

## Mission Statement

*“The Office of Research Compliance is a catalyst for advancing the research missions of the University of North Carolina at Greensboro”*



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## An Exciting Year to Come

### Federal Changes

All three committee (Institutional Review Board [IRB], Institutional Animal Care and Use Committee [IACUC], and Institutional Biosafety Committee [IBC]), are in the midst of drastic changes. There is a uniform shift toward enforcement of the regulations and modifications of them to increase clarity/consistency with their interpretation and application. These efforts are going to be very exciting for researchers. In regard to the IACUC, there is new guidance that will modify various aspects of research. Human research is embarking on revolutionary proposed changes in the near future, including expanding and simplifying the exempt category, providing more clarity to expedited studies, eliminating renewals, and establishing standards for safeguarding social behavioral research to name a few potential changes. Stay connected to the ORC as more is to come. For more details, please visit <http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm>.

# Introduction

## First Edition of the ORC Newsletter

The Office of Research Compliance (ORC) has initiated the creation of the First Annual ORC Newsletter for August 2011. The purpose of this newsletter is to provide a recap of the previous year of committee information, changes to regulations, ORC educational updates, and other compliance-related activities at the University of North Carolina at Greensboro (UNCG). Also, it is a method to provide information about research compliance updates on the local, state, and national level. Enclosed you will find a compilation of research compliance information summaries that are relevant to improve the awareness of the UNCG community of scholars, which will in turn protect the standards for excellence among research compliance.



## Office of Research Compliance

### About Us

The ORC coordinates compliance measures on campus and acts as a resource for the university community's concerns regarding compliance requirements.

### Our Responsibilities

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 UNCG 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.

### Resources

#### *Open Office Hours:*

IRB- Related Questions  
Monday - Friday 8:30am - 11:30am  
2716 MHRA Building  
See Cristy McGoff

IACUC- Related Questions  
Monday - Friday 9:00am to 12:00pm  
2718 MHRA Building  
See Cat Collins

#### *ORC Drop Box:*

Located outside of our office (2714 MHRA Building)

#### *Live Chat:*

Real-time chat with ORC staff. Visit: <http://www.uncg.edu/orc/>.

#### *ORC Facebook:*

<https://www.facebook.com/pages/UNCG-ORC/153625965167>

# Office Goals

Planning ahead for excellence

## Strategic Goals

- I. **Establish Responsible Conduct of Research (RCR) Program:** This program will accommodate the federal mandate and will continually change as research trends and legal and institutional requirements change.
- II. **Marketing Strategy:** As policies, procedures, and guidance documents are revised, it is crucial that this information be provided to researchers to ensure that the changes are being implemented.
- III. **Nurture Graduate School/Faculty Relationship:** The Graduate School graciously collaborates with the ORC to provide resources to students and their advisory faculty concerning research practices at UNCG.
- IV. **ORC Quarterly Periodical:** Developing a periodical that will be sent electronically to the UNCG faculty, staff, and students regarding compliance information and ORC updates.

## Programmatic Goals

- I. **Policy and Procedure Evaluation:** The ORC will evaluate all compliance committees' policies and procedures to ensure that they are consistent with federal regulations.
- II. **Committee/Campus Enrichment Programs:** This program will develop uniform educational standards for all committees. Committee members will be engaged in developing/improving procedures and policies.
- III. **Best Practices Evaluation:** The ORC will review the procedures of other institutions in the UNC system and nationwide to determine what is considered best practices for compliance operations.
- IV. **Spartan Animal Care System (SACS):** SACS is a database management system for IACUC protocols. The ORC will review, edit, and present SACS to the IACUC for endorsement.
- V. **Develop IBC Process/ Application Overview:** The IBC Chair and the Director of the ORC will develop an overview document to guide investigators through the approval processes.
- VI. **Develop IBC Fundamental Education Program:** The ORC and the Office of Safety will work together to create educational information for the use of biohazardous materials.
- VII. **Develop ORC Infomercial Video:** The ORC will develop a video to advertise its resources and services.

# IBC Information

## Institutional Biosafety Committee

### IBC News and Updates

- ◆ The ORC will be revamping the training and educational program to provide up-to-date safety procedures for the use of biohazardous materials.
- ◆ The ORC has created the [IBC Fast Facts](#) in order to provide concise information about approval, training, and other IBC-related information.

### 2011-2012 IBC Meeting Dates

August 15, 2011  
October 17, 2011  
December 5, 2011  
January 23, 2012  
March 19, 2012  
May 14, 2012

# IACUC Information

## Institutional Animal Care and Use Committee Updates

### Changes for 2011-2012

The UNCG IACUC strives to continually improve the institutional quality of animal research and teaching activities. Beginning August 15, 2011, all of the following improvements will take effect. All documents are available through the IACUC website: <http://www.uncg.edu/orc/iacuc.html>.

**Updated Website** - The ORC has revamped its website with a new look and feel.

**SOP and Form Annual Update** - The IACUC annually reviews all forms and the Standard Operating Procedures (SOPs). Several changes have been made. All updated documents are available on the IACUC webpage.

**New FAQ** - A new FAQ document has been created and is available on the IACUC webpage.

**New Protocol Routing Process** - All protocol submissions (i.e. new submissions, renewals, and amendments) should be sent to the ORC first, and the ORC will facilitate the remainder of the review process. A flow diagram can be found at the following link <http://www.uncg.edu/orc/Routing%20process.pdf>.

**Occupational Health** - As of July 3, 2011, all occupational health clearances will be done at the UNCG Student Health Services. This will be free for all currently enrolled students and discounted for all faculty and staff. Individuals will also have an option of using their own physician under certain circumstances and with additional documentation.

**Animal Facility Security Upgrades** - Upgrades to the Animal Facility security system are underway. Cameras are being installed in both facilities to monitor persons entering and exiting animal rooms. A new key reader system has been installed on the main entry doors as well as each animal room. Researchers will only have access to their assigned animal room. We hope these upgrades will add to the existing security methods that were already in place.

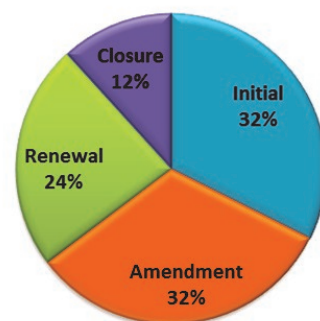
**Animal Facility Manual** - The Animal Facility Manual has been updated with minor revisions. A condensed version of the Manual is available on the ORC website. For a full version of the updated Manual, please contact Angie Hansing or the ORC.

## IACUC Annual Submissions Summary

### 2010-2011 Research

The IACUC Annual Submissions Summary included an examination of all submissions that occurred between July 1, 2010 and June 30, 2011. There were a total of 34 submissions to the IACUC during the past year. There were 11 initial applications, 8 annual review submissions, 11 amendment submissions, and 4 submissions for the closure of a protocol.

Type of IACUC Submissions



# IRB Committee Information

## Institutional Review Board Updates

### Changes for 2011-2012

The UNCG Institutional Review Board (IRB) strives to continually improve the institutional quality of human participant research protections. With this goal in mind, please be aware of the following procedural changes and new documents. All changes are effective August 15, 2011, and the updated documents are available through the IRB website: <http://www.uncg.edu/orc/irb.html>.



**Toll-Free Number** - The ORC now has an 800 number that should be added to consent forms and any other document that refers people to the ORC. This will allow those populations that do not have personal phone access the ability to contact us if and when necessary.

**Mock IRBs for Classes** - An IRB member and Assistant Director to the ORC will conduct in-class educational sessions on the function of protocol review. Upon request, sample protocols will be presented to the class for evaluation. Guidance will be provided on ethical and regulatory perspectives.

**Guidance of DXA Scans** - The IRB has developed guidance on pregnancy testing for females of child-bearing age when they are being scanned. See IRB SOPs 7.5.12 for more details.

**Document Name Change** - Due to the increased usage and discussion about NIH Certificates of Confidentiality, the ORC has changed the name of the UNCG "Certificate of Confidentiality" to the "Statement of Confidentiality" to reduce confusion. This can be found at [http://www.uncg.edu/orc/doc/Confidentiality\\_agmt.doc](http://www.uncg.edu/orc/doc/Confidentiality_agmt.doc).

**New Federal Rules Around Maintaining Data** - An investigator can retain and use data collected from participants that have withdrawn or the investigator has terminated their involvement in the study. However, if the participant requests that the investigator destroy his or her data, the investigator must honor this request. UNCG's IRB will require a notification to participants in both the informed consent form and consent process. The entire federal document can be read at <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html>.

**Updated Website** - The ORC website has been redesigned with a new look and feel. Please visit the site!

**SOP & Form Annual Update** - The IRB annually reviews all forms and the Standard Operating Procedures (SOPs) and has made several changes to these documents. There were no changes made to the Modification and Renewal forms. All updated documents are available on the IRB webpage, at <http://www.uncg.edu/orc/irb.html>.

**Updated FAQs** - New questions have been added to the IRB FAQs and new HIPAA FAQs have been added. <http://www.uncg.edu/orc/files/irbfaqs.doc>.

**Survey Harassment** - The IRB has established limits on the number of contacts a PI can attempt with potential recruits. See IRB SOPs 11.2.1 for more details.

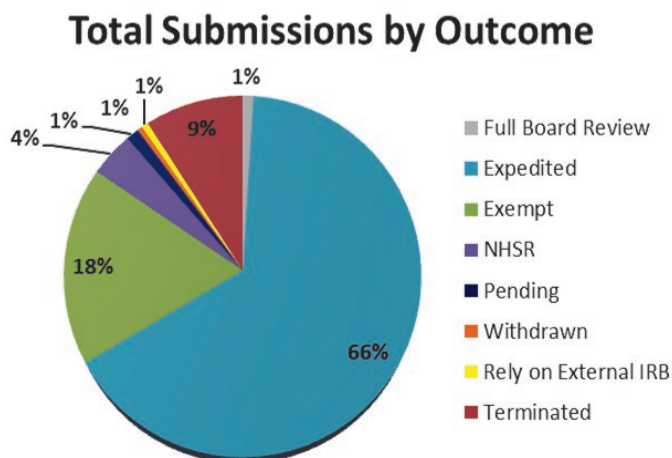
# IRB Annual Submissions Summary

We took a look at the past year's research protocol records

## Number of Protocols Submitted

In 2010-2011, there were 1298 IRB-related submissions to the ORC. This included 440 Initial submissions, 411 renewal submissions, 329 modification submissions, and 118 termination submissions. Comparatively, the ORC received 1251 submissions during the 2009-2010 year. And this academic year, there were approximately 1100 active protocols. The 2010-2011 protocol submissions were further broken down by the type of submission, which included Full Board Review, Expedited Review, Exempt Review, Withdrawal Request, Termination Request, Pending Submissions (Not Approved), situations where oversight will rely on external IRB, and protocols considered not human subjects research (NHSR).

Full Board:	13
Expedited:	852
Exempt:	231
NHSR:	53
Termination Request:	119
Withdrawal Request:	7
Pending Submissions:	15
Rely on External IRB:	8



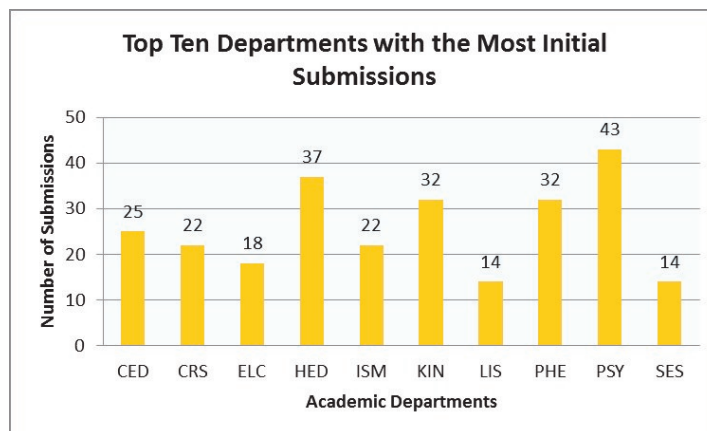
## Initial Submissions

### Initial Submission by Outcome

Category	Count	Percentage
Full Board Review	2	0.5%
Expedited	189	43.0%
Exempt	176	40.0%
NHSR	52	11.8%
Pending/ Not Approved	13	3.0%
Withdrawn	7	1.6%
Rely on External IRB	1	0.2%
<b>Total</b>	<b>440</b>	<b>100%</b>

## Initial Submissions by Department

IRB protocol submissions come from various departments on the UNCG campus. The total of 440 initial submissions were broken down by academic department to get a closer look at submission volume across the campus.

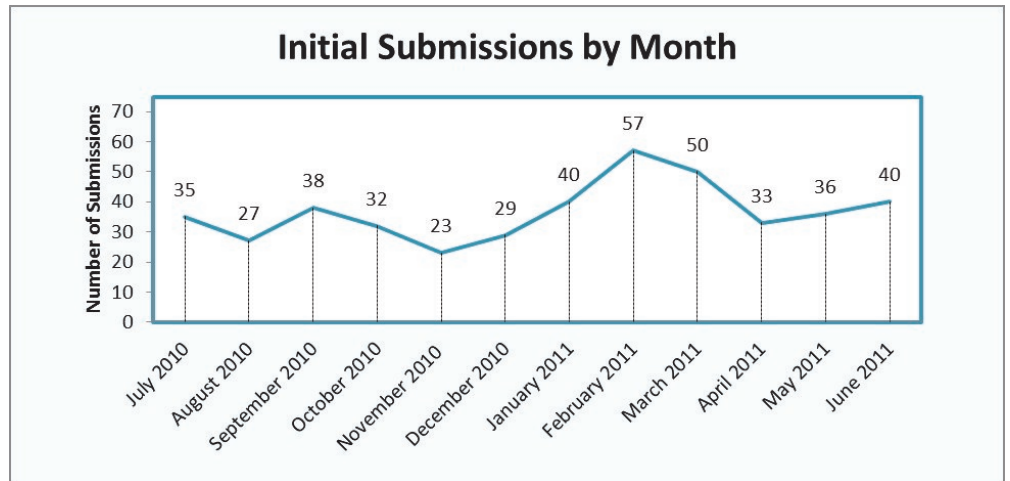


As seen in the figure above, the Psychology Department (PSY) submitted a total of 43 protocols in the past year. Not far behind was the Teacher Education and Higher Education Department (HED) with 37 protocols. The volume per department varies from year to year.

## Initial Submissions by Month

Looking at the submission volume throughout the year

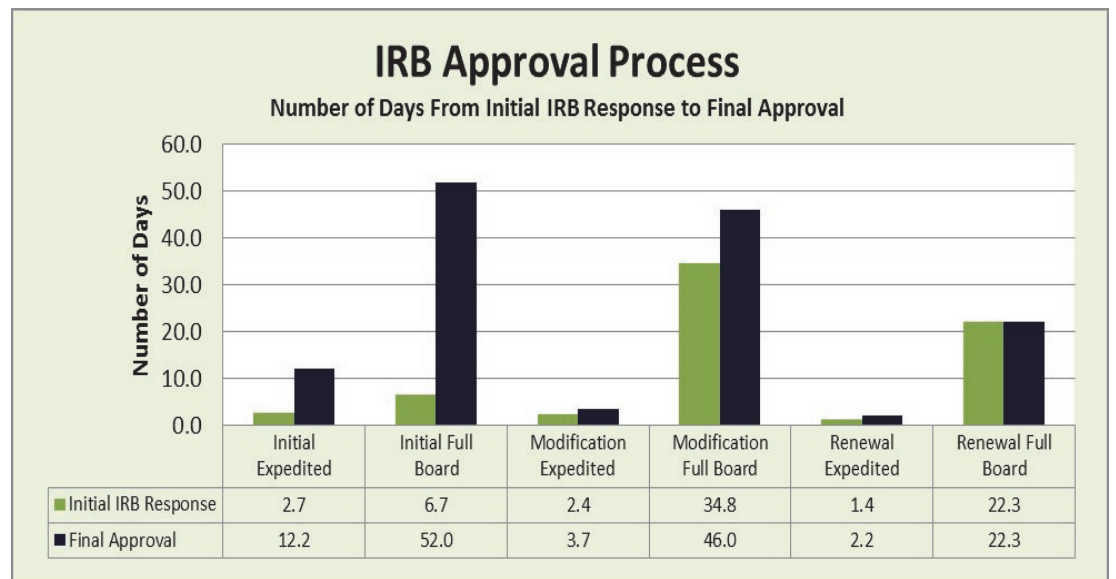
The number of initial submissions fluctuate throughout the year. However, it seems that a few weeks into a new semester is when submissions pick up. Between June 2010 and July 2011, the months with the most initial submissions were February and March, the 2011 Spring semester.



## Submission to Approval

We thought you would want to know the time frame for the approval process

There are several steps to the approval process. Once a submission arrives in our office, it must be examined for initial approval. Then, if there are questions or stipulations to the existing submission, there are correspondences with the Principal Investigator(s) so that the appropriate changes can be made. As seen in the figure below, the initial IRB response time to the final approval displays how the process of approval can be delayed for missing submission items, unclear procedures, and various other concerns. Only 13 submissions of 1298 were considered Full Board Reviews. The wait time for Full Board Reviews can be much shorter if the submission documents are complete and details are clearly stated with the IRB forms.



The full report is available on our website at <http://www.uncg.edu/orc/pdf/20102011IRBAnnualReport.pdf>.

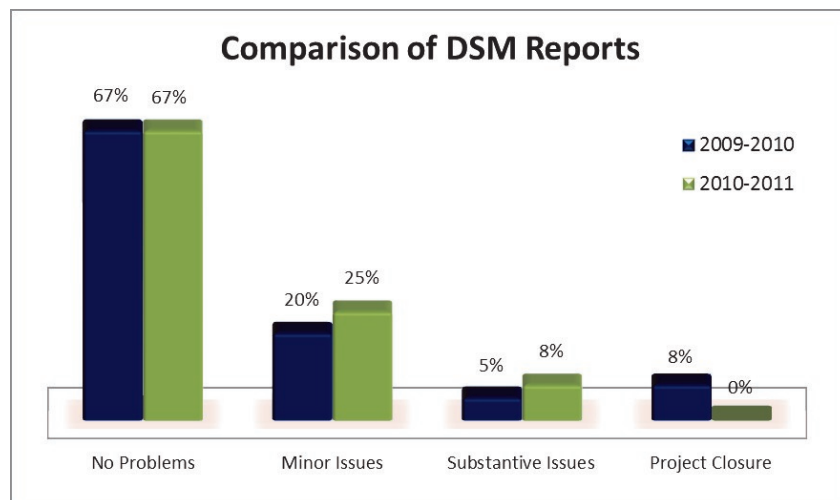
# Data Safety Monitoring

## Revisiting protocols with Principal Investigators to promote education

The UNCG IRB strives to continually improve the institutional quality of human subject protection on the UNCG campus. The annual Data Safety Monitoring (DSM) audits are part of that process. The DSM audits were conducted by the Assistant Director of the Office of Research Compliance. They began in November 2010 and continued until April 2011.

The ORC randomly selected 5% of protocols from all active, non-exempt (Expedited and Full Board) IRB protocols. The 5%, along with a few mandated DSM reviews, totaled 36 protocols for the 2010-2011 DSM audit. Prior to the audit, the investigators were provided with a pre-audit checklist to aid in their preparation. The reviewer used a DSM checklist that resulted in one or a combination of the following three outcomes: No Problems, Minor Issues, or Substantive Issues. There were no studies that resulted in closure this year. The chart below displays the findings from the 2010-2011 review, as well as the comparative data from the 2009-2010 DSM review.

DSM Status	2009-2010		2010-2011	
	Number	Percentage	Number	Percentage
No Problems	25	67%	24	67%
Minor Issues	7	20%	9	25%
Substantive Issues	2	5%	3	8%
Project Closure	3	8%	0	0%
	37	100%	36	100%



This was the fifth year that campus-wide DSM audits were conducted at the UNCG by the ORC. The ORC's intention is for DSM to be seen as a tool to educate both the IRB and the investigators, and to potentially improve the ethical conduct of research.

The full report is available on our website at <http://www.uncg.edu/orc/pdf/2011dsmreport.pdf>.

# ORC Informational Updates

Informational Notes from the ORC are periodically released to inform and educate UNCG faculty, staff, and students about issues related to human subjects research. The purpose of the information provided is to heighten the UNCG campus awareness of the various IRB practices, federal regulations, and other relevant topics that are circling the national arena.

## IRB Informational Note 1 November 2009

### Noncompliance among Social Behavioral Institutions

With research focuses continuing to diversify, IRBs work with researchers to find balance between research practice growth and regulations. It is a misconception that only biomedical institutions are in danger of violating regulations and receiving serious suspensions. In September 2007, Bluefield State College in West Virginia made national news when their institution was forced by the Office of Human Research Protections (OHRP) to terminate all funded research projects. Some of the issues identified by the OHRP included a lack of resources, failure to report to OHRP as required, use of inappropriate informed consent forms, lack of written IRB procedures, and lack of sufficient records to prove that substantive IRB reviews had occurred. It is important to note that universities both large and small must follow the federal guidelines set forth by the OHRP. For more details, visit <http://www.uncg.edu/orc/files/InformationalNote1.doc>.

## IRB Informational Note 2 December 2010

### Pilot Studies and IRB Approval

There are differing opinions on whether or not pilot studies should be approved by the IRB. The Common Rule makes no distinction between pilot studies and any other studies and does not refer to “preliminary” or “pilot” studies; therefore, research communities are left to their own devices on the level of review a pilot study should receive. Some universities do not require approval for pilot studies and others require all research to be approved. At UNCG, the IRB asks that if a pilot study is proposed, it should be clear to participants that it is indeed a pilot study. In addition, the UNCG IRB prefers that if a principal investigator has any intention of presenting or publishing the results as research data and/or use them as contributing to “generalizable knowledge,” then it should be submitted to the IRB for approval. This is the most advisable way to avoid risk or harm to subjects, which could seriously affect the research community and the University as a whole. For more details, visit <http://www.uncg.edu/orc/files/InformationalNote2.docx>.

## IRB Informational Note 3 August 2011

### Social Behavioral Research and Biospecimens

The National Research Council released a recent report regarding the increased amount of social behavioral research studies that are using biospecimens as part of the data collection, which may require Institutional Review Boards to take a closer look at how they review protocols containing this type activity.<sup>(1)</sup> One concern is informed consent, particularly the collection of biospecimens and the security of how they are stored. Biospecimens may not be considered “human subjects” according to two major documents that state federal guidelines, the Common Rule and the HIPAA Privacy Act. It appears that the definition of *human subject* may need to be clarified in order to properly determine the risks to subjects. In the meantime, IRBs need to focus on the qualifications of the researchers, informed consent documents, and procedures for use of biospecimens. For more details, visit <http://www.uncg.edu/orc/files/InformationalNote3.docx>.

1— National Research Council. (2010). *Conducting Biosocial Surveys: Collecting, Storing, Accessing and Protecting Biospecimens and Biodata*. Washington, DC: THE NATIONAL ACADEMIES PRESS

# ORC Educational Projects

## Repercussions of Research Errors

### Research Noncompliance among Universities: A Review of the Determination Letters Issued by the Office for Human Research Protections in the 2000s

Eric Allen, Traci Collins  
May 25, 2011

#### Abstract

Determination letters, responses to investigation into allegations of noncompliance with HHS regulations, are posted online by the Office for Human Research Protections (OHRP). The letters issued to universities (total=485) between June 2000 and December 2010 were examined for noncompliance infractions, required actions, and consequences to researchers and the university research compliance practices. The infractions were categorized based on a list of common noncompliance issues posted by OHRP and were revised to include a total of 56 specific infractions. The most commonly occurring infraction was Inadequate Informed Consent Document Lacking Basic Elements, which was cited in 50% of the letters. In roughly 11.9% of the determination letters, the researcher's studies were suspended until the issues of noncompliance were resolved. In approximately 7.6% of the letters, research was suspended across the university. The binary dependent variable was examined using a probit nonlinear regression model, and the estimates of the marginal effect of each infraction on the likelihood of research study suspension were obtained. For several infractions, the results indicate that research study suspension was significantly more likely with the presence of the particular infraction ( $p < .10$ ). If the combination of infractions and the OHRP investigation reveal foundational concerns about IRB competence and the general standards for protections of human subjects, then a university-wide suspension was more likely indicated than in sole research studies. It is important for the university compliance staff, the IRB, and the researchers to be aware of regulations in order to prevent suspensions and risk to human subjects.

Full text and a list of resources can be found at <http://www.uncg.edu/orc/pdf/DeterminationLettersReport2000s.pdf>.

*The ORC investigated university research noncompliance that occurred over the last 20 years*

#### Results

In the past decade, only **7.6%** of determination letters issued by the OHRP to universities included cases where research was stopped or suspended across the University due to research noncompliance.

The most commonly occurring noncompliance infraction found within the determination letters issued from 1990 to 2010 was

**Inadequate Informed Consent Document Lacking Basic Elements**

which was listed in 50% of the determination letters.

## Research Noncompliance: A Review of Determination Letters Issued in the 1990s and the 2000s

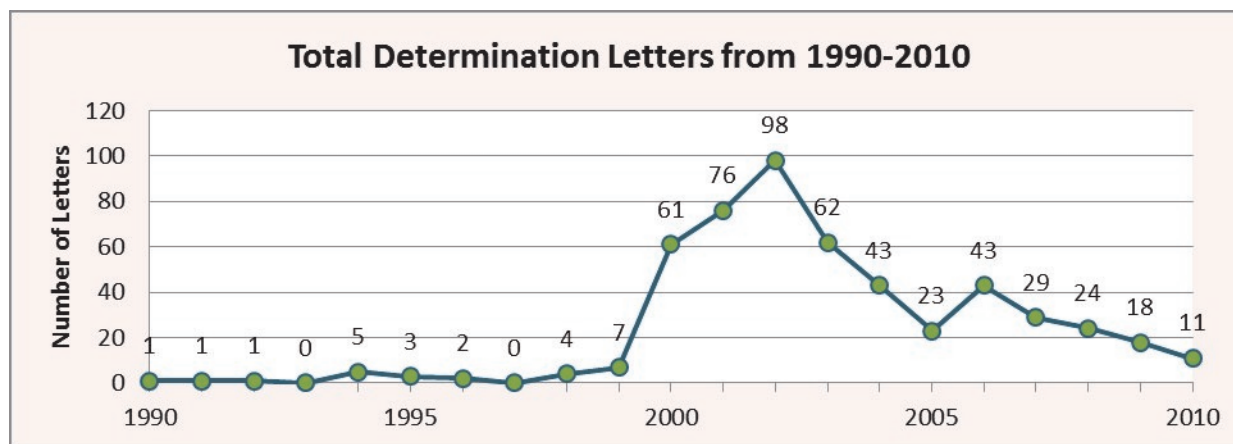
Eric Allen, Traci Collins

August 1, 2011

### Abstract

The Office for Human Research Protections (OHRP) issues determination letters in response to allegations of research noncompliance with the federal regulations. The ORC examined a total of 27 determination letters issued between January 1990 and June 2000. The letters were reviewed and information was collected concerning noncompliance infractions, required actions, and the consequences to researchers and the university research compliance practices. The infractions were categorized based on a list of common noncompliance issues posted by OHRP and were revised to include a total of 56 specific infractions. The most commonly occurring infraction was Inadequate Informed Consent Document Lacking Basic Elements, which was cited in 44% of the letters. Twenty-three letters resulted in suspension of the assurance and therefore research activity. The determination letters from the 1990s were compared with the determination letters from the 2000s. There was significantly more determination letters issued in the 2000s (485 letters). It is noted that the large majority of the determination letters from the 2000s did not result in suspension, compared to 85% of determination letters from the 1990s. The analysis revealed how the noncompliance issues remained similar across the decades; however, the volume of determination letters and the percentage of suspensions varied significantly.

Full text and a list of resources can be found at <http://www.uncg.edu/orc/pdf/DeterminationLettersReport1990s.pdf>.



## Office for Human Research Protections OHRP

*“The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.”*

For more information, please visit <http://www.hhs.gov/ohrp/>.

# Customer Service

We surveyed the UNCG campus for thoughts and suggestions

The ORC focuses on being available and receptive to the UNCG community. As the federal regulations continue to change, it is our intention to continually improve our processes as well. To aid in this process, a survey was sent to UNCG ORC customers. The 2010-2011 annual customer service survey yielded 198 responses.



Graduate Students:	44%
Faculty:	43%
Staff:	10%
Undergraduate Students:	3%
Administrators:	3%
Others:	3%

Number of Protocol Submissions	Percentage of Respondents
1	33%
2-3	33%
4-5	15%
6-9	9%
10+	10%

## Results:

### Clarity and Accessibility of Forms/Documents

The overwhelming majority of respondents indicated that the IRB documents were easily accessible (91% strongly agreed; mean=4.13, sd=.73) Similarly, the majority of respondents indicated that the guidance documents were clearly written and forms were user friendly. Suggestions for improvement seemed to center around format and clarity of the forms. The ORC has revamped the forms, addressing these specific issues until online submissions become available. Also, the ORC has revamped the FAQs and provided contact information for IRB members by expertise to assist researchers further.

### Satisfaction with the IRB Process

Again, the overwhelming majority of respondents indicated their satisfaction with the IRB process, and only 13% indicated any dissatisfaction. The comments for improvement ranged from total time of review, investigator ability to check protocol status, protocol review consistency, clarity in requirements, and options for communicating with the investigators. The IRB process continues to run more efficiently each year. This will dramatically decrease with the inclusion of online submission, which will also change investigator's ability to check the protocol status. At this time, it is important to note that the IRB approval process can be greatly slowed down by protocol complexity and protocol incompleteness. In conclusion, the ORC will continue to keep the suggestions in mind and make adjustments where possible. As always, we suggest that researchers contact our office at any time for assistance with completing forms or to check the status of protocols. **The full report is available on our website at <http://www.uncg.edu/orc/pdf/2011AnnualSurveyResponse.pdf>.**



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