CLINICAL RESEARCH ETHICS CONSULTATION SERVICE

CHARTER

1. BACKGROUND/MISSION: The Clinical and Translational Science Award from the NIH’s National Center for Research Resources to MUSC in 2009 contains a Core Clinical Research Ethics (CRE) program within South Carolina Clinical and Translational Research Institute (SCTR).

The SCTR Clinical Research Ethics Program has three main components: the Workshop/Conference Program, the Fellowship in Clinical Research Ethics Certificate Program, and the Clinical Research Ethics Consultation Service (CRECS). The first two are managed by The Institute of Human Values in Health Care, the third by the MUH Ethics Committee.

CRECS is part of the Medical University Hospital (MUH) Ethics Committee, which has provided patient care and organizational ethics consults for many years. This Healthcare Ethics Consultation service and the Clinical Research Ethics Consultation Service are the service arms of the MUHA Ethics Committee and act in an advisory capacity only. Policy and procedure for ethics consultations are outlined in the MUHA Medical Center Policy Manual and on the SCTR Clinical Research Ethics Program website.

CRECS contributions to clinical research ethics are advertised as a service of the MUH Ethics Committee and through SCTR’s SPARK informatics system.

The Mission of the Clinical Research Ethics Consultation Service (CRECS), is to address ethical concerns throughout the translational stages of research – from bench to bedside. For example, these issues range from concerns about research misconduct to utilization of biobank tissues for MUSC research start-ups. The CRECS may respond to consult requests from groups within SCTR and MUSC, as well as other groups and individuals outside the institution.

2. CLASSIFICATION: CRECS is a University level entity, responsive to the Provost, as well as a service arm of the MUHA ethics committee, responsive to the MUHA Executive Committee. The MUHA Ethics Committee reviews the Charter periodically to determine any necessary updates.

3. FORMAL CHARGES: The duties of the Clinical Research Ethics Consultation Service (CRECS), related to the SCTR Clinical Research Ethics Program, specifically include:

   1. Case consultations addressing ethical concerns throughout the translational stages of research – from bench to bedside
2. Peer review of case consultations and continuing self-education in research ethics issues

3. Providing didactic support for Fellowship in Clinical Research Ethics Certificate Program

4. Participating in activities of the CTSA CRE workgroups, specifically the consultation workgroup, and publishing appropriate consultation case examples.

4. **MEMBERSHIP/TERMS OF APPOINTMENTS**: Members broadly represent the health care professions, the humanities, and the social sciences. They are drawn from the faculties of institutions of higher education in South Carolina. Members are appointed for terms of five years, without limit on reappointment, renewable at the discretion of the Chair of the MUHA Ethics Committee.

5. **SUBCOMMITTEES**: Ad hoc, task-oriented subcommittees are appointed by the Chair as needed.

6. **THIS UNIVERSITY CHARTER** is effective as of February 5, 2013.

7. **FREQUENCY OF MEETINGS**: The CRECS membership meets every 3 months. Written notice is provided each CRECS member in advance of each formally scheduled meeting. A formal meeting agenda and appropriate supportive materials are attached to the written notice of each meeting.

8. **MINUTES**: Summary minutes of each meeting are prepared by the Chair or designate and submitted to all members prior to each membership meeting. Copies are also distributed to the University Provost.

9. **CRECS REPORTS**: Each year the CRECS files a written report, summarizing major activities for the prior period, with the Provost.

10. **QUORUM**: A simple majority will constitute a necessary quorum to conduct business at any meeting of the membership.

11. **AMENDMENT TO THIS CHARTER**: Should any amendment to this Charter be required between scheduled annual reviews, the Director shall work with the Provost in developing amendments suitable to all parties.
Web Access:
MUSC Medical Center Clinical Policy C-008 Ethics Consultation. Available at

Approved ___________________________ Date 2/5/13

Mark S Sothmann, Ph.D.
Vice President for Academic Affairs and Provost