

October 6, 2000

Dear Principal Investigator,

Effective October 1, 2000, the NIH is requiring that each individual identified as "key personnel" in the research proposal must complete training in the protection of human subjects. Submitting documentation of such training will follow the "just in time"<sup>1</sup> procedures, and **applies to any proposal funded by the NIH that involves the use of human subjects**<sup>2</sup>, and includes:

- new grants,
- new contracts,
- competing or non-competing renewals, and
- any new project that is to start in the year 2001.

**Certification letters documenting human subjects training must be incorporated into annual progress reports for currently funded NIH awards.**

You can be certified by the Research Institute's Institutional Review Board by reviewing the training materials that are available to you and completing a test (25 questions) that you should be able to answer after reading these materials. Two documents, the *Guidelines for Research Involving Human Subjects* and our NIH *Assurance of Compliance*, should contain all the answers to the certification exam. We have also included some additional materials that provide more background on how institutional review boards work and issues related to using human tissues for research.

When you complete the quiz and receive a passing score (21 out of 25 correct answers), the IRB will provide you with a certificate. You may take the test until you pass, and it is an "open book" test. We have exams that are slightly different for basic science and clinical investigators. Training materials will be distributed to principal investigators and will be available from the IRB office.

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<sup>1</sup> *Just in Time procedures are those that allow items such as biosketches to be submitted at the request of the funding Institute after the initial peer review process.*

<sup>2</sup> *A human subject is a living individual about whom an investigator obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information. A definition of a human subjects includes bodily materials such as cells, blood, urine, tissues, organs, hair . . . , residual diagnostic specimens including specimens obtained for routine patient care that would have been discarded if not use for research, and private information such as medical information that can be readily identified with individuals (Research on Human specimens <http://www-cdp.ims.nci.nih.gov/brochure.html#conducting>).*

You may get the "examination" you will need to complete by contacting Madeliene Carlos at the IRB office (2340 Clay Street, Room 533; fax # (415) 561-1753; [mcarlos@cooper.cpmc.org](mailto:mcarlos@cooper.cpmc.org)). When you have finished the exam, please return it to Madeliene. She will score the exam, and when you pass, provide you with the certificate. If you have any questions, please do not hesitate to call the IRB Office (Madeliene Carlos, IRB Coordinator) at (415) 923-3688 or Martha Anderson, Ph.D., at (415) 923-3686.

Finally, when the "just in time" materials are requested from the NIH, each principal investigator will have to provide a cover letter indicating that all key personnel have been certified. In addition, the letter should include information about the content of the educational program. We will provide you with a form letter that you can use with your grant.

Sincerely yours,

Madeliene Carlos

Martha Anderson

CC: Charles Ahlfors, MD  
Allison Brady  
Connie Christensen  
David Fielder  
Edie Heller  
Sandy McDade

Karen Allen  
Warren Browner, MD  
Lynne Day  
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Elin Horwedel  
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Joy Becker  
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