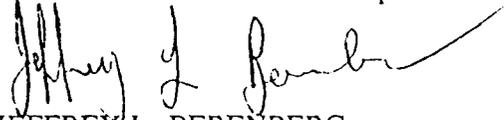


APPLICATION FOR CLINICAL INVESTIGATION PROJECT

1. **PRINCIPAL INVESTIGATOR:** COL Jeffrey Berenberg, MC, Chief, Medical Hematology-Oncology Service, Department of Medicine
2. **PROJECT TITLE:** SWOG 9015:A Randomized Trial of Pre- and Post-Operative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-Small Cell Carcinoma of the Lung, Phase III
3. **OBJECTIVE:** To compare the survival of patients with operable non-small cell lung cancer treated with surgical resection alone versus surgical resection combined with pre- and post-operative chemotherapy.
4. **MEDICAL APPLICATION:** Patients with operable non-small cell lung cancer which exceed 3 centimeters in size have less than a 50% 5 year survival. Better treatment is needed.
5. **STATUS:** Six recent randomized trials have shown that cisplatin-based chemotherapy results in longer survival (7-17 weeks longer) than supportive care alone in patients with metastatic non-small cell lung cancer. Two other trials have shown that carboplatin-based chemotherapy results in survival essentially identical to cisplatin in metastatic non-small cell lung cancer. Carboplatin is much less toxic and deserves a trial resected non-small cell lung cancer.
6. **PLAN:** Patients agreeing to participate and who have operable non-small cell lung cancer over 3 centimeters in size will be randomized to: 1) surgery alone or 2) 2 cycles of carboplatin plus VP-16 followed by surgery and then 3 more cycles of the same chemotherapy.
7. **BIBLIOGRAPHY:** Appendices.
8. **FACILITIES TO BE USED:** Hematology-Oncology Clinic, General Medicine Wards.
9. **TIME REQUIRED TO COMPLETE:** Until closed by the Southwest Oncology Group
10. **PERSONNEL TO CONDUCT PROJECT:** COL Jeffrey Berenberg, MC, Chief, Adult Hematology-Oncology Service; LTC William J. Uphouse, MC, Assistant Chief, Adult Hematology-Oncology Service; MAJ Paul Fishkin, MC, Staff, Adult Hematology-Oncology Service; MAJ Evans Smoot, MS, Oncology Pharmacy; COL Lawrence Sakas, MC, Chief, Anatomic Pathology; COL Arthur Larson, Chief, Cardio-thoracic Surgery; LTC Alfred B. Brooks, MC, Staff, Adult Hematology-Oncology Service.
11. **FUNDING IMPLICATION:** Basic funding for this project comes from the National Cancer Institute through direct grants to the Southwest Oncology Group (SWOG).
12. **NUMBER OF PATIENTS TO BE STUDIED:** Estimated number; 2 per year
13. **GIFTS:** None

14. **DATE PREPARED:** 8 September 1992


JEFFREY L. BERENBERG
COL, MC
Chief, Adult Hematology-Oncology Svc.
Department of Medicine
Tripler Army Medical Center
Tripler AMC, Hawaii 96859-5000
PRINCIPAL INVESTIGATOR


J. CRAIG HOLLAND
LTC, MC
Chief, Department of Medicine

ADDITIONAL REQUIRED INFORMATION

1. **Group/Group Number:** Southwest Oncology Group, SWOG 9015 (92)
2. **Expected duration of study:** 4 years
3. **Expected number of subjects:** 400; 8 from Tripler Army Medical Center
4. **Source of subjects identified as:** Hospital-Outpatient
5. **Type of subject identified as:** Patient
6. **Type of subject identified as:** Adult
7. **Local facilities to be used:** Hematology-Oncology Clinic, Pharmacy (Oncology), General Medicine Wards
8. **First Principal Investigator who submitted study and medical center:** Jeffrey L. Berenberg, COL, MC, Tripler Army Medical Center.
9. **List of chemotherapeutic agents:** carboplatin, VP-16, G-CSF

IMPACT STATEMENT

Patients: Adult patients

Bed Occupancy: None beyond good patient care

Laboratory: None beyond good patient care

Radiology: None beyond good patient care

Pharmacy: Oncology pharmacy to prepare necessary drugs

Nursing Services: None beyond good patient care

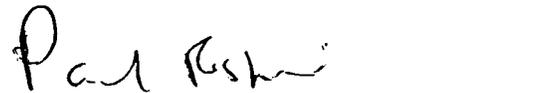
Registrar: None beyond good patient care

APPROVALS:

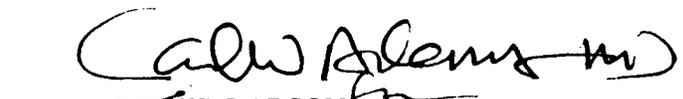

JEFFREY L. BERENBERG
COL, MC
Chief, Adult Hematology-Oncology Service


LAWRENCE SAKAS
COL, MC
Chief, Anatomic Pathology


WILLIAM J. UPHOUSE
LTC, MC
Asst. Chief, Adult Hematology-Oncology Service


PAUL FISHKIN
MAJ, MC
Staff, Adult Hematology-Oncology Service


EVANS SMOOT
Major, MS
Oncology Pharmacy


ARTHUR LARSON
COL, MC
Chief, Cardio-thoracic Surgery


ALFRED B. BROOKS
LTC, MC
Staff, Adult Hematology-Oncology Service