

Office of Human Research Ethics

Daniel K. Nelson, Director

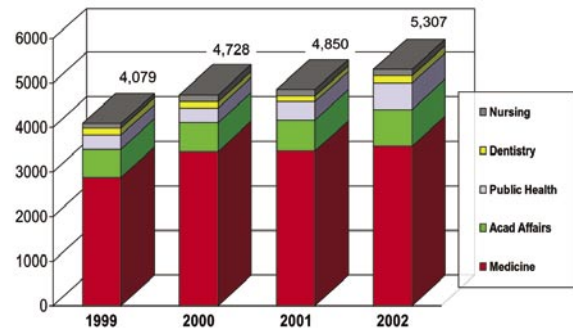
The Office of Human Research Ethics (OHRE) is responsible for ethical and regulatory oversight of research at UNC-Chapel Hill that involves human subjects. The OHRE administers, supports, guides, and oversees the work of the Institutional Review Boards (IRBs) and all related activities. Any research projects 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. These IRBs are federally mandated review committees, operating under regulations promulgated by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). The IRBs are a critical component of a program that serves to protect the rights and welfare of human research subjects. All components of this program, coordinated through the OHRE, must work together to ensure institutional compliance with ethical principles and regulatory requirements. The following is a draft Mission Statement developed for that integrated program, which encompasses the OHRE:

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 subject 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 1999-2002



Submissions reviewed by the IRBs have grown along with the university's research effort.

Major Accomplishments During the Past Year

[NOTE: Because the OHRE is newly created, just now coming into existence with the 2003–04 academic year, this report will focus on the background that led to its formation and preliminary efforts thus far.]

The existing system of protections at UNC-Chapel Hill evolved in a very decentralized manner, with eight IRBs operating out of five separate school-based offices. This has resulted in inefficiencies and variability that compromise the university's ability to fulfill these important obligations and leave us exposed to compliance problems. Both the volume and complexity of submissions reviewed by the IRBs have grown considerably, reflecting the growth of the university research effort (over 5,000 submissions per year). New technologies and approaches invariably bring new ethical and regulatory challenges. In addition, pressures on the program have increased dramatically over recent years as the national system for protecting human research subjects has come under intense scrutiny by the public, the press, and federal agencies. Deficiencies in this area have led to suspensions of all research and freezing of funds at several major universities, including Duke, Johns Hopkins, et al. In some cases these deficiencies have been linked to deaths of research subjects. Federal regulators have identified inadequate institutional support as "the number one root cause" of these compliance problems.

These pressures have prompted national efforts to establish standards for certification of the professionals who run IRBs and accreditation of the institutional programs in which they work. UNC-Chapel Hill has made a commitment, up to and including the chancellor, to pursue accreditation as a means of (a) ensuring that our obligations in this area are met, (b) enhancing our program, and (c) demonstrating our commitment to the highest standards in all research endeavors, as espoused by the Mission Statement above. The ongoing self-evaluation process toward accreditation confirmed that steps must be taken to integrate and centralize the locus for ethical

and regulatory oversight of human research studies. Toward that end, the OHRE has been established, reporting to the vice chancellor for Research and Economic Development. This newly formed office will integrate the current decentralized structure and will administer the resulting operation. When combined, the OHRE will encompass 15 to 20 staff, reporting through a single Director (Fig. 2). The reorganized structure received input from IRB chairs and administrators, deans, investigators, and campus officials, and will go far toward bringing UNC-Chapel Hill in line with national peers and with current expectations.

An effective date of July 1, 2003, has been set for the official launch of OHRE, but much work has already occurred:

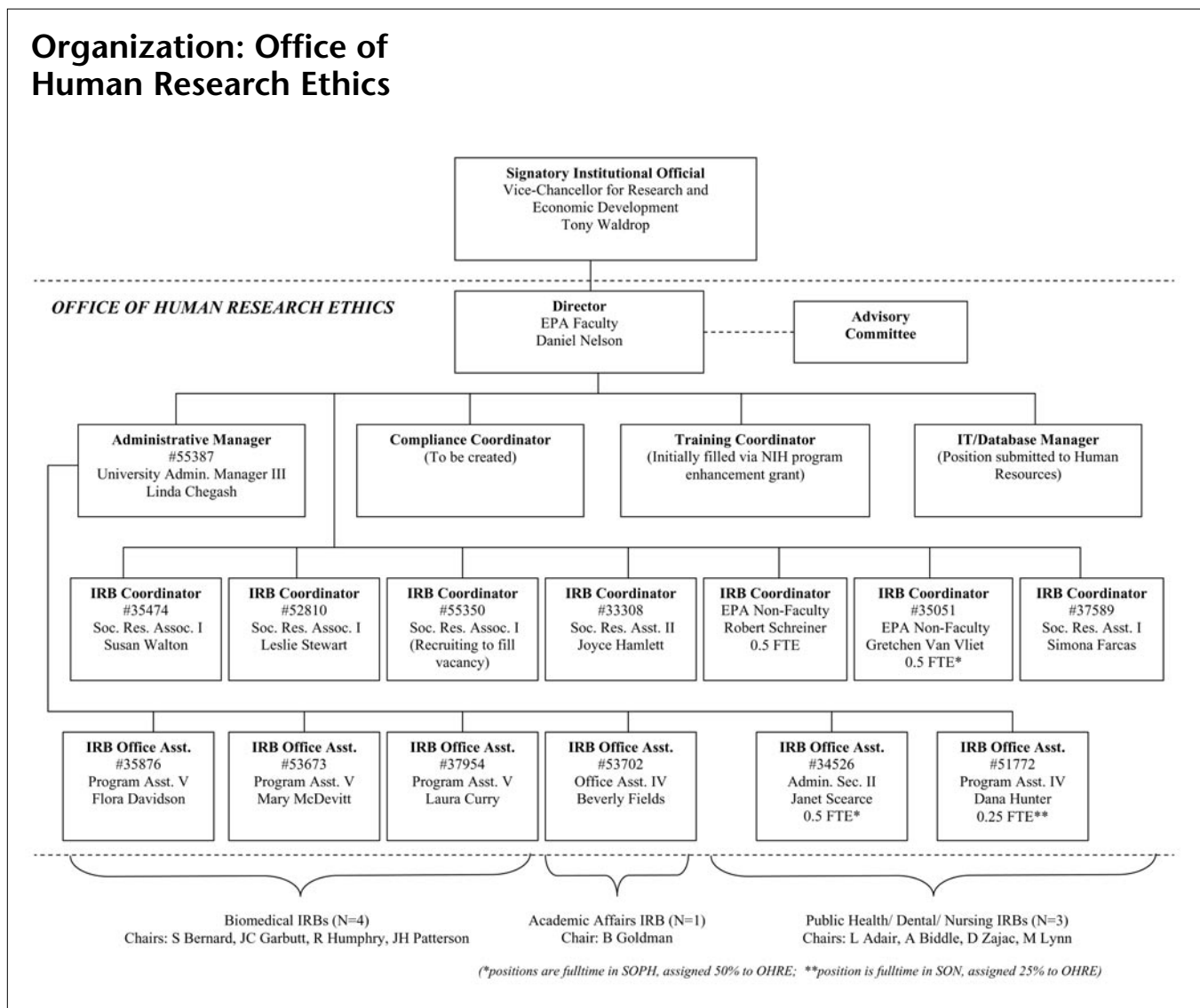
- The conceptual, political and financial groundwork has been laid for a successful transition.
- An Advisory Committee has been recruited, representing

a breadth of research and administrative perspectives. This group will help ensure that this initiative stays on course, that it remains responsive to both institutional obligations and to investigator needs, and that appropriate mechanisms are in place for financial support.

- A new Federalwide Assurance (FWA) has been approved by OHRP, updating this important documentation to new federal standards and reflecting changes in institutional leadership.
- Working groups have been established and work is proceeding on several major projects.

Goals for Coming Academic Year

- Consolidate and integrate the five existing IRB operations into one, under the OHRE. *Challenge:* Campus space will not allow a physical relocation of all units for some



time. Ultimate gains in efficiency and effectiveness will not come until the office staff can work in closer proximity.

- Create new positions under reorganized structure, including an administrative manager, a training coordinator, a compliance coordinator, and an information technology manager. *Challenge:* Several of these positions overlap with projects under the NIH Enhancement Grant received to improve IRB systems, and these efforts will need to be coordinated.
- Announce the reorganized structure to the research community, and begin channeling users through the centralized resource.
- Develop a common OHRE web site and application for use by all IRBs and investigators across campus.
- Consolidate and integrate funding for the OHRE. *Challenge:* Only one of five existing operations has had a separate budget tied to the IRB office as a discrete entity, so there is little idea of the true aggregate cost of operations. Moreover, there are some units that generate work for the IRBs but have not previously contributed to their support. There may ultimately be eight to ten sources that must come together to fund the new operation, lending considerable budgetary complexity. The administrative manager position will be key in this regard.
- Convene the Advisory Committee. As above, we will

look to this group to consider mechanisms for fair and equitable allocation of costs, and to advise on several major policy decisions.

- Develop a common database for use by all nodes of the operation, even if they cannot combine geographically. *Challenge:* There have been several abortive attempts to do this over the past five years, and there is no system or platform that is clearly optimal, in terms of meeting complex needs. The IT manager position will be key here, with guidance from other campus resources.
- Develop common Standard Operating Procedures (SOPs).
- Continue to strengthen links to other entities involved in oversight or conduct of human research at UNC-Chapel Hill, including the Conflict of Interest Committee, Office of University Counsel, Institutional Biosafety Committee, Radiation safety Committee, Data and Safety Monitoring Board, General Clinical Research Center, Oncology Protocol Office, Radiation Safety, Office for Sponsored Research, and Office of Clinical Trials.
- Apply for accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). *Challenge:* All the foregoing goals must be met, or immediately within grasp, before such an application will be viable.