



Policy Name: Research Subject Advocacy Policy and Procedures		
Approved		
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Replaces Policy: 02/20/2009		

I. POLICY

A. Introduction

Federal regulations require that IRBs give special consideration to protecting the welfare of special research participant groups that are more vulnerable than general participants. These research participant groups include, but are not limited to: pregnant women, children, cognitively impaired persons, prisoners, comatose patients, terminally ill patients, elderly/aged persons, minorities, students, and employees.

Human research participant advocates are part of the overall human research risk protection program. They can enhance the protection of special vulnerable groups as noted above and serve as liaisons to the IRB on behalf of research participants. Research participant advocacy encompasses a variety of roles which may be provided by a number of individuals trained to serve in this capacity. Research participant advocates at MUSC may come from many backgrounds and perspectives and may include: faculty or staff volunteers who have special expertise with the vulnerable population of a study; community members who have a background in working with vulnerable populations, and single providers who serve as the research participant advocate for research requiring such services.

B. Responsibilities of the Research Participant Advocate

The primary responsibilities of research participant advocates are to provide assurance to institutional officials, our community, the IRBs, the principal investigators, and other officials that appropriate efforts are being made to protect vulnerable populations and to ensure that safety receives the highest priority. Duties of a research participant advocate are diverse and may vary according to the request of the IRB, University officials, principal investigator, or the unit conducting the research. Research participant advocates may serve as educators to participants and researchers. They may participate as observers of the consent process and may monitor specific research procedures. Research participant advocates may assist potential research participants in their understanding of research participation as well as research staff with the resolution of questions regarding selection of human subjects in research.

Other duties may be specified by the IRB, Director of the Office of Research Integrity, or other officials as needed. IRBs occasionally request that the Principal Investigator of a particular study find a research participant advocate to observe, monitor, and report to the board on various aspects of research studies. The MUSC Conflict of Interest Committee may request the provision of a research participant advocate as part of a comprehensive management program of perceived conflict of interest.

II. PROCEDURES

A. Sources of Research Participant Advocates

Since 2008, the Core Clinical Research Training (CCRT) has included content addressing topics relevant to the service and training of research participant advocates. Individuals taking this course learn the bioethical foundations, federal regulations, and University policies regarding the special needs of vulnerable populations as a part of the Good Clinical Practice (GCP) module. In addition, specialized training curricula for human research advocates is designed and taught under the guidance of SCTR as needed. Over time, this model will create a cadre of faculty and staff with specialized training and expertise in serving as advocates. Advocates may also be selected from the community, faculty, and staff of the Medical University and its affiliates. Those selecting a research participant advocate for any particular human research study should keep in mind that the advocate should have some background knowledge in working with the particular vulnerable population and have the time commitment available to participate with the research participants on an on-going basis for the duration of the research endeavor.

B. Institutional Responsibilities

The research advocate program and all research advocates have direct access to the Director of the Office of Research Integrity and other organizational officials. Advocates may also report to the IRBs. It is the responsibility of the University to create an atmosphere of advocacy for special populations and to ensure that principal investigators, centers, departments, and special research units all support the use of research participant advocates. The institution periodically assesses the research participant advocate program and its effectiveness

C. IRB Responsibilities

Each of the Institutional Review Boards, Chairs, Vice Chairs, and staff will be responsible for assessing the types of participants being selected for studies. The IRB may suggest or require that studies have a research participant advocate. The IRB will review the research participant

advocate nominated by the Principal Investigator to ensure that the advocate is appropriate and not conflicted. When a Research Participant Advocate is required to be present during the consent process, the IRB approved informed consent document will include a signature line for the Advocate to sign and date.

III. REFERENCES

- A. [45CFR 46 Sub Part B, C, D.](#)
- B. [OHRP Policies, Chapter 7, Special Classes of Subjects; Institutional Review Board Guidebook](#)