



## **I. Policy**

### **A. Introduction**

The Belmont Report's principle of justice requires the fair distribution of the overall benefits and burdens of research. One of the federally required criteria that the IRB must assess when determining whether research may be approved is that the selection of subjects is fair and equitable. (45 CFR 46.111).

### **B. Research Obligations**

In making this assessment, the IRB must take into account the purposes of the research and the setting in which the research will be conducted. Particular attention must be given to vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. When research does not involve a therapeutic component, the IRB will consider who should participate and accept the risks of the research and will assess whether overburdened classes of subjects are being included solely for reasons such as easy availability or their economic status.

## **II. Procedures**

During review and assessment of subject selection, the IRB must determine the procedures outlined by the investigator reflect a fair distribution of the risks and benefits of research among the populations. In making this assessment, the following items are considered:

- A.** The purpose of the research and its target population.
- B.** Methods of recruitment, including the screening procedures and the settings for recruitment and conduction of the research.
- C.** The inclusion/exclusion criteria to be used and how it relates to the representative population that potentially stands to potentially benefit from the research.
- D.** Justification for exclusion of certain populations.

E. The amount and timing of payments to participants.

**F. 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”.

Studies should permit entry of non-veterans only when there are insufficient veterans available to complete the study.

**III. References**

A. [45 CFR 46.111 Criteria for IRB Approval of Research](#)