

OFFICE OF RESEARCH COMPLIANCE



2010-2011 DATA SAFETY MONITORING REPORT

April 15, 2011

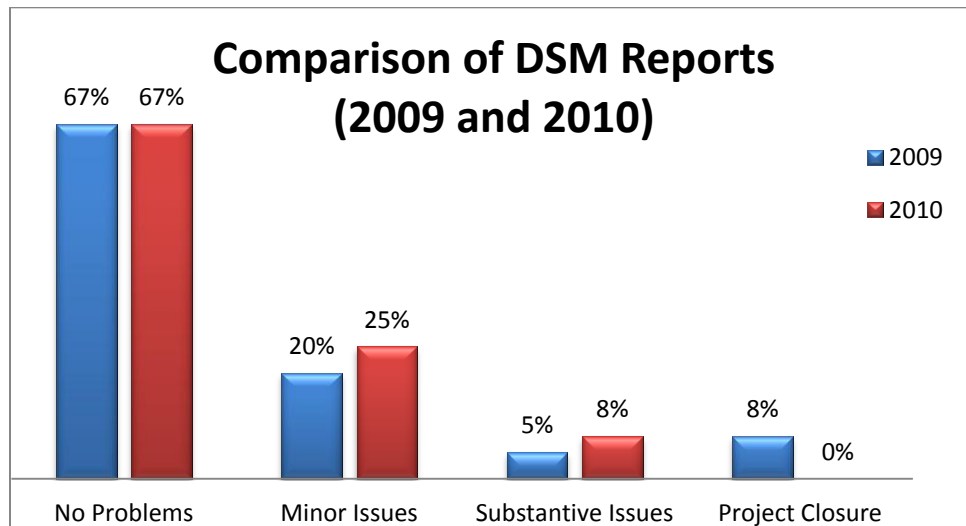
November 2010 marked the beginning of audits for UNCG Data Safety Monitoring (DSM) for 2010-2011 to coincide with the Institutional Review Board DSM policy. The audits were carried out by the Assistant Director of the Office of Research Compliance and were completed on April 26, 2011.

The Office of Research Compliance randomly selected 5% of active, non-exempt (Expedited and Full board) Institutional Review Board (IRB) protocols. This year 36 research studies were reviewed. A small selection included investigators currently mandated to DSM audits. The sample included funded, unfunded, faculty, and student research projects. Prior to the audits, each Principal Investigator (PI) was provided a pre-audit checklist to aid in their preparation. Each audit was scheduled at the PI's convenience and the Assistant Director followed the DSM checklist for human participants in research.

Audits resulted in one or a combination of the following three outcomes: No problems, minor issues, or substantive issues. There were no closures this year.

The below charts show the comparison between the 2009 DSM audits and this year.

DSM Status	2009		2010	
	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%



Based on the information from the chart above, the majority, 24 (67%), of the audits went very smoothly and concluded with no problems. This is the same result from the prior year. This appears to indicate that the ORC's efforts at providing a supportive and informative environment for researchers at UNCG as well as keeping everyone aware of the needs of their research and how it affects the individually.

Minor issues were noted in 9 (25)% of the audited files. 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 3 (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. The three issues were unique to each other. 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 second issue was a bit more complicated. The PI had renewed the active study as begin in data analysis only, but had re-enrolled subjects, who were minors, halfway into the renewal without letting the IRB know of the plan to re-enroll. The PI did not get an updated, approved stamped consent form to use with these subjects. The PI was made aware of this error, and the study has now been updated and modified to reflect the study's status, which has returned to the enrollment of new subjects. 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.

The third issue was one that is considered "minor", the use of an unstamped consent form; however this PI has already been placed in mandatory DSM audits due to the fact that this had been a continuing error. If this continues, the PI will go into the category of "continuing noncompliance". This PI was given an additional year of mandatory DSM auditing. If the situation is found in the future, this will be evaluated as noncompliance.

This was the fifth year campus wide DSM audits were conducted at the University of North Carolina at Greensboro by the Office of Research Compliance. 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. A formal recommendation based upon this year's audit is noted below.

Respectfully Submitted,

Cristy McGoff
Assistant Director

Office of Research Compliance
Recommendation to IRB

The following report outlines the Data Safety Monitoring findings reported in the above report and corresponding tables with suggestions for corrective actions further reduce the possibility of negative findings.

Closure of Research Projects

There were no closures occurring in this year's DSM audits, indicating that there is an improved understanding as to the process and importance of terminating a protocol as compared with the last DSM audit. To further improve the termination process, the ORC will be offering a new Closure form, separate from the Renewal application, which will make it easier to close a study at the appropriate time and explain the nature of the closure.

Minor Issues

Three years ago, the IRB's decision to require investigators to only use the IRB approved and stamped informed consent form with the valid to and from date stamp seems to be working well among the majority of the protocols. Last year, the IRB also implemented the scanning of the final consent forms to the PI upon their approval. This has helped to eliminate the use of any unapproved versions of the consent form being used in the course of study, and most of the studies cited for this minor issue in the DSM audits this year were older studies where this hadn't occurred. The ORC needs to continue to educate investigators as to the importance of this practice. Hopefully, by the next round of DSM audits, this should decrease significantly.

Those PI's who were lacking human subject training certificates for certain research team members submitted these immediately after their audits. The ORC continues to keep track of the existence and validity of human subjects certificates on a research team. Regarding the inconsistency of where the items will be stored between the consent form and application, the ORC can only track these errors during a DSM audit, so this highlights the value of the audits.

Substantive Issues

The major infractions seemed to have resulted in a lack of communication regarding updates in the files for the two protocols reviewed. There needs to be a commitment on the part of the PI to make the ORC aware of any changes that may alter the study significantly so any matters of noncompliance are avoided. The ORC should also increase communication about this need to the PI's in the regulations and on the applications as well as in any public speaking events. This may help decrease these types of events and help the ORC and research staff functions more efficiently, avoiding problems and making sure that any increase in risk to participants does not occur.