

September 20, 2000

Re: New Educational Requirements for Human Subject Researchers

Dear Human Subject Researcher,

This letter is to inform you of the new procedures that are being applied to all University of Rochester studies, including those undergoing review by both the Research Subjects Review Board (RSRB) and the Western Institutional Review Board (WIRB) [See attachment I]. This policy is the result of the University's continued commitment to ensure that all research staff receives education in the protection of human research subjects.

**For research that involves greater than minimal risk** (e.g., clinical trials)

After January 1, 2001, in order to conduct research involving human subjects, all sub-investigators, research coordinators and individuals obtaining informed consent must complete the Human Subjects Protection Program (HSPP) and pass the examination. Currently, this is only required for principal and co-principal investigators.

Documentation of successful completion of the HSPP by these individuals must be provided at the time of IRB submission for all new studies, and prior to the annual review of ongoing studies after January 1, 2001.

**For research that does not involve greater than minimal risk** (e.g., surveys and interviews)

After January 1, 2001, in order to conduct research involving human subjects, all principal and co-principal investigators, sub-investigators, research coordinators, and individuals administering informed consent must successfully complete a newly developed educational program, Ethical Principles in Research Program (EPRP) and pass the examination.

Documentation of successful completion of the EPRP must be provided at the time of IRB submission for all new studies, and prior to the annual review of ongoing studies after January 1, 2001.

For both programs, documentation is to be submitted on the IRB Application Face Sheet for Research Review. Please see the attachment for further details on these two programs.

**National Institutes of Health (NIH) Proposal Requirements**

After October 1, 2000, all investigators submitting projects to NIH will be required to complete an education program on the protection of human research subjects and must include a description of such education in the application (see NIH Guide at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html> ). Currently, because of NIH "Just-in-time" procedures for human subject research, this will only effect investigators submitting their non-competing renewal applications (progress reports). These progress reports must include the education program description.

To assist investigators with their applications, the Office of Research and Project Administration (ORPA) has prepared appropriate language that can be accessed on the ORPA homepage under "Proposal Information" and put into the progress report. The address for this information is <http://www.rochester.edu/ORPA/PropInfo/>. There are two versions of this language, one for research that involves greater than minimal risk and another for research that is minimal risk. Investigators with collaborative relationships with other institutions (subcontracts) will be responsible for ensuring that their progress reports contain a similar statement from the subcontractor(s).

Investigators funded by new and competing grants and contracts after October 1, will be required by NIH to provide a description of education completed in the protection of human subjects for each named key personnel in the research proposal. (NIH defines "key personnel" as any individual responsible for the design and conduct of the study.) This information, along with the RSRB approval, Other Support, etc., will be requested by NIH "Just-in-time," and will be provided in the form of a cover letter from ORPA. The letter will be provided by ORPA on request.

Should you have any questions about these procedures, call the RSRB office at 275-2398 or ORPA at 275-4031.

Thank you,

Gary Chadwick, PharmD, MPH  
Executive Director, RSRB

Gunta J. Lidars  
Director, ORPA

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Attachments

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