



TO: Chairs/Department Managers/Principal Investigators

FROM: Andrew J. Sylvester, Secretary, IRP
Michelle Christy, Director, Office of Research and Project Administration

SUBJECT: Training and Certification Program for Human Subjects Research

DATE: September 20, 2004

The Department of Health and Human Services has promulgated regulations requiring implementation of training and certification for all researchers who work with human subjects, in the fall of 2000. These regulations are applicable to all key personnel on grants who either work directly with subjects or who have access to identifiable data about subjects. Consistent with University policy, they apply to all researchers working with human subjects.

To meet these regulations, the University has implemented the following revised program:

1. All researchers whose research involves human subjects and who have not already been certified should visit the NIH training website, "Human Participant Protections Education for Research Teams" <http://phrp.nihtraining.com/>
2. The researchers should read the information presented on the website, and complete the exercises at the end of every section. When all sections are finished a 'Proof of Completion' certificate will be generated by the website.
3. The researchers should then send a copy of the 'Proof of Completion' certificate to ORPA. This may be done via email to: jbroderi@princeton.edu or by campus mail to: Joe Broderisk, 4 New South Building, ORPA.
4. ORPA will retain a master list of these certificates and use them to verify human subjects approval for submission to the NIH.
5. Where there is consortial or subcontract activity on a grant and that activity involves work with human subjects, an appropriate certification of training of key personnel must be obtained from the institution or organization undertaking that work.

These regulations arose in large part out of concerns about the conduct of clinical research at medical schools. While such research does not occur at Princeton, the basic ethical considerations are not limited to clinical activities, even though our research activity does not involve greater than minimum risk to subjects.

All principal investigators whose research involves or potentially involves the use of human subjects should initiate this program within their research group or laboratory. As new personnel join, please coordinate their immediate training as well. Training and certification also applies to all undergraduate and graduate students and their advisors.

Training and certification of all key personnel on their grants should be completed prior to submission of proposals to sponsors and Questionnaire submission to the IRP. **In the section of grant applications that deals with human subjects, the following statement and information must be provided:**

“The following key personnel have completed Princeton University’s Human Subject Protection Program. This self-directed instructional program is designed to provide education in the ethics and regulations governing the use of human subjects in research. The program is based upon the NIH training website “Human Participant Protections Education for Research Teams”

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>.

LISTING OF NAMES”

Thank you for your cooperation in implementing this new federal requirement.