home and no fast or restaurant foods. The food



restrictions also included restrictions to pork, uncooked vegetables and some fruit that are grown in soil and have thin skin. These post transplant restrictions are implemented by the medical team because of the transplant recipient's potential to develop high risks of bacterial, viral or fungal infections. All five of the participants are required to wear a mask when going to CHLA hospital for visits. Three reported having this restriction to not only their visits to CHLA but at other times when exposed to public areas. There were (n=3) participants who reported receiving in home tutoring rather than attend general (public/private) school due to their low immune system. Other post transplant restrictions may exist that have not been reported by the study participants.

#### *Post Transplant Quality of Life*

Participants were asked about their post transplant outpatient clinic visit experiences when interacting with doctors, nurses, social workers, pharmacy providers, interpreters and other medical providers. They were also asked about their experiences with medical recommendations, medicines, treatments and post transplant restrictions as a way to further investigate and address the important issue of post transplant quality of life that impacts not only bone marrow transplant recipients, but also their parent(s)/caretakers, family and health care providers.

The treatment of hematopoietic blood stem cell (bone marrow) transplantation may provide curative options to treatment of malignancies and other life threatening medical conditions that may not respond to traditional treatment. Transplantation, however, also presents other high-risk life threatening complications related to the treatment and impact transplant recipient's quality of life. The transplant recipients and

their parent(s)/caretaker in this study have reported not only the impact of suffering from life threatening conditions but they have also shared their personal experiences pertaining to their quality of life after having received a blood stem (bone marrow) transplant.

The participants were asked what have your lives been like after having had a transplant? One patient recounted seven years after having received an unrelated transplant her life has changed. She reflected on the social support aspects of her family's initial reaction to her diagnosis and condition. She reported the following:

Well during the first few years it was hard because lots of people in my family didn't understand what I had. But now it is easier, mm...it's better because my family knows what I have and my problems. They know all of the medicines I still have to take.

The participant was asked how many medications do you still take? She responded, "thirteen medicines. I take seven in the morning and six at night. I didn't know I was going to have to take so many medicines. Yes, they told me but I didn't expect to take them daily." Other common themes shared among the teens/young adults pertained to transplant and medicine related complications and psychological factors were shared by the teens/young adults and the parent(s)/caretaker. There were participants (n=9) who responded that their lives were impacted by the medical diagnosis, medical and transplant treatments and transplant related complications. One participant reported the following after having been discharged from transplant hospitalization:

Yes, but after I got sick with GVHD and they had to increase another medication and then another medicine because I was having problems with the virus. They had to give me prednisone to help control it and they had to increase it more and more, because the dose was not helping me, so they increased the milligram and when they increased the milligrams then my blood pressure started going up and then they had to give me three other medicines for my blood pressure and then just other normal problems with the virus.

Two other teens/young adults also reported secondary complications to transplant medications causing other medical complications ranging from high blood pressure, kidney dysfunction, diabetes, nausea and vomiting as well as other complications described in the medications and complication section of this chapter. The post transplant food and medically regulated public contact and visitor restrictions was also a commonly shared quality of life impact on the transplant recipients and the parent(s)/caregiver. A parent reported the following:

He used to get bored at home. It was very hard for him to be locked up and then to have him do school work and you have to be there to make sure they are being good kids. I know it's very hard.

Psychological factors reported by the participants were related the communication patterns between them and the health care providers. The participants indicated different aspect of communication including language barriers impacts their post transplant medical adherence, treatment adjustments, acceptance and quality of life. The participants (n=10) reported that having transplant understanding, knowledge and “explanations” regarding treatments, treatment plans would decrease their feelings of “helplessness”, decrease “anxiety” feelings of being “disregarded” and minimize their “fears.” One participant reported the following:

When you ask questions something that to them is normal because they know, they have studied for years. You want to ask questions and know about the prognosis and the treatment plans. As a mother you know your child perfectly, yes, yes you know if he/she is in pain or is hurting, or if he/she feels bad or if he/she doesn't, but you share this and the response is oh..everything is okay; tomorrow he/she will be fine.

The majority of participants (n=10) also indicated they were psychologically affected by “sadness,” “frustration” and “anger” due to the life changes they have

endured. The teens/young adults (n=5) reported their mood was affected and four reported “anger” because of the multiple medications they had to take post transplantation and the frequency of the medication. Many reported having difficulty understanding and following the post transplant restrictions, particularly the restrictions regulating contact in public areas and not being able to spend time with family and friends. The lack of normalcy among the teens/young adults was reported as being different. One participant reported the following:

It’s a little like a routine. You know that you have to do it, but at the same time you want to ah..you just want to do it because you know that you have already received the transplant but you still have to wait. You have to take care because you are not like other people that haven’t been sick with an illness like, like us.

The parent(s)/caretaker also identified psychological factors that impacted their day-to-day lives. Five parent(s)/caretaker reported fear of relapse in the case of malignancies and post transplant complications. The parent(s)/caretaker maintained spiritual beliefs and hoped their teens/young adults would continue to make progress post transplant. The psychological impact varied among the participants and the fifth parent/caretaker participant reported the following, “she doesn’t look sick.”

### *Recommendations*

In this last section the participants were asked to provide recommendations that would help other families and transplant recipients with the process of transplantation while improving communication patterns with health care providers. One participant stated the following:

To have people like you who take an interest in the problems that we go through. I have thought that there are many people that will come after we leave and for us

mother's is as though the skies and earth come together when your child is diagnosed, you wish to be able to spin the world around and change things to not be, and not have them happen to you. But I have always thought that there should be people that provide support related to what transplant really is. I know that the doctors explain but they only explain the risks and tell you about the worse things that may happen, but you come out of the conference room where we are conference and you don't want to even look outside, the sun and even more, I say this because I felt that I couldn't even feel my footing, so I feel that there also should be people that will give you hope and explain how things will be. I understand that not everyone is as open as we are here and I know that not everyone will experience the same things, but I think that there is a need for support and to clearly explain about, about the treatment. Not to only be informed of the bad things because it's very hard to have to go through this and to not have clear explanations from doctors. They know, they know because they have studied and they have received training but when asked questions they get upset, but because we are parents we want to be informed.

A second participant made the recommendation of having a video about transplant. This participant's response to recommendations to help new transplant recipient's parent(s)/caretakers and families understand the process of transplantation and improve communication patterns with transplant health care providers was reported as follows:

I think that videos about transplant would be good because as she said, we come away from the conference worried and they tell you this is like this and this but they don't explain well and we are scared. Having an explanation about transplant, what it is because we don't know. I used to think that they would poke her and from the same place they would insert a bone (she points to her bone in her arm), I don't know, so we are very dumb because we don't know and we are very ignorant and we are scared. If they would have explained look this is like a transfusion then we worry less. Our race is very ignorant about this and about marrow donation. Our people don't know. We only know now because we are going through it. Having a video to help orient mothers so that we don't leave the conference in fear and we have a better understanding of what it is and be less scared. Yes, because I assure you that the teens were scared when they heard about transplant.

A response from another parent/caretaker participant is as follows: “our own families, brothers and sisters ask where does he have the incision? How big is it? How was the surgery? And it wasn’t a surgery.”

The parent(s)/mother’s of the transplant recipients (n=5) who reported Spanish as their primary language spoken were asked what recommendations they would make to improve communication patterns with health care providers? All five of the parent(s)/mother’s indicated the following, “well we prefer to have people that speak our language, we would be better off.” The response from another parent was “yes because they don’t always interpret entirely.” When asked who “they” were the parent’s response was the interpreters. The same participant explained that she did not speak English and “I can understand a little more, and sometimes when they are interpreting they don’t tell me everything.”

Other participant responses included two teens/young adults who reported that having less medically technical information provided to them would help communication between them and the medical providers. A third participant reported understanding better when the participant’s mother explained the medical information. Another participant reported visual tools, like pictures would be more useful in understanding and the last participant indicated having medical information explained by the health care providers helped communication. Five of the parent(s)/caretaker participants reported having interpreters helps communication patterns with doctors, nurses and other health care providers. From these five participants, two also answered having explanations provided, with one responding having “clear explanations” and requesting help when

needed. The sixth participant reported receiving medical updates or medical information from doctors helps communication between the participants and health care providers.

### *Summary*

The findings of this chapter have been presented from Part I of the behavioral observations and Part II of the focus groups. There were 28 questions asked during the two focus group meetings to five teens/young adult between the ages of 13 to 21 who had received stem cell (bone marrow) transplant and five transplant recipient parent(s) and one caretaker. The majority of the participant's answers supported this study's question of culture and language barriers impacting post transplant medical adherence, transplant recovery and long-term quality of life. The participants varied responses not only supported this study's question but their answers also supported ineffective communication patterns between the participants and transplant health care providers also impacted medical adherence, post transplant recovery and the participants long term quality of life.

The major study findings confirmed there were cultural and language barriers that impacted communication patterns between participants and health care providers, though the participant responses varied from the outpatient BMT clinic observation visits and the focus groups. First, the clinic observations revealed there were not only language barriers between the transplant recipients, their parent(s)/caretaker but there also were problems with lack of participant's medical understanding resulting in confusion. Second, the participant's focus group responses from the semi-structured open-ended questions

elicited unrestricted discussion among the participants allowing them to openly discuss personal and medical transplantation experiences. The focus groups findings confirmed cultural and language barriers as well as ineffective communication between the transplant health care providers have an impact on post transplantation adherence and in the long run in the participant's transplant recovery and long-term quality of life. The ineffective communication patterns from the focus group findings also included participants' report of lack of understanding, lack of medical explanations provided by health care providers, lack of medical trust and evasive communication.

Through the behavioral observations, the participants recollections, memories and personal experiences, it is this study's findings that there are not only cultural and language barriers that impact this specific population of Latino/Hispanic bone marrow transplant teens/young adult recipients and their parent(s)/caretaker ability to follow medical recommendations made post transplantation, but the findings also conclude that ineffective communication between the participants and the transplant health care providers further creates barriers impacting post transplantation outcomes for this population. Regardless of the participant's report of culture and language barriers impacting medical adherence, post transplant recovery and quality of life, findings demonstrated a need for medical understanding and explanations significantly would reduce their "nerves", "anxiety" and "fears", while providing them with parental validation and empowerment.

Finally, the participants recommendations of having health care providers be culturally competent by either communicating in Spanish and/or providing transplant information in Spanish, having medical information simplified with and without the use



of medical interpreters, having medical information explained and lastly, having bilingual transplant videos are a few of the participants recommendations they believe will increase their transplant understanding and increase medical adherence, transplant recovery and quality of life.

## CHAPTER V

### DISCUSSION

The focus of this qualitative study was to investigate the impact and correlations of culture and language on medical adherence, transplant recovery and quality of life among Latino/Hispanic pediatric blood stem cell (bone marrow) transplant recipients and their parent(s)/caretakers. This ethically important issue for this medically high-risk population group was explored through the participants' personal experience narratives. This chapter discusses the study's findings and researcher input in the following subsections: major findings, implications, limitations, recommendations and conclusion.

#### *Major Findings*

The major findings indicate that the Latino/Hispanic blood stem cell (bone marrow) transplant recipients and their parent(s)/caretakers are indeed impacted by culture and language barriers and these barriers also correlate with post transplantation medical adherence, transplant recovery and long-term quality of life. This finding conformed to the literature from the National Council of La Raza (NCLR) (2004) that states there are health care gaps in the Latino population accessing health care services and communication with health care personnel. Similarly to the NCLR, the American Friend Service Committee (AFSC) (2009 and Flores et al., (2002) indicate language barriers and communication issues are a primary variable in Latino's being able to access health care services and communicate with health care personnel.

As language has been an unequivocal barrier that impacts effective communication patterns between the population of Latinos/Hispanics and health care providers, this study's participants further described ineffective communication with by lack of medical understanding, lack of medical explanations and lack of medical trust they experienced in their interactions and experiences with transplant health care providers. Other correlations between language barriers and pediatric health care has been measured in this study by the participants self reported limited English proficiency (LEP), which similarly interphases with McCarthy (2001) and the National Alliance for Hispanic Health report that immigrants who have limited English proficiencies have increased language and communication barriers that impact health care services.

Although the majority of the participants in this study verbally reported requesting medical interpreters when communicating with health care providers, the researcher observed that these behaviors did not occur and that interpreters were not requested when communicating with transplant health care providers. The transplant recipients and one caretaker were observed providing interpreting for their parent(s) and for the transplant health care providers. An explanation for why this occurs may stem from participant self-perception, lack of engagement with health care providers, and or feelings of being devalued by health care providers. Participants throughout the study spoke of how they perceived doctors and other health care providers to be "rushed", distant, and methodical in their interactions with them. Some participants even spoke of how health care providers seemed to "assume" that they [patients and family members] understood medical jargon, medications, and expectations. This being the case, it is

highly likely that individuals do not ask for help or for translation for fear of being further devalued or overlooked.

Unfortunately when interpreters are not provided and participants are left to interpret for each other or to fall prey to whomever is available, many communication errors occur. For example, during this study's observations, the researcher noted numerous interpretation errors made by three transplant recipients, which included incomplete interpretation between health care providers and the transplant recipient's parent(s)/mothers. As mentioned in the findings, there were 137 errors made in a time span of approximately 30 minutes where the teens/young adults did not fully interpret the interactions between the health providers and the parent(s)/mother's (see table 1.6). Also when interpreters were not available the transplant recipients and the health care providers communicated with one another excluding the transplant recipient's parent(s) from the discussions. It was further observed that although all of the transplant recipients reported to be English proficient there were problems with medical terms and knowing the Spanish word or name for medications, doses and medical recommendations.

Lastly, all participants in this study were well informed of the study's goals and objectives. A study in-service was provided by the researcher to the transplant health care team prior to the start of this study. The in-service pre-informed and prepared the health care providers for the observed behavioral outpatient clinic visits and interactions between the transplant health care providers, transplant recipient's and parent(s)/caretaker. They were also informed that the observations were being documented and they provided authorization to participate in the study and have the observations audio recorded.

The participants' report of their personal, medical and transplant related experiences were consistent with the reports made by NCLR (2004), Flores et al., (2002) and Siegel, Martin & Bruno (2001), which conclude that health care providers' limited English proficiencies result in communication and language barriers that contribute to lack of knowledge/understanding, lack of medical trust in medical system, discrimination in the delivery of health care services and lack of available medical interpreters. In the 1,100 study conducted by Flores, Abreu & Tomany-Korman (2005) they noted limited English proficiency (LEP) from participants self reported language spoken at home did not have a direct correlation to the status of children's health; they instead reported the lack of parental education, length of U.S residency, parental employment and family combined income did indicate LEP correlation. The current study also has determined that the participants' reported language spoken at home does not directly impact their ability to provide the transplant recipients with health care services. Instead this study noted that the parental education level, the length of U.S residency, and acculturation level contribute to the transplant recipients' post transplant health care and medical adherence.

Consistent with Martinez-Schallmoser, Tellen & MacMullen (2003) and Britigan, Murnan & Rojas-Guyler (2009) the level of immigrant acculturation is measured by determining level of custom, values, language and ethnicity adjustments, which the transplant recipient's parent(s)/caretaker in this study retained years after they had immigrated to the U.S. The six parent(s)/caretaker in this study reported having retained their Latino/Hispanic ethnicity, identity, customs, values and more importantly, language. The transplant recipients, although they reported having been born in the U.S, all five of

them, retained their Latino/Spanish customs and belief systems including their Spanish language.

The findings from this study were in accordance with the findings from the literature from Rodrigue, Pearman & Moreb (2000) in that the importance of having medical information provided to the participants regarding diagnosis, treatments, treatment plans and prognosis provides increased knowledge in helping participants with a sense of being better informed; and as and Ulrich, Dussel, Hilden, et al., (2010) noted, maximize the level of comfort and quality of life.

The findings of this study further conclude that the importance of effective communication increases knowledge and the participants' post transplant medical adherence, transplant recovery and quality of life; and that culture and language are equally important. This study participants' recommendations to have native Spanish medical providers and/or medical interpreters inform them regarding transplantation not only better informs the participants but their reported anxieties, fears and nerves are minimized.

In the role of social worker we not only provide a bridge in communication between health care providers and blood stem cell (bone marrow) transplant recipients, parent(s)/caretakers and families but social workers also provide empowerment by giving them a voice to their heartfelt experiences that impact their every day lives.

The findings of this study speak to the importance of culturally competent health care providers. It suggests that the need for interpreters for doctors and health care providers is just as important as interpreting for patients and family members. Communication is a two-way process; thus giver and receiver of communication must be

able to equally understand each other. This is most critical in life and death situations and in situations where medical adherence is correlated to quality of life.

### *Implications*

The implications of this study are far reaching. As previously mentioned, the need for culturally competent health care providers cannot be overlooked. With the increasingly high volume of immigrants and non-English speaking entering the United States, the need for open communication, understanding, sensitivity and integration is more prevalent than ever. Without proper health care, open dialogue with health care providers, trust, and access to health services, our health care system and its outreach and proficiency will fail both citizens and non-citizens.

This study also has implications for addressing discriminatory practices, inequities, stereotyping, and myths. It has become evident that some practitioners are treating stereotypes, or perceptions of cultural groups rather than individuals with distinct needs, diagnoses, and prognoses. Perceptions of economic status, social status, education level, and support system should not be at the forefront of treatment; the patient's illness should be the center of treatment and how economic status, social status, education and environment interact or influence patient illness should be incorporated in the healing process. This and only this will lead to improved quality of life.

This study also has implications for administrators, educational institutions, and policy makers. The need for leadership, training, laws and regulations, advocacy and skill building in preparing social workers, health care professionals, and hospital administrators in culturally-sensitive and culturally-based practices cannot be overlooked.

### *Limitations*

The main limiting factor in this study was time. Childrens Hospital Los Angeles IRB approval was three months for an expedited review. This time limitation restricted the amount of time and coordination available to this investigator; thus leading to modifications within the study's design. Other limitation factors are from limited literature available on culture and language barriers among Latino/Hispanic blood stem cell (bone marrow) transplant recipients, their parent(s)/caretakers and families. Prior studies have been limited to language impacting access to health care services.

The generalizability of the study's population size should not be assumed since the study sample was relatively small, with eleven participants. The study does not reflect the greater radius of Latino/Hispanic children, teens, young adults and parent(s), caretakers and legal guardians. Additionally, there was potential relational bias between the study investigator and the pediatric population of transplant recipients and parent(s)/caretakers due to the investigators past work history with this transplant population. To reduce this potential bias, however, the investigator recruited nine participants who were not known or familiar to the investigator.

The study's validity and reliability as in every investigative study should be considered. The investigator's prior work history may present sympathetic biases in the study. The semi-open structured guided questions developed by the researcher may present biases since they were developed to specifically explore the impact of cultural, language and communication barriers on transplant medical adherence, transplant recovery and quality of life.



### *Recommendations*

The findings of this study concluded that cultural competence practice is imperative in addressing the disparities Latinos/Hispanics experience in seeking and receiving health care services. Therefore, this investigator recommends that not only should health care providers become culturally competent when providing health care services to a diverse population, but also should empower other health care recipients and families to become English and medically proficient. This investigator recommends making English as a Second Language (ESL) classes available at outpatient clinics or collaborate with community agencies such as the local Ronald McDonald House to have ESL classes offered and available to CHLA patients and parent(s) or identified primary caretakers. ESL beginning/basic classes may help increase limited English proficiencies among Latinos/Hispanics and reduce the number of medical interpretation errors made by patients and non-trained medical interpreters. This investigator also recommends on site (outpatient) medical training geared towards increasing medical understanding and knowledge regarding specific medical diagnosis such as blood stem (bone marrow) transplant, treatments and side-effects of medical conditions and treatment related side effects. Specific recommendations to the blood stem cell (bone marrow) transplant recipients, parent(s), caretakers, legal guardians and families is made by this study's participants of having bilingual videos available to incoming transplant recipients and their parent(s)/caretakers and families, regarding the transplant process prior to transplant admission. As reported by the study participants a transplant video will increase their knowledge and understanding. The last recommendation is to have Spanish and English pre-transplant orientation trainings to transplant recipients and their identified primary

caretakers prior to their admission, as increasing the transplant recipients and their parent(s)/caretakers knowledge and understanding regarding transplantation will provide increase transplant recovery and long-term quality of life. Once completion of training and medical (transplant nurse) check off has been established the transplant recipients and primary caretakers will be recommended to follow-up with transplant consent and assent conference followed by transplant admission. This is necessary to ensure that all medical issues and concerns are satisfied prior to transplantation.

### *Conclusion*

In conclusion the study has provided information pertaining to health care gaps in the population of Latinos/Hispanics. The study further examined these gaps and determined that culture and language are barriers that unequivocally impact communication patterns between health care providers and health care recipients not only in relationship to health and access to health care services, but the study provides information on the correlations and impact between culture, language barriers, medical adherence, post transplant recovery and long-term quality of life among a specific population of Latino/Hispanic blood stem cell (bone marrow) transplant recipients that suffer from life threatening medical conditions. The importance of communication in this population is not only an ethical issue but it may be the difference between the transplant recipients life and death. The participant's subjective narratives provide insight into the positive and negative experiences of transplant recipients and their parent(s)/caretaker when communicating and receiving health care services from transplant health providers.

This study provided knowledge and awareness of culture and language in communication patterns between health care providers, health care systems, health care recipient outcomes and long-term quality of life. Insight into how medical social workers, who already provide alliances around the complex culture, language and sociocultural factors, impact health care recipients, their parent(s)/caretakers and families also were defined.

## REFERENCES

- American Friends Service Committee. (2009). A new path toward humane immigration. Retrieved June 10, 2009 from <http://www.afsc.org/ImmigrantsRights/>
- Britigan, D. H., Murnan, J., & Rojas-Guyler, L. (2009). A qualitative study examining Latino functional health literacy levels and sources of health information. *J Community Health*, 34, 222-230.
- Butz, A. (2006). Evidence-based practice: What is the evidence for medication adherence in children? *Journal of Pediatric Health Care*, 20(5), 338-341.
- Diamond, L. C., & Reuland, D. S. (2009). Communicating with Spanish-speaking patients reply. *JAMA*, 301(22), 2327-2328.
- Falkenstein, K., Flynn, L., Kirkpatrick, B., Casa-Melley, A., & Dunn, S. (2004). Non-compliance in children post-live transplant. Who are the culprits? *Pediatr Transplantation*, 8, 233-236.
- Flores, G., Abreu, M., & Tomany-Korman, S. C. (2005). Limited English proficiency, primary language at home, and disparities in children's health care: How language barriers are measured. *Public Health Reports*, 120, 418-430.
- Flores, G., Fuentes-Afflick, E., Barbot, O., Carter-Pokras, O., Claudio, L., Lara, M., et al. (2002). The health of Latino children urgent priorities, unanswered questions, and a research agenda. *JAMA*, 288(1), 82-90.
- Flores, G., Laws, B., Mayo, S. J., Zuckerman, B., Abreu, M., Medina, L., et al. (2003). Errors in medical interpretation and their potential clinical consequences in pediatric encounters. *Pediatrics*, 111(1), 6-14.
- Gil, E., & Drewes, A. A. (Eds.). (2005). *Cultural issues in play therapy: From sensitivity to competence in working across cultures* (pp.3-25). New York, London: Guildford Press.
- Hoefler, M., Rytina, N., & Baker, B. (2009). *Population estimates. Estimates of unauthorized immigrant population residing in the United States: January 2008*. Washington, DC: U.S. Department of Homeland Security. Retrieved June 10, 2009 from <http://www.dhs.gov/xingtn/statistics>
- Lee, J. & Rytina, N. (2009). *Annual flow report. Naturalizations in the United States: 2008*. Washington, DC: U.S. Department of Homeland Security. Retrieved June 10, 2009 from <http://www.dhs.gov/xingtn/statistics>

- Leighton, K., & Flores, G. (2005). Pay now or pay later: Providing interpreter services in health care. *Health Affairs*, 24(2), 435-444.
- Martinez-Schallmoser, L., Tellen, S., & MacMullen, N. J. (2003). The effect of social support and acculturation on post-partum depression in Mexican American women. *Journal of Transcultural Nursing*, 4(14), 329.
- McCarthy, M. (2001). US mental-health system fails to serve minorities, says US Surgeon General. *The Lancet*, 358, 733.
- National Alliance for Hispanic Health. *Communication is a Quality of Care Issue*. Retrieved February 12, 2010 from [http://www.hispanichealth.org/lep3\\_communication](http://www.hispanichealth.org/lep3_communication).
- Parkman, R. (1986). Current status of bone marrow transplantation. *Cancer*, 58, 569-572.
- Phipps, S., & DeCuir-Whalley, S. (1990). Adherence issues in pediatric bone marrow transplantation. *Journal of Pediatric Psychology*, 15(4), 459-475.
- Rodrigue, J. R., Pearman, T.P., & Moreb, J. (2000). Morbidity and mortality following bone marrow transplantation: Predictive utility of pre-bmt affective functioning, compliance and social support stability. *International Journal of Behavioral Medicine*, 6(3), 241-254.
- Rojas-Guyler, L., King, K.A., & Montieth, B.A. (2008). Health seeking behaviors among Latinas: Practices and reported difficulties in obtaining health services. *American Journal of Health Education*, 39(1), 25-33.
- Shin, H.B., & Bruno, R. (2003). *Language use and English –speaking ability: 2000*. US Census Bureau. Retrieved August 1, 2009 from [www.census.gov/main/www/a2z](http://www.census.gov/main/www/a2z).
- Siegel, P., Martin, E., & Bruno, R. (2001). *Language use and linguistic isolation: Historical data and methodological issues*. Retrieved August 2, 2009 from [www.census.gov/population/socdemo/language/li-final.pdf](http://www.census.gov/population/socdemo/language/li-final.pdf).
- Smart, J. & Smart, D. (1995). Acculturative Stress of Hispanics: Loss and challenge. *Journal of Counseling and Development*, 73, 390-396.
- Suarez-Orozco, M. M., & Paez, M. M. (2008). The Research Agenda (In. Suarez-Orozco, M. M. & Paez, M. M.) *Latinos Remaking America (Introduction)*. Berkeley: The University of California Press.
- The National Council of La Raza (2004). The health of Latino communities in the south: Challenges and opportunities. Retrieved June 21, 2009 from <http://www.nclr.org/content/publications/detail/26898>

Ullrich, C. K., Dussel, V., Hilden, J.M., Sheaffer, J.W., Lehman, L., & Wolfe, J. (2010). End-of-life experience of children undergoing stem cell transplantation for malignancy: Parent and provider perspectives and patterns of care. *Blood*, 115(4), 3879-3885.

US Census (2000). *Race and Hispanic or Latino Origin by Age and Sex for the United States: 2000*. Retrieved August 8, 2009 from [http://www.census.gov/population/www/cen2000/briefs/phc\\_t8/tables/tab08.pdf](http://www.census.gov/population/www/cen2000/briefs/phc_t8/tables/tab08.pdf)

US Census Bureau (2000). *Language Use and English Speaking Ability: 2000*. Retrieved August 8, 2009 from <http://www.census.gov/main/www/a2z>

Attachment A

Clinic/Pharmacy Observation Form

CLINIC/PHARMACY OBSERVATION FORM

VISIT #: \_\_\_\_\_

**ATTACHMENT A**  
CHILDRENS HOSPITAL LOS ANGELES  
DIVISION OF RESEARCH IMMUNOLOGY/BMT  
LANGUAGE BARRIERS STUDY  
(CCI-09-00331)  
PI: LORENA MOCORRO

Subject UPN#: \_\_\_\_\_ Age: \_\_\_\_\_ Date (Month/Yr): \_\_\_\_\_

Sex: F / M

Place of Birth: \_\_\_\_\_ Ethnicity: \_\_\_\_\_

Date Immigrated to the US: \_\_\_\_\_  
Highest educational level completed: Primary / Secondary / Tertiary Other: \_\_\_\_\_

Primary Languages Spoken at Home: \_\_\_\_\_

If Spanish: How much English is Subject able to understand?  
 None  Little  Some  A lot (fluent)

How much English is Subject able to speak?  
 None  Little  Some  A lot (fluent)

Is subject able to write in English? Y / N

Language spoken when communicating with the healthcare providers: \_\_\_\_\_

Language spoken by the healthcare provider with the Subject: \_\_\_\_\_

Was an interpreter needed during this visit? Y / N

Is a medical interpreter provided during this visit? Y / N

Does the Subject request for an interpreter at each visit? Y / N

Who does the interpretation when a hospital medical interpreter is not available? \_\_\_\_\_

Is the Subject able to understand the instructions given by the healthcare provider?

Always  Sometimes  Never

Diagnosis: \_\_\_\_\_ Month and year of Diagnosis: \_\_\_\_\_

Month and year of Transplant: \_\_\_\_\_ Number of Transplant: \_\_\_\_\_

Type of Transplant:

- Autogeneic
- Allogeneic (unrelated / related)
- Bone Marrow
- Umbilical Cord Blood
- Peripheral Blood

Name of Institution where transplant was performed, if different from CHLA:

Name of Transplant Center: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Country: \_\_\_\_\_

Post Transplant Complications:

3/29/10 ver1

Page 1 of 1

- GVHD
- Mucositis
- VOD
- Infections
- Other (specify) \_\_\_\_\_

Do subjects/parents/legal guardian know their medication names and schedule? Y / N  
Is the subject experiencing or has experienced post transplant medical complications? Y / N  
Is the subject able to follow all medical recommendations and medication instructions? Y / N  
Are there medical indicators for lack or poor medical adherence? Y / N

Describe:

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Is the subject able to do the same things he/she did or ate before having a transplant? Y / N  
Describe:

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Notes:

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Attachment B  
Focus Group Form

FOCUS GROUP FORM

VISIT #: \_\_\_\_\_

**ATTACHMENT B**  
CHILDRENS HOSPITAL LOS ANGELES  
DIVISION OF RESEARCH IMMUNOLOGY/BMT

LANGUAGE BARRIERS STUDY  
(CCI-09-00331)  
PI: LORENA MOCORRO

Subject UPN#: \_\_\_\_\_ Age: \_\_\_\_\_ Date (Month/Yr): \_\_\_\_\_

Sex: F / M

Place of Birth: \_\_\_\_\_ Ethnicity: \_\_\_\_\_

Date Immigrated to the US: \_\_\_\_\_

Primary Language: \_\_\_\_\_ Primary Languages Spoken at Home: \_\_\_\_\_

If Spanish: How much English is Subject able to understand?  
 None  Little  Some  A lot (fluent)

How much English is Subject able to speak?  
 None  Little  Some  A lot (fluent)

Is subject able to write in English? Y / N

Language spoken when communicating with the healthcare providers: \_\_\_\_\_

Language spoken by the healthcare provider with the Subject: \_\_\_\_\_

Was an interpreter needed during this visit? Y / N

Is a medical interpreter provided during this visit? Y / N

Does the Subject request for an interpreter at each visit? Y / N

Who does the interpretation when a hospital medical interpreter is not available? \_\_\_\_\_

Diagnosis: \_\_\_\_\_ Month and Year of Diagnosis: \_\_\_\_\_

Month and year of Transplant: \_\_\_\_\_ Number of Transplant: \_\_\_\_\_

Type of Transplant:

- Autogeneic
- Allogeneic (unrelated / related)
- Bone Marrow
- Umbilical Cord Blood
- Peripheral Blood

Name of Institution where transplant was performed, if different from CHLA:

Name of Transplant Center: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Country: \_\_\_\_\_

Post Transplant Complications:

- GVHD
- Mucositis
- VOD
- Infections

3/29/10 ver1

Other (specify) \_\_\_\_\_

What helps subjects communicate with healthcare providers?

\_\_\_\_\_

\_\_\_\_\_

What are subjects' language preferences when communicating with health care providers?

\_\_\_\_\_

What recommendations do subjects provide for increase post transplant recovery and long-term quality of life?

\_\_\_\_\_

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Notes:

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## Attachment C

### Mental Health Referrals

#### **ATTACHMENT C** **Mental Health Referrals**

##### **Catholic Charities of Los Angeles**

1531 James M. Wood Blvd.  
LA, CA 90015  
(213) 251-3495

Provides catholic counseling services.  
Some Spanish speaking staff.

##### **Didi Hirsch Community Mental Health**

4760 S. Sepulveda Blvd.  
Culver City, CA 90230  
(310) 390-6612

Counseling for all ages, group & individuals  
Staff speaks Spanish.

##### **Edelman Westside Mental Health Center**

11080 West Olympic Blvd., First Floor  
Los Angeles, CA 90064  
(310) 966-6500  
Monday-Friday from 8:30 am to 5:30 pm

County Mental Health Center. Individual, group &  
family therapy. Psychological evaluations & medication  
provided. Serves children with special needs.  
Some Spanish speaking staff.

##### **El Centrito De Apoyo**

2677 Zoe Avenue, Suite 303-B  
Huntington Park, CA 90255  
(323) 312-0640

Provide peer support groups for adults.  
Staff speaks Spanish.

##### **El Nido Family Centers**

10200 Sepulveda Blvd., Suite 350  
Mission Hills, CA 91345  
(818) 830-3646

Provides counseling, family life education and service  
Coordination to children, adolescents & families.  
Staff speaks Spanish.

**Maple Counseling Center**

9107 Wilshire Blvd., Lower Level  
Beverly Hills, CA 90210  
(310) 271-9999

Provides individual, couples, family and group therapy for all ages. Sliding scale from \$1.

**Southern California Counseling Center**

5615 West Pico Blvd.  
Los Angeles, CA 90019  
(323) 937-1344

Provide individual and family therapy. Intake fee \$20.  
Monday-Thursday 6:00 pm and 8:00 pm (first come first served basis)  
Saturday intakes from 12 pm to 2pm  
Children under the age of 18 years will be seen by appointment only.  
One Spanish speaking counselor available.

**Westside Children's Center**

Family Support Services  
12049 West Jefferson Blvd.  
Culver City, CA 90230  
(310) 578-1750  
Monday-Friday from 8:30 am to 5:30 pm

Home and center-based family & child therapy.  
Staff speak Spanish.

## Attachment D

### Culture and Language Barriers Study Information

#### ATTACHMENT D

##### Culture and Language Barriers Study Information

Attention: Health Care Provider

You are being asked to participate in a research study conducted by Lorena Mocerro, MSW student from Smith College School for Social Work. This research is sponsored by Dr. Ami Shah from Bone Marrow Transplant and Research Immunology at Childrens Hospital Los Angeles.

The purpose of this study is to examine communication patterns between post transplant Latino recipients between the ages of 13-21, who have undergone either an allogeneic or autologous transplant, their parents and health care providers to determine if culture and language barriers impact medical adherence and post transplant recovery and long term quality of life among transplant recipients and their parents/legal guardian.

The study design has two parts. You will be asked to participate in Part I of the research. Part I will be conducted at the BMT outpatient clinic during transplant recipients and their parents/legal guardian post transplant visits with their doctor and nurse. Your verbal authorization to have these visits observed and audio recorded is needed to execute the study. Other visits to be observed and audio recorded are the transplant recipients and their parents/or legal guardian interaction with Walgreen's pharmacy providers located at CHLA Outpatient Tower. Part II of this study will involve parents/ legal guardians and patients.

The study researcher prior to conducting the clinic observation and pharmacy visits will telephone the transplant recipients, parents, doctor, nurses and pharmacy provider to confirm participation. The participants' health care services will not be compromised in any way and the transplant recipients medical needs will continue as medically recommended by their health care providers. If you decide to participate in this study, your verbal consent is required before the researcher's observation and audio recording of the BMT outpatient clinic and pharmacy visits. Your participation is voluntary and you may decline to participate without jeopardizing your employment at CHLA.

If you have any questions or concerns please feel free to contact Lorena Mocerro at (323) 361-2546 at Childrens Hospital Los Angeles Department of Research Immunology/Bone Marrow Transplant.

Date of Preparation: 3-23-10

## Attachment E

### Childrens Hospital Los Angeles Notice of Approval of Protocol

Page 1 of 2



Tue Mar 30 11:43:51 2010

To: [Lorena Moco](#)  
BONE MARROW TRANSPLANT AND RESEARCH IMMUNOLOGY - CHLA

[Connie Jackson](#)  
BONE MARROW TRANSPLANT AND RESEARCH IMMUNOLOGY - CHLA

From: Alan B. Lewis, M.D.  
Vice-Chair, Committee on Clinical Investigations, MS# 23

Re: CCI-09-00331 [Lorena Moco](#)  
Assessing The Impact of Culture and Language Barriers Among Latino/a Bone Marrow Transplant Patients and Their Parents. ([Language Barriers](#))

Expiration Date: **3/29/2011**

#### NOTICE OF APPROVAL OF PROTOCOL

Document(s) Reviewed and/or Approved:

- iStar Application (dated 3/29/10)
- Data Collection Form- Clinic/Pharmacy observation form (dated 3/29/10)
- Data Collection Form-Focus Group Form (dated 3/29/10)
- Health Care Provider Letter (dated 3/23/10)
- Smith College School for Social Work IRB approval letter (dated 3/28/10)
- Patient Consent-Permission-Assent Form (dated 3/29/10)
- Parent Consent Form (dated 3/29/10)

Thank you for your submission to the CCI office. The above named study was reviewed in an expedited manner on **3/30/2010** (45 CFR 46.110, Federal Register categories 6 and 7). The Committee is pleased to inform you that your study has been approved (45 CFR 46.404/21 CFR 50.51 ). The copies of the stamped approved consent documents can be found under the documents tab of the protocol workspace. Only informed consent documents with the CCI approval stamp may be used.

As a reminder, please note the following conditions for conduct of this study:

1. Adequate provisions should be made for soliciting the assent of the minor child subject and the permission/consent of at least one parent or guardian. Please note that the person obtaining informed consent must also sign the informed consent document at the time consent is obtained.
2. One copy of the signed informed consent document and *Experimental Subject's Bill of Rights* and the HIPAA Authorization Form for Research should be placed in the subject's Childrens Hospital Los Angeles Medical Record, one copy of each should be given to the subject/ parent, and one copy of each should be kept by the principal investigator in a research study file. CCI approval is not necessary for the HIPAA Authorization forms, as long as the standard template remains unchanged. Any changes proposed to the HIPAA forms must be submitted to the CCI for



approval. Please see the CCI Website for further information on HIPAA or contact the CCI Office with any questions at 323-361-2265.

3. Only the principal investigator, co-investigators, and other persons specifically designated in the protocol may obtain informed consent from potential subjects. All must be *Certified* by the CCI that they have received education in protecting human research subjects.
4. In order to protect confidentiality of research subjects, investigators are strongly encouraged not to have personal identifying information (name, CHLA#, etc.) on data sheets. Data should be coded, with the key linking code numbers to subjects' identities kept in a separate locked file.
5. The principal investigator is required to report to the CCI any unanticipated adverse events or serious problems encountered by a subject enrolled in any human research protocol within five working days (*45 CFR 46.103[b][5]*).
6. Research performed in this protocol cannot be changed or altered without CCI approval. Any change or amendment to the protocol or informed consent document must be reviewed and approved by the CCI before the change can be implemented.
7. After considering the relative risks and benefits of this study, the CCI will require continuing review of the progress on this study on the expiration date indicated above.
8. Your study will expire on the expiration date noted above. In order to continue your study beyond the expiration date, a *Progress Report for Continuing Review* must be received by the CCI Office at least 8 weeks before the expiration date, and continuation of the study must be approved by the CCI. Similarly, a *Final Report* must be submitted when you close your study.
9. Childrens Hospital Los Angeles (CHLA) is committed to protecting the rights and welfare of human research subjects in all human research which is: 1) sponsored by CHLA; 2) performed by CHLA faculty or staff; 3) performed using CHLA facilities; and/or 4) performed using CHLA patients or nonpublic information about CHLA patients. The Committee on Clinical Investigations (CCI) is the institutional review board at CHLA. The CCI is organized and operates according to Federal regulations (*45 CFR 46* and *21 CFR 56*) and ethical principles. CHLA has negotiated a *Federal-Wide Assurance* (00001914) with the Office for Human Research Protections. Further, the CCI is organized and operates according to California regulations and *Good Clinical Practice* guidelines of the *International Conference of Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)*.

This memorandum constitutes official approval by the CCI to conduct your study.

If you have any comments or questions, please do not hesitate to contact the CCI Office or me at ext 12265. Thank you very much for helping to protect the rights and welfare of human research subjects at Childrens Hospital Los Angeles.

This is an auto-generated email. Please do not respond directly to this message using the "reply" address. A response sent in this manner cannot be answered. If you have further questions, please contact your IRB Administrator or IRB/CCI office.

The contents of this email are confidential and intended for the specified recipients only. If you have received this email in error, please notify [istar@usc.edu](mailto:istar@usc.edu) and delete this message.

Attachment F

Smith College School for Social Work HSR Approval Letter



Smith College  
Northampton, Massachusetts 01065  
T (413) 585-7950  
F (413) 585-7094

March 28, 2010

Dear Lorena,

Your application and attached materials have been reviewed by the Human Subjects Review Committee at the Smith College School for Social Work. Children's Hospital completed a very extensive review and we concur with their decision. We approve your study.

*Please note the following requirements:*

**Consent Forms:** All subjects should be given a copy of the consent form.

**Maintaining Data:** You must retain all data and other documents for at least three (3) years past completion of the research activity.

*In addition, these requirements may also be applicable:*

**Amendments:** If you wish to change any aspect of the study (such as design, procedures, consent forms or subject population), please submit these changes to the Committee.

**Renewal:** You are required to apply for renewal of approval every year for as long as the study is active.

**Completion:** You are required to notify the Chair of the Human Subjects Review Committee when your study is completed (data collection finished). This requirement is met by completion of the thesis project during the Third Summer.

Good luck with your project.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Ann Hartman'.

Ann Hartman, D.S.W.  
Chair, Human Subjects Review Committee

CC: Narviar Calloway, Research Advisor



# Attachment G

## Childrens Hospital Los Angeles HSR Application

Print: CCI-09-00331 - Language Barriers

Page 1 of 22



iStar ID: CCI-09-00331

Application Version Date: 3/29/2010  
Version: 1.7

Date: Sunday, May 30, 2010 9:47:50 AM

[Print](#) [Close](#)

### 1. Project Identification Information

#### 1.1. \* Type of Submission:

- Research Protocol or Study  
 Grant/Contract Only  
 Facilitated Review (NCI CIRB)  
 USC/CHLA Collaborative Review

#### 1.2. \* Full Title of Research Protocol

Assessing The Impact of Culture and Language Barriers Among Latino/a Bone Marrow Transplant Patients and Their Parents.

#### 1.3. \* Short Title

Language Barriers

1.3.1. (HSC/CHLA only) If there is a sponsor protocol number associated with this file, specify it here:

#### 1.4. \* Please indicate which IRB you are requesting review from:

Childrens Hospital Los Angeles (CHLA)

iStar ID: CCI-09-00331

Application Version Date: 3/29/2010  
Version: 1.7

### 2. Study Personnel

#### 2.1. Study Personnel and their roles:

Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent
<a href="#">View</a> Mocco	Lorena	BONE MARROW TRANSPLANT AND RESEARCH IMMUNOLOGY - CHLA	Principal Investigator	HS	yes
<a href="#">View</a> Daluro	Laure	BONE MARROW TRANSPLANT AND RESEARCH IMMUNOLOGY - CHLA	Research Coordinator	HS	no
<a href="#">View</a> Jackson	Connie	BONE MARROW TRANSPLANT AND RESEARCH IMMUNOLOGY - CHLA	Research Coordinator	HS	no

#### 2.2. Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar?

Yes  No

#### 2.2.1. Please designate a Faculty Advisor:

[Ami Shah](#) HS Certification: Current (8/11/2011)

2.3. If there are any individual collaborators from other institutions, check here:

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
Version:1.7

### 2a. Collaborators from other institutions

*This screen is required if there are collaborators from other institutions (Question 2.3.)*

Collaborators from other institutions:

Last Name	First Name	Institution	Role
<a href="#">[View]</a> Calloway, PhD	Narviar	Smith College School for Social Work	Thesis Advisor

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
Version:1.7

### 3. Required Department Approvals (for a study already submitted to the IRB)

*This screen indicates the division/department approvals received once the proposal has been submitted. This screen is not required during presubmission and should be left blank.*

3.1. Pending Division/Department Approvals:  
Name Division/Department Parent Campus  
There are no items to display

3.2. Received Division/Department Approvals:

Name	Division/Department	Parent Campus
BONE MARROW TRANSPLANT AND RESEARCH IMMUNOLOGY - CHLA	Division	Childrens Hospital Los Angeles (CHLA)
PEDIATRICS - CHLA	Department	Childrens Hospital Los Angeles (CHLA)

3c.3. (CHLA Only) Other CHLA hospital committees that will need to review and approve this protocol:  
Committee Name Committee Chair Approval Memo  
There are no items to display

3c.4. (CHLA Only) Are you planning to submit this study to the GCRC for review?  
 Yes  No

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
Version:1.7

### 4. Type of Study Review

4.1. Please indicate the type of review that you are requesting for this study:  
[Expedited Review](#)

4.2. (HSC or CHLA Only) Attach the protocol or sponsor's template informed consent. For

simple investigator initiated studies, a separate protocol may not be necessary. However, larger, complex, or multi-site studies require a fully developed protocol. If you have questions contact the IRB office to discuss.

name Version Modified  
 There are no items to display

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
 Version:1.7

#### 4a. Type of Study Review - Expedited Review

*This screen is required if you are requesting an expedited review for this study (Question 4.1.)*

4.1. Please indicate the type of review that you are requesting for this study:  
[Expedited Review](#)

4a. If you checked expedited review, please choose the applicable category from the list and attach your data collection forms below (click on the abbreviated category to receive the full description):  
 Short Description (click for full description)

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met...
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture...
- (3) Prospective collection of biological specimens for research purposes by noninvasive means...
- (4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves...
- (5) Research involving materials that have been collected, or will be collected solely for nonresearch purposes...
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies...

4a.1. If you checked expedited review category 5, please attach a copy of the data collection forms, if applicable:

name	Version	Modified
<a href="#">CCI ATTACHMENT A</a>	0.03	3/29/2010 3:18 PM
<a href="#">CCI, ATTACHMENT B</a>	0.03	3/29/2010 3:18 PM

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
 Version:1.7

#### 5. Study Location(s)

5.1. Indicate the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

- Location
- HSC - Health Sciences Associated Locations
  - UPC - University Park Associated Locations
  - CHLA
  - Other Sites/Institutions (In the US)

Other Sites/Institutions (Outside the US)

5.2. (HSC or CHLA only) Is this a multi-site study?

Yes  No

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
Version:1.7

### 8. Funding Information

8.1. Are you or the institution receiving any financial support for the conduct of this study?

Yes  No

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
Version:1.7

### 9. Methods and Procedures - Selected Descriptors

Note: Each list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. \* Social-Behavioral Procedures (check any or all that apply):

Specific Descriptor

- Behavioral Observations and/or Behavioral Experimentation
- Behavioral Interventions
- Deception
- Interview/Focus Groups
- Population-based Field Study
- Psychophysiological Testing
- Surveys/Questionnaires/Psychometric Testing
- Other Social-Behavioral Procedures
- None of the above Social-Behavioral Procedures apply to this study.

9.2. \* Medical Procedures/Considerations (check any or all that apply):

Specific Descriptor

- Biohazardous Substances
- Controlled Substances
- Emergency Treatment
- Gene Transfer Study
- Stem Cell Research
- Magnetic Resonance Imaging (MRI)
- Investigational/Approved Drugs and Biologics

- Investigational/Approved Devices
- Radiation exposure other than clinically indicated tests and/or therapy
- Radionuclides
- Substance Abuse Treatment (with medication)
- Surgery
- Venipuncture
- Other Medical Procedures/Considerations
- None of the above Medical Procedures/Considerations apply to this study.

9.3. \* **Data Collection Types (check any or all that apply):**  
**Specific Descriptor**

- Banking of Specimens/Data (Creation of a repository)
- Prospective Collection of Specimens/Data
- Genetic Specimens
- Audio/Video Recordings or Photographs
- None of the above Data Collection Types apply to this study.

9.4. \* **Does this study involve the use of existing/retrospective data/specimens?**

- Yes  No

9.5. \* **Is this project a trial of a drug, biologic, or device that is initiated by the investigator?**

- Yes  No

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
Version:1.7

## 10. Characteristics of the Study Subject Population

10.1. **What is the maximum number of subjects you plan to recruit for this site? (Integer values only)**

12

10.1.1. **If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)**

10.1.2. **Please provide further explanation of accrual goals, if necessary.**

10.2. **Indicate the inclusion criteria for enrollment. (HSC: refer to specific sections of the protocol/grant, if applicable)**

1. Patients must be 13-21 years of age.
2. Patients and their parent (s) are of Latino/Hispanic descent from a Latin American country who have immigrated or have been born in the United States.
3. Are monolingual in Spanish or bilingual in English and Spanish.
4. The patient has received either an allogeneic (the stem cells are from related or unrelated person called a donor or autologous (the stem cells are from the patient) bone marrow transplant from bone marrow, cord



- blood or hematopoietic stem cell transplant (HSCT) as treatment for the patient's disease.
5. One or both parents/legal guardian will be able to participate in the study.
  6. One or both parents may participate in the study with or without their child or young adult enrolled in the study.
  7. The transplant recipient may participate in the study without the participation of their parent, parents or legal guardian.
  8. The patient has been discharged from Childrens Hospital Los Angeles (CHLA) and is currently followed at BMT outpatient clinic for post transplant care.
  9. Patients are medically stable.

**If needed, please upload any tables at item 40.1 and reference in the question above.**

**10.3. Indicate the exclusion criteria for enrollment. (HSC: refer to specific sections of the protocol/grant, if applicable)**

1. Patients are not medically stable.
2. Patients and parents are not able to participate in both parts of the medical and pharmacy observation clinic visits and the focus groups.

**If needed, please upload any tables at item 40.1 and reference in the question above.**

**10.3.1. If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.**

Due to this study's specific objective in determining if Latino and Hispanic culture and language barriers impact medical adherence and quality of life among adolescent and young adult bone marrow transplant recipients and their parents, this study has excluded other ethnicities. The population in this study has targeted to include Latino or Hispanic participants who have immigrated or have been born in the United States and are of Latino or Hispanic descent. The study participants are either the parents of bone marrow transplant recipients or are the transplant recipients between the ages of 13 and 21 years of age and are monolingual in Spanish or bilingual in both English and Spanish. Both males and females are included in the study.

iStar ID: CCI-09-00331

Application Version Date:3/29/2010  
Version:1.7

## 11. Study Summary

**11.1. Abstract: The abstract should provide a simple explanation of the study and should have 1 or 2 sentences written to address each of the following points: background and rationale; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; intervention and follow-up; statistics and plans for analysis.**

The purpose of the proposed study is to examine correlations between culture with particular emphasis in language barriers and medical adherence among Latino/Hispanic parents and patients that are female and male teenagers between the ages of 13 to 21 who have undergone either autologous or allogeneic bone marrow transplant and are monolingual in Spanish or are bilingual in both English and Spanish. A sample size of 10 to 12 voluntary participants will be enrolled in the study. Findings from the study will address how culture impacts medical adherence among Latino teenagers and their parents, and specifically how language barriers a specific component of culture impacts the process of medical adherence and post transplant long-term quality of life. Please see Attachment D, which includes a Healthcare Study Information Letter.

**11.2. Research objectives and background**

**11.2.1. Describe the specific objectives or aims of the study and hypotheses or research questions. (HSC: refer to specific sections of the protocol/grant, if applicable)**

The central focus of the study will examine if culture and language barriers impact medical adherence and post transplant quality of life among the study participants.  
The specific research objectives for this study are to:

1. Define if culture and language barriers impact the participant's communication and adherence to health care providers medically recommended medications and treatments post transplant.
2. Measure the impact of culture and language barriers on post transplant recovery and long term quality of life.
3. Determine what effective patterns of communication between study participants and health care providers may help provide recommendations and educational information that help improve post transplant recovery and long term outcomes.

**11.2.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations. (HSC: refer to specific sections of the protocol/grant, if applicable)**

There are many variables that affect medical adherence among Latino teenagers within the health care systems. In a qualitative study conducted by the National Council of La Raza (NCLR), (2004). NCLR reported that health care gaps in the population of Latinos contributed to un-insurance, immigration status, discrimination in the delivery of services, lack of knowledge regarding available resources, lack of trust in medical system, lack of transportation to health care agencies and lack of available interpreters. Other studies (Flores, et al., (2002); Hoefner, et al., (2007); and Lee, et al., (2009) support these findings. Language barriers however consistently proves to be the primary variable in determining access to health care services for Latinos, and in their ability to communicate with health care personnel. Failure to effectively communicate or to understand medical personnel can lead to other negative consequences such as non-medical adherence. This is especially true among minority groups and Latinos whose primary language is not English. Culture and language barriers obstacles among many vulnerable populations are well documented; and when medical adherence is critical to long-term survival and quality of life, language communications may be the difference between life and death. The proposed study will examine if culture and language barriers impact medical adherence and quality of life among parents (s) and male and female Latino bone marrow transplant teenagers ages 13-21 who have undergone either an autologous or allogeneic transplant.

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## 12. Methods and Procedures - Prospective Studies

**12.1. Describe in detail the design and methodology of the study. If applicable, include information on stratification or randomization plans. Identify and distinguish between those procedures that are standard of care and those that are experimental. Include the frequency and duration of each activity and the total length of subject participation. (HSC: refer to specific sections of the protocol/grant, if applicable)**

The proposed study will examine if culture and language barriers impact medical adherence and quality of life among parent (s) and male and female Latino bone marrow transplant children ages 13-21 who have undergone either an autologous or allogeneic transplant.

The study design has two parts. Part I includes behavioral observations and part II includes focus groups.

### Part I- Outpatient clinic and/or Walgreen's Pharmacy Observation

-The study investigator will observe a maximum of two bmt outpatient medical clinic visit interactions and communication between the study participants and the participants doctor, nurse and/or Walgreen's pharmacy visit located at Childrens Hospital Outpatient Tower.

-The study investigator will observe the participants bmt outpatient medical clinic visits for the duration of their scheduled appointment and/or pharmacy visit ranging from 15 minutes to 1hour, and will not exceed more than a total of 2 visits during the study.

-Study participants are not required to attend additional outpatient clinic visits.

-The study investigator will meet the participants at their scheduled bmt doctor and nurse outpatient clinic visit and/or when participant's visit Walgreen's pharmacy.

-The study investigator prior to each clinic observation visit will contact you.

### Part II-Focus Groups

-Study participants will be asked to participate in post transplant outpatient focus groups held at Childrens Hospital Los Angeles (CHLA)

-The groups will be held on Saturday and will not exceed more than two group meetings in a total of four

months and the meetings will be for the duration of 1 hour.

-The group dialogue will be guided by study questions developed by the investigator.

Both Part I, the outpatient clinic/pharmacy observation visits and Part II, the focus groups will be audio recorded to ensure accuracy.

**If needed, please upload any tables at item 40.1 and reference in the question above.**

**12.2. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. (HSC: refer to specific sections of the protocol/grant, if applicable)**

Enrollment: clinical data includes, ethnicity, age, self reported primary (native) language, medically stable and type of transplant.

Data collection phase: The study's planned data collection will be through two modes: (1) outpatient clinic and Walgreen's pharmacy encounters observation visits; and (2) focus groups

Data to be collected will include audio-recorded outpatient observations of communication and interactions between transplant recipients, parents and health care provider from BMT and Walgreen's pharmacy both located at CHLA Outpatient Tower and audio recordings from focus groups where study participants interact with one another during open group dialogue. Both the BMT outpatient clinic and/or pharmacy visits and the information collected from the focus groups will be audio recorded and documented to ensure accuracy.

Audio recordings will be transcribed and the paper data and documented data (field notes) will be collected during participant's outpatient BMT clinic or pharmacy visit and during the focus group meetings.

Qualitative analysis of the data will take place after each behavioral observation and/or pharmacy visits and focus group meetings. Summarized results will be reviewed in detail through analytic induction (observations) of both latent and manifest content of analysis.

The specific outcomes of the study will (1) define if culture and language barriers impact transplant recipients and their parent's communication and adherence to health care providers recommendations. (2) Measure the impact of culture and language barriers post transplant recovery and long-term quality of life and finally the outcomes will be able to (3) provide effective patterns of communication between study participants and health care providers that will improve post transplant recovery and long-term outcomes.

Pending IRB approval, most of the data collection will take place between March 5, 2010 and April 15, 2010.

**If needed, please upload any tables at item 40.1 and reference in the question above.**

**12.3. Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable. (HSC: refer to specific sections of the protocol/grant, if applicable)**

The estimated study population will be a maximum of 12 bone marrow transplant recipients and their parents who will participate in the two part study which includes (1) BMT outpatient clinic and/or pharmacy visits and (2) focus groups. An estimated total of 36 encounters with study participants will be collected. This number is believed to be an adequate number to establish if culture and language barriers among Latino/Hispanics impact medical adherence post transplantation recovery and long-term quality of life.

In the proposed study the investigator will define and measure if culture and language barriers impact post transplant medical adherence, recovery and long-term quality of life. Each outpatient clinic and/or pharmacy visits, focus group meeting, documented data and audio recording will be analyzed.

The qualitative data will be analyzed through analytic induction (observations) of both latent and manifest content of analysis. The investigator will use the clinic/pharmacy observation and the focus group data



collection forms to gather data (Attachments A & B). Intra-transcript (field notes) analysis will also be used during the focus groups to maintain and coordinate themes as well as to note commonalities and differences among participants. The outpatient clinic/pharmacy encounters will be categorized based on communication and interactions between study participants and health care providers, participants' medical adherence and post transplant quality of life. The focus group data will be analyzed by the groups dialogue and by study guided questions that will be provided by the study investigator (see Attachment B). The collected data will also be categorized between common discussed group themes and differences of reported participants experiences.

The researcher will examine patterns, links, and relationships within the data while conducting constant comparisons. This will involve categorizing, the data and continuously examining the data for patterns until there are few or no new categories of data encountered.

Findings will reveal a comprehensive view of the impact of culture and language barriers on medical adherence and post transplant recovery and long term quality of life among this study's transplant recipients and their parents/legal guardian.

If needed, please upload any tables at item 40.1 and reference in the question above.

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### 19. Methods and Procedures - Interview/Focus Groups

*This screen is required if you indicated the use of Interview or Focus Groups under social-behavioral procedures (Question 9.1.)*

**19.1. Attach copies of any scripts and/or questions that will be used to guide the interviews/groups.**

name	Version	Modified
CCI, ATTACHMENT B	0.01	3/5/2010 9:30 PM

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### 22. Special Subject Populations

**22.1. Special Subject Populations (Check all that apply).**

Population
<input type="checkbox"/> Normal Volunteers
<input type="checkbox"/> Employees
<input type="checkbox"/> Students
<input type="checkbox"/> Adults not Competent to Consent
<input checked="" type="checkbox"/> Non-English Speaking Populations
<input checked="" type="checkbox"/> Minors (subjects under 18 years of age)
<input type="checkbox"/> Pregnant Women, Human Fetuses, or Neonates
<input type="checkbox"/> Prisoners/Detainees
<input type="checkbox"/> Wards

None of the above

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## 22d. Special Subject Populations - Minors

*This screen is required if you indicated Minors (subjects under 18 years of age) as a special subject population (Question 22.1.)*

### 22d. If you selected Minors, answer the questions below.

#### 22d.1. Provide a justification for involving minors in this research.

-The majority of the patients who receive hematopoietic stem cell transplant (bone marrow transplant) are children under the age of 18 years of age.

-The parent (s) and/or legal guardians of minors participating in the study will be fully informed of the purpose, risks and benefits of the study.

-Participant's who are minors will be asked to sign assent forms.

-The parent (s) and/or legal guardians will be provided with the opportunity to ask questions and express any concerns related to the study.

#### 22d.2. Choose the proposed category of permissible research with children.

##### Category

- a. 46.404 - Research not involving greater than minimal risk.
- b. 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- c. 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- d. 46.407 - Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
- None of the above categories; Minors will not participate in this study.

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## 23. Subject Identification and Study Resources

### 23.1. Describe the method(s) by which subjects will be identified, eligibility will be determined, and by whom.

The bone marrow transplant recipients and their parents will be identified to participate in the study by the co-faculty advisor, who is a transplant program attending physician and is familiar with the pool of patients who have undergone transplantation and is aware of the recipients health status and condition. Additional participants will be identified by word of mouth and referrals from the bone marrow transplant clinical team.

Prior to the participant's enrolling in the study they will be asked to sign study consent and/or assent.

### 23.2. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient.

-The investigator will remain flexible to the participant's scheduled outpatient clinic visits and will be available to conduct the research.

-A maximum of two outpatient observation clinic visits per participant will be completed varying in the length of time from 15 minutes to 1 hour per visit.

-Focus groups will be held for one hour and will take place on two Saturday's for the duration of 1 hours per group meeting.

**23.3. Describe the staff and justify they are adequate in number and qualifications. If this study involves interviews, focus groups and/or assessments, please also identify the specific members of the study team responsible for conducting the interviews/focus groups and/or administering the assessments in your response.**

The study faculty advisor and the investigator are trained and are qualified to conduct this study.

**23.4. Describe the study facilities and justify they are adequate.**

The study facilities that will be used in the study are the outpatient bmt clinic and Walgreen's pharmacy located at CHLA Outpatient Tower. Both of these facilities are adequate for the observation part of the study. The second part of the study which includes two focus groups will be held at the Smith Tower 4th floor conference room at CHLA. The facility will provide study participants with adequate room space as well as privacy for information discussed in each group.

**23.5. Describe how staff and others will receive necessary information and training to assist in the conduct of this study.**

The study investigator will provide bmt clinic doctors, nurses, pharmacists and other health care providers with detailed information and inservice regarding the study. The investigator will also remain available to address any questions and/or concerns.

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**24. Subject Recruitment**

**24.1. Recruitment Tools (Check all that apply):**

- | Tool   |
|--|
| <input type="checkbox"/> E-mail/Electronic Mailing List            |
| <input type="checkbox"/> Flyers                                    |
| <input type="checkbox"/> Letters                                   |
| <input type="checkbox"/> Newspaper/Magazine Advertisements         |
| <input type="checkbox"/> Radio/Television Announcements            |
| <input type="checkbox"/> Subject or Participant Pool               |
| <input type="checkbox"/> Telephone Scripts                         |
| <input checked="" type="checkbox"/> Verbal (Personal Solicitation) |
| <input type="checkbox"/> Website                                   |
| <input type="checkbox"/> Other                                     |
| <input type="checkbox"/> None of the above                         |

**If Other Recruitment Tool, please specify:**

**24.1.1. If Other Recruitment Tool, please specify:****24.2. Attach copies of all recruitment tools indicated above.**

name	Version	Modified
There are no items to display		

**24.3. Describe in detail all recruitment strategies for each participant group (including controls) involved in this study. Explain who will approach the participants, how and when the participants will be approached, and what will be said.**

-Recruitment of subjects will be through the assistance and referral of Dr. Ami Shah who is a transplant program attending physician and is familiar with the pool of patients who have received a hemopoetic stem cell transplant. Other referrals will be by word of mouth from the bone marrow transplant clinical team which includes, physicians, nurses and other bone marrow transplant staff.

-The study investigator will approach the potential participants once they have been identified by Dr. Ami Shah. The investigator will explain the purpose, benefits and risks of the study while specifying that the study is entirely VOLUNTARY and will not interfere with any medical treatments the transplant recipient is or will receive.

**24.4. What measures will be taken during the recruitment and consent process to safeguard against potential coercion or the appearance of coercion?**

-The investigator will present to the bone marrow transplant recipient's and their parent (s) and/or legal guardian that study participation is entirely VOLUNTARY and their decision will not affect current or continued medical treatments.

-The bmt recipient's, parent (s) and/or legal guardian will be provided with ample time to decide if they wish to participate in the study. They will also be provided with ample time to review the consent forms and ask any questions. Questions and/or concerns will be addressed by the study investigator.

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Version:1.7**25. Financial Obligation and Compensation****25.1. Financial Obligation: Describe any financial obligations that the subject may incur as a result of participating in the study. Indicate which costs will be covered by the study.**

There are no financial obligation to the study participants. All study services will be done free of charge.

**25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.**

The participants will not be offered nor receive payment for participation in this study.

**25.3. Emergency Care, Injury and Compensation for Injury: For studies of greater than minimal risk, if participants require care, medical services, or psychological services as a consequence of the research, Who will provide this care? If applicable, describe who will pay for research-related injuries.**

The study does not have more than minimal risks involved, however, in the event that participants experience emotional discomfort or stress related to how he/she deals with events in their life or when talking about health outcomes, there will be a referral list of free and low cost counseling provided to each participant.



The investigator and CHLA are not able to offer financial compensation or absorb the costs of treatment should there be an injury as a result of participating in this study.

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## 26. Participant Privacy and Data Confidentiality

### 26.1. Describe the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research. (e.g. consenting/screening subjects in a private office or area versus a busy hospital waiting room). NOTE: See guidance link for definition of privacy and examples.

Study subjects will be consented to participate in this voluntary study when they are scheduled for post-transplant follow up clinic visits with their doctor, nurse and Walgreen's pharmacy. The consent process will take place at the outpatient exam rooms where subjects will have privacy from public areas where confidentiality is less private.

Privacy and confidentiality will also be provided to study participants during the focus groups and the outpatient behavioral observation visits at the BMT clinic. The focus groups will be held at the Smith Research Tower, 4th floor Conference Room at CHLA. The location of the conference room will provide participants with adequate room space and privacy from public areas. The conference room will be closed to only study participants that have been consented and assented to participate and they at the start of each focus group meeting will be reminded of the importance to maintain privacy and confidentiality of group discussions from the general public. Participants will be informed that conversations outside of the group meetings should not be shared outside of the focus groups. Once participants acknowledge and agree to the groups standards for privacy, the group will start.

The BMT outpatient clinic observation visits between the participants, doctor, nurse and pharmacy provider will take place at the BMT outpatient examination room and at Walgreen's pharmacy. The examination rooms will provide the study participants, and the health care providers with privacy and confidentiality from public areas. The pharmacy visits will be conducted during the participants interaction with pharmacy providers and the observations will only be carried out if the participants feel comfortable that their privacy is being protected from the general public.

Participants will be referred to by name in both the outpatient clinic and pharmacy observation visits and during the Focus groups.

The data collected will be coded with assigned unique subject numbers to ensure identification protection, privacy and confidentiality.

The investigator prior to the participants outpatient BMT visit will telephone 2-3 times to confirm their participation. If telephone contact is not made with the participants, the investigator will attempt to make 1 in person contact. The investigator will further confirm observation visit with the participants doctor, nurse and pharmacy providers to ensure that participants medical care is not in any way jeopardized or delayed and participants are provided with privacy and confidentiality. In the event that participants, doctor, nurse and pharmacy providers request to have the observation visit rescheduled, the investigator will remain available to reschedule to another BMT clinic day.

The investigator will telephone participants prior to each scheduled focus group to confirm their attendance. The focus group meeting dates will be scheduled based on the majority of the participants' availability. The meetings will be scheduled on two Saturdays for the duration of 1 hour.

### 26.2. How will the data be recorded to protect personal confidentiality (select one)?

Coded (Data will be linked to subjects with a code)

#### 26.2.1. If Other is selected, please specify.

### 26.3. How will the data be recorded and stored? Please specify the physical location and describe how data will be secured to protect confidentiality.

The data that is collected will be given a unique subject number code. The same unique number will be used for the outpatient clinic/pharmacy and focus groups and will adhere to local, State and Federal privacy laws.

The research data will be stored at the Division of Research Immunology and BMT Clinical Research Office

Smith Tower, 4th floor. The office is locked and secure at all times and only authorized personnel are provided access.

Electronic data will be contained in a secure password protected database. Transcribed audio recordings and paper documentation will be secured under lock and key by the Clinical Research office staff at the Division of Research Immunology and BMT.

Data collected from the study will be audio recorded and documented to ensure accuracy. The audio recording will be used for educational purpose and the participants identity will be number coded to protect and disguise them.

Paper data that is transcribed from the audio recordings from the outpatient behavioral clinic/pharmacy observation visits and focus groups will be destroyed after they are no longer needed or when the study is completed.

The unique number code identifiers and master code key identifier list will also be destroyed as soon as no longer needed or once the study is completed. Paper data that is transcribed from digital or audio tape recordings, and any other paper data collected will be kept for six years after the study is closed by the IRB. The anticipated date to have the paper, digital or tape audio recording transcriptions destroyed by either shredding and/or erasing will be no later than December 31, 2016 or earlier if the data is no longer needed.

**26.4. Who, other than the specified study team, will have access to the study records or data? Specify their name, role and affiliation. Do not list study personnel already listed on screen 2.**

**Name Role Affiliation**

There are no items to display

**26.5. If coded or identified data will be released, specify the persons, agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will maintain confidentiality.**

The data will be released to Smith College School for Social Work and the coordinating thesis advisor, Narviar Calloway, PhD, using the unique identifier number code. No other identifying information will be used to link the data to the subject

**26.6. Describe what will happen to the data or data set, when the study is completed. Please indicate your plans for destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable.**

The audio recordings from the outpatient clinic and the focus groups will be electronically maintained and password protected. In the event that audiotapes are used, the tapes or the digital audio recordings will be transcribed and the transcription and any other paper documentation that is collected will be maintained and protected under lock and key for six years at the Division of Research Immunology and BMT Clinical Research Office. The digital or audio tape recordings will be destroyed once they have been transcribed.

The digital audio recordings will be electronically maintained and password protected and the digital or tape recordings will be destroyed after they have been transcribed. The transcribed digital or audio tape recordings from the outpatient BMT clinic, pharmacy and focus groups will be stored under lock and key at the Division of Research clinical office where only authorized personnel have access. The transcribed digital audio recordings and audiotapes will be maintained and protected for six years. After the approximated date of December 31, 2016 the transcribed digital or audiotape recording data will be destroyed.

The digital or tape recordings from both Part I of the outpatient observation clinic/pharmacy visit, and Part II, focus groups will be destroyed once the data collected has been transcribed.

The audio recordings and documented data from the outpatient clinic, pharmacy and focus groups will be provided a unique subject number code as it is collected to protect privacy and maintain the participants confidentiality. The investigator will maintain a master key log with the assigned unique subject number code and participants personal identifiers. The master log will be maintained under lock and key at the Division of Research clinical office until no longer needed or when the study is completed. Only the study investigator will have access to this information. Once the study is completed the unique number code identifiers and master key log will be destroyed.

The paper data that is transcribed from the digital or audio tape recordings and paper data collected will be maintained under lock and key for six years after the study is closed by the IRB. The transcribed audio recording and paper collected data will be destroyed no later than December 31, 2016 or earlier if the data is

no longer needed.

If study participants desire to have access to the audio recordings, they will be provided access. If the participants do not wish to have the audio recording shared or disclosed the participants will be given an opportunity prior to the start of the audio recordings at the outpatient clinic/pharmacy visits and focus group meetings to not be audio recorded.

26.7. Will a Certificate of Confidentiality be obtained for this study?

Yes  No

26.8. If audio/video recordings or photographs will be used, will you be anonymizing or deidentifying materials? If so, how will this be done and when.

The audio recordings from the outpatient clinic, pharmacy and focus groups will be provided a unique subject number code as it is collected to protect privacy and maintain the participants confidentiality.

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## 27. Risk/Benefit Assessment - Risks

27.1. Risk classification for this study (select one).

Minimal Risk

27.2. Risks, Discomforts and Potential Harms: Describe the risks associated with each intervention. Include consideration of physical, psychological, social, and other factors. If data are available, estimate the probability that a given harm may occur and the potential reversibility. (HSC: refer to specific sections of the protocol/grant, if applicable)

-There is a potential risk of inadvertent breach of confidentiality by focus group participants. In attempt to reduce this potential risk, however, the study investigator at the start of each focus group session will address the importance of maintaining privacy and confidentiality regarding information that is shared and discussed at the focus groups.

-A second potential risk is that participants may experience is emotional discomfort or stress in how he/she deals with events in their life or when talking about health outcomes. -A referral list will be provided to all participants for free and low cost assistance for counseling (see Attachment C, uploaded to item 40.1).

-In the event that a risk and/or discomfort to participant is identified the investigator will also contact the participants assigned hospital social worker.

If needed, please upload any tables at item 40.1 and reference in the question above.

27.3. Describe the precautions that will be taken to minimize risks/harms. (HSC: refer to specific sections of the protocol/grant, if applicable)

-Educating participants in privacy and confidentiality will take place at the start of each focus group meeting.

-A counseling free and low cost referral list will be provided to all participants.

-The hospital assigned social worker will be contacted for collaboration of supportive services and counseling.

If needed, please upload any tables at item 40.1 and reference in the question above.

27.4. Data Safety Monitoring Plan: Describe who will monitor the studies for the safety of the participants (investigators, sponsor, independent monitor, DSMB, etc). Provide a plan ( Monitoring provisions) which may include information on: the type of data or events to be captured, who is responsible for monitoring data related to unanticipated problems and adverse events, time frames for reporting adverse events and unanticipated problems to the monitoring entity, the frequency of assessments of data / events captured by monitoring, specific triggers or stopping rules that dictate when an



action is required, and procedures for communicating to the IRB, sponsor, investigator, and other appropriate officials the outcome of the reviews by the monitoring entity.

**27.4.1. (CHLA Only) Attach the CHLA Research Monitoring Plan.**

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**28. Risk/Benefit Analysis - Potential Benefits and Alternatives**

**28.1. Describe any potential for direct benefits to participants in the study. There may be no direct benefits.**

The anticipated benefits for subjects to participate in the study are:

- Subjects will have an opportunity to meet other children, parent (s) and/or legal guardian who have either had a hemapoetic blood stem cell transplant or have gone through the experience of undergoing a transplant.
- Subjects will learn more effective ways of communicating with health care providers.
- Subjects will learn to advocate for own needs.

**28.2. Describe potential benefits to society, if any.**

- Subjects participation will help in the collection of information that may contribute to a better understanding of cultural, language and communication barriers.
- The information collected may lead to better methods of interventions by having communication be more effective between the subjects and health care providers and in turn improve the recovery and quality of life of transplant recipients.
- The information collected from the study may also help future patients and families who undergo bone marrow transplant.

**28.3. What are the alternatives to participation? (This could include not participating in the study)**

The study is entirely VOLUNTARY and if the transplant recipient, parent (s) and/or legal guardian choose not to participate he/she will continue to receive the standard treatment of care for their condition.

**28.4. Risk/Benefit Analysis: This analysis should indicate if the risks to subjects are reasonable in relation to the benefits (if any) to the subjects and the benefit or importance of the knowledge expected to result.**

The risk associated to the study are minimal in that there may be inadvertent breach of confidentiality among focus group participants and there may be a minimal risk of emotional stress related to talking about health outcomes, however, the minimal risks in the study are reasonable to the benefits of increasing effective communication patterns and maximizing medical adherence and long term post transplant quality of life.

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**29. Informed Consent and Waivers**

**29.1. \* Indicate the types of consent that will be involved in this study (check all that apply):**

**Consent Type**

- Written/signed consent by the subject
- Written/signed consent by a legally authorized representative (for an adult)
- Written/signed permission for a minor by a parent or legal guardian
- Written/signed assent by a minor



- Verbal consent or written information sheet
- Consent will not be obtained for this study

**29.1.1. Attach copies of all of the informed consent/assent, information sheet, verbal script, and statements of new information/findings documents that will be used for this study.**

name	Version	Modified
CCI 09-00331 Consent/Assent/Permission for Patient	0.01	3/29/2010 4:41 PM
Consent (Adult) 03-29-10 CLEAN	0.01	3/29/2010 3:07 PM
Consent (Adults) 02-27-10 CLEAN	0.02	3/8/2010 4:16 PM
Consent (Adults) 02-27-10 Tracked changes	0.01	3/8/2010 4:15 PM
Consent (Adults) 03-23-10 Tracked Changes	0.01	3/23/2010 9:50 AM
Consent (Adults) 03-29-10 with track changes	0.01	3/29/2010 3:07 PM
Consent (Adults) CLEAN 03-23-10	0.02	3/26/2010 2:12 PM
Consent (Patient) 03-23-10 CLEAN	0.02	3/26/2010 2:11 PM
Consent (Patient) 03-23-10 Tracked Changes	0.01	3/23/2010 9:52 AM
Consent/Assent/Permission for Patient 02-27-10 Tracked changes	0.01	3/8/2010 4:14 PM
Consent/Assent/Permission for Patient 03-29-10 with track changes	0.01	3/29/2010 3:09 PM
Consent/Assent/Permission for Patient 02-27-10 Clean	0.02	3/8/2010 4:14 PM

**IRB Informed Consent Templates and Forms**

**29.2. \* Waivers: If you are applying for any waivers of consent (check all that apply).**

**Waiver Type**

- Waiver of consent
- Waiver of assent
- Waiver of parental permission
- Waiver of written or signed consent (i.e., information sheets, telephone consent, verbal script)
- I am not applying for a waiver

**Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except the following.**

**FDA Exception from general requirements:**

1. **Waivers of Informed Consent in FDA-regulated studies are permissible in case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk [21CFR50.23];**
2. **If the study satisfies the requirements under 21CFR50.24 "Exception from Informed Consent Requirements for Emergency Research."**

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**30. Description of Informed Consent Process**

**30.1. Personnel Obtaining Consent: Please ensure that all study personnel involved in obtaining consent are designated as such in items 2.1.**

(For existing studies) Names and qualifications of study personnel who will be involved in the informed consent process. (\*\*Please note that as of 10/1/08 personnel mentioned here should be moved to 2.1 and REMOVED from here)

- 30.2. Describe the consent process. Discuss when and where the consent process will take place relative to the initiation of the study procedures. Describe how prospective participants/families will be permitted to discuss their participation with others before signing the consent form. Describe the steps taken to provide the prospective participant sufficient opportunity to consider whether or not to participate in the study. If more than one consent form will be used in the study, explain when and how each form will be used to obtain consent from participants.**

-The consent and assent process will take place prior to the start of the study. The study will be presented and explained to the subjects at a bmt outpatient clinic visit.

-The potential subject, parent (s) and/or legal guardian will have adequate time and opportunity throughout the consenting process to ask questions and discuss their participation with family and friends.

-If the potential subject, parent (s) and/or legal guardian agree to participate in the study he/she will be asked to sign and date the informed consent and assent forms.

-All questions asked will be answered to the subjects, parent (s) and/or legal guardians satisfaction.

-If participants are in need of additional time to consent for the study he/she will be provided with additional time.

- 30.3. Describe the steps that will be taken to make certain that research participants (including children) understand what is going to happen to them in the research. For example, participants can be asked to answer the following questions (as applicable): (1) What are you being asked to do? (2) What question is this study trying to answer? (3)What are the potential risks of participating in this study? (4) How often will you need to come in for study visits? (5) What is the difference between participating in this study and your standard medical care? (6) What should you do if you decide to withdraw from the study?**

-The investigator will be responsible for reviewing the consent and assent forms with the subject, parent (s) and/or legal guardian.

-Consent and assent will be obtained by the investigator at the presence of the subject's parent (s) and/or legal guardian.

-The subject, parent (s) and/or legal guardian will be provided with the Experimental Subject's Bill of Rights prior to signing consent and/or assent.

- 30.4. Will you be recruiting non-English speaking subjects?**

Yes  No

- 30.5. Describe how capacity for consent will be determined if some or all of the participants have cognitive impairments.**

-Children who have cognitive problems will have the study explained to them by the study investigator and the parent (s) and/or legal guardian will sign the Experimental Bill of Rights and consent form.

-Copies of all signed forms will be provided to the study participants.

-Individuals who are identified by the participants as friends, family or trusted advisors will be permitted to be involved in the consent and assent process to assist in validating comprehension on behalf of the study participants.

-In the event that the child or minor shows evidence of not understanding the study, it's purpose and the minimal risks, other strategies will be sought to assist in the process of informing the child/minor.

- 30.5.1. If applicable, attach any instruments that will be used to determine the subject's capacity to consent.**

**name Version Modified**

There are no items to display

- 30.6. Describe the procedures for identifying a legally authorized representative/guardian for those unable to consent (adults) or for minors not accompanied by their parents, as applicable.**

Assent for Minors:

-Assent from minors in addition to the parent (s) and/or legal guardian consent will be the only means of consenting minors to participate in the study.

Adult participants:

-Competent adult participants will be approached for consent.

Parent (s) and/or legal guardians:

-Parents (s) and/or legal guardians will have to provide study consent in order to participate.

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### 35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, use or disclose protected health information (PHI) in order to abstract medical record data (even if you are de-identifying the data abstracted), identify potential participants or to conduct your research?

Yes  No

35.2. If Yes, do you intend to use data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

Yes  No

The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] lists 18 specific elements that are considered to be personal identifiers. The list includes:

- Name/initials
- Street address, city\*, county\*, precinct\*, zip code\*, or equivalent geocodes\*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)\*
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

35.3. Are you only going to obtain data marked with an asterisk (\*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization under the HIPAA privacy rules regarding "limited data sets". If applicable, attach a copy of the signed Data Use Agreement below.

name	Version	Modified
There are no items to display		

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### 36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

If you are using or accessing protected health information in order to identify potential

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate whether these activities fall under the rules for Activities Preparatory to Research or whether you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting.

- (CHLA Only) Activities Preparatory to Research
- Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying subjects
- None of the Above

36.1.1. (CHLA only) If you have indicated that your access of clinical records (PHI) to identify subjects falls under the classification of Activities Preparatory to Research (36.1 above), please certify the statements below and ensure they are addressed in question 22.1. and sponsors protocol.

By checking the "I Agree" box you are providing assurance to the following:

- The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes;
- No PHI will be removed from the covered entity during the review; and
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

I agree to all of the above.

36.2. For study research, please indicate whether you will be obtaining authorization from the subject or requesting a Full Waiver of HIPAA Authorization.

- Obtaining HIPAA authorization from subject
- Full Waiver of HIPAA Authorization

36.2.1. If you are obtaining authorization from the subject, attach the HIPAA authorization forms here (USC Only).

name	Version	Modified
There are no items to display		

### 39. Conflict of Interest Information

39.1. Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project? (See [Guidance for CHLA Conflicts of Interest and Commitment in Research policy.](#))

- Yes  No

39.2. If yes, attach a completed Financial and Intellectual Interest Disclosure Form for each person who has a potential conflict to be managed. ([download the form here](#))

name	Version	Modified
There are no items to display		



- 39.3. **To the investigator's knowledge does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project?**  
 Yes  No

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#### 40. Additional Supporting Documents

- 40.1. **Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB Review.**

name	Version	Modified
<a href="#">ATTACHMENT D TRACKED CHANGES 03.19.10</a>	0.01	3/19/2010 5:20 PM
<a href="#">ATTACHMENT D TRACKED CLEAN 03.19.10</a>	0.02	3/26/2010 2:16 PM
<a href="#">CCI, ATTACHMENT D</a>	0.01	3/5/2010 9:26 PM
<a href="#">Smith IRB Approval Letter</a>	0.01	3/29/2010 9:20 AM

- 40.2. **If there is any additional information that you wish to communicate about the study please include it below. Please note, this section should not be used instead of the standard application items.**

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#### 41. Non-English Speaking Subjects

*This screen is required if you indicated you will be recruiting non-English speaking subjects (Question 30.4.)*

- 41.1. **Describe how you will explain the study and assure that the non-English speaking participants understand the study and their participation in research. (For example, the use of translators, translated informed consent documents, short forms, and any other methods that will be used.)**  
 -A consent/assent Spanish short form will be used for non-English speaking participants.  
 -The investigator will consent and assent the study participant in Spanish and when needed will request CHLA's hospital interpreting services.  
 -CHLA HIPPA forms will be signed and dated by the study investigator, the subject, parent (s) and/or legal guardians.  
 -Copies of the consent, assent, short forms and HIPPA forms will all be provided to the participants.

- 41.2. **If the study will likely include subjects and families for whom Spanish is the primary language, the consent documents must be translated into Spanish. Please indicate the method of translation.**

- Request that the IRB office translate (HSIRB Only)
- Request that the IRB office provide contact information of qualified translation services (translation agreements made by study team)
- Investigator will provide the IRB with a translation of the approved consent form

- 41.3. **If the research will primarily include subjects who speak a language other than English or Spanish, the informed consent documents should be translated into that language. Please indicate the languages and method of translation.**

Language Translation Method  
There are no items to display

- 41.4. (CHLA Only) If the consent translation fee is in the contract for this study, please record the cost center to be charged. If there is no cost center, indicate "Not Applicable".  
Not applicable

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## 99. Instructions for Study Submission

**Congratulations! You have completed the application for a new protocol. When you are sure of the content, the following steps may be taken to submit your study for review.**

1. Click the "Finish" button on the top or bottom application navigator bar to return to the study folderspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Use the "Send Study Ready Notification" activity to send an email to the Principal Investigator and Co-Investigator's with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (Question 2a.3, 2b.3, or 2c.3.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (Question 2a.1, 2b.1, or 2c.1.) can submit the study by using the "Submit Application to \_\_\_\_\_", where \_\_\_\_\_ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The study is submitted. The state indicator in the top left of the study folderspace will no longer display Pre Submission.
8. The PI and Study Coordinator will receive an email confirming the application has been submitted.

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## 2d. Collaborator from Other Institution

- 2d.1. \* First Name:  
Narviar
- 2d.2. \* Last Name:  
Calloway,PhD
- 2d.3. \* Institution:  
Smith College School for Social Work
- 2d.4. \* Role:  
Thesis Advisor

Attachment H

Study Protocol

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## 1.0 BACKGROUND AND RATIONALE

### 1.1 Overview

The purpose of the proposed study is to examine correlations between culture with particular emphasis in language barriers and medical adherence among Latino/Hispanic parent (s) and patients that are female and male teenagers and young adults between the ages of 13 to 21, who have undergone either an autologous or allogeneic bone marrow transplant and are monolingual in Spanish or bilingual in English and Spanish. A sample size of 10-12 voluntary participants will be enrolled in the study. Findings from this study will address how culture impacts medical adherence among Latino teenagers and their parents, and specifically how language barriers, a specific cultural component impacts the process of medical adherence and post transplant long term quality of life. Recommendations for more effective communication patterns between health care providers and medical recipients and educational information that improves post transplant recovery and quality of life will be provided.

### 1.2 Background

There are many variables that affect medical adherence among Latino children within the health care systems. [1] In a qualitative study conducted by the National Council of La Raza (NCLR), (2004), NCLR reported that health care gaps in the population of Latinos contributed to un-insurance, immigration status, discrimination in the delivery of services, lack of knowledge regarding available resources, lack of trust in medical system, lack of transportation to health care agencies and lack of available interpreters. Other studies [2] Flores, G., et al., (2002); [3] Hoefner, M., et al., 2007; and [4] Lee, J. et al., (2009) support these findings. Language barriers however consistently proves to be the primary variable in determining access to health care services for Latinos, and in their ability to communicate with health care personnel. Failure to effectively communicate or to understand medical personnel can lead to other negative consequences such as non-medical adherence. This is especially true among minority groups and Latinos whose primary language is not English.

*Culture and language barriers* obstacles among many vulnerable populations are well documented; and when medical adherence is critical to long-term survival and quality of life, language communications may be the difference between life and death. The proposed study will examine culture with emphasis in language barriers that affect medical adherence among parent (s) and patients that are male and female Latino teenagers ages 13-21, who have received either an autologous or allogeneic bone marrow transplant.

## **2.0 DEFINITIONS**

- 2.1 *Autologous bone marrow transplants* are used to treat medical conditions that do not affect the blood stem cell factory (bone marrow).
- 2.2 *Allogeneic transplant* is the infusion of healthy blood stem cells from a compatible donor who is related to the patient, such as a parent or sibling, or the donor may be someone outside of the family system who is identified by bone marrow registries as genetically compatible with the patient.

## **3.0 HYPOTHESIS**

- 3.1 The study findings will determine how culture and language barriers impact medically recommended instructions or advice to medications and treatments (medical adherence) among Latino/Hispanic parents and bone marrow transplant recipient's between the ages of 13 to 21, who have undergone either an autologous or allogeneic transplant.
- 3.2 The study will also determine if culture and language barriers impact the process of post transplant recovery and long-term quality of life.

## **4.0 OBJECTIVES**

Specific research objectives for this study are to:

- 4.1 Define if culture and language barriers impact the transplant recipients and their parent's communication and adherence to health care providers medically recommended medication and post transplant treatment.
- 4.2 Measure the impact of culture and language barriers post transplant recovery and long-term quality of life.
- 4.3 Determine what effective patterns of communication between study participants and health care providers may help provide recommendations and educational information that improve post transplant recovery and long-term outcomes.

## **5.0 STUDY DESIGN**

### **5.1 Description**

The proposed research is a qualitative study that will examine if culture and language barriers impact medical adherence and quality of life among parent (s) and male and female Latino/Hispanic bone marrow transplant teenagers and young adults between the ages of 13-21, who have undergone either and autologous or allogeneic

transplant. The study design has two parts. Part I includes behavioral observations and part II includes focus groups.

5.2 Part I- Outpatient clinic and/or pharmacy observation

- The first part of the study the investigator will observe the participants during outpatient bone marrow transplant (BMT) clinic interactions and communication with doctors, nurses, and during pharmacy interactions with pharmacy providers at Walgreen pharmacy at Childrens Hospital Outpatient Tower.

5.3 Part II- Focus Group

- The second part of the study will request that study participants take part in two Saturday outpatient focus groups held at Childrens Hospital Los Angeles (CHLA).
- The focus group interactions and communication among group participants will be examined in a group setting where the participants interact with one another.
- The group dialogue will be guided by study questions that will be used by the investigator (see attachment B).

**6.0 Approximate Duration of Subject Participation**

Subjects will participate in the study for approximately four months.

**7.0 Approximate Duration of Study**

This study will be completed in approximately six months.

**8.0 Approximate Number of Study Subjects**

Approximately 10-12 male and female transplant recipient's who have undergone autologous or allogeneic bone marrow transplant ages 13-21 and their parent (s) will participate in this study at Childrens Hospital Los Angeles. Subjects who withdraw from the study will be replaced within the study's duration of six months.

**9.0 SELECTION OF SUBJECTS**

The institutional review board (IRB) must review and approve the study protocol, informed consent form and informed assent form before any subjects give consent. Each subject or subject's parent/legal guardian (as appropriate according to age) must participate in the informed consent process and sign and date an informed consent form for this protocol before taking part in this study. As required, assent must be obtained. Throughout this protocol the requirements for informed consent also apply to assent.

**9.1 Inclusion Criteria**

Patient and parent(s) criteria include:

1. Patients must be 13-21 years of age.
2. Patients and parent(s) are of Latino/Hispanic descent from a Latin American country who have immigrated or been born in the United States.
3. Are monolingual in Spanish or bilingual in English and Spanish.
4. The patient has received an allogeneic (the stem cells are from related or unrelated person called a donor or autologous (the stem cells are from the patient) bone marrow transplant (a treatment o Hematopoietic stem cell transplant, i.e. bone marrow, cord blood or peripheral blood) as treatment for your disease.
5. The patient has been discharged from CHLA hospital and is currently followed at BMT outpatient clinic for post (after) transplant care.
6. Patients are medically stable.

## **1.2 Exclusion Criteria**

1. Patients are not medically stable.
2. Patients and parents are not able to participate in both parts of the medical and pharmacy observation visits and the focus groups.

## **0.0 PROCEDURES**

### **0.1 Informed Consent**

The investigator or authorized designee is responsible for obtaining written informed consent from the parent/legal guardian and a written assent from each subject (age dependent on local requirements) enrolled.

The parent/legal guardian by signing the informed consent form confirms the child/minor voluntary participation and their intention to follow the study protocol and the investigator's instructions.

A study assent form will be provided to the minor subjects. Additionally, both the informed consent and assent forms will need signatures and dates. A copy of the signed consent and assent forms will be provided to the subject's and their parents/legal guardian.

Consent and assent will be obtained prior to the subject's and parents/legal guardian participation in the study.

### **0.2 Study Visit Procedures**

#### **0.2 a. Outpatient clinic and pharmacy observation visits**

- The study investigator will observe one outpatient medical clinic visit interaction and communication between the study participants and the participants' doctor, nurse and/or Walgreen's pharmacy visits located at Childrens Hospital Los Angeles Outpatient Tower.

- The study investigator will observe the participants BMT medical clinic visits for the duration of their scheduled appointment and/or pharmacy visit ranging from 15 minutes to 1 hour.
- Study participants are not required to attend additional outpatient clinic visit in this part of the study.
- The study investigator will meet the participants at their scheduled bmt doctor and nurse outpatient clinic visit and/or when participants visit Walgreen's pharmacy.
- The study investigator prior to each outpatient clinic observation visit will contact you.

#### **10.2 b. Focus Group Visits**

- The study subjects will be asked to attend two Saturday post transplant focus group meetings at Childrens Hospital Los Angeles (CHLA).
- The two Saturday group meetings will be held over the course of four months and the meetings will be for 1 hour.
- The group dialogue will be guided by study questions developed by the investigator.

The BMT outpatient clinic and/or pharmacy visits and the information collected from the focus groups will be audio recorded and documented to ensure accuracy.

#### **11.0 SUBJECT IDENTIFICATION**

Each subject participating in the study will be assigned a unique subject number. A subject who discontinues or is withdrawn from the study before meeting inclusion and exclusion criteria and who enrolls at a later time will be assigned a new subject number. The use of numbers will not be reused or be reassigned for any reason. The study investigator will maintain a subject master log linking the subject number to the subject's name. The investigator will adhere to all applicable privacy laws in order to protect the subject's identity, privacy and confidentiality.

#### **12.0 POTENTIAL RISKS AND DISCOMFORT**

The study has minimal risks in that focus group participants may unintentionally disclose the information discussed during the groups. Another potential risk may involve emotional discomfort or stress in how participants cope with life events or when talking about potential health outcomes. If this occurs, the participants will be encouraged to use the referral list that will be provided for free and low cost assistance in speaking with a counselor (see attachment C).

#### **13.0 PRIVACY AND CONFIDENTIALITY**

The data that is collected during the study will adhere local, State and Federal privacy laws and will be maintained in a locked file for the duration of six years at the Bone Marrow Transplant clinical research office before the information is erased or shredded.

## Bibliography

1. No author, *The health of Latino communities in the south: Challenges and opportunities*. The National Council of La Raza, 2004. Retrieved June 21, 2009 from <http://www.nclr.org/content/publications/detail/26898>.
2. Flores, G., et al., *The health of Latino children: Urgent priorities, unanswered questions, and a research agenda*. JAMA, 2002. 1 (228): p. 82-90.
3. Hoefner, M., et al., *Population estimates. Estimates of unauthorized immigrant population residing in the United States, January 2008*. Washington, DC: U.S. Department of Homeland Security, 2009. p. 1-7. Retrieved June 10, 2009 from <http://www.dhs.gov/xingtn/statistics>.
4. Lee, J., et al., *Annual flow report. Naturalization in the United States: 2008*. Washington, DC: U.S. Department of Homeland Security, 2009. p. 1-4. Retrieved June 10, 2009 from <http://www.dhs.gov/xingtn/statistics>.

# Attachment I

## Consent/Assent for Patient

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Childrens Hospital Los Angeles  
**CONSENT/PERMISSION/ASSENT<sup>1</sup> TO PARTICIPATE IN A RESEARCH STUDY  
(PATIENT)**

*ASSESSING THE IMPACT OF CULTURE AND LANGUAGE BARRIERS AMONG LATINO/A  
BONE MARROW TRANSPLANT PATIENTS AND THEIR PARENT (S)*

Subject's Name:	_____
CHLA#	_____ Birth Date: _____

### • INTRODUCTION

You are being asked to participate in a study conducted by Lorena Mocerro at Childrens Hospital Los Angeles (CHLA). This research is sponsored by Dr. Ami Shah, from Childrens Hospital Los Angeles from the department of Bone Marrow Transplant & Research Immunology. The study will enroll 10-12 parent(s) and teenagers/ young adults 13 –21 years of age. You have been asked to participate in this study because: You are Latino/Hispanic or from a Latin American country who has immigrated or have been born in the United States. You have received an allogeneic (the stem cells are from related or unrelated person, called a donor) or autologous (the stem cells are from the patient) bone marrow transplant (i.e. bone marrow, cord blood or peripheral blood) as treatment for your disease. Participation in this study is completely voluntary and will not prevent you from getting your regular medical care and treatments. Please carefully read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

### • PURPOSE OF THE STUDY

This study is being done to determine if culture and language barriers impact the ability to follow medically recommended instructions or advice to medications and treatments after transplantation; and whether culture and language barriers impact transplantation recovery and long-term quality of life among teenagers/young adults between the ages of 13-21, who have undergone bone marrow transplant and their parents. In addition, the findings of the study will provide recommendations and educational information that address (1) issues relevant to communication between transplant patients, parent (s) and medical providers and (2) after transplant long-term quality of life.

<sup>1</sup> This form will also serve as the "Consent/Permission for Child to Participate in Research" form for the parents to read and sign. In this case, "You" refers to "your child."

Date of Preparation: 03/29/10  
CCI#: 09-00551

Study ID: CCI-09-00331 Valid From: 3/30/2010 To: 3/29/2011



- **PROCEDURES**

There are two parts to this study described below. If you volunteer to participate, you will be asked to do the following:

Part I- Outpatient clinic and/or Pharmacy Observation

- The study investigator will observe your outpatient medical clinic visit interactions and communication with your doctor, nurse and/or Walgreen's pharmacy visit located at Childrens Hospital Outpatient Tower.
- The study investigator will observe your outpatient medical clinic visits for the duration of your medical appointment and/or pharmacy visit ranging from 15 minutes to 1 hour, and will not exceed more than a total of 1 visit during the study.
- Your participation in this study will not require you to attend additional outpatient clinic visits. Instead the study investigator will meet with you at your scheduled doctor and nurse outpatient BMT clinic visit and/or when you visit Walgreen's pharmacy.
- The study investigator prior to each clinic observation visit will contact you to confirm your participation.
- The encounter will be audio-recorded.

Part II- Focus Groups

- You will be asked to participate in a focus group held at Childrens Hospital Los Angeles.
- The focus group will be held on a Saturday and will last about 1 hour.
- The discussion will be audio recorded.
- The group dialogue will be guided by study questions developed by the investigator.

The discussion will involve the following topics:

- (1) Culture and language barriers impact your ability to follow recommended medical instructions or advice to medications and treatments after transplantation.
- (2) Culture and language barriers affect post-transplant recovery and long-term quality of life.
- (3) Culture and language barriers impact communication between you and your health care providers.
- (4) Determine what factors may help create change to improve post (after) bone marrow transplant outcomes.

The BMT clinic outpatient visits with your doctor, nurse and pharmacy providers as well as the information collected from the focus groups will be audio recorded and documented to ensure accuracy.

Date of Preparation: 03/29/10  
CCI#: 09-00531



- **POTENTIAL RISKS AND DISCOMFORTS**

There is potential risk that other participants in the group may unintentionally disclose the information that is discussed during focus groups. There is also a risk of unintentional disclosure of information during the outpatient visits. Access to the collected information will be restricted to only individuals that are part of the study team. Another potential risk involved in the study is that you may experience some emotional discomfort or stress in how you deal with events in your life or when talking about your health outcomes. If this occurs, you will be encouraged to use the referral list that will be provided to you for free and low cost assistance in speaking with a counselor.

- **ANTICIPATED BENEFITS TO SUBJECTS**

- You may meet other transplant teens/young adults that have also undergone bone marrow transplantation.
- You may be able to learn more effective ways of communicating with your health care providers by participating in the focus groups.
- You may learn to advocate for your needs.

- **ANTICIPATED BENEFITS TO SOCIETY**

This research may help in the collection of information that may contribute to a better understanding of cultural, language and communication barriers. The information collected may lead to better methods of interventions by improving communication between patients and their health care providers and in turn improving transplant patients recovery and quality of life. The information collected from the study may also help future patients and families who undergo a bone marrow transplant.

- **ALTERNATIVES TO PARTICIPATION**

The alternative to this study is not to participate.

- **PAYMENT FOR PARTICIPATION**

You will not receive any money or compensation for your participation in the study. You will, however, be provided with food and snacks when you attend the focus group meetings.

- **FINANCIAL OBLIGATION**

You are not responsible for any costs involved in this study and your participation is free of charge. Neither you nor your insurance company will be billed for your participation in this research.

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- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

The investigator and CHLA are not able to offer financial compensation or absorb the costs of treatment should you be injured as a result of participating in this research.

If during your participation in the study you experience emotional discomfort or stress related to how you deal with events in your life or when talking about your health outcomes, you will be provided with a list of enclosed referral for free and low cost counseling.

- **PRIVACY AND CONFIDENTIALITY**

Members of the outpatient medical team if appropriate, your physicians and nurses will be informed of your participation in the study. All results will be kept confidential to study participants. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law (i.e., child abuse, reports of certain infectious diseases).

When the results of the research are published or discussed, no information will be included that would reveal your identity. Audiotape recordings of you will be used for educational purposes only and your identity will be protected or disguised. The data that is collected during this study will adhere (follow) local, State and Federal privacy laws and will be stored at the Division or Research Immunology & BMT Clinical Research Office. The office is locked and secure at all times and only authorized personnel are provided access. If you desire access to review the audio recordings, you will be provided access. If you wish not to have the audio recordings shared or disclosed you will be given an opportunity prior to the start of the audio recordings at the outpatient clinic, pharmacy visits and focus group meetings to not be audio recorded. Field note documentations and paper data transcribed from audio recordings will be maintained and protected for six years before it is shredded and destroyed. Digital audio and tape recordings will be destroyed once the data has been transcribed.

Authorized representatives of the Department of Health and Human Services and the CHLA Committee on Clinical Investigations may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. Your choice about whether or not to participate will have no effect on your care, services or benefits at Childrens Hospital Los Angeles. If you agree to participate, but later decide to withdraw from this study, you may do so by contacting the primary investigator at any time. Your rights to health care services or other benefits at Childrens Hospital Los Angeles will not be compromised in any way if you decide to withdraw from the study.

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- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if necessary to protect your health or if other situations arise that make it necessary to do so. If you experience emotional discomfort or stress or become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Lorena Mocerro, will make the decision and let you and your parents know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions about this research, please immediately contact the investigator or study sponsor listed below.

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the primary investigator, Lorena Mocerro at (323) 361-2546 or you may call the study sponsor Dr. Ami Shah at (323) 361-2546.

If your questions are not an emergency, you can obtain better information by calling Lorena Mocerro, Monday through Friday, 8:00 a.m. through 4:30 p.m., than by calling Dr. Ami Shah on call service after hours.

- **FINANCIAL INTEREST OF THE INVESTIGATOR**

There are no available funds for this study. There are not financial incentives to the study investigator if you or your parent (s) agrees to participate. You are not under any obligation to participate in this study.

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the CHLA Office for Protection of Human Subjects at (323) 361-2265.

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**SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)**

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form, the *Experimental Subject's Bill of Rights* and the HIPAA authorization form.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

**SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)**

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form, the *Experimental Subject's Bill of Rights* and the HIPAA authorization form.

\_\_\_\_\_  
Name(s) of Parent(s)/Legal Guardian

\_\_\_\_\_  
Signature of Parent/Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent/Legal Guardian

\_\_\_\_\_  
Date

**SIGNATURE OF INVESTIGATOR/PERSON OBTAINING CONSENT**

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give assent/consent/permission to participate.

\_\_\_\_\_  
Name of Investigator/Person obtaining consent

\_\_\_\_\_  
Signature of Investigator/Person obtaining consent

\_\_\_\_\_  
Date (must be the same date as subject's)

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**SIGNATURE OF WITNESS (if applicable)**

My signature as Witness indicates that the subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed this assent/consent/permission form in my presence.

\_\_\_\_\_  
Name of Witness

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date (must be the same date as subject's)

**SIGNATURE OF INTERPRETER (if applicable)**

\_\_\_\_\_  
Name of Interpreter

\_\_\_\_\_  
Signature of Interpreter

\_\_\_\_\_  
Date (must be the same date as subject's)

Routing of signed copies of the consent form:

- 1) Give to the adult subject or parent/legal guardian (copy)
- 2) Place in the CHLA Medical Record (copy)
- 3) Place in the Principal Investigator's research file (original)



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## Attachment J

### Consent for Parent(s)/Caretaker

Page 1 of 6

Childrens Hospital Los Angeles  
**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**  
(PARENT)

*ASSESSING THE IMPACT OF CULTURE AND LANGUAGE BARRIERS AMONG LATINO/A  
BONE MARROW TRANSPLANT PATIENTS AND THEIR PARENT(S)*

• **INTRODUCTION**

You are being asked to participate in a research study conducted by Lorena Mocerro, Master in Social Work (MSW) student at Childrens Hospital Los Angeles (CHLA). This research is sponsored by Dr. Ami Shah, from Childrens Hospital Los Angeles from the department of Bone Marrow Transplant & Research Immunology. The study will enroll 10-12 parent(s) and teenagers/young adults 13 -21 years of age. You have been asked to participate in this study because: You are Latino/Hispanic or from a Latin American country who has immigrated or have been born in the United States. Your teenager/young adult has received an allogeneic (the stem cells are from related or unrelated person, called a donor) or autologous (the stem cells are from the patient) bone marrow transplant (a treatment of Hematopoietic stem cell transplant, i.e. bone marrow, cord blood or peripheral blood) as treatment for your teenager's disease. Participation in this study is entirely voluntary. Please carefully read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

• **PURPOSE OF THE STUDY**

This study is being done to determine if culture and language barriers impact the ability to follow medically recommended instructions or advice to medications and treatments after transplantation and whether culture and language barriers impact after transplantation recovery and long-term quality of life among Latino teenagers/young adults between the ages of 13-21, who have undergone allogeneic or autologous bone marrow transplants and their parents. In addition, the findings of the study will provide recommendations and educational information that (1) address issues relevant to interactions and communication between parent (s), patients and medical providers and (2) after transplantation recovery and long-term quality of life.

• **PROCEDURES**

There are two parts to this study described below. If you volunteer to participate in this study, you will be asked to do the following:

Part I- Outpatient clinic and/or Pharmacy Observation

- The study investigator will observe your outpatient medical clinic visit interaction and communication with your child's doctor, nurse and/or Walgreen's pharmacy visit located at Childrens Hospital Outpatient Tower.

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Study ID: CCI-09-00331 Valid From: 3/30/2010 To: 3/29/2011

- The study investigator will observe your outpatient medical clinic visits for the duration of your medical appointment and pharmacy visits ranging from 15 minutes to 1 hour, and will not exceed more than a total of 1 visit during the study.
- Your participation in this study will not require you to attend additional outpatient clinic visits. Instead the study investigator will meet with you at your child's scheduled doctor and nurse outpatient BMT clinic visit and/or when you visit Walgreens pharmacy.
- The study investigator prior to each clinic observation visit will contact you to confirm your participation.
- The encounter will be audio-recorded.

Part II- Focus Groups

- You will be asked to participate in a focus group held at Childrens Hospital Los Angeles.
- The focus group will be held on a Saturday and will last about 1 hour.
- The discussion will be audio-recorded.
- The group dialogue will be guided by study questions developed by the investigator.

The discussion will involve the following topics:

- (1) Culture and language barriers impact your ability to follow recommended medical instructions or advice (medical adherence) to medications and treatments after transplantation.
- (2) Culture and language barriers affect after transplantation recovery and long-term quality of life.
- (3) Culture and language barriers impact communication between you and your health care providers.
- (4) Determine what factors may help create change to improve after bone marrow transplant outcomes.

The BMT outpatient clinic visits with your child's doctor, nurse, pharmacist and other health care providers as well as the information collected from the focus groups will be audio recorded and documented to ensure accuracy.

**• POTENTIAL RISKS AND DISCOMFORTS**

There is potential risk that other participants in the group may unintentionally disclose the information that is discussed during focus groups. There is also a risk of unintentional disclosure of information during the outpatient visits. Access to the collected information will be restricted to only individuals that are part of the study team. Another potential risk involved in the study is that you may experience some emotional discomfort or stress in how you deal with events in your life or when talking about health outcomes. If this occurs, you will be encouraged to use the referral list that will be provided to you for free and low cost assistance in speaking with a counselor.

**• ANTICIPATED BENEFITS TO SUBJECTS**

- You may meet other transplant parent(s) who have gone through the process of transplantation with your teenager/ young adult.

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- You may also learn more effective ways of communicating with your health care providers and your child's health provider.
- You may learn to advocate for the needs of you and your child.

• **ANTICIPATED BENEFITS TO SOCIETY**

This research may help in the collection of information that may contribute to addressing issues of cultural, language and communication barriers. The information collected may lead to better methods of interventions by improving communication between patients, parents and their health care providers and in turn improving transplant patient recovery and quality of life. The information collected from the study may also help future patients and families who undergo a bone marrow transplant.

• **ALTERNATIVES TO PARTICIPATION**

The alternative to this study is not to participate.

• **PAYMENT FOR PARTICIPATION**

You will not receive any money or compensation for your participation in the study. You will, however, be provided with food and snacks when you attend the focus group meetings.

• **FINANCIAL OBLIGATION**

You are not responsible for any costs involved in this study and your participation is free of charge. Neither you nor your insurance company will be billed for your participation in this research.

• **EMERGENCY CARE AND COMPENSATION FOR INJURY**

The investigator and CHLA are not able to offer financial compensation or absorb the costs of treatment should you be injured as a result of participating in this research. If during your participation in the study you experience emotional discomfort or stress related to how you deal with events in your life or when talking about your health outcomes, you will be provided with a list of enclosed referral for free and low cost counseling

• **PRIVACY AND CONFIDENTIALITY**

Members of the research team and, if appropriate, your physicians and nurses will be informed of your participation in the study. All results will be kept confidential to study participants. No information about you or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law (i.e., child abuse, reports of certain infectious diseases).

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When the results of the research are published or discussed, no information will be included that would reveal your identity. Audiotape recordings of you will be used for educational purposes only; your identity will be protected or disguised. The data that is collected during this study will follow local, State and Federal privacy laws and will be stored at the Division of Research Immunology & BMT Clinical Research Office. The office is locked and secure at all times and only authorized personnel are provided access. Digital and tape recordings will be destroyed once the data has been transcribed. If you desire access to review the audio recordings, you will be provided access. If you wish not to have the audio recordings shared or disclosed you will be given an opportunity prior to the start of the audio recordings at the outpatient clinic, pharmacy visits and focus group meetings to not be audio recorded. Field note documentation and paper data transcribed from audio recordings will be maintained and protected for six years before it is shredded and destroyed.

Authorized representatives of the Department of Health and Human Services and the CHLA Committee on Clinical Investigations may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. Your choice about whether or not to participate will have no effect on your care, services or benefits at Childrens Hospital Los Angeles. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your child's rights to healthcare, services or their benefits at CHLA.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if necessary to protect your health or if other situations arise that make it necessary to do so. If you experience emotional discomfort or stress, or become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Lorena Mocerro, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **IDENTIFICATION OF INVESTIGATORS**

If you have questions about this research, please immediately contact one of the investigators listed below.

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Lorena Mocerro at (323) 361-2546.

If your questions are not an emergency, you can obtain better information by calling Lorena Mocerro, Monday through Friday, 8:00 a.m. through 4:30 p.m., than by calling Dr. Ami Shah on call service after hours.

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**• FINANCIAL INTEREST OF THE INVESTIGATOR**

There are no available funds for this study. There are no financial incentives to the study investigator if you agree to participate. You are not under any obligation to participate in this study.

**• RIGHTS OF RESEARCH SUBJECTS**

You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the CHLA Human Subjects Protection Program at (323) 361-2265.

**SIGNATURE OF RESEARCH SUBJECT**

Your signature below indicates:

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to participate in this research study; and
- You will be given a signed copy of this form, the *Experimental Subject's Bill of Rights* and the HIPAA authorization form.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

**SIGNATURE OF INVESTIGATOR/PERSON OBTAINING CONSENT**

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely gives consent to participate.

\_\_\_\_\_  
Name of Investigator/Person obtaining consent

\_\_\_\_\_  
Signature of Investigator/Person obtaining consent

\_\_\_\_\_  
Date (must be the same date as subject's)

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**SIGNATURE OF WITNESS (if applicable)**

My signature as witness indicates that the subject voluntarily signed this consent form in my presence.

\_\_\_\_\_  
Name of Witness

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date (must be the same date as subject's)

**SIGNATURE OF INTERPRETER (if applicable)**

\_\_\_\_\_  
Name of Interpreter

\_\_\_\_\_  
Signature of Interpreter

\_\_\_\_\_  
Date (must be the same date as subject's)

Routing of signed copies of the consent form:

- 1) Give to adult subject (copy)
- 2) Place in the CHLA Medical Record (copy)
- 3) Place in the Principal Investigator's research file (original)



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Attachment K

HIPAA-English



**ChildrensHospitalLosAngeles**

*International Leader in Pediatrics*

AUTHORIZATION FORM

**PERMISSION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

Patient/Subject Name: \_\_\_\_\_

Medical Record Number: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

**BACKGROUND and DEFINITIONS**

**HIPAA** stands for the **Health Insurance Portability and Accountability Act**. HIPAA contains federal regulations that govern the privacy and confidentiality of medical information maintained by healthcare providers. Participants in research studies are protected by HIPAA regulations. Information used in research studies may include data that identifies you<sup>1</sup>. When you consider taking part in a research study, you must give permission for your protected health information to be released from the research team at Childrens Hospital Los Angeles and your doctors to the outside researchers involved in conducting the research study.

**Protected health information** is personal information that can identify you or that can be linked to you. Examples of protected health information include personal information such as your date of birth or where you live and information about your medical condition. Only you or your legal

<sup>1</sup> This form will also serve as the authorization form for parents to read and sign when their child is the subject in a research study. In that case, "you" refers to "your child".



representative can give permission for your protected health information to be released.

By agreeing to sign this authorization form, you are allowing researchers at Childrens Hospital Los Angeles to collect your protected health information and share it with others involved in doing this research study as detailed below, consistent with California and Federal laws concerning the privacy of this information.

### RESEARCH STUDY INFORMATION

Your protected health information will be used for the following research study:

CCI# 09-00331 PRINCIPAL INVESTIGATOR: Lorena Mocerro

TITLE: ASSESSING THE IMPACT OF CULTURE AND LANGUAGE BARRIERS AMONG LATINO/A BONE MARROW TRANSPLANT PATIENTS AND THEIR PARENT(S).

The protected health information that is needed for this research study includes: *(Please describe below, examples are provided)*

- *Personal demographic information;*
- *History and diagnosis of your medical condition;*
- *Specific information about the treatments you have gotten, including treatment(s) you may have had in the past;*
- *Information about other medical conditions that may affect your treatment;*
- *Medical data including laboratory test results, results of tests measuring organ function (e.g., kidney, heart, lung), results from radiology scans, pathology or other test results;*
- *Information on treatment and the side-effects you may experience during this research study and how they were treated; and*
- *Long-term information about your general health status and the status of your medical condition.*

*Note: Disclosure of psychotherapy notes or HIV status have to be specifically indicated in a separate paragraph*

---

California law prohibits the disclosure of any protected health information not listed in this authorization unless another authorization form is obtained from you or unless such disclosure is specifically required or permitted by law.

In addition, your medical records may need to be reviewed and the researchers may need to discuss your health information with your healthcare providers. This research may also create new information about you as a result of research procedures, tests, questionnaires, interviews, and visits.

The research team at Childrens Hospital Los Angeles receives *does not receive* payment for your participation in this research study and subsequent use of your protected health information.

#### **DISCLOSURE OF PROTECTED HEALTH INFORMATION**

You give permission for the following persons, groups or organizations to use or disclose (release) your protected health information for the research study described in this authorization form.

1. Lorena Mocorro and his/her research staff Connie Jackson and Laure Daluro.
2. Physicians and other healthcare providers Ami Shah, MD
3. The Committee on Clinical Investigations for oversight and compliance purposes
4. Other:

#### **RECEIPT OF PROTECTED HEALTH INFORMATION**

You give permission for the following persons, groups or organizations to receive your protected health information for the research study described in this authorization form.

1. The sponsor of the study Ami Shah, MD or its representatives
2. The following institutions/investigators that are participating in this research: Smith College School for Social Work, Narviar Calloway, PhD and CHLA.
3. Federal and State agencies that have authority over the research when required by law.

4. Hospital or other accrediting agencies
5. A data safety board that may be formed to monitor the safety of the research.
6. Your health insurer or payer, if necessary, to secure their payment for any covered treatment not paid for by the research.
7. Information that may affect clinical care will be placed in your medical record to be used by hospital and medical staff who are not involved in the study.

#### **CONFIDENTIALITY and PRIVACY**

Efforts will be made to ensure that your protected health information will not be shared with other persons, groups or organizations outside of the research study. However, your protected health information may be disclosed to others as required by law and/or to individuals that may not be held to the same legal privacy standards as are doctors and hospitals. The research team cannot guarantee absolute confidentiality and privacy.

#### **EXPIRATION**

This authorization will expire on December 31, 2099. This is because information that is collected for research purposes continues to be analyzed for many years and it is not possible to determine when it will be complete.

#### **YOUR RIGHTS**

You may decide not to sign this authorization form. If you do not sign this authorization form, you will not be able to take part in this research study. Your regular healthcare including treatment, payment or enrollment in any health plans or your eligibility for benefits will not be affected if you decide not to sign.

You may cancel your permission at any time for Childrens Hospital Los Angeles to use or share your protected health information collected for this research study. However, even if you cancel this authorization, the hospital and the research team may still use information about you that was collected as part of the research project (ie: side-effects related to the



research) between the date you signed the current form, and the date you cancelled the authorization. This is to protect the quality of the research results. Once you cancel your authorization, no further protected health information will be disclosed.

You must cancel your authorization in writing. You may request a form for this purpose from the Committee on Clinical Investigations, (323) 361-2265. This document must be signed by you or on your behalf and delivered to the following address: Lorena Mocerro, Childrens Hospital Los Angeles, 4650 Sunset Boulevard MS #62, Los Angeles, California 90027.

Your cancellation will be effective upon receipt, but will not be effective to the extent that the Childrens Hospital Los Angeles research team or others have acted in reliance upon this Authorization.

You will receive a copy of this Authorization Form.

You have the right to review and/or copy your medical records containing your protected health information kept by Childrens Hospital Los Angeles. You will not be allowed to review these medical records collected for research until after the study is completed. When the study is over, you will have the right to access the information again. You will not have the right to review and/or copy your research specific records.

Under no circumstances are you required to authorize the disclosure of psychotherapy notes.

**SIGNATURES**

Your signature below indicates: that you give permission for the use and disclosure of your protected health information as described in this document. This authorization form may not be valid if it has not been filled out completely.

Printed Name \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_



Please indicate the relationship:

patient/research subject  legal representative \_\_\_\_\_  
(indicate relationship)

Printed Name of Person Obtaining Permission:

\_\_\_\_\_

Signature of Person Obtaining Permission:

\_\_\_\_\_ Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_

*Routing: Investigator's file, Subject, Health Information Management (Medical Records)*

Attachment L

HIPAA-Spanish



**ChildrensHospitalLosAngeles**

*International Leader in Pediatrics*

## FORMULARIO DE AUTORIZACIÓN

### PERMISO PARA EL USO Y DIVULGACIÓN DE LA INFORMACIÓN DE SALUD PROTEGIDA PARA PROPÓSITOS DE INVESTIGACIÓN

Nombre Completo del Paciente/Sujeto \_\_\_\_\_

Número del Expediente Médico: \_\_\_\_\_

Fecha de Nacimiento: \_\_\_\_\_

#### ANTECEDENTES Y DEFINICIONES

**HIPAA** es la abreviación de **Health Insurance Portability and Accountability Act (Acta de Portabilidad y Responsabilidad de Seguros de Salud)**. El HIPAA contiene regulaciones federales que rigen la intimidad y confidencialidad de información médica que mantienen los proveedores de servicios de salud. Las regulaciones HIPAA protegen a los participantes en estudios de investigación. La información utilizada en los estudios de investigación puede incluir datos que lo identifican a usted<sup>1</sup>. Cuando usted considera tomar parte en un estudio de investigación, usted debe dar permiso para que el grupo del Childrens Hospital Los Angeles y los médicos de usted revelen su información protegida de salud a investigadores externos que participan en la gestión del estudio de investigación.

<sup>1</sup> Este formulario también sirve como el formulario de autorización del niño para que los padres lo lean y firmen. En este caso "usted" se refiere a "su niño".

**Información protegida de salud** es información personal que puede identificarlo a usted o que puede ser relacionada con usted. Los ejemplos de información protegida de salud incluyen información personal tal como su fecha de nacimiento o dónde vive usted e información sobre su afección médica. Solo usted o su representante legal pueden dar permiso para que su información protegida de salud sea revelada.

Al estar de acuerdo en firmar este formulario de autorización, usted permite que los investigadores en el Childrens Hospital Los Angeles reúnan su información protegida de salud y la compartan con otros involucrados en la gestión de este estudio de investigación tal como se detalla más adelante, de acuerdo con las leyes Federales y de California acerca de la intimidad de esta información.

#### **INFORMACIÓN DEL ESTUDIO DE INVESTIGACIÓN**

Su información protegida de salud se utilizará para el siguiente estudio de investigación:

CCI # **09-00331**

INVESTIGADOR PRINCIPAL: Lorena Mocerro

TÍTULO: ASSESSING THE IMPACT OF CULTURE AND LANGUAGE BARRIERS AMONG LATINO/A BONE MARROW TRANSPLANT PATIENTS AND THEIR PARENT(S).

**AVALUANDO LOS IMPACTO Y OBSTÁCULOS DE CULTURA Y LENGUAJE ENTRE PACIENTES LATINOS/AS DE TRASPLANTE DE MEDULA OSEA Y SU PADRE(S).**

La información protegida de salud que es necesaria para este estudio de investigación incluye:

- *Información demográfica personal;*
- *Historial y diagnóstico de su afección médica;*
- *Información específica acerca de los tratamientos que usted ha recibido, incluyendo tratamiento(s) que ha tenido en el pasado;*
- *Información acerca de otras afecciones médicas que pueden afectar su tratamiento;*
- *Datos médicos incluyendo resultados de pruebas de laboratorio, resultados de pruebas que miden el funcionamiento de órganos (por ejemplo: riñón, corazón, pulmones), resultados de imágenes radiológicas y resultados de patología u otros exámenes;*

- *Información de tratamientos y los efectos secundarios que pudiese manifestar durante este estudio de investigación y cómo fueron tratados; y*
- *Información de largo plazo acerca de su estado de salud general y el estado de su afección médica.*

Nota: La divulgación de notas de psicoterapia o de estado de VIH debe ser indicada específicamente en un párrafo separado.

---

La ley de California prohíbe la divulgación de cualquier información protegida de salud que no se describa en esta autorización a menos que se obtenga de usted otro formulario de autorización o que dicha divulgación sea específicamente requerida o permitida por la ley.

Además, se pudiesen tener que revisar los expedientes médicos/de salud de usted y los investigadores pudiesen tener que platicar con sus profesionales de salud acerca de la información de la salud de usted. Esta investigación podría generar nueva información acerca de usted a resultado de los procedimientos de la investigación, pruebas, cuestionarios, entrevistas y visitas.

El grupo de investigación en el Childrens Hospital Los Angeles no recibe pago por la participación de usted en este estudio de investigación y el uso subsecuente de su información protegida de salud.

#### **DIVULGACIÓN DE LA INFORMACIÓN DE SALUD PROTEGIDA**

Usted da permiso para que las siguientes personas, grupos u organizaciones usen o divulguen (revelen) su información protegida de salud para el estudio de investigación descrito en este formulario de autorización.

1. Lorena Mocerro y su grupo de investigación, Connie Jackson y Laure Daluro.
2. Médicos y otros proveedores de servicios de salud Dra. Ami Shah
3. El Comité de Investigaciones Clínicas para propósitos de supervisión y de cumplimiento
4. Otros:



## RECEPCIÓN DE INFORMACIÓN DE SALUD PROTEGIDA

Usted da permiso para que las siguientes personas, grupos u organizaciones reciban su información protegida de salud para el estudio de investigación descrito en este formulario de autorización *Smith College School for Social Work y CHLA*.

1. El patrocinador del estudio Dra. Ami Shah o sus representantes
2. Las siguientes instituciones/investigadores que participan en esta investigación: Smith College School for Social Work, Narviar Calloway, PhD y CHLA.
3. Agencias Federales y Estatales que tienen autoridad sobre la investigación cuando sea requerido por ley.
4. Hospital u otras agencias acreditadas
5. Una junta de seguridad de datos que puede formarse para vigilar la seguridad de esta investigación.
6. Su asegurador médico o pagador, en caso de ser necesario, para asegurar el pago de cualquier tratamiento cubierto que no sea pagado por la investigación.
7. La información que pudiese afectar la atención clínica se incluirá en su expediente médico para uso del hospital y del personal clínico que no sean parte del estudio de investigación.

## CONFIDENCIALIDAD Y ANONIMIDAD

Se realizarán esfuerzos para asegurar que su información protegida de salud no se comparta con otras personas, grupos u organizaciones fuera del estudio de investigación. Sin embargo, su información protegida de salud puede ser revelada a otros según lo requiera la ley y/o a individuos que pueden no estar bajo los mismos estándares de intimidad legal que rigen a los médicos y hospitales. El grupo de investigación no puede garantizar confidencialidad e intimidad absolutas.

## VENCIMIENTO

Esta autorización se vence el 31 de diciembre de 2099. Esto se debe a que la información que se recauda para propósitos de investigación se continuará analizando por muchos años y no es posible determinar cuándo se completará la investigación.

## **SUS DERECHOS**

Usted puede rehusar a firmar este formulario de autorización. Si usted decide no firmar este formulario de autorización, no podrá tomar parte en este estudio de investigación. El cuidado regular de su salud, pago o inscripción en cualquier plan de salud o su derecho a beneficios no se verán afectados si usted no desea firmar.

Usted puede revocar su permiso en cualquier momento para que el Childrens Hospital Los Angeles utilice o comparta su información protegida de salud recabada para este estudio de investigación. Sin embargo, aún cuando usted revoque esta autorización, el hospital y el grupo de investigación podrán aún utilizar información acerca de usted que fuera recabada como parte del estudio de investigación (por ejemplo: efectos secundarios relacionados con la investigación) entre la fecha en la que usted firma el presente formulario y la fecha en la que usted revoca la autorización. Esto es para proteger la calidad de los resultados de la investigación. Una vez que usted revoque su autorización, no podrá divulgarse ninguna otra información protegida de salud.

Su revocación debe ser por escrito. Usted puede solicitar un formulario para este propósito de parte del Comité de Investigaciones Clínicas, (323) 361-2265. Este documento debe estar firmado por usted o en su nombre y entregado en la siguiente dirección: Lorena Mocoero, Childrens Hospital Los Angeles, 4650 Sunset Boulevard Mail Stop #62, Los Angeles, California 90027.

Su revocación entrará en vigencia al momento de su entrega, pero no tendrá efecto en cuanto a que el Childrens Hospital Los Angeles u otros hayan actuado basados en esta Autorización.

Usted recibirá una copia de este Formulario de Autorización.

Usted tiene el derecho de revisar y/o copiar los expedientes médicos que contengan su información protegida de salud que guarda el Childrens Hospital Los Angeles. No le permitirán revisar la información que se recaude de la investigación hasta cuando se complete el estudio. Cuando se complete el estudio, usted volverá a tener el derecho de acceder la

información. Usted no tendrá el derecho de revisar y/o copiar sus expedientes específicos de investigación.

Bajo ninguna circunstancia se le requiere que autorice la divulgación de notas de psicoterapia.

**FIRMAS**

Su firma al calce indica que usted permite que se use y divulgue su información de salud protegida tal como se detalla en este documento. Este formulario de autorización no es válido a menos que se hayan llenado todos los espacios en este documento.

Nombre Completo en Letra de Imprenta \_\_\_\_\_

Firma \_\_\_\_\_

Fecha \_\_\_/\_\_\_/\_\_\_

Por favor indique relación:  paciente/sujeto bajo investigación   
representante legal \_\_\_\_\_

(indique

relación)

Nombre Completo en Letra de Imprenta de la Persona que Obtiene Permiso:

\_\_\_\_\_

Firma de la Persona que Obtiene Permiso: \_\_\_\_\_

Fecha \_\_\_/\_\_\_/\_\_\_

*Routing: Investigator's file, Subject, Health Information Management (Medical Records)*

Attachment M

Study Short Form-Spanish

Short Form - Spanish (03/23/02)
(This form should be accompanied by the Experimental Subjects' Bill of Rights and the CCI approved consent document)



Childrens Hospital Los Angeles
International Leader in Pediatrics

Childrens Hospital of Los Angeles
Consentimiento para Participar en un Estudio de Investigación

Form with fields for Nombre del Sujeto, # de CHLA, and Fecha de Nacimiento.

Se le pide a usted o a su niño que participen en un estudio de investigación. Un estudio de investigación es la manera en la cual los científicos (médicos, enfermeras y otros profesionales) tratan de entender cómo funcionan las cosas y aprender más.

Antes de decidir si usted o su niño participarán en este estudio de investigación, el investigador debe informarle acerca de (i) los propósitos de la investigación, las actividades que se realizarán, a éstas se les llama procedimientos y por cuánto tiempo durará la investigación; (ii) cualquier procedimiento que sea experimental (bajo estudio); (iii) cualquier riesgo, molestias y beneficios que se anticipen resulten de esta investigación; (iv) cualquier otro procedimiento o tratamiento que pudiesen ser benéficos y (v) cómo se mantendrá confidencial su información.

El investigador también debe informarle, en los casos correspondientes, acerca de (i) los pagos o tratamientos médicos que existen en caso de una lesión o daño; (ii) la posibilidad de riesgos desconocidos; (iii) situaciones por las cuales el investigador termine la participación de usted en el estudio; (iv) cualquier otro gasto adicional para usted; (v) qué ocurre si usted decide salirse del estudio; (vi) cuándo le avisarán acerca de descubrimientos que pudiesen afectar su deseo de participar; y (vii) cuántas personas participarán.

Si usted acepta participar, le deben una copia firmada de este documento y una copia del formulario de consentimiento aprobado para este estudio escrito en inglés.

Usted puede comunicarse con Lorena Mocerro al (323) 361-2546 en cualquier momento que tenga preguntas sobre la investigación o sobre qué hacer si se lesiona.

Si usted tiene cualquier pregunta acerca de sus derechos como sujeto bajo investigación, se puede comunicar con el Comité de Investigaciones Clínicas, al 323-669-2265.

Su participación en esta investigación es voluntaria (su propia decisión) y no perderá beneficios o se le castigará si rechaza participar o si decide no seguir participando.

Su firma en este documento indica que el estudio de investigación junto con la información mencionada anteriormente, le fueron descritos verbalmente, y que usted consiente voluntariamente en participar.

Form with signature lines for Participante, Padre/Madre, and Testigo, and corresponding date lines.

Routing of signed copies of the consent form: 1) Give to family; 2) CHLA Medical Record; 3) Investigator's file.
Date of Preparation: 03/29/2010
CHLA CCI#: 09-00331
Protocol Expiration Date: 03/29/2011



Attachment N

Experimental Subjects Bill of Rights-English



**Children's Hospital Los Angeles**  
International Leader in Pediatrics

**Study Title: Assessing the Impact of Culture and Language Barriers Among Latino/a Bone Marrow Transplant Patients and Their Parents (CCI-09-00331)**

**Principal Investigator: Lorena Mocorro, B.A., MSW Candidate**

**EXPERIMENTAL SUBJECT'S BILL OF RIGHTS  
FOR PSYCHOSOCIAL STUDIES**

Any person who is requested to consent to participate as a subject in a research study involving a psychosocial study, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the study.
2. Be given an explanation of the procedures to be followed in the study.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from your/your child's participation in the study.
4. Be given an explanation of any benefits reasonably to be expected from your/your child's participation in the study.
4. Be given a disclosure of any appropriate alternatives that might be advantageous to you/your child, and their relative risks and benefits.
6. Be informed of avenues of resources, if any, available to you/your child after the study procedure if complications should arise.
7. Be given an opportunity to ask any questions concerning the study or the procedures involved.
8. Be instructed that consent to participate in the study may be withdrawn at any time, and that you/your child may discontinue participation in the study without prejudice.
9. Be given a copy of this form and the signed and dated written study consent form.
10. Be given the opportunity to decide to consent or not to consent to participate in the study without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on your decision.

You have carefully read the information contained above in the *Experimental Subject's Bill of Rights for Psychosocial Studies*, and you understand fully the rights of a potential subject in a research study involving people as subjects.

Date: \_\_\_\_\_ Subject: \_\_\_\_\_  
Parent: \_\_\_\_\_  
Witness: \_\_\_\_\_

## Attachment O

### Experimental Subjects Bill of Rights-Spanish



**ChildrensHospitalLosAngeles**  
International Leader in Pediatrics

**Título de Estudio: Assessing the Impact of Culture and Language Barriers Among Latino/a Bone Marrow Transplant Patients and Their Parents (CCI-09-00331)**

**Investigadora Principal: Lorena Mocerro, B.A., MSW Candidata**

#### **DECLARACIÓN DE LOS DERECHOS DEL SUJETO BAJO INVESTIGACIÓN PARA ESTUDIOS SICOSOCIALES**

Toda persona a la cual se le solicite participar como sujeto en un estudio de investigación que incluya un estudio sicosocial, o de la cual se solicite que consenta a favor de otra, tiene derecho a:

1. Recibir información sobre la naturaleza y propósito del estudio.
2. Recibir una explicación de los procedimientos que se seguirán en el estudio.
3. Recibir una descripción de cualquier molestia y riesgos que usted/su hijo razonablemente puedan esperar al participar en el estudio.
4. Recibir una explicación de cualquier beneficio que usted/su hijo razonablemente puedan esperar al participar en el estudio.
5. Recibir información de cualesquiera otras alternativas que sean apropiadas y que pudiesen ser de ventaja para usted/su hijo y los riesgos que tengan en comparación con sus beneficios.
6. Recibir información sobre los distintos recursos, de haberlos, disponibles para usted/su hijo después del procedimiento del estudio si se presentaran complicaciones.
7. Tener la oportunidad de hacer cualquier pregunta acerca del estudio o los procedimientos que incluye.
8. Que se le advierta que puede retirar su consentimiento para participar en el estudio en cualquier momento, y que usted/su hijo pueden discontinuar su participación en el estudio sin perjuicio.
9. Recibir una copia de este formulario y una copia firmada y fechada del formulario de consentimiento del estudio.
10. Tener la oportunidad de decidir a consentir o a no consentir al estudio sin la intervención de ningún tipo de fuerza, fraude, engaño, coacción, coerción, o influencia excesiva en su decisión.

Usted ha leído atentamente la información descrita anteriormente en la *Declaración de los Derechos del Sujeto Bajo Investigación para Estudios Sicosociales* y usted entiende completamente los derechos como posible sujeto en un estudio de investigación en el que participan seres humanos.

Fecha: \_\_\_\_\_ Sujeto: \_\_\_\_\_  
Padre/Madre: \_\_\_\_\_  
Testigo: \_\_\_\_\_

Spanish version dated 03/02