

Office of Human Research Ethics

Daniel Nelson, Director

The Office of Human Research Ethics (OHRE) is responsible for ethical and regulatory oversight of any research at the University of North Carolina at Chapel Hill that involves human subjects. OHRE administers, supports, guides, and oversees the work of the Institutional Review Boards (IRBs) and all related activities. Any human 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, which serves to protect 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 this 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 and inform them of procedures to be followed and the risks and benefits of participating in research.
- Research using human subjects at UNC-Chapel Hill conforms with all local, state, and federal laws and regulations and with the policies of the university.

Major Accomplishments During the Past Year

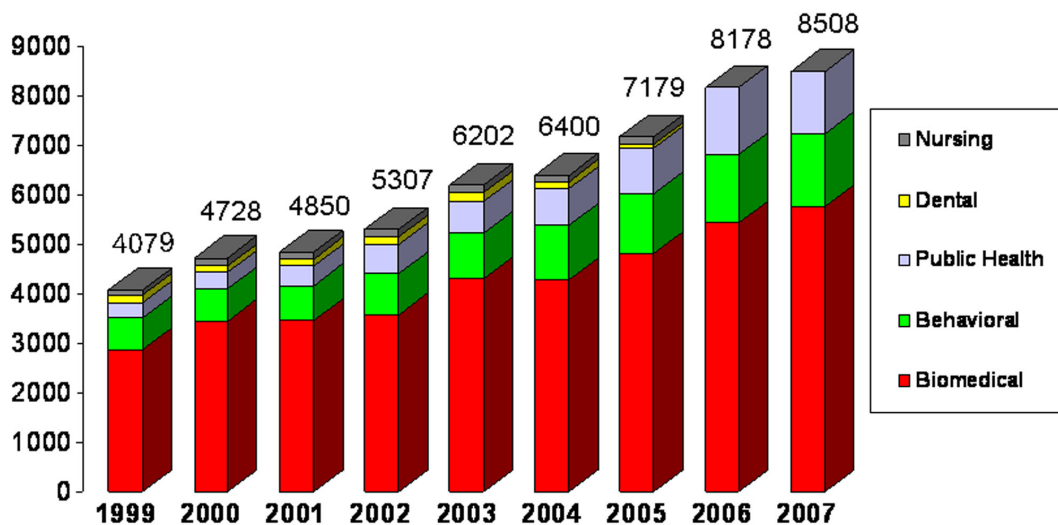
This was the fifth year of operation for OHRE, which was established in 2003 through the integration of five existing school-based offices. Our overarching goal is to maximize protection of human research subjects at UNC-Chapel Hill. The reorganized structure supports this goal through the effective and efficient use of campus resources, increased capacity and accountability, and standardization of best practices. Below are highlights from the past year.

The IRBs reviewed and approved 8,508 submissions in 2007, which relate to nearly 4,000 new and existing research studies. The number of submissions has grown by 14 percent per year since 1999, which reflects growth in the university's research portfolio.

Timely processing of IRB submissions remains a top priority for OHRE. Improved data-tracking systems allow us to monitor turnaround time from date of submission to the date the investigator receives the results of IRB review, which is approximately five days for expedited reviews and 20 days for studies that require review by the full convened committee. These turnaround times compare very favorably to those of other universities.

While our primary concern is research that requires IRB oversight, we also addressed what many perceive to be a growing "mission creep" for IRBs across the country, which have extended regulatory oversight to nonresearch activities. Considerable effort has been given to more carefully defining what constitutes "human subjects research" at a policy level, and therefore what requires IRB approval at a practical level. In the last year alone, over 500 projects or activities that might formerly have required full approval were determined through an abbreviated process to not require further review.

Additional policy efforts clarified and streamlined requirements in other areas of concern to both IRBs and investigators,



Total IRB submissions at the University of North Carolina at Chapel Hill, 1999-2007.

including the following:

- collection of Social Security Numbers for subjects' payments
- informed consent for tissue banking and repositories
- adverse-event reporting, to reflect new federal guidance issued in 2007

The Standard Operating Procedures for the Human Research Protection Program have been revised, completing the first major update since these guiding policies were first drafted in 2003. This was a necessary prelude to applying for accreditation (see Goals for the Coming Academic Year), and was accomplished through internal reassignment of current employees rather than hiring external consultants who would not be familiar with local operations.

Last year marked the first time that all campus IRBs were housed together in a single operational headquarters, using a single information system. With this final geographic and electronic consolidation, we are now reaping the benefits of a pooled staffing model that shares expertise and experience, provides better cross-coverage, and equilibrates workloads.

The Collaborative IRB Training Initiative (CITI), adopted in January 2005, is a web-based vehicle for satisfying educational requirements in research ethics and IRB practice. After the first year, Carolina had become the largest user of CITI out of several hundred universities and now has over 13,000 certified research personnel. 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.

Educational seminars and lectures were provided in a variety of settings across campus and in the local community, and addressed ethics-related issues with students, faculty, staff, and interested members of the public.

OHRE personnel continued to serve on multiple university committees, and to provide national leadership in the evolving

area of human research protections. National activities include the following:

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

Goals for the Coming Academic Year

Reorganizing and standardizing previously independent IRB operations laid the groundwork for significant campuswide enhancements. Carolina's research community has been realizing the benefits of a more efficient and effective system for human research oversight, and this will continue. In the year ahead, our goals include the following:

- Provide a new, user-friendly web portal for online reporting of unanticipated problems and adverse events in order to reflect recent policy changes; this will be a pilot test for eventual online submission of all IRB application materials.
- Achieve full accreditation through the Association for the Accreditation of Human Research Protection Programs, which will culminate several years of work toward this goal and validate our universitywide program.
- Develop coordinated IRB oversight models for research in a growing number of collaborative initiatives in which Carolina plays a key role. Each of these presents an opportunity to cooperate with partner institutions to minimize redundancies and barriers in multisite research. These initiatives include the North Carolina Research Campus in Kannapolis, the national network of academic centers joined through the Clinical and Translational Science Award from NIH, and statewide clinical research networks established through the University Cancer Research Fund.