

# Office of Human Research Ethics

Daniel K. Nelson, Director

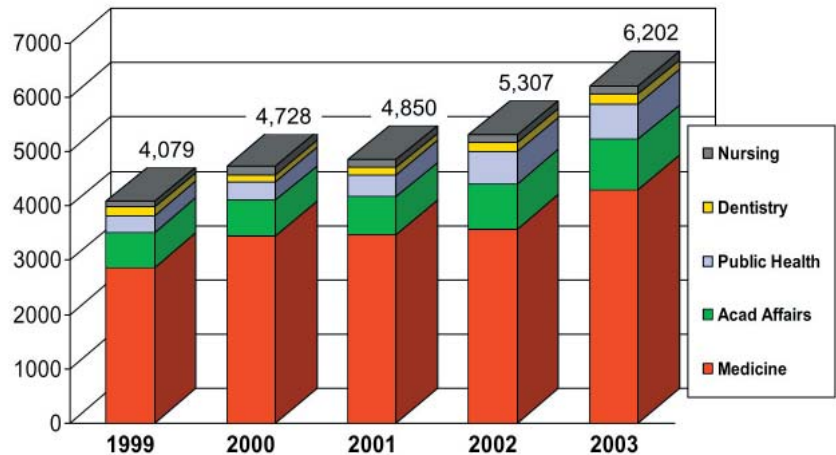
The Office of Human Research Ethics (OHRE) is responsible for ethical and regulatory oversight of research at UNC-Chapel Hill that involves human subjects. The OHRE administers, supports, and guides the work of the Institutional Review Boards (IRBs) and all related activities. Any research involving human subjects 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 the coordinated Human Research Protection Program, which 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 the 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, human subjects research 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*

- (1) *the rights and welfare of human subjects are paramount in the research process;*
- (2) *the highest standards of ethical conduct are employed in all research involving human subjects;*
- (3) *research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;*
- (4) *research investigators deal honestly and fairly with human subjects, informing them fully of procedures to be followed, and the risks and benefits of participating in research; and*
- (5) *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.*

**Total IRB Submissions at UNC-Chapel Hill 1999-2003**



Growth in the university's research efforts is reflected in the numbers of submissions reviewed by campus IRBs, which increased by 17 percent over the last year. (Tim M. Henderson)

## Major Accomplishments During the Past Year

This was the first full year of operation for OHRE, which was established in July 2003 through the integration of five existing school-based offices. A primary focus during this inaugural year has been the ongoing reorganization of this decentralized structure into a centralized unit with a single line of authority, reporting to the Vice Chancellor for Research and Economic Development. 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.

Specific highlights from the past year include:

- OHRE became an administrative and functional reality, encompassing 17 employees, 10 part-time IRB chairs, and over 100 faculty, staff, and community representatives who serve as IRB members. The eight IRB committees provide a diversity and breadth of expertise appropriate to the scope of research at Carolina.
- More than 6,000 protocol submissions were reviewed and approved. This represents a 17 percent increase in IRB workload from the previous year, and a 52 percent increase over the last five years. Despite the concerted effort toward reorganization, timely processing of IRB submissions remains a top priority for OHRE.
- Standard Operating Procedures (SOPs) were written and adopted, providing the first common guidance for IRBs and investigators across all areas of human subjects research. These SOPs are serving as a much needed platform to standardize what have been disparate processes and procedures across campus.
- Several new positions were established and filled, serving

pan-campus needs for coordination of administrative, compliance, training, and IT activities. In addition, existing staff positions were standardized and consolidated, correcting for internal equity and allowing for better coverage across all parts of the operation.

- Communications with federal regulatory agencies were standardized, utilizing the new compliance coordinator as a common channel. Also standardized through this position were processes for appointing IRB members and documenting complex relationships with external entities, previously handled through a variety of mechanisms.
- An advisory committee of researchers and administrators was established to help guide OHRE on structural and policy issues that affect the research community.
- For FY05, an integrated budget model was implemented with the aim of developing a fair and equitable funding mechanism to support important institutional obligations.
- Links were established and strengthened with other units involved in oversight of human research at Carolina.
- Working groups were established in several areas to identify best practices and develop standardized tools for the campus IRBs and research community. Ongoing projects include developing common IRB application forms, common consent form templates, a common web site, and a common information management system, as well as enhancing training and public outreach activities
- OHRE staff and IRB members continued to be recognized for their national leadership in the evolving field of human subjects protections, resulting in multiple opportunities to serve as faculty at national conferences and as expert consultants to federal agencies. For example, Nancy King and David Weber of the Biomedical IRB served on National Institutes of Health advisory committees; OHRE staffer Robert Schreiner led a workshop at the annual meeting of the Applied Research Ethics National Association (ARENA); and Daniel Nelson was honored with ARENA's Special Service Award and delivered the keynote address at the inaugural meeting of the Canadian Association for Research Ethics.
- Daniel Nelson, Nancy King, and colleagues contributed to successful grant applications that support research on ethical issues in genomics at Carolina and support IRB capacity building in developing countries and at other institutions across North Carolina.

### Goals for Coming Academic Year

Much of the foregoing describes what has occurred behind the scenes as OHRE builds the necessary infrastructure to meet current needs and support future enhancements. The next phase of reorganization will produce changes more visible to the research community. Within the next year, we plan to

- launch the common website, IRB application form, and consent form templates for consistent, interchangeable use by all IRBs and investigators across campus;

- continue to work toward truly standardized practices across all IRBs and implement a common database, with a longer term goal of providing provide online access to the entire research community for queries on protocol status;
- develop an investigators manual in collaboration with the Office of University Counsel and others, by drawing on those sections of the SOPs most directly relevant to research teams;
- provide enhanced training on human subjects issues for research teams and IRB committee members;
- convert the compliance coordinator position to a full-time role;
- sponsor an education symposium in September 2004 for the North Carolina IRB Consortium for Human Subjects Protection;
- produce and disseminate public education materials to increase awareness of research at Carolina and what it means to participate as a research volunteer; and
- apply for accreditation through the Association for the Accreditation of Human Research Protection Programs.



Above: A reception was held to recognize Linda Adair for 11 years as chair of the public health IRB, with presentations by Interim Dean Margaret Dardess (left), Vice Chancellor Tony Waldrop, and others. This service exemplifies the commitment by 100 faculty, staff, and community representatives who serve the university as IRB members.



Left: Daniel Nelson received the Special Service Award from the Applied Research Ethics National Association (ARENA) at the annual meeting in Washington, DC, with 2,500 people in attendance. Nelson is past president of ARENA, and a leader of several national initiatives in this evolving area.