

**Office of Research Compliance
Strategic Plan 2009-2014**



Introduction

This Strategic Plan is established to guide the Office of Research Compliance (ORC) from Fiscal Year 2009 through Fiscal Year 2014. During this five-year time frame, the plan—as well as staff and work assignments related to it—may change based on the changing needs of the Office. The ORC intends to review and make modifications to this Plan as necessary in order to respond to the rapidly changing environment in which it operates. The Office will establish employee work plans based upon the elements of this Strategic Plan, and work to further the goals established herein.

This, the ORC's second Strategic Plan, sets out to separate programmatic and strategic goals and differs from the previous Plan in two significant ways: First, the initial plan outlined the parameters for the successful creation of an office. Now that the office is established this plan sets the framework for sustaining the ORC while adapting to internal and external factors. Second, the previous plan focused on slow gradual growth in office activity which has been exceeded beyond expectation. This Plan includes management strategies for current growth and additional strategic efforts to manage additional responsibilities or growth.

Success in some areas of this plan may ultimately be beyond the ORC's control, as certain goals are contingent upon budgetary approval and/or changes in federal regulations along with changes with the direction of the UNCG research community. The ORC will embrace any changes that present themselves and will foster all established relationships on or off campus and will leverage its resources to accomplish the goals set forth in this plan.

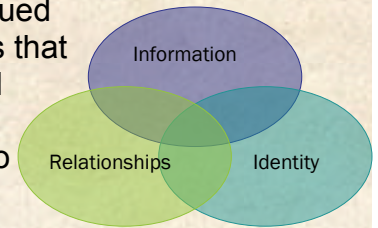
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1 Executive Summary

The Office of Research Compliance's (ORC) initial focus was to establish itself in the University of North Carolina at Greensboro community at large. This goal was accomplished within the first five years of the ORC's existence. The ORC achieved this goal through an analytical review process. The process separated all components that make up the ORC and its areas of purview for an independent study in isolation to occur. Following this, the results from the independent study were put back together as a unit in an enhanced manner which is illustrated in this strategic plan.

Now with the ORC's firm foundation at UNCG, the department focus has evolved to becoming an interactive networking system. The system will work within a tripod approach utilizing information, identity, and relationships. Information will be obtained through reaching out to the campus community and tapping into departmental resources to obtain knowledge, insight, and guidance. The information gathered will aid in contributing to the continued molding of the positive identity of the ORC and identifying specific areas that require growth. The ORC identity aspires to incorporate the institutional purpose along with investigator perceptions of compliance to yield an identity that will withstand adversity. Relationships are the pathways to an intelligent networking system (organization). Through relationships, information is created and transformed into useful actions/transactions.



This will expand the ORC's identity to include more stakeholders and the ORC will become more efficient. The more access the ORC has to people/organization through relationships the more possibilities there are to foster collaborative research. These relationships will allow the ORC to respond with speed and effectiveness to investigators' needs with our access to intelligence of our dynamic system.

The ORC's future hinges upon building on the foundation established with the completion of the first strategic plan. Maintaining a proactive mentality will enable the ORC to eliminate some adversities along with self assessment which will be used to modify this strategic plan as necessary. The benefits to the institution through the ORC's strategic plan are simple: reduced liability, increased compliant visibility, and the development of a collegial atmosphere that will satisfy faculty investigators.

2 Who are we?

The ORC has oversight of four regulatory committees (animal, human, biohazards, & radiation) and two institutional programs (research misconduct and drug free workplace certifications). The ORC staff works to ensure consistent observation of federal and state regulation, as well as institutional policies, in all research activities conducted by UNCG affiliates. To assist researchers in complying with these regulations policies, formal training sessions and individual consultations are available through the ORC. The office works closely with investigators, administrators and regulators to further the University's goals of ensuring that research at UNCG adheres to the highest ethical and scientific standards.

To this end, an important component of the ORC's activities is careful oversight of research participants' well being in studies conducted by UNCG faculty, staff, or students. In order to ensure that adequate protections are in place for participants in each study, committees specializing in reviewing particular types of research or procedures have been formed to review all study protocols. The ORC is responsible for receiving research protocols and other submissions, and ensuring that they are reviewed by members of the appropriate committee(s).

2.1 Current Status

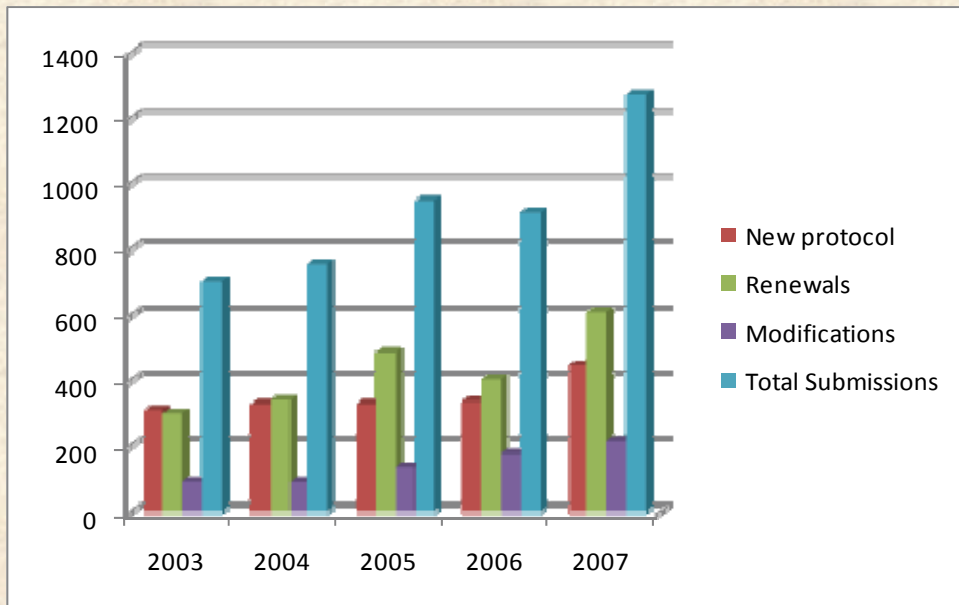
The Office of Research Compliance (ORC) is still on the rise to its peak in management of research activities funded and unfunded. Over the past six years we have experienced growth in all areas of its purview, but most astronomically in the human research area. We anticipate continual growth in this area due to the current economic hardships facing the nation and North Carolina. With the lack of jobs more individuals will enroll in graduate programs, which is good for UNCG's educational focus and research initiatives.

Over the past few years the ORC along with the Institutional Review Board (IRB) has spent considerable time educating the campus in regards to when IRB protocols are necessary and how detrimental failure to submit IRB protocols are to individual investigators and the institution. The chart that follows illustrates this growth over the last five academic years.

Since the ORC's inception in 2003, new protocol submissions and total submissions have increased 61-81% respectively.



IRB Protocol Submission Chart from 2003-2007



The ORC has developed a plan to manage the significant growth in human research along with a plan for potential growth in other areas. This plan also includes a strategy for other responsibilities potentially placed on the ORC. The management plan includes reorganization of office personnel, modifying committees, establishing better protocol routing processes, and outreach programs. The components of the management plan are discussed or illustrated throughout this document.

3 Strengths, Weaknesses, Opportunities & Threats (SWOT) Analysis

The following SWOT Analysis is part of the ORC’s strategic planning method used to evaluate the Strengths, Weaknesses, Opportunities, and Threats involved in successful running of its department. It involves specifying the objectives of the ORC and identifies the internal and external factors that are favorable and unfavorable to achieving the ORC objectives.

3.1 Strengths and Weaknesses

Strengths

- Experienced professional and administrative staff
 - * ORC professional staff are engaged in professional development through appropriate agencies and the university system to ensure that they have current information to apply to their respective roles.
 - * ORC administrative staff are engaged in professional development through the university and university system to keep them abreast of institutional changes.
- Adequate funding
 - * Due to the current financial restraints, the ORC, along with the institution, has endured budget cuts, however the ORC is still capable of conducting its core operations.
- Appropriate authority for the Director
 - * The Director has been delegated the appropriate level of signature authority, security clearance, advisory seats on appropriate committees, and decision making authority. This delegation allows the ORC to function as necessary to be both efficient and precise.
- Connections with federal agencies
 - * The ORC has developed strong working relationships with the Office of Laboratory Animal Welfare, Office of Human Research Protections, and consultants of the federal government.
- Communications infrastructure
 - * The ORC has a well established communication infrastructure throughout the campus and external to the campus. The ORC is connected with the UNC consortium, various compliance list serves, and has built a personal network of national compliance colleagues.

Weaknesses

- Acceptance of new/additional initiatives
 - * As compliance regulations change or as institutional needs increase, the ORC may have to accept additional responsibilities. These responsibilities will first be evaluated to determine additional time requirements, necessary resources, institutional support, and disposition of additional authority if necessary. Following this assessment, a formal report encompassing the results of the assessment will be presented to the head of the appropriate administrators/ governing bodies. Upon agreement with all parties an arrangement will be established.
- Institutional technology
 - * Lack of assistance from the institutional technology group inhibits the research community and ORC from taking advantage of various tools. These tools consist of network space for data storage, electronic data collection tools, electronic signature, electronic authentication of individuals, and guidance on appropriate levels of password/firewall protection. As research efforts move in this direction this technological weakness will become a threat as the institution would be conducting research that it could not assure was compliant with federal mandates.
- Institutional image
 - * There are various negative opinions on campus regarding compliance that are based on historical events prior to the existence of the ORC. Changing the perception of compliance through the ORC is difficult and challenging but remains a primary focus of the office through various initiatives.

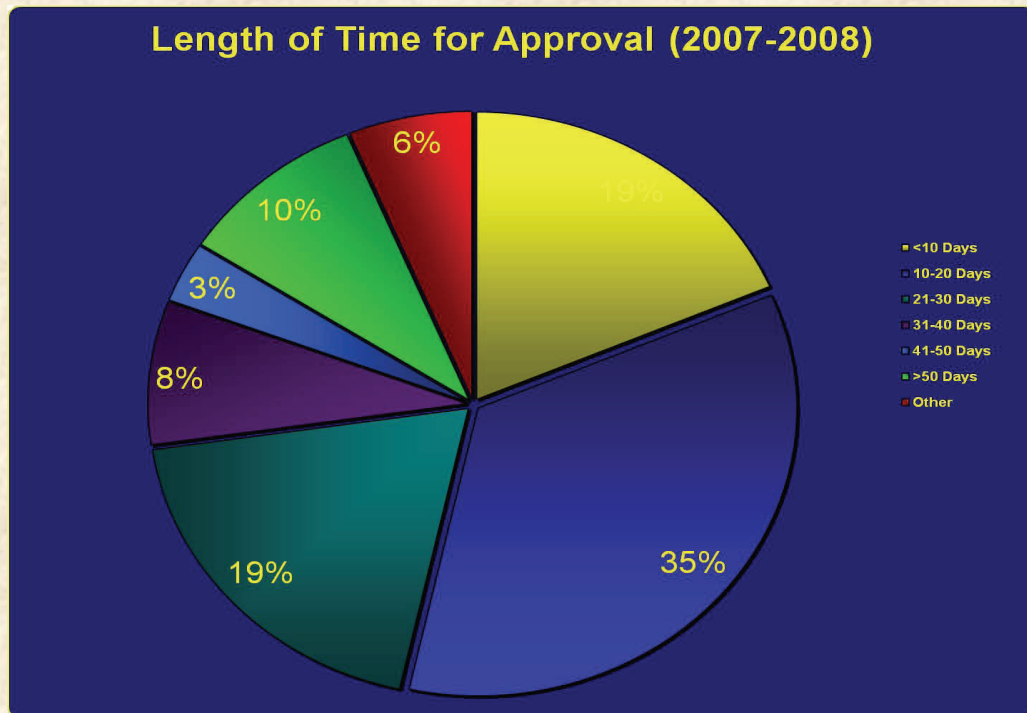
3.2 Opportunities and Threats

Opportunities

- Paperless protocol review and management
 - * The ORC has obtained a software package for both IRB and IACUC that will allow investigators to submit protocol online and conversely allow committee members to review protocols online. These systems offer the campus numerous opportunities that will allow for reduced effort for all individuals involved in the creation and routing processes. This will also allow the ORC and the investigators to follow the status of the protocol in real time. Additionally, these systems will reduce burden on the ORC as file management will be greatly reduced.
- External and internal evaluation
 - * The ORC has been evaluated by the National Council of University Research Administrators (NCURA) as a component of the UNCG research enterprise. NCURA's final report provided the ORC with substantive guidance and information to improve its functionality. This evaluation also provided concrete information to campus administration in regards to the ORC productivity and future concerns/needs. The final report will serve as a catalyst for re-evaluation, creation, and revision to current policies, procedures, and objectives.
 - * The ORC solicits input from all individuals that it interacts with throughout the year with an annual customer service survey. The results of this survey are reviewed by the ORC to determine what can be done to facilitate the request. Once this assessment is completed, a plan is devised to make appropriate changes and a document outlining these changes is sent to the campus community.
- Professional development
 - * Professional development allows professional staff to better educate and assist researchers, other administrators, and committee members. The ORC professional staff continues to be engaged with various professional associations, certification programs, and take advantage of educational resources. These efforts allow the professional staff the ability to be current with revised rules and alternate ways of interpreting existing regulation.
 - * The ORC support staff engages in professional development through taking advantage of institutional and UNC system initiatives that will diversify and improve their skill sets.
- Researcher symposiums
 - * The ORC in concert with appropriate faculty will develop biannual symposiums to address research and compliance related concerns. These symposiums will incorporate a representative for the compliance arena and the area of concern/question. It is anticipated that the ORC, IRB and faculty will develop a broader understanding of critical topics that affect their research and a different way to evaluate ethics.
- Faculty Forums
 - * The chair of the IRB in partnership with the Vice Chancellor for Research (no ORC personnel will attend these sessions) will host open faculty forums to explore the role of the IRB and faculty experiences with protocol submission and review in conjunction with current federal/institutional regulations. The open forums will provide the opportunity for faculty to bring specific experiences forward for discussion and this will provide valuable feedback to the IRB to assess currency of these situations.

Threats

- Staff reduction
 - * The current staffing level is appropriate for the volume of current activity and allows the ORC to have an acceptable turnaround time. With any reduction in staff the turnaround time would be greatly increased and the quality of protocol reviews would diminish which in turn places the institution at risk for litigation, restriction of obtaining federal funding, and damaging the institution's character.
- Funding reduction
 - * The ORC along with the rest of the university has endured serious budget cuts. Any additional cuts would inhibit the ORC from functioning as necessary to meet federal guidelines and facilitate demands for time sensitive funded projects and graduate student research.
- Faculty knowledge
 - * Noncompliance is usually attributed to a lack of knowledge on behalf of the researchers. Even though a lack of knowledge is unintentional, the institution is still held liable for any and sometimes all repercussions for failure to follow the federal guidelines.



This chart, for the 2007-2008 fiscal year shows 54% of IRB protocols were reviewed in 20 days or less.

4 Vision and Mission



Vision Statement

With leadership and support from the Office of Research and Economic Development, the Office of Research Compliance will achieve the highest level of customer service, compliance, innovative training and provide a safe world-class research campus to facilitate discoveries that will greatly enhance our knowledge base and significantly benefit the institution along with the public.

ORC Mission Statement

The Office of Research Compliance is a catalyst for advancing the research mission of the University of North Carolina at Greensboro. Our responsibilities include:

- Developing compliance policies and infrastructure that promote creativity and an entrepreneurial culture.*
- Ensuring that compliance policies and educational programs promote both a culture of innovation and a culture of compliance on the University of North Carolina at Greensboro campus.*
- Providing service and resources in areas of compliance that enhance research, teaching, and other creative endeavors.*
- Enhancing partnerships and interdisciplinary compliance collaborations with government, industry and other research enterprises of higher learning.*

5 Goals

The overarching strategic goal of the ORC is to maintain a compliant campus culture and reduce institutional liability while maintaining the ORC's status as a "user friendly research service center."

Strategic Goals

- Establish Responsible Conduct in Research (RCR) program

The program will be dynamic in that it will continually change as research trends, legal, and institutional requirements change.

- The program will accommodate the federal government's mandate to have a RCR program

The program will be created collectively with the following offices/individuals:

- Office of Research Compliance;
- The Graduate School;
- Sponsored Programs;
- University Legal Counsel;
- Vice Chancellor for Research; and
- Other appropriate individuals

-This strategic goal will be initiated in the fall of 2009

- Human Research Accreditation

The ORC is in the process of obtaining accreditation for its human research protection program through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The result is a more cohesive HRPP, with the systems in place not only to protect research participants but also to advance research more efficiently and effectively. Obtaining AAHRPP accreditation will drive future goals and future initiative of the ORC from 2012 to 2014.

AAHRPP accreditation will generate many positive aspects. Two of the most prominent aspects are improved efficiency/effectiveness and boosting public trust/confidence in UNCG research. An additional tangible aspect would include separate but equal standards for funded and unfunded research commensurate with the risk associated with the study.

- * Improved efficiency/effectiveness is accounted for as all policies and procedures are revised to ensure appropriate documentation is also translated into practice, which results into more streamlined and effective processes.
- * Boosting public trust/confidence comes into place when prospective research participants and the general public discover that the institution has gone above and beyond the minimal federal regulations to ensure research is conducted safely and ethically.
- * AAHRPP will assist in developing an additional set of guidelines that will allow the IRB to legally and ethically reduce requirements applied to unfunded and minimal risk studies. These additional guidelines will reduce unnecessary burden on investigator and the IRB while still ensuring the safety and wellbeing of all research participants.

-This strategic goal is anticipated to continue to move forward in the 2010 to 2011 academic year.

- Marketing Strategy

As the ORC and its affiliated committees complete various activities inclusive of revised policies, procedures, or guidance documents providing this information to the end user, researchers/administrators, is critical to ensure that the rules are being implemented.

-This strategic goal is anticipated to continue as necessary from 2010 to 2014.

- Revise COI policy

As a part of the COI task force the ORC will contribute the revision of current COI policy and helping resolving pending conflicts. The ORC will ensure that necessary information regarding regulatory committees is incorporated in discussions and policy creation.

-This strategic goal will be initiated in 2009 and will continue until completed.

- Nurture graduate faculty relationship

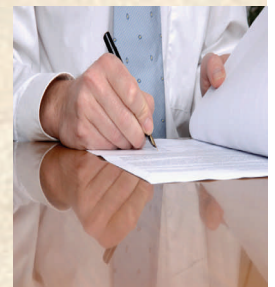
The graduate school has graciously worked with the ORC collaboratively in IRB certification courses for graduate students, supplying information to the graduate faculty, and entertaining ad hoc meetings to discuss compliance related concerns. As UNCG's graduate programs grow, cultivation of this relationship will prove to be extremely beneficial.

-This strategic goal is anticipated to continue to move forward from 2009 to 2014.

- ORC quarterly periodical

Communicating with the UNCG campus is extremely important to ensure that faculty, staff, and students have access accurate information. Providing this information will reduce confusion and delays related to submitting and managing research protocols. The ORC plans to develop a periodical that will be distributed quarterly to the UNCG campus electronically.

-This strategic goal will be initiated in the 2011 academic year.



Programmatic Goals

Policy and Procedure Evaluation

The ORC will evaluate all compliance committees' policies and procedures annually to ensure that they are accurate and consistent with federal regulations and applicable guidance documents. This review process may prompt revisions as deemed appropriate to policies and procedure documents. Additionally, these reviews will aid in maintaining accreditation the IRB. Accreditation will help advance the Office of Research and Economic Development mission of building public trust in UNCG research and instilling confidence in external sponsors for UNCG research efforts. The IRB will be accredited through the Association for Accreditation of Human Research Protection Programs (AAHRPP) by the end of the 2010/2011 academic year. This effort will demonstrate to the federal government, the

UNC system, and the community at large of our institution's commitment to ensuring compliance.

-This programmatic goal is anticipated move forward in the 2010 to 2011 academic year.

Committee/Campus Enrichment Programs

This program will develop uniform educational standards for all committees which are spelled out in the IRB and IACUC Standard Operating Procedures (SOPs). All committee members will be engaged in developing/improving procedures and policies. This will provide a baseline for future use by faculty, staff, students, committee members and administrators. Each committee will receive a training binder with pertinent information relating to the respective committee. During the committee meetings, there will be time devoted to educating the committee members. Various workshops and webinars for the IACUC and IRB will be hosted for committee members, researchers and administrators. The ORC also will distribute updated information in the form of articles and prerecorded seminars for the RSC and IBC. Chairmen of the IRB and IACUC along with the director of the ORC will conduct mini awareness seminars for selected departments to give brief overviews of committees' requirements and procedures. Feedback from these sessions will help the ORC update training materials to better accommodate researchers. Additionally, committee chairmen will attend national/regional workshops annually to increase their ability to lead the committee and obtain useful knowledge. The ORC will host biannual research forums on topics such as oral history and electronic, virtual, and international research to aid researchers in developing a better understanding of regulatory issues in relation to current research practices.



-This programmatic goal will be initiated in 2010 and will continue to move forward through the 2014 academic years.

Best Practices Evaluation

The ORC will review other institutions within the UNC system and nation wide to determine what is considered best practices for compliance operations. The ORC will evaluate forms, procedure documents, database systems, committee structure and functions, personnel responsibilities and expectations, and resources needs.

-This programmatic goal will be initiated in 2011 and repeated biannually.

Spartan Animal Care System (SACS)

The ORC will review, edit, and present Spartan Animal Care System (SACS) to ensure consistency with UNCG policy, procedures, and high ethical standards. Upon completion of these modifications, SACS will be presented to the IACUC for endorsement. Following the IACUC endorsement, the committee will pilot test the system.

-This programmatic goal will be implemented in the 2009/2010 academic year.

Continue Self Evaluation

The ORC will review, edit, and present Spartan Animal Care System (SACS) to ensure consistency with UNCG policy, procedures, and high ethical standards. Upon completion of these modifications, SACS will be presented to the IACUC for endorsement. Following the IACUC endorsement, the committee will pilot test the system.

-This programmatic will be reestablished in the 2010 academic year.

Develop IBC process/application overview

The IBC chair and the Director of the ORC will work collectively to develop a clear and concise overview document. This document aims to provide investigators with useful information that will guide them through IBC processes.

-This programmatic goal will be initiated during the 2010/2011 academic year.

Develop IBC fundamental education program

All investigators and research staff, including students, need to be adequately trained with the basic elements of laboratory safety and management of biohazards. The IBC will work with the Office of Safety to develop these educational programs that will be offered to the campus.

-This programmatic goal will be implemented in the 2011/2012 academic year.

Spartan IRB Management System (SIMS)

SIMS will be implemented completely including online submission of IRB protocols in the 2009 academic year. In 2008, the ORC worked closely with UNC to verify accuracy with data conversions and implementation of SIMS in the ORC as a database. Once this is in place, a portion of the ORC functions will move to electronic transactions, including but not limited to, education certificate reminder notices, notice of protocol approval, renewal notice reminders, and maintain accurate data in each protocol.



-This programmatic goal will be implemented in the 2009/2010 academic year.

Develop ORC Infomercial video

The ORC will develop a videography to advertise its functionality, available resources/ services for researchers, accomplishments and future goals. The video will be used as a marketing tool to show the UNCG campus community the ORC in a positive light. In addition, the video will send a clear message that the ORC is truly a “user friendly research service center.”

-This programmatic goal will be initiated in the 2012/2013 academic year.

6 Executive Support

Executive support from the Provost and Vice Chancellor for Research (executive team) is essential for the successful implementation of this strategic plan. It is not possible to operate a compliance office “below the radar” without executive support. This jeopardizes successful completion of this strategic plan. The success of the ORC is not only beneficial to individuals that conduct research, it is important to the Provost and Vice Chancellor for Research as the outcomes of ORC actions affects the institution’s image.

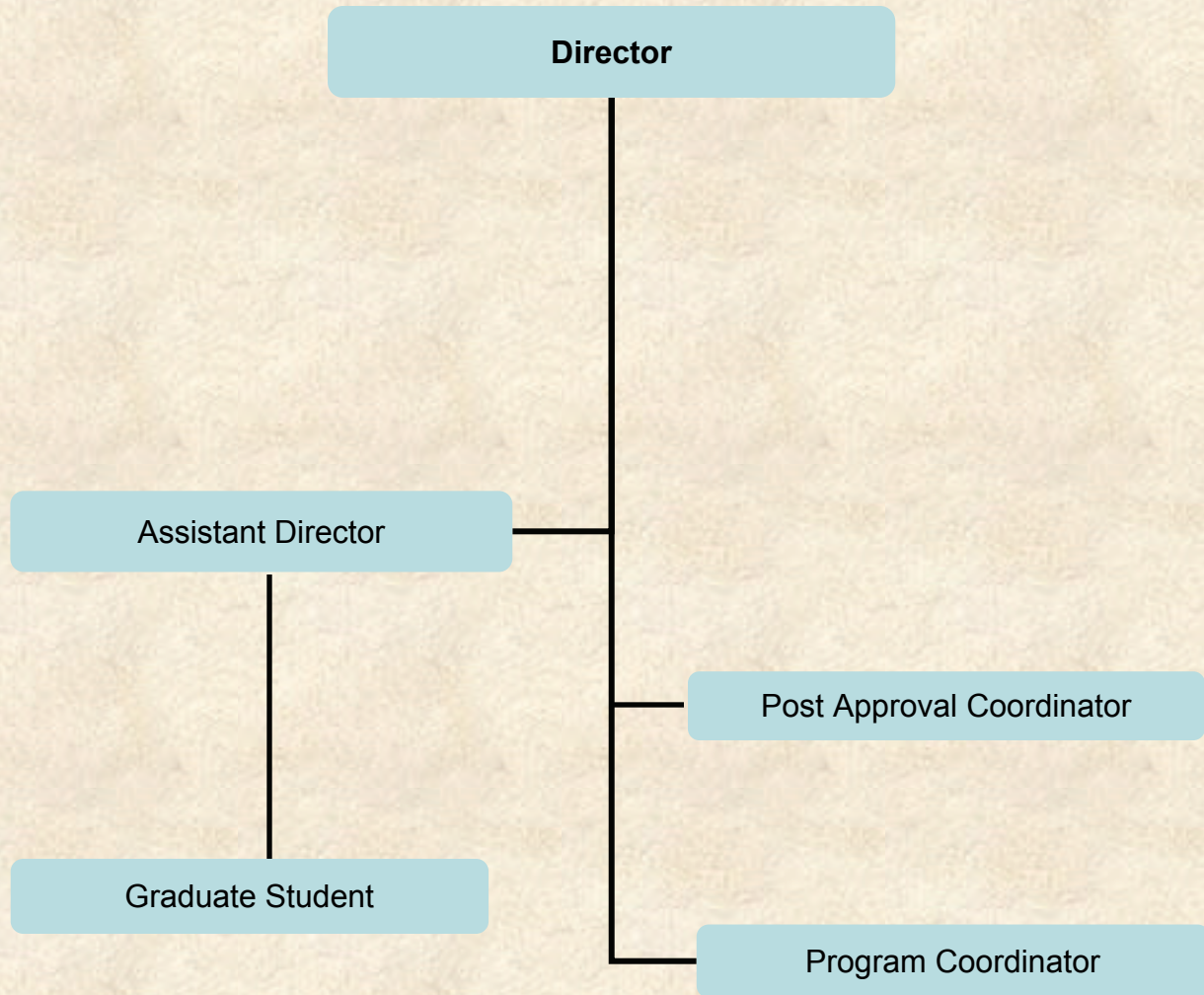


The ORC intends to ensure that the executive team is apprised of this strategic plan and the ORC will work directly with the Vice Chancellor for Research as necessary to discuss concerns, problems, departmental needs, and strategies. An open line of communication between the ORC and the executive team is critical to the ensure success of ORC objectives.

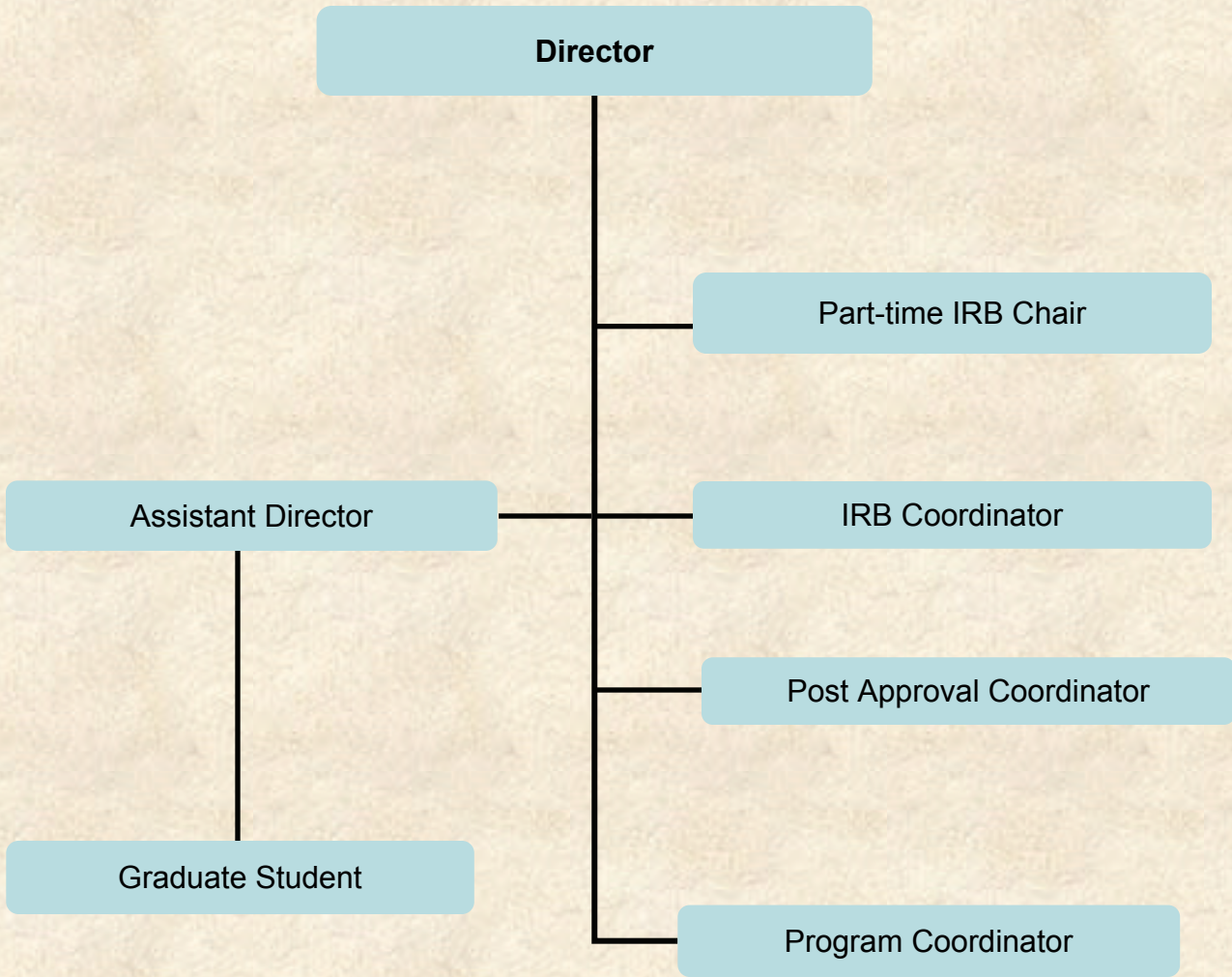
Title	Reports To	Responsibilities
Director	Vice Chancellor For Research and Economic Development	<p>Oversight of the Research Compliance Office staff and initiatives</p> <p>Administer policies and Standard Operation Procedures for entities under the ORC purview</p> <p>Serve as liaison to RED, the Office of Sponsored Programs, Contracts and Grants, University Counsel, Graduate School and the campus at large</p> <p>Meeting with Vice Chancellor for RED and other administrative faculty as necessary to ensure transparency with ORC efforts in association with upper administration</p> <p>Serve as liaison to Federal and State regulators</p> <p>Serve as liaison to community requests for information</p> <p>Management of COI committee and program</p> <p>Serve as Research Integrity Officer for research misconduct</p>
Assistant Director	Director of Research Compliance	<p>Implementation of university day to day operation of the IRB and IACUC</p> <p>Management of IRB, IBC, and IACUC protocol initial review</p> <p>Drafting sample Standard Operating Procedure for IRB and IACUC for review and approval from the Director and appropriate committees</p> <p>Review and evaluation of reports and results of quality assurance assessments and quality improvement activities</p> <p>Monitoring changes in federal and state regulations and university policy that relate to human and animal research protection programs</p> <p>Providing education on human and animal subject protections to investigators and IRB members</p> <p>Serve as voting member of IRB</p>
Post-approval Coordinator	Director of Research Compliance	<p>Pre-review of all IRB and IACUC protocols for completeness</p> <p>Conduct all post approvals (and some initial reviews) for IRB and IACUC</p> <ul style="list-style-type: none"> - Renewals - Modification/amendments - Exemptions - Determinations <p>Output oversight</p> <p>Liaison to investigators and student investigators</p> <p>Oversee student human participant research efforts</p> <p>Serves as a nonvoting member of the IRB and IACUC</p> <p>Generates reports including minutes for IRB and IACUC within database</p> <p>Serve as backup support for the Program Coordinator</p>

Title	Reports To	Responsibilities
Program Coordinator	Director of Research Compliance	Administrative assistance Maintenance of the ORC website Human resources liaison Payroll liaison Scheduling all committee meetings and distributing pre-meeting materials Maintaining official rosters of all committee members Maintaining all committee documentation and files Oversight of student workers Management of ORC budgets
Graduate Student	Assistant Director for Research Compliance	Assisting ORC with program coordination Provide assistance to Assistant Director with administrative and core tasks Aid with internal animal subject research management efforts Coordinate statistical analysis for office initiatives and audits Assist with technological needs inclusive of website development, database management/development, and system support

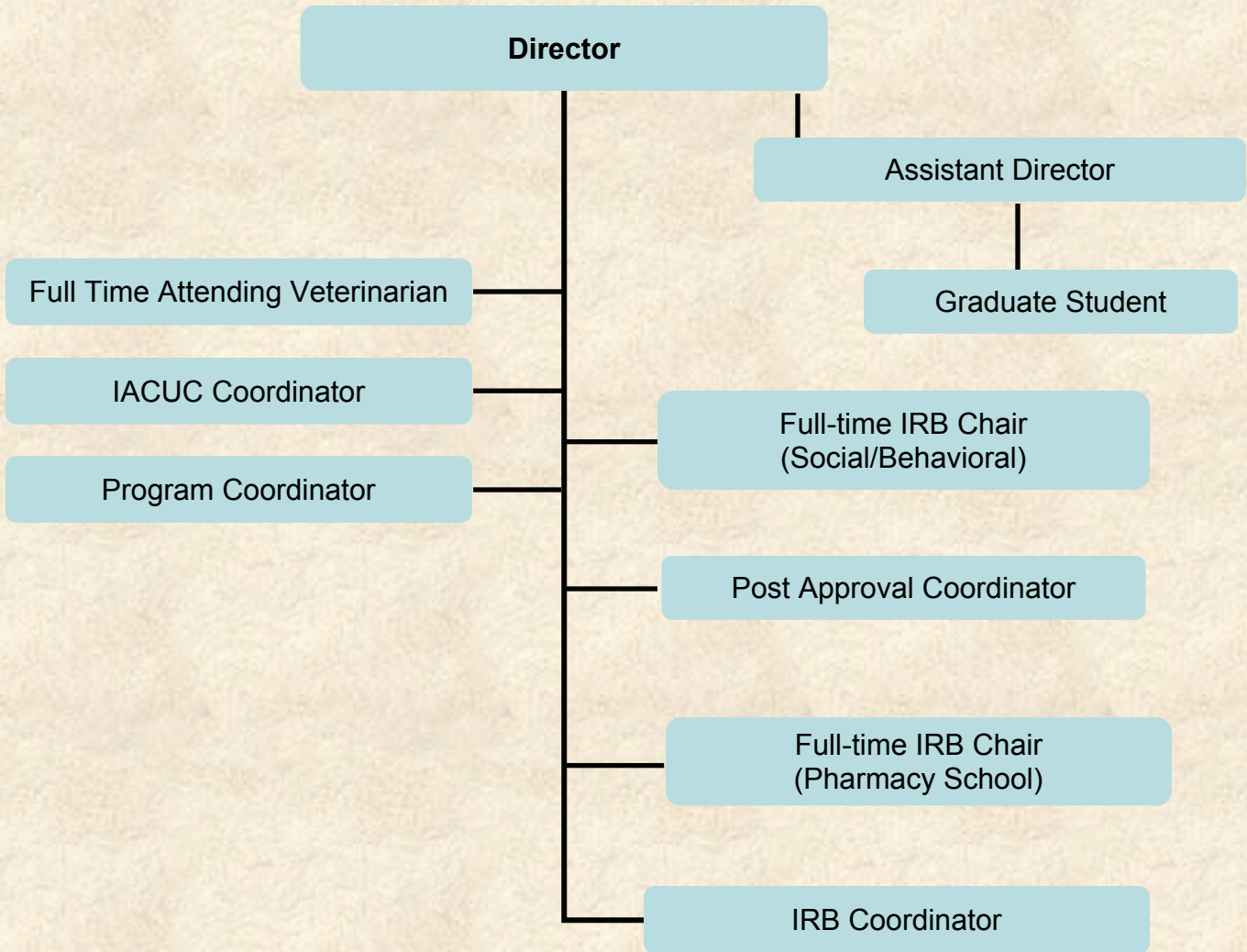
Organizational Chart 2009



Organizational Chart 2010



Organizational Chart 2013



7 Management Plan

The ORC's growth is dependant upon the growth of the institution in relation to increases in:

- New/expanded graduate programs
- Additional research active faculty
- Advancement of campus research initiatives
 - UNC Tomorrow
 - Kannapolis research campus
- Increase in protocol submission
- New/modified federal regulations



**The creation of a pharmacy school will generate a need for an additional IRB & IACUC to be developed along with appropriate staff and resources to fund the program prior to implementation.*

The current ORC personnel (Org. chart 2009) includes the Director, Assistant Director, Post Approval Coordinator, Program Coordinator, and one graduate student. The current staff is barely capable of handling the current workload.

Subsequent increases in workload over the next two to three years due to UNC Tomorrow and the North Carolina Research Campus will need the assistance of at least a half time appointment of the IRB chair. Also, in order to be efficient, timely, and provide a high level of customer service an IRB coordinator needs to also be added to the ORC personnel (Org. chart 2010). This additional FTE will allow the ORC to continuously have coverage in the office and will allow for guaranteed review timelines.

Creation of the pharmacy school will elicit additional guidelines that will need to be followed including USDA for regulate animal species and FDA for clinical trials. This will also prompt the need for an additional IRB to manage the tremendous workload increase. An increase in ORC FTE's (Org. chart 2013) will include an IACUC coordinator, Full time IRB chair for the pharmacy school, upgrade the half time IRB chair to a full time Social Behavioral IRB chair position, and a Full time Attending Veterinarian. Following the year 2013 the ORC will need to evaluate the workload distribution for IRB and determine if an additional coordinator is necessary.

Resources

1. Office space
 - a. Confidential information needs to be discussed/stored in secure confined areas
 - b. New personnel will need work space and adequate space for impromptu meetings, document storage, and appropriate training sessions
 - c. Committee Chairs need space to review protocol files to render decisions and discuss actions with faculty
 - d. Output staff need adequate space for compilation of documents and resource materials
2. Office furnishing
 - a. Standard equipment/furnishings to accommodate staff, visitors, and researchers
 - b. High capacity scanner/copier is necessary reduce copying cost and improve efficiency
3. Computers
 - a. Moving towards a solely electronic systems will require high powered/up to date equipment to aid in ensuring security, rapid access to data and compatibility to all forms of technology researchers will be using
4. Financial negotiations with Graduate School
 - a. Continual availability of access to graduate students with funding
5. Professional development
 - a. Access to professional workshops/seminars will allow staff to gain insight of compliance changes and identify colleagues that can provide assistance when necessary
6. Storage space
 - a. All ORC files must be stored in a secured (fire/natural disaster resistant) area to ensure institutional integrity and compliance
7. Specialized ITS support
 - a. With two independent compliance database systems, ITS support to ensure systems are running appropriately with adequate backup is critical
 - b. ITS support with various strategies to maintain compliance while overseeing investigators using various advanced technologies to conduct their research
 - c. ITS annual systems/equipment evaluation and recommendation report on adequacy of equipment available to ORC staff
8. Appropriate fiscal resources
 - a. Budget expansion to cover increase in ORC responsibilities, personnel, necessary expenditures and inflation

Appendix A Major accomplishments 2004-2008

2004

- Developed compliance training schedule for all committees
- Composed and distributed IRB committee training binders
- Composed and distributed IACUC training binders
- Developed a new member training program
- Conducted IRB training workshops
- Conducted IACUC training workshop
- Conducted IACUC emergency preparedness workshop
- Developed IRB brochure
- Conducted internal audit with use of the Office for Human Research Protection (OHRP) Quality Assessment tool
- Hired full time administrative assistant
- Developed ORC website
- Hosted compliance appreciation banquet
- Interacted with UNCG faculty, staff, and students to increase awareness of the ORC operation and university compliance research efforts
- Created training manual for graduate students working in the office
- Added an IRB tutorial that focus on behavioral and social science research



2005

- Conducted annual review of IRB, IBC, & IACUC policies/procedures
- Hired consultants to review IRB & IACUC program
- Drafted strategy for revised COI Policy
- Updated IRB, IBC, & IACUC resource manuals
- Continued to conduct educational sessions in committee meetings
- Collaborated with Office of Safety on distribution of new training videos
- Conducted departmental IRB training sessions for the School of Business and Education
- Supported IACUC chair attendance at PRIM&R training session

- Evaluated the IRB with the OHRP quality self-assessment tool
- Conducted 1st annual customer service survey to researchers and committee members
- Updated ORC website and added the IRB ZONE
- Held compliance chair meetings with Associate Provost for Research
- Established Drug Free Work Place training program
- Composed HIPAA security guidance for IRB

2006

Initiated revisions to IRB, IBC, & IACUC policies/procedures

- Drafted strategy to improve IRB & IACUC programs upon recommendation of consultants
- Assisted with the Animal Facility manual revisions
- Updated IRB, IBC, & IACUC resource manuals
- Conducted IRB & IACUC retreats
- Conducted IRB certification training sessions for graduate school
- Drafted IRB SOPs
- Conducted annual customer service survey
- Conducted annual Data Safety Monitoring audits
- Conducted compliance committee chair meetings with Associate Provost for Research
- Revised Research Misconduct policy
- Help with appreciation banquet for committee members
- Developed the ORC brochure
- Finalized the Occupational Health Guidance document for IACUC
- Implemented IRB mentoring program
- Conducted IRB Brown Bag sessions
- Developed document approval process through provost office
- Developed IACUC/Animal Facility Emergency plan

2007

- Completed IACUC SOPs draft
- Updated IRB & IACUC resource manuals
- Updated ORC website
- Conducted IRB certification training sessions for graduate school
- Conducted compliance brown bag sessions
- Initiated IRB accreditation process
- Conducted annual customer service survey
- Conducted Data Safety Monitoring audits
- Conducted compliance committee chair meetings with Associate Provost for Research
- Hired Assistant Director for the Office of Research Compliance
- Developed IRB Fast Facts Booklet
- Revised IRB SOPs & coinciding forms
- Purchased electronic data management systems for IRB, COI, & IACUC
- Updated IACUC/Animal Facility Emergency plan
- Implemented IBC policy

2008

- Completed first phase of accreditation
- Conducted IRB certification training sessions for graduate school
- Conducted annual customer service survey
- Conducted brown bag sessions
- Conducted Data Safety Monitoring audits
- Revised IRB SOPs & coinciding forms
- Completed IBC manual
- Implemented SIMS for ORC internal use
- Updated IACUC/Animal Facility Emergency plan
- Collaborated with graduate school to develop a RCR program