

Office of Human Research Ethics

Daniel Nelson, Director

The Office of Human Research Ethics (OHRE) is responsible for ethical and regulatory oversight of research at UNC-Chapel Hill that involves human subjects. The OHRE administers, supports, guides, and oversees the work of the Institutional Review Boards (IRBs) and all related activities. Any human subjects research proposed by faculty, staff, or students must be reviewed and approved by an IRB before research may begin and before related grants may be funded. OHRE and the IRBs are critical components of a coordinated Human Research Protection Program that serves to protect the rights and welfare of human subjects. All components of this program must work together to ensure institutional compliance with ethical principles and regulatory requirements. The following is a mission statement for this coordinated Human Research Protection Program:

The University of North Carolina at Chapel Hill is committed to expanding and disseminating knowledge for the benefit of the people of North Carolina and the world. An important part of that commitment to knowledge is research of the highest quality on all aspects of the health and behavior of people, and such research is only possible through the participation of humans as research subjects.

Human subjects are partners and participants in research and a precious resource to the university. At UNC-Chapel Hill, research with human subjects is a privilege, but not a right. Consistent with that philosophy, it is the mission of the UNC-Chapel Hill Human Research Protection Program to ensure that

- *the rights and welfare of human subjects are paramount in the research process;*
- *the highest standards of ethical conduct are employed in all research involving human subjects;*
- *research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;*
- *research investigators deal honestly and fairly with human subjects, informing them of procedures to be followed, and of the risks and benefits of participating in research; and*
- *research using human subjects at UNC-Chapel Hill conforms with all applicable local, state and federal laws and regulations and the policies of the university.*

Major Accomplishments During the Past Academic Year

This was the second year of operation for OHRE, established in July 2003 through the integration of five existing school-based offices. The overarching goal is to maximize protection of human research subjects at UNC-Chapel Hill; reorganization will support this goal through the effective and efficient use of campus resources, increased capacity and accountability, and standardization of best practices. Building on extensive work behind the scenes during the inaugural year, this year was marked by the public roll out of many changes and program enhancements. Highlights are listed below.

Unveiling of OHRE to the Campus

The creation and purpose of OHRE were formally announced in September, 2004 by the provost and the vice chancellor for research and economic development. This was followed by the release of one consolidated web site in January 2005 and simultaneous

implementation of one set of forms across all IRBs. The former school-based names of the IRBs were revised to reflect their scope of expertise. Presentations on the new structure and related changes were made to groups including investigators, departmental administrators, and the UNC Board of Trustees.

Adoption of Standardized Web, Application, and Consent Templates

These tools represent a major step toward standardizing processes across all IRBs at UNC-Chapel Hill. All researchers now apply for IRB review in the same manner, provide the same information, and receive the same guidance through the instructions on the web site.

Ongoing Review of Research Projects

Once again more than 6,000 submissions were reviewed and approved by the IRBs, relating to more than 4,000 new and existing research studies. Despite the concerted effort toward reorganization, timely processing of IRB submissions remains a top priority for OHRE.

Researcher's Guide to the IRB Process and Human Subjects Research

Produced in collaboration with the Office of University Counsel, the "Researcher's Guide" joins other web-based materials to provide guidance on the conduct and review of human subjects research. This is another example of the consolidation and standardization of practices across IRBs.

Collaborative IRB Training Initiative (CITI)

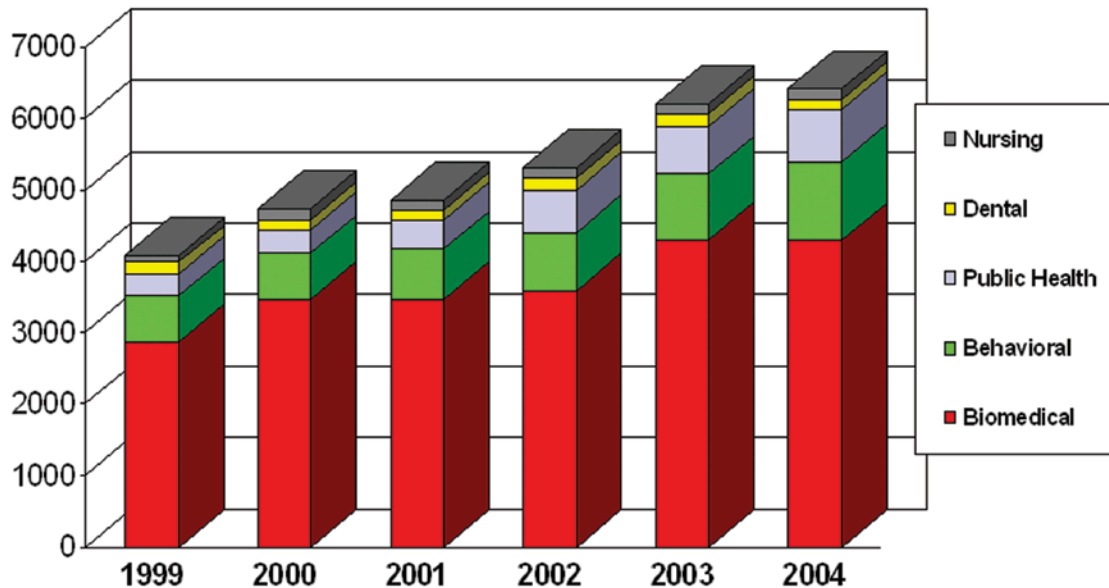
University policy for educational requirements in human research issues was updated and enhanced with primary reliance on the Collaborative IRB Training Initiative (CITI). CITI provides access to web-based modules on topics relating to ethics, regulations, and processes produced through a national consortium of universities and organizations. Separate tracks are available for biomedical research, social and behavioral research, and researchers who primarily use existing specimens or data. CITI provides a more rigorous introduction to this complex and changing area, successfully completed by over 6,000 UNC-Chapel Hill personnel to date.

Educational Retreat

OHRE held its first campus-wide educational retreat, with 125 IRB members, staff, and guests in attendance. The keynote speaker was Dr. Bernard Schwetz, director of the federal Office for Human Research Protections (OHRP), followed by panel discussions and audience participation on relevant topics. The retreat also provided an important opportunity to acknowledge the importance of IRB service, with welcoming remarks and thanks from senior university officials. OHRE is committed to providing continuing education for IRB members and staff, as well as the research community.

Staffing, Offices, and Committees

Prior to the formation of OHRE, the campus IRBs were supported by five groups of staff operating in separate quarters, which duplicated technical and administrative infrastructures and hindered cross coverage. By the end of this academic year, the number of operational headquarters was reduced from five to two. Consolidating staff and systems in fewer places will facilitate sharing of expertise, equilibration of workloads, and cross training for critical functions. This also opens the door to reconfiguring the IRB committees, where warranted. This year the dental IRB, with a



Growth in the university's research efforts is reflected in the numbers of submissions reviewed by campus IRBs.

relatively low volume of submissions requiring full committee review, was integrated with one of the biomedical IRB panels, improving efficiencies while retaining appropriate expertise. In addition to IRB staff, we established two specialist positions to coordinate compliance activities and manage information systems, the web site, and other special projects.

Public Outreach and Education

With grant support from the National Institutes of Health, an informational brochure and video were produced to educate the public about participating in human subjects research at UNC-Chapel Hill. Entitled "Should You Volunteer?," these materials support the informed consent process through a balanced discussion about the potential risks and benefits of volunteering and the rights of subjects, presented in both English and Spanish.

N.C. Consortium for Human Research Protections

Supported by the same NIH grant, this statewide network of IRBs was established to share training, expertise, and resources among public and private institutions in North Carolina. An inaugural conference was hosted in Chapel Hill, with subsequent regional efforts across the state.

National Leadership

OHRE personnel continue to play a leading role in national initiatives in this evolving field. Daniel Nelson was appointed co-chair of a federal subcommittee (under the Secretary's Advisory Committee on Human Research Protections, U.S. Department of Health and Human Services), charged with reviewing and making recommendations on the complex regulations that govern this area.

Goals for Coming Academic Year

OHRE is well along the path of integrating the previously independent IRB operations, and that process will continue in 2005-06. Within the next year, we expect to

- complete the first major revision of our Standard Operating Procedures (SOPs), first adopted in December 2003;
- further integrate staffing, locations, and IRB committees, as needs dictate and circumstances allow;
- adopt a standardized information system across all IRBs (Goals for this system include efficient automation of standardized office procedures, aggregation of critical data, and integration with other university systems.); and
- apply for and attain national accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP), capitalizing on two years of effort toward this goal.