



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 Description of Research by Investigator is complete, accurate, and understandable to a research subject or surrogate who possess standard reading and comprehension skills. [] YES [] NO
2. The informed consent will be obtained by the principal investigator or a trained and supervised designee under suitable conditions. [] YES [] NO
3. Every effort has been made to decrease risk to the subject(s). [] YES [] NO
4. The potential research benefits justify the risk to the subject(s). [] YES [] NO
5. If subject is incompetent and surrogate consent is obtained, all the following conditions been met: (a) the research cannot be done on competent subjects; (b) there is no risk to the subject, or if risk exists, the direct benefit to the subject is substantially greater; (c) if an incompetent subject resists, he/she will not have to participate; and (d) if there exists any question about the subject's competency, the basis for the decision on competency has been fully described. [] YES [] NO
6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. [] YES [] NO [] N/A
7. Members of minority groups and women have been included in the study population whenever possible and scientifically feasible. [] YES [] NO
8. Expedited review? [] YES [] NO

Comments:

RECOMMENDATION: [] Approve [] Disapprove/Revise

SIGNATURE OF CHAIR

DATE