

## American Cancer Society – Institutional Research Grants 2015

“Factors affecting Parental Satisfaction, Anxiety and Comprehension of Informed Consent in Pediatric Oncology Clinical Trials”

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**BACKGROUND:** Pediatric cancer survival rates have improved dramatically, in part due to high patient enrollment in clinical trials. Hispanic children have higher incidences of certain cancers than Non-Hispanic Whites, but poorer survival rates. Postulated reasons for these worse outcomes include the lower participation of Hispanics in clinical trials. Current informed consent (IC) standards are aimed to promote equality when conducting research across diverse populations. However, Hispanics and those with limited English proficiency may face increased barriers during the IC process. Low participation of racial/ethnic minorities in clinical trials may result from the complexity of IC. Our recent work at the University of California San Diego- Rady Children’s Hospital showed that there is significant underrepresentation in research participation for children who are Hispanic or have Spanish-speaking parents even though Hispanic patients comprise 41% of the population at our institution. Therefore, characterization of the factors affecting participation in research of underserved groups is urgently needed.

**OBJECTIVE:** We aim to examine the influence of race/ethnicity, language, socio-economic status (SES), health literacy and acculturation in the IC process in pediatric oncology clinical trials, with particular focus on Hispanics.

**SPECIFIC AIMS:** Our primary aim is to examine factors affecting parental comprehension of the basic concepts of the IC for pediatric oncology clinical trials. Secondary aims include exploring the effects of parental level of satisfaction, perception of voluntariness, anxiety and decisional regret on the IC process. We will examine the role of parental race/ethnicity, language, health literacy and acculturation as covariates for the proposed informed consent outcomes, with particular focus on Hispanics.

**STUDY DESIGN:** For this prospective cohort study, we will use standardized instruments to assess comprehension, satisfaction, perception of voluntariness, anxiety, and decisional regret. Anxiety, decisional regret and comprehension will be also assessed longitudinally. We will recruit parents/guardians of newly diagnosed pediatric cancer patients who have participated in an IC discussion for a pediatric oncology clinical trial. We plan to enroll 140 subjects, 70 Hispanics and 70 Non-Hispanic Whites. We will assess levels of comprehension, satisfaction, perception of voluntariness, anxiety and decisional regret between different groups of interest based on race/ethnicity, parental language, SES, health literacy and acculturation. We will conduct univariate and multivariate analyses.

**CANCER RELEVANCE:** There is tremendous need to address cancer disparities in underserved and minority groups. Little is known about the influence of race/ethnicity, language, SES, health literacy and acculturation in the IC process for pediatric oncology clinical trials. To our knowledge, there is no similar study with significant representation of Hispanic and Spanish-speaking participants. Thus this study will address this knowledge gap. Findings derived from this study will inform future research on interventions to improve the IC process for pediatric oncology clinical trials. The importance of our findings is highly relevant to the rapidly changing demographics in the U.S, where Hispanics are the largest growing ethnic group. The eventual aim of our research program is to improve clinical outcomes of pediatric cancer patients among Hispanic, Spanish-speaking individuals, patients from lower SES, and in those with lower health literacy and acculturation.