

Office of Research Compliance

Institutional Review Board Annual Report 2010–2011

August 2011



*Looking over the past
year of research at
UNCG*

this issue

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THE UNIVERSITY of NORTH CAROLINA
GREENSBORO
Office of Research Compliance

Introduction

The Office of Research Compliance (ORC) conducts an Annual Review of the Institutional Review Board (IRB) submission activity at the end of each academic year. The following report includes information about IRB Meetings and Membership, Data Safety Monitoring, Serious Adverse Events, Unanticipated Problems, and Noncompliance Incidents, and an analysis of IRB Submissions for June 2010- July 2011 year.

Institutional Review Board Overview

The IRB scheduled meetings from 3:00pm to 5:00pm on the 2nd and 4th Wednesdays of each month. On dates that no Full IRB reviews or other business were pending, meetings were cancelled. Special meetings were held to conduct Full reviews as necessary. The specific dates of the IRB meetings for the 2010--2011 academic year can be seen in the chart below. During the past year, the IRB members represented a variety of departments of the UNCG campus. More details about the members of the IRB can be seen below:

IRB Meeting Dates (2010-2011)
July 28, 2010
August 11, 2010**
August 25, 2010
September 8, 2010**
September 22, 2010
October 13, 2010**
October 27, 2010
November 10, 2010**
December 15, 2010
January 12, 2011**
January 26, 2011**
February 9, 2011**
February 23, 2011
March 16, 2011**
March 30, 2011
April 13, 2011**
April 27, 2011**
May 11, 2011
May 25, 2011
** There were no submissions for review at that time, so the meeting was canceled

IRB Membership (2010-2011)			
Represents	Name	Term	Category
SWK	Dr. Cathryne Schmitz	June 30, 2012	Non-Scientist
APL	Mr. Joel Dunn	June 30, 2013	Non-Scientist
BUS	Dr. Eric Ford	June 30, 2013	Non-Scientist
LIS	Dr. Julia Hersberger	June 30, 2013	Non-Scientist
CRS	Dr. Byoungho Jin	June 30, 2012	Non-Scientist
NUR	Dr. Heidi Krowchuk	June 30, 2011	Scientist
MUS	Dr. Sandra Mace	June 30, 2011	Non-Scientist
PHE	Dr. Joseph Telfair	June 30, 2012	Scientist
KIN	Dr. Laurie Wideman Gold	June 30, 2013	Scientist
SRV	Melissa Williams	June 30, 2013	Non-Scientist
ORC	Ms. Cristy McGoff	June 30, 2013	Non-Scientist
External	Mr. Robert Hamilton	June 30, 2013	Non-Scientist
SRV	Dr. Pam Finney	June 30, 2013	Alternate (Non-Scientist)
ELC	Dr. Carl Lashley	June 30, 2011	Alternate (Non-Scientist)
NUT	Dr. Cheryl Lovelady	June 30, 2012	Alternate (Scientist)
PSY	Dr. Julia Mendez	June 30, 2012	Alternate (Scientist)
External	Dr. Mary Parker	June 30, 2012	Alternate (Scientist)

IRB Applications and Submissions

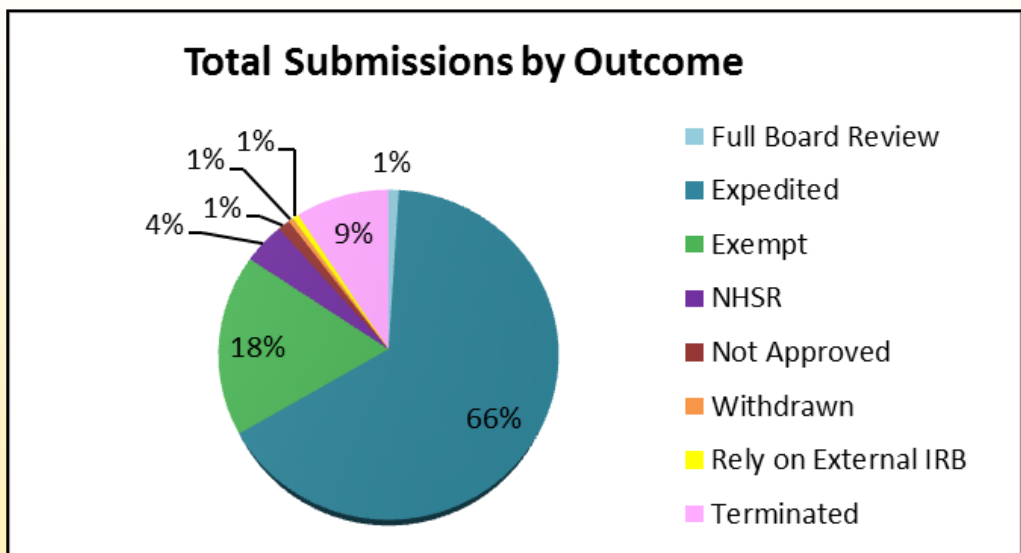
Between June 2010- and July 2011, the IRB conducted reviews of 1298 submissions, which was an increase of about 50 protocols from the previous year. The 1298 total submissions included: 440 initial submissions, 411 renewal submissions, 329 modification submissions, and 118 termination submissions.

As seen below in Figure 1 and Figure 2, the large majority of all submissions fell under the expedited and exempt review categories. Full Board Reviews were held for 13 submissions, which was nearly half of the previous year. The Full Board Reviews were broken down as follows: 2 initial submissions, 7 renewal submissions, and 4 modification submissions. Next, a little over 9% of all submissions to the ORC office were regarding the termination of a protocol. Roughly 4.1% of the submissions were considered Not Human Subject Research (NHSR). The remaining submissions included: withdrawn submissions (7), Rely on External IRB submissions (8), and Not Approved/ Pending submissions (15).

Figure 1:

Total Submissions by Outcome		
Category	Count	Percentage
Full Board Review	13	1.0%
Expedited	852	65.6%
Exempt	231	17.8%
NHSR	53	4.1%
Not Approved/ Pending	15	1.2%
Withdrawn	7	0.5%
Rely on External IRB	8	0.6%
Terminated	119	9.2%
Total	1298	100%

Figure 2:



Initial Submissions

There were 440 initial applications submitted to the ORC during the 2010-2011 year. As seen in Figure 3, only 2 initial submissions required Full Board review. More than 80% of all initial submissions were considered expedited review or exempt review. Next, 11.8% of all initial submissions were categorized at Not Human Subject Research (NHSR). The remaining percentage of all initial submissions were categorized as not approved/pending, withdrawn, and rely on external IRB.

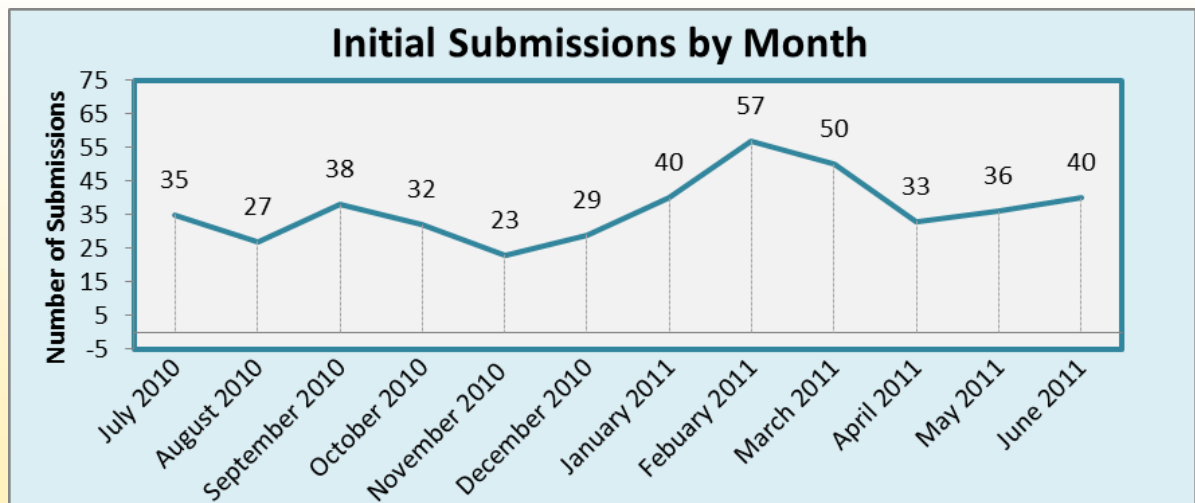
Figure 3:

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%
Not Approved/Pending	13	3.0%
Withdrawn	7	1.6%
Rely on External IRB	1	0.2%
Total	440	100.0%

Initial Submissions by Month

Between June 2010 and July 2011, the months with the most initial submissions were February and March, the 2011 Spring semester.

Figure 4:



Initial Submissions by UNCG Department

The 440 initial submissions were broken down by the affiliated department of the Principal Investigator. There are many departments across the campus that submits initial applications each year. As you can see in Figure 5, each initial submission for the 2010-2011 year is broken down by the department and type of submission.

Figure 5:

Initial Submissions by Department and Outcome (2010-2011)								
Dept.	NHSR	Exempt	Expedited	Full	Withdrawn	Not Approved/ Pending	Rely on External IRB	Total
ACF		1						1
ADN	1	2	3					6
ART	1							1
ATY		2	1			1		4
BAE	1							1
BUS		5				1		6
CDR		1	1					2
CED	2	12	11					25
CMP		1						1
CON		1	6		1			8
CRS		11	10			1		22
CSD		4	7		1			12
CSR	6	2						8
CST		3	7					10
DCE		3						3
ECO		1	1					2
ELC	1	1		15		1		18
ENG		1						1
ERM	1	4						5
FAC	1							1
GAR			1					1
GEN	1	4	2					7
GEO		3	1		1			5
GRO	1							1
HDF	2	1	5					8
HED	2	13	18		1	3		37
HIS	2							2
IAR	2	1			1			4
IHS		1			1			2
ISM	6	14	1			1		22
KIN	3	6	22	1				32
LIB	4	1						5
LIS	4	8	1			1		14
LRC		1						1
MRI	1		1					2
MST			1					1
MUE		3				1		4
MUS	5	5	1					11

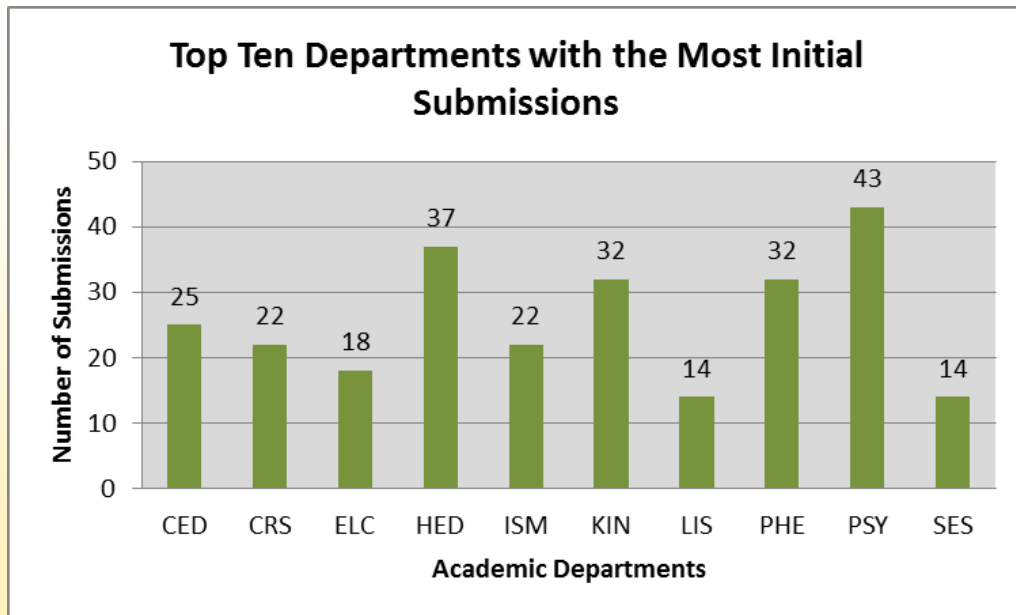
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Chart Continued

	NHSR	Exempt	Expedited	Full	Withdrawn	Not Approved/	Rely on External IRB	Total
NTR		1	7					8
NUR		1						1
OUR	1							1
PCN		1					1	2
PHE		19	13					32
PSC		1						1
PSY		15	27	1				43
REL			2					2
ROM			1					1
RLI		1						1
RTH		2	5					7
SAF		4	1			1		6
SES		4	9		1			14
SHP			1					1
SOC	1	3	3			1		8
SRV	2	8	1					11
SWK			3			1		4
UES	1							1
Totals	52	176	189	2	7	13	1	440

The Psychology department (PSY) submitted the most protocols within this time period with 43 applications. Teacher Education and Higher Education (HED), Kinesiology (KIN) and Public Health Education (PHE) were closely behind at 37 and 32, respectively. The chart below (Figure 6) highlights the top ten departments with the most *initial* submissions.

Figure 6:

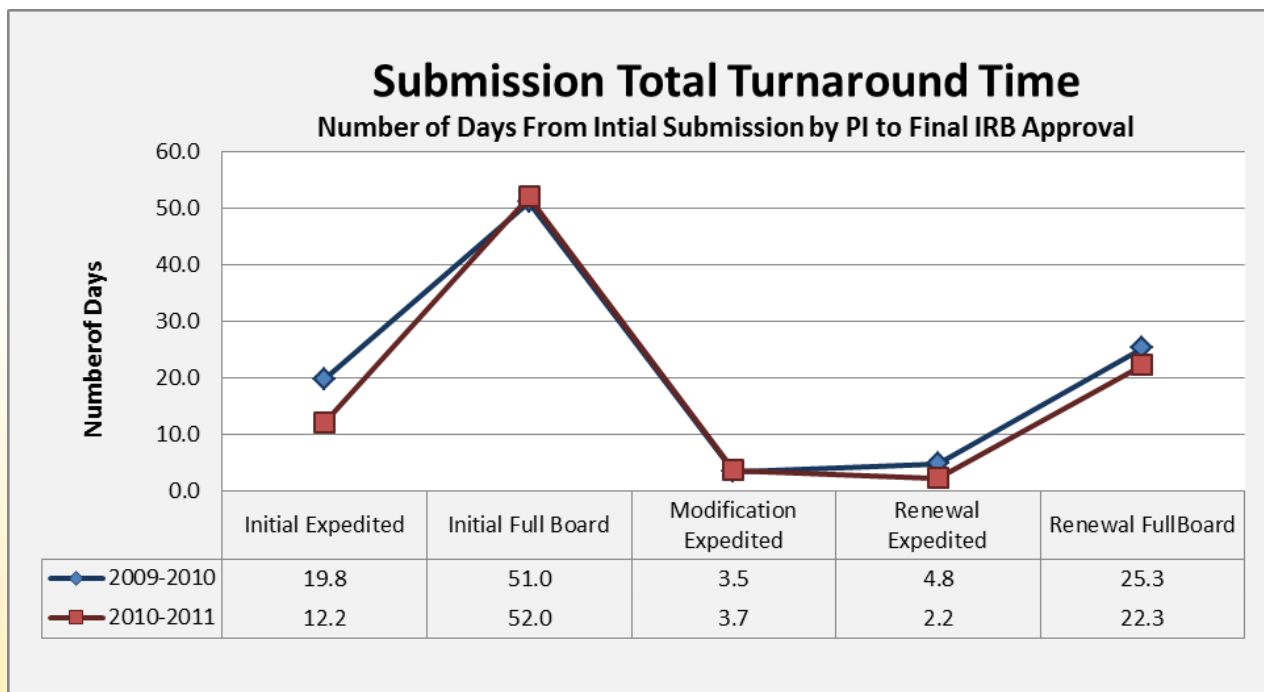


Total Submissions by Approval Time

The total of 1298 submissions was evaluated based on the time between various steps in the IRB approval process. First, it is important to examine the number of days from the initial submission by the PI until the final approval letter is sent to the PI. As seen in Figure 7, this time length is called the Submission Total Turnaround Time. The total turnaround times from the 2010-2011 and the 2009-2010 years were compared. The turnaround time comparison displayed that during the past year, the ORC was able to trim down the process even further in several areas. The most common factors that go into the time it takes to approve a study are the time of year the protocol is submitted, whether it is determined a study needs to go to the full board, whether the submission is returned to the researcher for revisions, and how quickly those revisions are sent back.

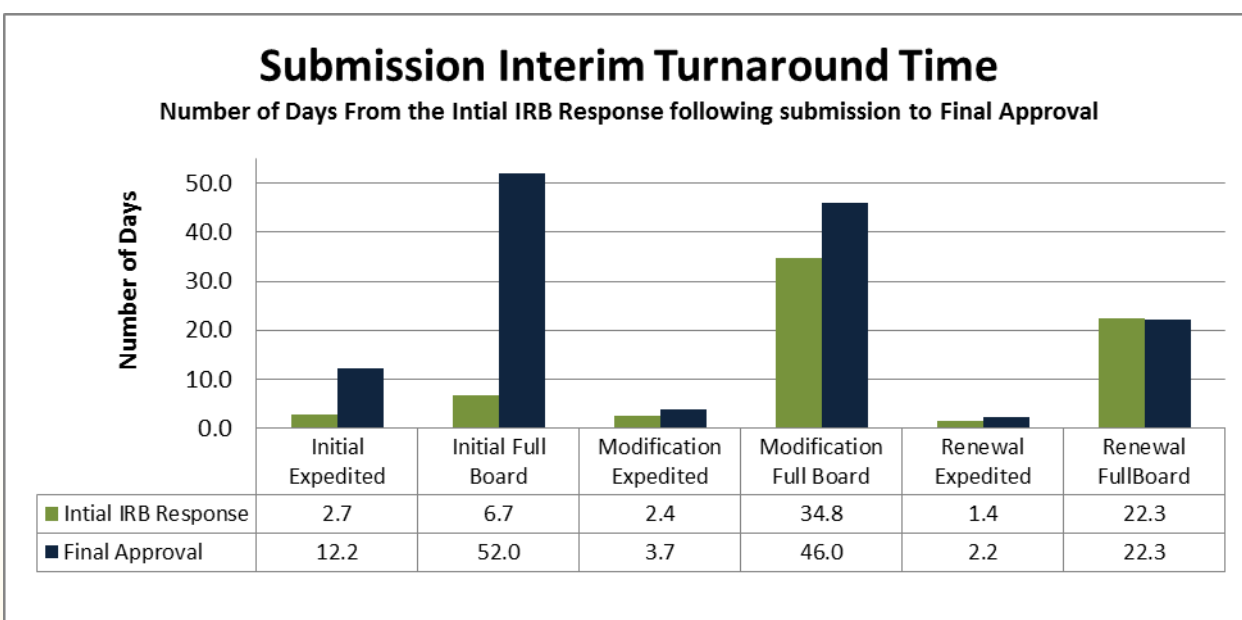
The average turnaround time for all expedited submissions was 6 days, and expedited renewals and modifications took an average of two to four days. There were only a total of 13 Full Board Submissions over the past year, which brings the average turnaround time for a Full Board submission to 37 days.

Figure 7:



The submission turnaround time was broken down even further. Once the IRB receives and processes a submission, the IRB issues an initial response, which may be an approval or a need for more clarification. In the IRB turnaround time, it is important to consider the time it takes between the initial IRB responses to the final IRB approval. This time includes IRB correspondence and time in which the PI is making changes to the submissions. As seen in Figure 8, this interim time is the greatest for Full Board Reviews. The factors that may delay a more than minimal risk (i.e. Full Board) protocol in its approval process may relate to whether a meeting will have a quorum, which is based on the availability of the faculty and the degree to which the study needs to be evaluated. The Interim time for Expedited and Full Board renewals is an average of less than 1 day due to the fact that there is often little need for IRB and PI correspondence.

Figure 8:



Serious Adverse Events, Unanticipated Problems, and Noncompliance Incidents

There were no Serious Adverse Events, but five Unanticipated Problems/Adverse Events were reported to the IRB for 2010-2011 and were handled through the ORC. Four of these were unanticipated problems, and one was a nonserious adverse event. Each was reported to the IRB/ORC and resolved by the research team.

There was one incident of serious noncompliance. This involved a student researcher using a participant's information to contact them for a study outside of the one approved originally by the UNCG IRB which had been expired at the time. This issue was reported to the OHRP, and handled through the ORC and IRB. The incident of nonserious noncompliance was related to a study using a recruitment method that was not approved by the IRB. This incident was reported to the IRB and handled through the ORC by amending the IRB protocol.

Data Safety Monitoring

Thirty-six research studies were reviewed by the Office of Research Compliance this past year during the continued campus-wide Data Safety Monitoring (DSM) visits again this year. A small selection included investigators currently mandated to DSM audits. The sample included funded, unfunded, faculty, and student research projects. Audits resulted in one or a combination of the following four outcomes: no problems, closure of research project, minor issues, or substantive issues

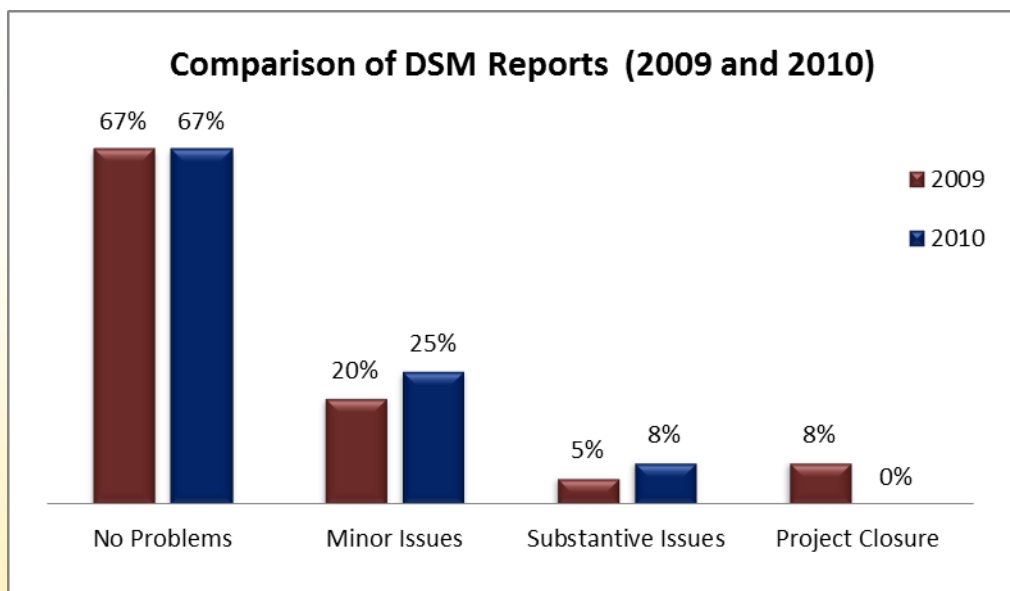
Figure 9:

No Problems	Closure of research project	Minor issues	Substantive issues
67%	0%	25%	8%

The majority, 24 (67%), of the audits went very smoothly and concluded with no problems. There were no closures. Minor issues were found in 25% of the audited studies. The minor issues included: student researchers not having an updated training certificate, inconsistency in the application's statement of where data and consent forms were to be stored and where consent forms were actually stored, and the use of unstamped consent forms. Individuals with these infractions were provided with educational information on the importance of adhering to IRB regulations and policies; appropriate corrective action/sanctions were also applied.

Substantive issues were found in 8% of the audits this year, which is up just slightly from last year's audit. None of the infractions jeopardized human participants with increased risks or decrease in benefits, however the infractions could have led to serious problems such as noncompliance. One project was found to be expired shortly after the DSM meeting was scheduled. This PI's role on the study turned out to be very minor (data analysis of deidentified data and study design consultation), in collaboration with another institution and therefore the issue was rectified with a termination of the old file, and opening a new study under an Exempt review. The other substantive issue was a PI recruiting new subjects without submitting a modification on a study that had stopped enrolling. The third issue was a matter of continued noncompliance involving a researcher who had been monitored before. The PIs on the projects received formal notices of these infractions along with appropriate corrective actions, educational information on the importance of adhering to IRB regulation and policies, and a timeline to correct infractions whenever possible. These issues were all corrected.

Figure 10:



The full DSM report is available through the ORC website: <http://www.uncg.edu/orc/>

Plans for 2011-2012

The ORC goes green!

We have significantly reduced the pages of our applications and formatted them so that it will take less time *and* energy.

Mock IRB's for Classes

A member of the IRB and the 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.

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 form can be found at: 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 their data the investigator must honor this request. Both UNCG IRB's will require a notification to participants in both the informed consent form and consent process. To read 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 to become familiar with it. <http://www.uncg.edu/orc/>

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 to the Modification and Renewal forms. All updated documents are available on the IRB webpage, at: <http://www.uncg.edu/orc/irb.html>

Updated FAQ's

New questions have been added to the IRB FAQ's and new HIPAA FAQ's have been added. These can be accessed on the IRB page, at: <http://www.uncg.edu/orc/irb.html>