

ARM1.950119.009d

HSHK-CI (40-38a)

13 NOV 1992

MEMORANDUM FOR COL Jeffrey L. Berenberg, Department of Medicine,  
Hematology-Oncology Service (ATTN: HSHK-DMO),  
Tripler AMC, HI

SUBJECT: Approval to Initiate More Than Minimal Risk Studies

1. Your clinical investigation projects listed below have completed required review and are approved to start immediately.

(a) SWOG 9015(93): A Randomized Trial of Post-operative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-small Cell Carcinoma of the Lung, Phase III

(b) SWOG 9108(93): A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate + Chlorambucil in Previously Untreated B-cell Chronic Lymphocytic Leukemia

2. Your studies have more than minimal risk, and the medical monitor assigned is LTC Philip Bruno, MC. He has the authority to require changes to your studies or even suspension of your research to protect the safety of the volunteers. It is your responsibility to keep him continuously informed of the status of your work and in particular to immediately notify him of any sign or symptom suggesting adverse effect or increased risk of a volunteer, whether or not that increased risk is thought to be due to the research. All his recommendations and requests are to be complied without failure or delay; if you cannot comply, suspend all research on this protocol immediately and notify me directly. Once a safety measure is instituted, it may not be dropped without review of the Human Use Committee and command decision.

3. Should any of the volunteers experience signs or symptoms of adverse effects or illness, you must insure immediate medical referral to the appropriate Tripler AMC health care team. You must document all such occurrences, whether or not caused by your research, and report them to the Human Use Committee. Your medical monitor will advise you whether or not that report can wait for your annual review.

4. You must report your study findings, including number of patients and adverse effects, to the Human Use Committee prior to one year from this date (or earlier if required to do so by the medical monitor). You must also report your study in the TAMC Annual Report of Clinical Investigation Activities. You will be given full instructions, including schedule of reports, from the C, Clinical Investigation, 30 days prior to any report suspense.

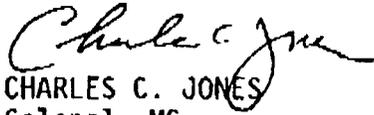
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5. Your study and its documentation, including list of volunteers and copies of the volunteers' informed consent statements, are subject to inspection at any time by your chain of command and by such inspectors of official audit agencies as obtain prior consent from this command. You must maintain your records such as to facilitate such inspections.

6. Any public presentations or publications of your work must receive prior clearance of this command. This includes academic lectures given outside TAMC, abstracts submitted to professional meetings, letters to the editor and press releases.

7. Your research study has been determined to be of potential importance to the academic and professional program of Tripler AMC. You are to give all possible priority to its completion. Should any problem arise that jeopardizes the success of your research, notify the Chief, Clinical Investigation, at 433-6709.

  
CHARLES C. JONES  
Colonel, MC  
Deputy Commander  
for Clinical Services