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**PROTOCOL SUMMARY**

**Title:** SWOG #9019, A Phase III Randomized Prospective Comparison Between Chemotherapy Plus Radiotherapy, and the Same Chemotherapy Plus Radiotherapy Together With Surgery for Selected Stage IIIA (Positive Mediastinal Nodes) and Selected Stage IIIB (No Malignant Effusion) Non-Small Cell Lung Cancer

**Principal Investigator:** [Redacted] Maj, USAF, MC/PSMH/2-7312

**Facility:** Wilford Hall USAF Medical Center

**1. SUMMARY:** The purpose of this study is to assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free overall and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with selected Stage IIIA (N2 positive) and selected Stage IIIB non-small lung cell cancer. This study will also evaluate the patterns of local and distant failure for patients enrolled in each arm of the study in order to assess the impact of the therapy on local controlled and distant metastases. Patients who fit the eligibility criteria with non-small lung cancer either Stage IIIA or IIIB will be treated with concurrent radiation therapy to the chest and chemotherapy consisting of Cisplatin and VP16. Patients will be randomized to then go on to either further chemotherapy or surgical resection depending upon the response of the disease to the initial phase of treatment. Treatment will take approximately 3 months to complete. Approximately 2 patients, 18 and older, will be enrolled in the study each year from Wilford Hall Medical Center.

**2. INVESTIGATIONAL DRUGS/DEVICES:** None

**3. LABORATORY, RADIOLOGY, OR OTHER SPECIAL SUPPORT REQUIRED:** Assuming 2 patients per year are accrued to this study, the following number of tests will be required.

TEST NAME	STD OF CARE (Y/N)	TYPE OF SPECIMEN	QUANTITY	TIME FRAME LENGTH OF STUDY
Complete Blood Count	Y	Blood	40	2 Years
Chemistry Profile	Y	Blood	20	2 Years
Chest X-ray	Y	X-ray	8	2 Years
Chest CT	Y	X-ray	8	2 Years
Bone Scan	Y	Nuclear Medicine Scan	2	2 Years
Brain CT or MRI	Y	X-ray	8	2 Years
EKG	Y		4	2 Years

**4. FUNDING:** None

INVESTIGATOR CATEGORIES: Principal Investigator - 1 Staff; Associate Investigators - 8 Staff and 10 Fellows

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