

Policy Memorandum No. 37

Subject: Certification of Education/Human Subjects

Departments Affected: All

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**CERTIFICATION OF EDUCATION
IN THE PROTECTION OF HUMAN SUBJECTS**

I. BACKGROUND

On May 30, 2000, several new initiatives to strengthen government oversight of medical research were announced by then Health and Human Services (HHS) Secretary Donna E. Shalala. One of the new initiatives addressed the education and training of clinical investigators. In response to this initiative, the National Institutes of Health (NIH) announced that investigators participating on government-funded research involving human subjects must undergo training on the protection of human research participants.

In order to comply with the NIH policy, SWOG requires all investigators to complete training on the protection of human research participants. Many Group institutions have developed educational programs on the protection of research participants and have made participation in such programs a requirement for their investigators. These courses as well as web-based training will be considered acceptable training.

II. POLICY

Applicability

In compliance with NIH Guide "Required Education in the Protection of Human Research" issued as *Notice OD-00-039* and dated June 5, 2000 (revised August 25, 2000), this policy is applicable to all scientists, investigators, SWOG personnel and others who are identified as key personnel in any proposed Group research, grant or contract.

Documentation in the form of a certificate of completion or a letter signed by an officer of your institution's Institutional Review Board (IRB) must be submitted to the Operations Office, affirming that each individual has completed education training on the protection of human research subjects.

III. SANCTIONS

Failure to submit certification on education training on the protection of human research subjects could result in the suspension of ability to register patients to Group trials and in the loss of privilege to participate in the activities of SWOG.