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**Non-Technical Abstract**

Injection of the Tumor Suppressor Gene(P53) into the Tumor of a Patient with Anaplastic Thyroid Cancer using the Cold Virus-Adenovirus as the Carrier.

This is a single patient request for a trial of this form of gene therapy. The patient is a 61 year old businessman with one of the most lethal and most rapidly growing cancers known, anaplastic thyroid cancer. It is a rare cancer that seems to evolve out of the more common thyroid cancers. Studies show that the dominant change seems to be a loss of the tumor suppressor gene called P53. Studies in other cancers have shown that if the gene can be inserted into the tumor cells the cancer can return to an earlier stage or even stop growing and regress. This has been shown for other cancers in humans. It has also been shown in the lab using tissue cultures of anaplastic thyroid tumors and in mice.

Studies of the safety of using this cold virus, adenovirus have shown no adverse effects. The company providing the modified virus reports no negative outcomes after over 600 human uses. This form of therapy has never been tried with this form of cancer in humans. There is no available therapy for this patient's stage of cancer. His prognosis is terminal with death with in the next few weeks to a month.

We plan to follow the same protocol already approved for another cancer, head and neck cancer with squamous cell type of pathology. This will include injections into the tumor twice a week. The procedure will be performed by the primary investigator and his associates at Vanderbilt Medical Center who are also running the head and neck protocol. The single patient protocol has been approved by the FDA and the Vanderbilt IRB.

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