**Office of Research Integrity**



**2014-2015**

 **Data Safety Monitoring Report**

**March 6, 2015**

October 2014 marked the beginning of audits for the UNCG Data Safety Monitoring (DSM) for 2014-2015 in compliance with the Institutional Review Board DSM policy. The audits were carried out by the Assistant Director of the Office of Research Integrity and were completed on January 6, 2015. A majority of the audits were completed by December 2014 with only one audit being conducted in January 2015.

The Office of Research Integrity randomly selected 5% of all active, expedited and full Board protocols. This year, 21 research studies were reviewed. The sample included funded, unfunded, faculty, and student research protocols. 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 significant issues. As in previous years, some of the studies initially selected had to be replaced for a variety of reasons including: the study being closed to enrollment, the study closing, or the student/PI no longer being at the institution. Each of these studies was replaced by another randomly selected study.

The charts below show the comparison between the 2013-2014 audits and:

|  |  |  |
| --- | --- | --- |
|  | **2013-2014** | **2014-2015** |
| **DSM Status** | **Number** | **Percentage** | **Number** | **Percentage** |
| No Problems | 4 | **20%** | 3 | **14%** |
| Minor Issues | 15 | **75%** | 18 | **86%** |
| Substantive Issues | 0 | **0%** | 0 | **0%** |
| Significant Deficiencies | 1 | **5%** | 0 | **0%** |
|  | 20 | **100%** |  | **100%** |

Based on the above information, a large majority of the 21 audits (86%) had minor issues, which was an increase over last year. Three of the audits went well with no issues, and there were no studies with substantive or significant issues.

Minor issues were found in eighteen (86%) of the protocols reviewed, including such issues as:

* Data not being stored per IRB protocol
* Changed data transfer plan without submitting a modification to the IRB
* Consent forms were not being stored per protocol, participants signed a consent form without and IRB stamp,
* A consent form being signed during study expiration.

In all instances of minor issues, the researchers were educated by the IRB reviewer as to how to prevent these issues in the future. A few educational examples are as follows:

 The investigators that did not have participants sign an IRB stamped consent were educated by the reviewer that a stamped consent from the IRB must be used with all participants.

For those investigators that did not have their data stored in the appropriate location were asked to submit modifications to revise their applications to be consistent with where they were storing their data.. All data in these cases were being stored securely; however, they were not being stored per the IRB protocol submitted.

The researcher who had the participant that signed the consent form during the study expiration was asked by the reviewer to either have the participant re-sign the consent form or to destroy the study data. The reviewer also reviewed that no participants are to be enrolled or data collected during a study expiration. The PI chose to destroy the participant’s data as the participant is no longer at UNCG.

The researcher who changed their data transfer plan without submitting a modification to the IRB submitted a modification immediately following the DSM meeting. The reviewer discussed the importance of submitting a modification for change in data storage/transfer prior to implementing the new plan.

There were no substantive or significant issues noted at any of the audits.

This was the ninth campus-wide DSM audit conducted at the University of North Carolina at Greensboro by the Office of Research Integrity. The ORI’s intention is for the DSM to be seen as a tool to educate both the IRB and the investigators and ensure that the research on this campus adheres to federal regulations and is ethically conducted. A formal recommendation based upon this year’s audit is noted below.

Respectfully submitted,

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**Recommendations to the IRB**

The following report outlines the Data Safety Monitoring findings reported in the above report and with suggestions for corrective actions to further reduce the possibility of negative findings. The new online system has a thorough application process and has been very beneficial to both the ORI and the UNCG researchers.

***Minor Issues***

Several of the minor issues in this year’s audit were issues that have been noted in previous audits.

As noted last year, the ORI has increased the effort to make researchers aware of the requirement that participants sign an IRB stamped consent form by adding a statement to all outgoing emails that include recently approved consent forms that researchers must use an IRB stamped consent form when enrolling participants. The ORI continues to send out this statement with all emails containing new/revised consent documents in order to educate and remind the researchers of the importance of using a stamped consent form.

Some of the other minor issues included study team members not being added to or removed from the study via a modification. Each researcher was informed that this needed to be done at least once a semester, if not more often, to ensure that the application stays up to date.

One of the minor issues was regarding a participant who signed the consent form during a time when the study had expired. The expiration reminder email sent by the IRBIS system contains a statement that states that no research is to be conducted, data collected, or participants enrolled after as study has expired and until a renewal has been reviewed and approved.

There seems to be a continued need for clarity as to who on the research team should sign statements of confidentiality. Further communication in the form of an informational email or a decision tree would be beneficial in helping to clarify.

The ORI also continues to make an effort to educate researchers and stress the importance of keeping statements of confidentiality on file for all study personnel. As mentioned in previous years, standard language to remind PI’s of this has been added to the online system to place in approval letters when appropriate.

The reviewer discussed the data storage issues with the individual principal investigators. The IRB applications and IRB reviewers continue to capture where data are being store and ensure that data are stored securely.

The reviewer also discussed with the researchers whose participants signed the incorrect version of the consent form, the importance of the participants signing the most recently approved version. The IRB continues to add the statement to modification emails containing the most recently approved version of the consent by stating “this is now the most recently approved version and must be used with all participants”.

***Future and Ongoing Efforts:***

The Office of Research Integrity continues to find creative ways to educate the UNCG campus.

The Office of Research Integrity also continues to increase the educational efforts in regard to Responsible Conduct of Research (RCR). This training is reflective of all areas of the responsible conduct of research training required by some NIH and NSF grants. RCR covers many research areas including: conflict of interest, data management and ownership, and research misconduct. The RCR training covers many of the same topics that are reviewed during the DSM audits. Although research misconduct and non-compliance are not prevalent on the UNCG campus, the RCR training is a proactive measure that the ORI office is taking to prevent these issues.

Through the “Slippery Slope Seminar” series, which the ORI office conducted from the spring 2014 semester to the spring 2015 semester, attendees were educated on a particular RCR topic at each session. To date, the ORI has had four sessions on the following topics: Research Misconduct, Authorship, Conflict of Interest and Intellectual Property. A fifth session was scheduled for the fall 2014 semester; however, the session had to be cancelled due to low enrollment. The low enrollment was thought to be due to the time of year the session was scheduled as it was scheduled only a week before Thanksgiving break and a few weeks before the end of the semester.

In March, the Director of the ORI, the IRB Chair and myself met to further discuss RCR training. We decided on conducting one session each semester which will last approximately 3-4 hours. The session will involve all RCR topics and will include a variety of speakers. Planning for this session is currently ongoing.

The ORI office has also been pulling grant submissions monthly and have been sending informational emails to all PI’s whose studies may qualify for RCR training.