Department of Veterans Affairs

REPORT OF SUBCOMMITTEE ON HUMAN STUDIES

Project/Program Title		
Principal Investigator		
VAMC	Review Date:	

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the <u>Description of Research</u> <u>by Investigator</u> is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills.	
 The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. 	○ YES ○ NO ○ YES
3. Every effort has been made to decrease risk to subject(s)?	ONO
4. The potential research benefits justify the risk to subject(s)?	
5. If subject is <u>incompetent</u> and surrogate consent is obtained, have all of the following conditions been met; a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described.	
6. If the subject is paid the payment is reasonable and commensurate with the subject's contribution.	⊖ YES ⊖ NO
7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable.	⊖ YES ⊖ NO

8. Comments: (Indicate if Expedited Review)

RECOMMENDATION:	O DISAPPROVE/REVISE	
SIGNATURE OF CHAIRMAN (Sign in ink)	DATE	