

*The University of Florida Proton Therapy Institute and St. Jude Children's Research Hospital have entered into a collaboration that will provide protocol-based proton therapy for St. Jude patients. The first protocol is a risk adapted clinical study to evaluate the use of proton beam therapy in conjunction with chemotherapy for rare brain tumors in children less than 3 years of age. In cooperation with St. Jude, we will have both clinical and research expertise to provide the best outcomes for patients and to create new knowledge that will guide the development of proton therapy for future patients.*

*Participants in this research study are less than 3 years of age and have been newly diagnosed with a malignant brain tumor. Conventional radiation for brain tumors in very young children may cause permanent problems with thinking, learning, and growing. Because of this limitation in therapy, and likely differences in tumor biology, children less than 3 years old with these tumors generally have a worse prognosis.*

*Proton therapy is an emerging method of radiation therapy which has the potential to reduce radiation dose to normal tissues to a greater extent than is possible with other methods of radiation therapy that use photons (x-rays). The use of proton therapy may decrease neurocognitive and neuroendocrine side effects of radiation therapy, and is currently being used with increasing frequency in the treatment of pediatric brain tumors. This study provides proton therapy for the treatment of very young children with brain tumors within the framework of a novel chemotherapy regimen.*

*Under the clinical protocol, St. Jude will refer patients enrolled on the SJYC07 protocol to receive proton therapy at the University of Florida Proton Therapy Institute in Jacksonville, Fla. The purpose of the clinical study is to improve response rates and decrease treatment-related side effects.*

*Radiation therapy using protons will be given to the tumor bed for a standard 30 treatments. However, radiation therapy is considered research in this protocol due to the following:*

*1) The area of the brain that receives radiation (treatment volume) is experimental. We will reduce radiation volume by eliminating radiation to both the head and spine (craniospinal irradiation) for intermediate risk patients with medulloblastoma, PNET, ATRT or similar tumors. We will treat only the tumor bed. The tumor bed is the site where the tumor was located at the time of diagnosis.*

*2) The edge of normal tissue (margin) surrounding the tumor or tumor bed that is treated is experimental. We will use a 5 mm margin which is smaller than the standard margin of 10-15 mm used to treat children with similar brain tumors including medulloblastoma, PNET, ATRT and ependymoma. Because the severity of radiation side effects is directly related to the margin surrounding the tumor that receives the highest doses, we think that reducing the margin will be safe and should result in fewer side effects.*

*3) The combination of surgery, chemotherapy and radiation therapy used in this research protocol has not been tested before. Therefore, the combination of treatments, which include radiation therapy, is experimental. There is limited experience irradiating children after surgery and induction chemotherapy younger than three years of age.*

*Patients will also be asked to participate in an optional PET-CT study.*

*In this study, we will use PET-CT to evaluate the width, depth and intensity of the proton beam to determine the difference between the calculated or planned radiation dose and the actual radiation dose to tumor and normal tissues. Unlike a traditional PET-CT scan, this study does not require injection of a radioactive marker/substance.*

*Immediately following the proton treatment, the patient will be moved to the PET-CT scanner for a 30 minute examination. The entire process including movement of the patient will take approximately 40 minutes. The number of times that the PET study will be performed during the course of treatment will be equal to the number of proton beams. We expect that most patients will have 3 PET-CT examinations.*

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