

Office of Human Research Ethics

Daniel Nelson, Director

The Office of Human Research Ethics (OHRE) is responsible for ethical and regulatory oversight of UNC-Chapel Hill research that involves human subjects. 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 protects the rights and welfare of human subjects. All components of this program work together to ensure institutional compliance with ethical principles and regulatory requirements. The following is a mission statement for the Human Research Protection Program:

UNC-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 Carolina, 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

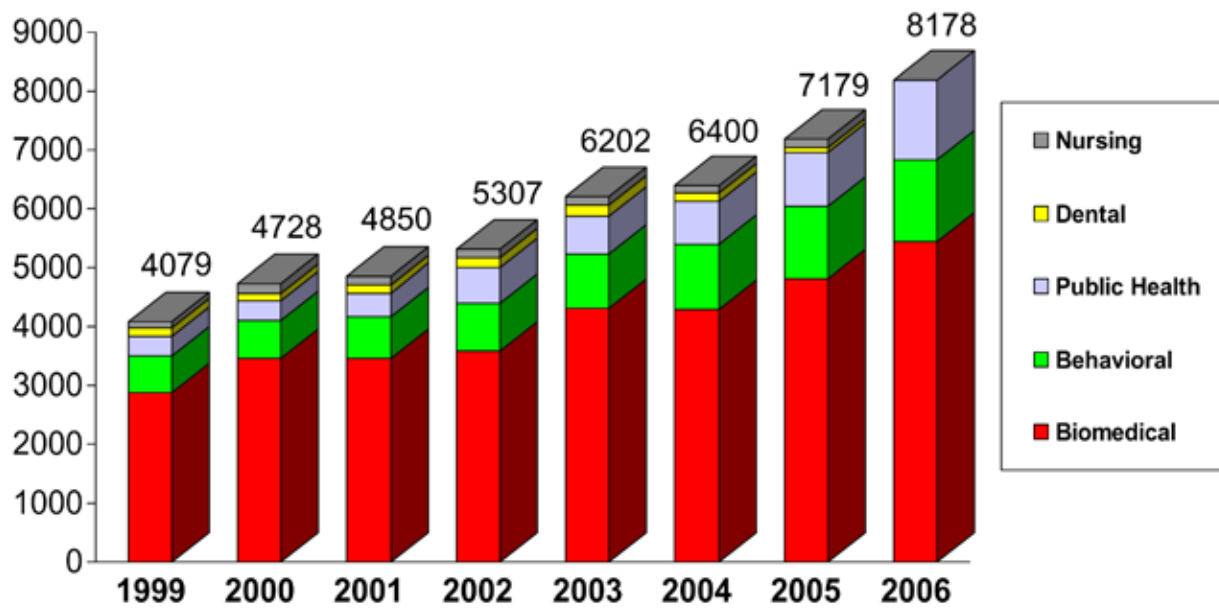
- the rights and welfare of human subjects are paramount in the research process;
- the highest standards of ethical conduct are employed in all research involving human subjects;
- research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;
- research 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;
- 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 Year

This was the fourth year of operation for OHRE, which was established in July 2003 through the integration of five existing school-based offices. OHRE's overarching goal is to maximize protection of human research subjects at UNC-Chapel Hill. The reorganized structure supports this goal through the effective and efficient use of campus resources, increased capacity and accountability, and standardization of best practices. This year we continued refinements introduced last year and initiated others. Highlights include the following.

- The IRBs reviewed and approved 8,178 submissions in calendar year 2006, which related to more than 4,000 new and existing research studies. The number of submissions has grown by 12 percent per year since 2000, reflecting growth in the university's research portfolio. Timely processing of IRB submissions remains a top priority for OHRE.

- The Behavioral IRB was moved from temporary offices on Franklin Street to join other IRBs in one integrated office location, housed in Medical School Building 52 on Mason Farm Road. This marks the first time that all campus IRBs have been together in a single operational headquarters.
 - With this final geographic consolidation, IRB coordinators and office staff have been merged into a pooled staffing model to share expertise and experience, provide better cross-coverage, and equilibrate workloads.
- Five legacy information systems have now been fully merged into a single customized system (IRB-IS), providing a common platform for data-management needs across all IRBs. This new system has greatly enhanced office procedures and communications with investigators, and provides the framework for our eventual transition to a "paperless" environment. IRB-IS also allows OHRE to provide investigators with protocol status information in real time via the "My Research at Carolina" web portal, which is populated by data across multiple nodes in the campus-wide review process.
- The Nursing IRB was merged into the Public Health IRB. The combined committee was populated with appropriate expertise, and the integrated service has been well received by investigators.
 - We now have three areas of IRB review: behavioral, biomedical, and public health/nursing. These areas are based on type of research rather than on geographic boundaries.
- The Collaborative IRB Training Initiative (CITI) was adopted in January 2005 as a web-based vehicle for satisfying educational requirements in research ethics and IRB practice. After the first year, UNC-Chapel Hill became the largest user out of several hundred universities using CITI, with over 13,000 research personnel now certified.
 - As part of information system enhancements, training data are now linked electronically to IRB application data, obviating the need for investigators to repeatedly submit paper copies of training certificates.
- New procedures and guidance in historical areas of confusion were developed and implemented. These areas included student research and classroom projects; secondary analysis of existing data; training and center grants; external agreements for collaborating sites and IRBs; and processes for review and certification of research involving prisoners.
- The common web site, application forms, and consent form templates were updated and refined, incorporating user feedback after two years with these standardized tools.
- New staff positions were created and filled: an additional IRB Coordinator (to process submissions), a Quality Improvement Coordinator (to monitor and provide feedback on documentation and procedures), and an Assistant Director for Operations (to harmonize and improve operations). These new positions contributed to the creation of our first true office procedures manual to guide internal operations, which has been a major advance for guiding existing employees and training new ones.
- OHRE personnel continued to serve on multiple university committees, and to provide national leadership in the evolving area of human research protections. Personnel on national committees include David Weber, member of



Total IRB submissions at UNC-Chapel Hill, 1999-2006.

the Recombinant DNA Advisory Committee, Office of Biotechnology Activities, National Institutes of Health; and Daniel Nelson, member and subcommittee chair, Secretary's Advisory Committee on Human Research Protections, Department of Health and Human Services, and member of the Council for Certification of IRB Professionals.

Goals for the Coming Academic Year

OHRE has accomplished much toward integrating previously independent IRB operations, laying the groundwork for significant enhancements. The campus research community at UNC-Chapel Hill has begun to realize the gains from a more efficient and effective system for human research oversight, and this efficiency will continue. Within the next year, we expect to accomplish the following:

- Continue refining the new IRB-information system, in response to internal and external feedback.
- Implement online IRB application submission, providing a user-friendly interface for research teams to create applications and submit them directly into the OHRE data stream.
- Participate in reshaping the electronic environment for research administration functions at Carolina, coordinated through the Office of the Vice Chancellor for Research and Economic Development, which will facilitate data sharing across multiple offices and more seamless delivery of services.
- Revise and refine standard operating procedures.
- Apply for accreditation through the Association for the Accreditation of Human Research Protection Programs, culminating several years of work toward this goal and validating our university-wide programs.