

## **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 by Investigator</u> is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills.	
2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances.	d YES NO
3. Every effort has been made to decrease risk to subject(s)?	YES NO
4. The potential research benefits justify the risk to subject(s)?	YES NO
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.	o YES
6. If the subject is paid the payment is reasonable and commensurate with the subject' contribution.	s YES NO NA
7. Members of minorities and women have been included in the study population whenever possible and scientifically desirable.	YES NO
8. Comments: ( <u>Indicate if Expedited Review</u> )	
RECOMMENDATION: APPROVE DISAPPROVE/REVISE	
SIGNATURE OF CHAIRMAN	DATE