MUSC
Medical University of South Carolina

I. Policy

A. Introduction

When some or all of the subjects in a protocol are likely to be vulnerable to coercion or undue influence, the IRB will include additional safeguards to protect the rights and welfare of these subjects. The review process will include one or more individuals who are knowledgeable about or experienced in working with the population involved in the research project.

B. Federal Regulations

45 CFR 46 has additional subparts which require extra protection for vulnerable populations and have additional requirements for IRBs.

1. Subpart B – Additional Protection for Pregnant Women, Human Fetuses and Neonates
2. Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
3. Subpart D – Additional Protections for Children Involved as Subjects in Research

C. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>).

D. ICH – Good Clinical Practice (GCP)

The MUSC IRBs operate in accord with ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. CGP standards contained in the ICH document are not regulatory requirements in the United States and vary from FDA and DHHS regulations. As such, the MUSC IRBs do not voluntarily agree to comply with all of the GCP statements unless requested to do so by sponsors as documented in contractual agreements. The MUSC IRBs comply with most aspects of ICH-GCP, and the MUC polices, procedures and forms require investigators to com ploy with most ICH-GCP guidance. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>).

E. Memorandum of Understanding

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

Restrictions on Vulnerable Populations Specific to VA Research Studies

The following are prohibited as VA research study protocols:

1. Research involving fetuses
2. Research involving neonates
3. Research involving *in vitro* fertilization
4. Research involving prisoners unless a waiver has been granted by the VACO Chief Research and Development Officer
5. Research involving children unless
    a) A waiver has been granted by the VACO Chief Research and Development Officer
    b) The study presents no greater than minimal risk
    c) The study meets all requirements of Subpart D of the DHHS or RDA regulations

d) The Ralph H. Johnson VAMC Medical Center Director certifies that the facility is able to respond to pediatric emergencies

e) The research is conducted by a contractor or non-VA employee and the individual or entity performing the research has appropriate liability insurance.

6. Research involving pregnant women unless

a) The research includes adequate provisions to monitor the risks to the participant and the fetus.

b) Adequate consideration is given to the manner in which prospective participants are going to be selected

c) Adequate provisions are made to monitor the actual consent process by procedures such as:

(1) Overseeing the process by which individual consents are secured either by:

(a) Approving enrollment of each individual

(b) Verifying, perhaps through sampling, that approved procedures for enrollment of individuals into the activity were being followed

(c) Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

F. EPA Research

1. EPA policy requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.

2. For research not conducted or supported by any federal agency that has regulations for protecting human research subjects and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research subjects apply as the EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.