



Policy Name: Research Subject Advocacy Policy and Procedures			
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I. POLICY

A. Introduction

Federal regulations require that IRB's give special consideration to protecting the welfare of special subject groups that are more vulnerable than general subjects. These subject groups include but are not necessarily limited to pregnant women, children and minors, cognitatively impaired persons, prisoners, traumatized, comatose patients, terminally ill patients, elderly/aged persons, minorities, students/employees and normal volunteers. Under certain circumstances other categories involving patients with psychiatric disorders or substance abuse disorders may fall into this category as well.

The human research participant advocate is part of the overall human research risk protection program. They can enhance the protection of special vulnerable groups as noted above. Traditionally, research advocates at MUSC have been faculty or staff volunteers who have special expertise with the vulnerable population of a study. Occasionally these advocates have been citizens of the community who also have a background in working with vulnerable populations. An example of the latter case has been social workers who have worked in prison populations. They have served as participant advocates in research studies involving prisoners. In the past, the IRB's have occasionally requested 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. Another traditional form of research participant research advocacy has been the role of Dr. Melissa Henshaw, a physician who is Associate Professor of Pediatrics and who serves as the research participant advocate for the Research Support Center (formally the GCRC). Dr. Henshaw has played a major role in forming the current policies.

B. Responsibilities of the Research Participant Advocate

The primary responsibilities of the research participant advocate is to provide assurance to institutional officials, our community, the IRB's, 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 subject advocates may serve as educators to participants and researchers. They may participate as observers of the consent process and may monitor specific research procedures. They may serve as facilitators to the reporting and review of adverse events. The research participant advocate may assist patients or research staff with the resolution of any staff or patient, questions regarding selection or participation 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. The conflict of interest committee of MUSC may request the provision for a research subject advocate as part of a comprehensive management program of perceived conflict of interest.

II. PROCEDURES

A. Sources of Research Participant Advocates

Beginning with the fall classes of 2008, the Core Clinical Research Training (CCRT) will include a new module on serving as a research participant advocate. Individuals taking this course will learn the bioethical foundations, federal regulations and University policies regarding the special needs of vulnerable populations. This course will be under the direction of Dr. Melissa Henshaw, the human subject advocate Director for the Clinical Research Support unit. Over time the human research advocate protection course module will create a cadre of faculty and staff individuals who will have special expertise in serving as an advocate. Advocates may also be selected from the community, the faculty and staff of the Medical University and its affiliates. The selection of a research participant advocate for any particular human research study should keep in mind that the advocate should have some background interest and 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 will have direct access to the Director of the Office of Research Integrity and the Organizational Officials. Advocates may also report to the IRB's. It will be 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 participants advocates. The institution will develop a quality assurance program to monitor and enhance the effectiveness of the research participant advocate program.

C. IRB Responsibilities

Each of the IRB Boards, Chairman, Vice Chairman and staff will be responsible for assessing the types of participants being selected for studies. A research participant advocate will be chosen for studies involving prisoners and will give consideration to appointing an advocate in studies for fetuses or other categories of vulnerable patients as noted above. The IRB is discouraged from suggesting that a principal investigator select a research participant advocate. This selection should be made by the IRB Chair, Vice Chair or their designee from the board. By allowing the principal investigator to select the research advocate there could be an appearance of conflict of interest

III. REFERENCES

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