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“Factors affecting parental satisfaction, anxiety and comprehension of the informed consent in pediatric oncology clinical trial”

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Background: Survival rates in pediatric cancer have improved dramatically, in part due to high patient enrollment in clinical trials. Current informed consent (IC) standards are aimed at promoting equality when conducting research. Low participation of minorities in clinical trials has been extensively reported and may result from the complexity of the IC process. Our previous work showed that whereas Hispanic patients comprise 41% of the population, there is significantly underrepresentation in research participation. Characterization of the factors affecting participation in research is urgently needed.

Hypothesis: In parents who are Hispanic, Spanish-speaking, from lower socio-economic status (SES), and in those with lower health literacy and acculturation, levels of satisfaction, voluntariness and comprehension of the IC are lower and anxiety and decisional regret are higher.

Specific Aims: We aim to examine parental satisfaction, voluntariness, anxiety, decisional regret and comprehension of the IC in clinical trials for children with newly diagnosed cancer. We will use the CCG-S9901 satisfaction questionnaire, the Decision Making Control Instrument, the State-Trait Anxiety Inventory-State subscale, the Decisional Regret scale and the Quality of Informed Consent instrument to assess the variables of interest.

Design: We propose a prospective observational study designed to evaluate the proposed outcomes. We plan to recruit a minimum of 140 patients, based on our power analysis. In our institution, participation in ancillary studies such as the one proposed here, was ~90% and loss to follow-up was ~2%. We also inflate the sample size estimation by 3% to take this into consideration. A univariate linear model will be fit with an adjustment for the baseline input to compare levels of QuIC, satisfaction, perception of voluntariness, anxiety and decision regret between different groups of interest. NHW/Hispanic, parental language, SES, health literacy and acculturation will be the covariates.

The results derived from this work will provide insights into how to improve the IC process for pediatric oncology clinical trials. We aim to 1) identify the factors that results in lower participation rates among Hispanics and other underserved individuals; 2) improve the IC process and increase participation in minorities; and 3) eventually 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.

Despite the great need to address disparities in the underserved, there is little investigation of the influence of race/ethnicity, language, health literacy and acculturation in the IC process. The proposed research will provide novel data regarding the barriers in IC process faced by Hispanics and Spanish-speaking parents of children with cancer parent with lower SES, health literacy, and acculturation and their effect in pediatric cancer clinical trial accrual.

We will examine for the first time satisfaction, voluntariness, decisional regret and the effect of parental health literacy and acculturation in the parent's decision to enroll their children in cancer clinical trials. We are not aware of prior research reporting data on comprehension and anxiety with the IC a sample that will include a significant representation of Hispanics and Spanish-speakers.