SUMMARY OF WORK

**Project Smart - Stories and Music for Adolescent/Young Adult Resilience During Transplant**
*(subcontract from Indiana)*

**Docherty, Sharron CPNP, PhD**
Assistant Professor
Director Pediatric Acute/Chronic Care Nurse Practitioner Specialty

Duke University School of Nursing (DUSON) has agreed to serve as a subject recruitment and data collection site for the multi site study Stories and Music for Adolescent/Young Adult Resilience During Transplant: The SMART Study. The subjects will be recruited from patients of the Pediatric Blood and Marrow Transplant Program (PBMT). The PBMT program is nationally and internationally recognized leader in both established techniques and research initiatives related to blood and marrow transplantation. The program has performed over 1400 autologous and allogeneic transplants in children and young adults with cancer and genetic diseases since 1990. From 08-01-2005 through 07-31-2007 this program performed transplants on 47 patients who would have met the eligibility criteria for the SMART study. Patients of the PBMT program are treated in the inpatient facility of Duke Children's Hospital and outpatient clinic in the adjacent Children's Health Center. DUSON agrees to recruit and enroll between 15 and 20 subjects per year between 12/1/07 and 11/31/09. Subject recruitment will occur in the outpatient clinic where patients are seen for their pre-transplant workup. The study intervention and data collection will all occur in both the inpatient and outpatient sites. DUSON agrees to administer the 3 week intervention and collect all of the data both pre-intervention and 100 days post intervention. The data collected will be downloaded and cleaned at the Indiana University site. DUSON agrees to participate in data analysis through participating in discussion and meaning-making related to the statistical findings. DUSON agrees to participate in dissemination of the study findings through manuscript publication and presentation of results at local and national meetings.

Duke University School of Nursing (DUSON) agrees to hire the following personnel to execute the SMART study: Site Principle Investigator, Site Project Manger, Certified Music Therapists (Interveners) and Intervention Evaluators. The personnel will be hired and available for study training given by the Indiana University School of Nursing that will be performed at the Duke University School of Nursing.

As Site Principal Investigator, Dr. Docherty will have ultimate responsibility for all facets of the research being conducted at the Duke Site, including hiring and coordinating the training of staff, helping with recruitment and enrollment of subjects, oversight of the study intervention and data collection. She will meet routinely with all research staff, on both an individual basis and in research team meetings. In particular Dr. Docherty will be responsible for: ensuring protocol compliance (including determining that inclusion/exclusion criteria are met, Ensuring recruitment goals are met, assessing overall protocol feasibility, following the trial's randomization procedures, reviewing with staff inclusion/exclusion criteria, schedule of visits, end point criteria); Ensuring initial and ongoing review by the Duke University Health System Institutional Review Board for Clinical Investigations and the Duke University Cancer Protocol.
Review (including evaluating for adverse experiences, reporting all serious adverse events to Indiana University and IRB, obtaining signed and dated informed consents from subjects or subject's legal representative); Ensuring the validity of the data reported to Indiana University (including ensuring the accuracy, completeness, legibility and timeliness of report forms, explaining any discrepancies between source documents and report forms); Ensuring documentation of study-related procedures, processes and events (including documenting deviations from approved protocol, documenting informed consent, ascertaining reasons for patient's premature study withdrawal, documenting adverse experiences, complying with written procedures to document changes to data and/or report forms); Ensuring the proper use and storage of study materials (including assuming responsibility for the computers and other materials provided by Indiana University at the site, assigning responsibility to appropriate research personnel, reviewing the proper use of the study materials by the subjects); and Direct site operations (including communicating with subjects, research team, IRB and Indiana University core team, providing the technical leadership and consultation to staff in regards to designing, conducting and interpreting the protocol, meeting regularly with the research team to discuss subject participation and protocol progress, ensuring that all research staff are informed about the protocol, participating in monitoring and auditing by Indiana University and regulatory authorities as requested, delegating