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HHS Issues Final Guidance Document on Financial Interests in Research Involving Human Subjects

By [Linda Anthony](#)
Program Manager

On May 12, the Department of Health and Human Services (HHS) released a final “guidance document”, not regulation, for protecting research subjects from possible harm caused by financial conflicts of interest that may arise in research studies. The new document, “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection,” applies to all human subjects research conducted or supported by HHS agencies or regulated by the Food and Drug Administration.

The current document replaces “HHS Draft Interim Guidance on Financial Relationships in Clinical Research”, dated January 10, 2001. It is intended to provide guidance only, and does not change any existing regulations or requirements, nor does it impose any new requirements. HHS will consider a more formal regulation only if such an approach is warranted in the future. In addition, this guidance expressly does not address regulatory requirements of research misconduct, which were released for public comment on April 16, 2004 (see April 19, 2004 GRC [GrantWeek](#)). It does, however, incorporate the ethical principles described in the policy guidance document known as the Belmont Report. See the [OHRP website](#). Also see the [OHRP website](#) for HHS human subject protection regulations, effective December 13, 2001.

The goal of the current guidance document is to raise points to consider in determining whether specific financial interests in research might affect the rights and welfare of human subjects, and if so, what actions could (not should) be considered to protect those subjects. The document provides important guidance for institutions, institutional review boards (IRBs), researchers and other interested members of the research community, by giving concrete suggestions on ways to better manage potential financial conflicts of interest, such as:

- Separate institutional responsibility for research activities from management of the institution’s financial interests;
- Establish conflict of interest committees (COICs) or identifying other bodies or persons and procedures to address financial interests in research;
- Use independent organizations to hold or administer the institution’s financial interest;
- Determine whether current methods for managing conflicts of interest are adequate for protecting the rights and welfare of human subjects and whether other actions are needed to minimize risks to subjects;
- Determine the kind, amount, and level of detail of information to be provided to research subjects regarding funding and financial interests; and
- Use special measures to modify the informed consent process when a potential or actual financial conflict exists.

The overriding goal is to protect the research subjects who

Instrumentation and Research Support for Hispanic-Serving Institutions

By [Jeffrey Lagda](#)
Program Advisor

The Department of Defense (DOD) has announced its FY 04 Instrumentation and Research Support for Hispanic-Serving Institutions (HSIs) Program. Grants will support projects in instrumentation/equipment acquisitions, research, or a combination of these. Awards will be limited to institutions having accredited, degree-granting programs in science, mathematics, and/or engineering. Approximately \$4 million in FY 04 funds is expected to be available for new awards under this solicitation. Grant awards will range from \$50,000 to \$500,000. The Army Research Office (ARO) is administering the program, and will base all awards on a merit competition. Proposals are due by **July 8, 2004**.

Program objectives include: enhancing programs and capabilities in scientific and engineering disciplines critical to the national security functions of DOD; and increasing the number of graduates, including underrepresented minorities, in the fields of science, mathematics, and/or engineering.

This competition is open only to Hispanic-Serving Institutions named in the U.S. Department of Education Accredited Postsecondary Minority Institutions list. The Office for Civil Rights, U.S. Department of Education, compiles a list using enrollment data reported by postsecondary institutions to the National Center for Integrated Statistics and the Office for Civil Rights in the Integrated Postsecondary Education Data System (IPEDS) Fall enrollment survey, formerly called the Higher Education General Information Survey (HEGIS). It is available at this [website](#).

For further information, see the [ARO website](#). Specific questions may be directed to Evelyn Kent, 703/696-0368. E-mail: Evelyn.Kent@osd.mil

Corporation for National and Community Service Announces FY 04 Challenge Grants Competition

By [Erika Thompson](#)
Program Advisor

On May 13th, the Corporation for National and Community Service (CNCS) announced that \$2.4 million is available through its Challenge Grants Competition. This Competition is open to various entities including non-profit organizations, state and local governments, and public and private institutions of higher education (IHEs). CNCS plans to make up to four awards between \$500,000 and \$1 million for one year. Applicants must be able to raise two dollars in private funds for every dollar of federal funds within the term of their award. All matching funds must be cash and applicants must be able to “expand services by engaging citizens in meeting community needs or offer new services through expanded citizen engagement.” *Optional* E-mail notices of intent are due **May 20, 2004**. Full applications are due **June 8, 2004**.

President Clinton created CNCS in 1993 as a result of a long community service history in the U.S. Currently, CNCS serves as the umbrella organization for three major programs: Senior Corps, AmeriCorps, and Learn and Serve America. Under these programs,

the public that the research is untainted by any real or potential financial conflicts of interest on the part of the researcher. The subject's best interests are always to be foremost in the minds of the researchers.

For more detailed information on managing financial interests in research using human subjects, see the [Final Guidance Document](#), or contact Glen Drew, Policy, at the Office of Human Research Protections, 301/402-4994; E-mail: gdrew@osophs.dhhs.gov.

One more thing...it can be fairly confusing for sponsored programs administrators to digest the many issues involved with regard to protecting the integrity of the research enterprise. Therefore it might make sense for GRC members to share information among and between themselves, using the GRC ListServ. Not yet signed on? Not a problem. Just contact Linda Anthony (anthonyl@aascu.org) for instructions.

"members and volunteers...help meet community needs in education, the environment, public safety, homeland security, and other critical areas." In addition, CNCS itself is currently part of the USA Freedom Corps, "a White House initiative to foster a culture of citizenship, service, and responsibility", which was created by President Bush in 2002.

This is only the second year that CNCS has conducted this Competition. In its inaugural year, CNCS received over 50 applications, but awarded only eight totaling \$6 million. Even though none of the initial eight awardees were IHEs, the Challenge Grants Competition is definitely a program to consider for those campuses looking for more civic engagement opportunities and/or those already involved in AASCU's [American Democracy Project](#). Some Competition-supported activities include, but are not limited to:

- Volunteer recruitment, training, and supervision;
- Expansion of current services;
- Supporting new or expanded fee for service activities which increase volunteer capacity;
- Scholarship programs related to promoting service;
- Support for organizations that engage citizens and communities in supporting schools in the education of children;
- Citizenship training that will be integrated into the service experience; and
- Programs that train and place education and health professionals in high-need areas.

Applications should be submitted through CNCS' [eGrants](#), but paper applications will be accepted with prior approval. See [solicitation](#) and [CNCS website](#) for more information. E-mail or call Thea Kachoris-Flores at tkachoris@cns.gov or 202/606-5000, ext. 420.