Department of
Veterans Affairs

Memorandum

Date: October 10, 2008

From: Chief Research and Development Officer (CRADO)(12)

To: VHA Research Facilities

INTERIM GUIDANCE ON RESEARCH WARRANTING SPECIAL SAFEGUARDS TO PROTECT THE RIGHTS AND WELFARE OF HUMAN SUBJECTS

In approving research, Department of Veterans Affairs (VA) regulations and the Federal Policy (Common Rule) for the Protection of Human Subjects at Title 38 Code of Federal Regulations Part 16 (38 CFR 16) require that Institutional Review Boards (IRBs) determine the following:

- The selection of subjects is equitable, "taking into account the purposes of the research and the setting in which the research will be conducted," and with particular attention to the "special problems of research involving vulnerable populations" [38 CFR 16.111(a)(3)].

- "Additional safeguards" are included "to protect the rights and welfare" of subjects who are likely to be vulnerable to coercion or undue influence" [38 CFR 16.111(b)].

Although the regulations provide examples of potentially vulnerable subject groups, individuals with a variety of physical or mental conditions may deserve special safeguards, depending upon the particular circumstances of a proposed research study.

IRBs should consider the following guidance in reviewing research that may warrant special safeguards to protect human subjects:

1. Where relevant, research protocols submitted to IRBs should include a narrative section that :

    a. Identifies any circumstances that may warrant special safeguards to protect the rights and welfare of subjects who are likely to be susceptible to coercion or undue influence; and

    b. Describes appropriate actions to provide such safeguards.

2. In determining that the approval criteria at 38 CFR 16.111(a)(3) and 16.116(b) have been satisfied, IRBs should, where relevant, include documentation that adequate safeguards have been included to protect the rights and welfare of subjects who are likely to be susceptible to coercion or undue influence.

3. Regardless of the need for special safeguards, IRBs approving research must determine that risks to subjects are minimized, monitoring procedures are adequate to ensure subject safety, and the remaining criteria at 38 CFR 16.116 have been satisfied.

Do not hesitate to contact ORD should you have any questions.