



Executive Memo

To: Jessica Sotelo, Executive Director, Partners for Prosperity
From: Ramona Higley, Ph.D., Research Specialist, Partners for Prosperity
Date: January 27, 2005
Re: Human Subjects Requirements for Non-profit Organizations

In 1991, the U.S. Department of Health and Human Services implemented a federal policy for the protection of human subjects (56 FR 28003). This policy addressed the ethical use of human subjects in research projects. Following a number of federally subsidized research projects that failed to protect the privacy, health, and safety of the research subjects, the regulation was passed to ensure the rights and welfare of human subjects in all federally subsidized research projects.

“The policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or agency.” The following exemptions were made to this policy: research conducted in established or commonly accepted educational settings, involving normal educational practices; research involving the use of educational testing; secondary data research; research designed to evaluate public benefit of service programs and related information; and taste and food evaluation studies. There is no specific exemption for non-profit organizations per se, however, only research that is somehow subsidized by federal funding is subject to the human subjects regulations. As long as Partners for Prosperity (P4P) is directly associated with Idaho State University (ISU) the research efforts of this organization are subject to this regulation. However, demographic information gathered in working meetings, evaluation of development activities including the working groups, and any other measures designed to evaluate the effectiveness of the service program that P4P provides is exempt from regulation. The Executive Director of P4P has the final judgment as to whether a particular activity is covered by this policy.

In short, the federal regulations mandate that the department or agency head certify that all research involving human subjects conducted by the organization undergo an Institutional Review Board (IRB) review. The IRB is responsible for ensuring that if conducted as proposed that persons involved in the research will undergo only minimal risk to their rights, health and/or safety. The Chair or agency head would then be responsible for providing official notification (certification) that the project or activity has been reviewed and approved by the IRB.

An essential element of the regulation is the establishment of an IRB. “The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.” Recommendations as to the diversity of the IRB are included in the regulations. Diversity should be based on gender, race, ethnicity, and experience. Membership on the IRB should include at least one person of scientific background and at least one person without scientific background. The IRB, however, must include at least one member that is not otherwise affiliated with the organization.



When Partners for Prosperity severs the legal relationship with ISU, as long as the organization does not receive federal funding in any form, P4P will not be regulated by the federal standard. However, if P4P receives federal funding the organization would be responsible for meeting the regulation requirements. There is, however, a political movement that is seeking to extend the umbrella of human subjects regulation to all organizations that are conducting human subject research regardless of funding source. In preparation for this change in regulation, private organizations have emerged that help ensure that non-federally subsidized programs also meet the federal standard. These organizations help to establish an IRB and to develop research criteria. Non-federally funded institutions can then offer a certification of compliance to these private organizations in the same way that federally funded institutions offer certification to the Department of Health and Human Services. These organizations accredit groups who conform to their standards.

Recommendations

Therefore, it is recommended that when P4P becomes an independent non-profit organization that an IRB be established following the federal guidelines. Although P4P may not have a legal obligation to establish an IRB or to certify compliance to the federal regulation, P4P would increase the level of trust within the community by doing so. In addition, P4P would be prepared to account to federal agencies in the event of future legislation that may require all organizations to meet this standard.

It is further recommended that a sub-committee of the Primary and Secondary data working group be established as this IRB. IRB members would not participate in the research discussions of the general body of the working group. Appointment to the IRB should be made by the Executive Director of P4P as the person ultimately responsible for certifying compliance to this regulation. An initial task of the IRB would be to make a recommendation as to the need for P4P to work with a private accreditation agency. However, since the final accountability as to the compliance with federal standard falls on the Executive Director, the Executive Director should have the final decision as to the implementation of the IRB and other regulations.