MUSC
MEDICAL UNIVERSITY OF SOUTH CAROLINA

Memorandum

To: All Investigators and Staff Potentially Involved in the Conduct or Oversight of Human Research/Clinical Investigation

From: Rosalie K. Crouch, Ph.D.
Kenneth Roozen, Ph.D.
John R. Raymond, M.D.
Ed Conradi, M.D.

Re: Further Clarification of Educational Requirements for Conducting Human Subjects Research

Date: November 5, 2001

1. This follow up memorandum (to that of October 4, 2001) is being issued jointly by the Provost's Office at MUSC and the Research Service at the Ralph H. Johnson VA Medical Center. It is intended to further clarify our policy for educational requirements for conducting or overseeing human research by MUSC and VA faculty, administration, and staff. We are issuing this clarification upon the request of various faculty members who have raised specific points for our consideration. We have obtained extensive feedback from our local faculty, NIH, VA and OHRP in order to make this clarification.

2. The following individuals will be required to complete the University of Miami-based CITI course[1] by December 3, 2001.
   a) All PI's, co-PI's, or investigators identified on any human subjects research protocol. In order to avoid any more confusion, **our local definition of a human subjects research protocol is: any protocol required to be submitted for IRB review of any type (full review, exempt review or expedited review)[2].** Investigators could be faculty, collaborators, consultants, post-docs, house staff, fellows, technicians or others who will play a substantial role in the human subjects research, including a major authorship role when the work is reported.
   b) All individuals responsible for obtaining informed consent for human subjects research as defined in 2a.
   c) All research study coordinators and full-time research nurses.
   d) All first year graduate students[3].
   e) All Deans, Department Chairs, Division Directors and others who sign off on the "Blue Sheet" for grant submissions.
   f) MUSC Departmental Research Compliance Officers and Liaisons, as well as VA Research Compliance Officers.
   g) MUSC Central Administrators who oversee research.
   h) All MUSC/VA IRB members.
   i) All VA R&D, Biosafety and IACUC Committee members.
   j) The Office Staff of the VA Research and Development Service.

3. We have been requested by faculty members to identify a less stringent requirement for individuals involved in human subjects research, but who are involved to a lesser extent than those described in section 2. We have done so[4]. The web-link is in footnote #4. The following individuals may take the less stringent course.
   a) Part-time research nurses.

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[1] (http://www.miami.edu/citireg for registration; http://www.ci4.miami.edu/courses/irbtraining for the course). This specific course is now required to perform human subjects research on more than 130 different campuses.

[2] The FDA, NIH, OHRP and VA definitions vary somewhat, and this has resulted in debate about the fine points of the various national definitions of human subjects research as they apply to specific local circumstances.

[3] This requirement was recently approved by the Dean of the College of Graduate Studies.

[4] http://ohsr.od.nih.gov/cbt/nonNIHpeople.html. Please note that this course is NOT the old NIH course.

b) Individuals who directly collect or provide human tissues or fluids or medical/personal data for explicit use in a research Tissue Bank or for human subjects research, but whose participation is less substantial than those individuals described in section 2.
c) Technicians who handle human tissues or fluids for human subjects research as defined in 2a, but whose participation is less substantial than those individuals described in section 2.
d) Managers of human subjects research data bases whose participation is less substantial than those individuals described in section 2. (This section is continued on page 2).
e) Upon completion of the course (identified in footnote #4), you must print a certificate of completion. In order for us to know that you have completed this particular course, please send a copy of your certificate to the Office of Academic Compliance, Room 505 Wachovia Bank Building. If you don't send us the certificate, we won't know that you completed the course. This course also awards 2 hrs of CME free of charge.

4. We expect that the PI's of grants and/or all human subjects research protocols will assume responsibility for identifying individuals described in sections 2 and 3 for the two levels of training. If the guidelines are not yet clear enough, you may contact your departmental compliance liaisons. If you don't know the identity of your departmental compliance liaison, you may contact the Compliance Office (2-4148) to find out who they are. Failing that, you may contact Dr. John Raymond (2-1106; raymondj@musc.edu; beeper 14669) or Dr. Ed Conradi (2-4148; conradie@musc.edu) for clarification.

5. If you do not perform or oversee the conduct of human subjects research, and do not fall under the categories of people outlined in sections 2 and 3, you are not required to take either course. Some examples of people who might not be required to complete either course would be secretaries or investigators who perform work solely on animals and non-human cells.

6. Hollings Cancer Center staff (or others) who have completed the University of Rochester book-based course do not need to take the courses described in sections 2 and 3. If you have completed the University of Rochester course through the Hollings Cancer Center, you do not need to contact us. We have already obtained that information from Hollings. If you have completed the University of Rochester book-based course through another mechanism, please send a copy of your certificate to the Office of Research Integrity[5].

7. Value added: We have attempted to add value to your time commitment for the Miami-CITI course. We are attempting to negotiate a reduced CME/CE rate for clinicians who complete the course. If we can obtain an acceptable institutional fee, the Office of the Associate Provost for Research will pay for the CME/CE credits. In addition, the Compliance Office has certified this activity for 2 hours credit for compliance education; this will be automatically tallied by your Departmental Compliance Liaison. Those who complete or have completed the University of Rochester book-based course through the Hollings Cancer Center will also receive 2 hours credit for compliance education.

8. Please be aware that this will not be the end of this type of training. NIH has made it clear that there must be a continuing component for human subjects research personnel education. As further requirements become necessary, we will communicate them to you as expeditiously as possible.

9. **If you believe you have received this memorandum in error**, please forgive us for inconveniencing you. We are beginning to construct mailing lists targeted specifically to human subjects investigators. This will be facilitated by the orderly completion of the human subjects training by those to whom it applies.

10. SUMMARY

In response to specific faculty requests, we have provided further clarification regarding Educational Requirements for Conducting Human Subjects Research.

a) We have further clarified who is required to take the Miami-CITI training (see section 2).
b) As requested, we have identified a less stringent requirement for individuals involved in human subjects research, but whose participation is less substantial than those individuals described in section 2 (see section 3).
c) Individuals who have completed the University of Rochester course will be awarded equivalent human subjects research educational credit as the Miami-CITI course (see section 5).
d) Miami-CITI and Rochester courses will be awarded 2 hours compliance credit toward requirements of the *qui tam* settlement. We are attempting to purchase CME/CE credits in bulk for clinicians who complete the Miami-CITI course.

11. We thank you in advance for your cooperation.

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