Cancer PROMIS Study (CaPS) – Abstract

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**Objective:** The primary objective of PROMIS Network testing is to test proposed item banks in the domains of physical functioning, pain, fatigue, emotional distress, and social role participation in a clinical sample of cardiology and cancer patients. The primary purpose of the Cancer PROMIS Supplement is to test proposed item banks for measuring cancer-specific outcomes in the domains of sleep wake function, perceived cognitive function, illness impact, and sexual function. Testing of item banks in other patient populations will take place at the other institutions that participate in the PROMIS network. Specific goals of the testing are:

- a) To create item calibrations for all of the items in each of the sub-domains
- b) To create profile scores for various disease populations
- c) To co-calibrate legacy measures
- d) To confirm the factor structure of the primary domains and the sub-domains within each domain, and to evaluate the unidimensionality of the sub-domains themselves
- e) To conduct provisional differential item functioning (DIF) analyses
- f) To target “floor” items to appropriate populations (“ceiling” items are expected to get ample exposure from the Normal sample)

**Background:** Conventional clinical and functional self-report measures of disease status do not fully capture the ways in which chronic diseases and their treatments affect individuals. Conventional clinical self-report measures are neither computerized nor adapted to the patient’s experiences. Many aspects of patients' subjective experience, such as symptom severity and frequency, emotional and social well-being, and perceived level of health and functional ability are important targets for disease management.

The Patient-Reported Outcomes Measurement Information System (‘PROMIS’) Network is a national collaborative network comprised of Duke University and 5 other primary research sites (PRS) associated with research universities, a statistical coordinating center, the National Institutes of Health (NIH), and the National Cancer Institute (NCI). A central goal of this collaborative network is to improve measurement of multidimensional outcomes through the use of computerized patient-reported instruments. Clinical outcomes research will be greatly enhanced by the availability of a dynamic system to measure Patient Reported Outcomes (PROs) that is both efficient and psychometrically validated. Further, such a system will be broadly applicable to patients participating in clinical trials and to routine clinical outpatients who have a wide range of chronic diseases and demographic characteristics.
The Cancer PROMIS Supplement was created to enhance PROMIS Network testing because cancer is underrepresented as a component of the PROMIS, especially given its prominence in terms of incidence, prevalence, mortality, and impact on patient well-being. The objective of the Cancer PROMIS supplement (CaPS) is to leverage the existing PROMIS infrastructure and funding to ensure that PROMIS generates high-quality measures of patient-reported outcomes relevant to and validated for patients with cancer across the continuum of care (diagnosis, treatment, survivorship, and end-of-life).

Preliminary item banks in the five initial PROMIS domains (physical function, pain, fatigue, emotional distress, social role participation) and the additional CaPS domains (sleep wake function, perceived cognitive function, illness impact, and sexual function) have been constructed through rigorous and previously detailed methodology.

Design: To accrue a broad-based sample of cancer patients for item testing, we will rely upon self-referrals, combining these referrals with cases identified from the cancer clinics, the Duke and NC Cancer Registries, and NexCura, a nation-wide online registry of 500,000+ cancer patients, encompassing a wide variety of cancer types and stages. We will recruit a representative subject population with a range of cancer diagnoses, race, gender, age, income level, and education. Participants will be self-referred or identified through cancer clinics or NexCura or Duke and NC cancer registries.