**Office of Research Integrity**

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**2012-2013**

**Data Safety Monitoring Report**

**March 13, 2013**

November 2012 marked the beginning of audits for the UNCG Data Safety Monitoring (DSM) for 2012-2013 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 February 6, 2013.

The Office of Research Integrity randomly selected 5% of all active, non-exempt (Expedited and Full Board) protocols. This year 28 research studies were reviewed. 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. Three of the studies initially selected were closed by the investigators prior to scheduling the audit, and these studies were replaced by three other randomly selected studies.

The charts below show the comparison between the 2011-2012 DSM audits and this year:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2011-2012** | | **2012-2013** | |
| **DSM Status** | **Number** | **Percentage** | **Number** | **Percentage** |
| No Problems | 26 | **86%** | 19 | **68%** |
| Minor Issues | 2 | **7%** | 7 | **25%** |
| Substantive Issues | 2 | **7%** | 5 | **18%** |
|  | 30 | **100%** | 28 | **100%** |

Based on the above information, a large majority of the 28 audits (68%) went well and had no problems; however the amount of protocols with issues has increased slightly this year.

Minor issues were found in seven (25%) of the protocols reviewed. This was an increase from last year. Minor issues included: research participants not signing an IRB stamped consent form, data not being stored in the location indicated in the initial application, and one instance where Spanish consent forms signed by Spanish-speaking participants did not have the official IRB approval stamp, and a statement of confidentiality not signed. .

The investigators that did not have participants sign an IRB stamped consent agreed that, in the future, they would use stamped consent forms. In one case, it was confirmed that the ORI office had inadvertently not sent a stamped consent form back to the PI to use. In that case, the PI was informed in the letter that if they did not receive a stamped consent form back from the ORI office, they were to contact the office immediately to obtain a stamped consent.

The investigators that did not have their data stored in the appropriate location were educated on the importance of keeping data secure and in a location consistent with the original proposal. The first investigator confirmed in a memo that she had moved her data to a locked filing cabinet and the second investigator was moving her data to a locked filing cabinet while the reviewer was present.

In the case involving the unapproved IRB stamp, the PI conducted a thorough review and discussed the situation with both her data collectors and the translator. Per an email from the PI on 1/22/13, the best explanation is that the translator translated the stamp upon preparation of the form and a school employee gave the parent a printed version of the consent form off a computer file, and not a photocopy of the stamped version. In the case where the statement of confidentiality was not signed, the PI has since had this doctoral student sign a statement of confidentiality, albeit retrospectively.

Unfortunately, a select few of the PI’s / Student Researchers were not prepared for the audit. Two required a second appointment when some of the files were not available, three student PI’s had to send digital photos of the location of their files since they were kept in secured locations off campus, and one student PI was not present at her appointment as she no longer lives in the state. This same student researcher took her data with her and had to email all of the de-identified data to the PI. She is now faculty at another university and has been added as a co-investigator to the study. The lack of preparedness did not seem to be an increase over last year.

Substantive issues were discovered in two (7%) of the protocols audited. The first protocol had three substantive issues:

The first issue involved a parent not signing the parental consent form for a minor to participate in research. The child did sign the assent form. Because permission was not received from the parent, data from this minor participant will not be permitted to be used.

The second issue involved a parent giving verbal permission over the phone for their child to participate, but did not sign the consent form. After a review of the initial application, it was noted that the PI did not request that parental permission be obtained over the phone. The reviewer did note that the phone conversation was documented on the parental consent form for a minor to participate in research. Because a request to obtain parental permission over the phone was not submitted in the initial application, data from this minor participant will not be permitted to be used.

The third issue involved the researcher video recording the focus groups. Videotaping was not requested in the initial application, nor was it mentioned in the consent forms or assent form. Because videotaping was not formally requested in the initial application or in a modification, the video will not be permitted to be used as data. Any written / electronic notes taken during the focus groups may be used. The PI did confirm at the meeting that only he and the research assistant viewed and had access to the video. The video was stored on a password protected iPad. This same PI also had a minor issue of not having participants sign IRB stamped consent forms/assent forms. This was a first time researcher and the project was no risk / low risk.

The PI addressed all the issues appropriately and agreed not to use the data mentioned above. The individual has been appropriately educated and is now aware of IRB requirements.

In the second case of substantive issues, the protocol had two noted substantive deficiencies:

The first issue involved a consent form not being signed by one of the participants. The PI has since obtained the participant’s signature.

The second issue noted was that data was being stored on a Blackberry device. This was not mentioned in the initial application. The PI has since removed the audio recording from the Blackberry and has placed them on a password protected site. This same PI also had a minor issue of not having participants sign IRB stamped consent forms/assent forms.

This was the seventh year campus-wide DSM audits were conducted at the University of North Carolina at Greensboro by the Office of Research Integrity. Some of the issues found in prior DSM audits did not occur at all this year such as any unreported adverse events. 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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Assistant Director

Office of Research Integrity

Office of Research Compliance

**Recommendations to the IRB**

The following report outlines the Data Safety Monitoring findings reported in the above report and corresponding tables with suggestions for corrective actions to further reduce the possibility of negative findings. The new online system has a thorough application process and requires that the application be updated each time there is a modification. The renewal process tracks any recent or new modifications to the study. This is an added benefit as the PI will consistently update the application to ensure they are working from the most recent protocol. Stamped consent documents are also encouraged to be uploaded and kept online so that the investigator can have access to the most recently stamped version at all times. Due to the electronic nature of the system, it will also help to prevent paperwork from becoming misplaced.

***Closure of Research Projects***

There were three closures that occurred prior to this year’s audit. The principal investigators were informed of the importance of submitting a closure report upon study completion. Investigators do not have to wait until their renewal period. This information was reiterated to investigators whose active studies were selected as part of the 2012-2013 DSM audits. They were informed that they were to submit a closure report immediately following study completion.

This is a topic that the ORI continues to receive questions about and the office staff has been instructed as to the appropriate closure procedures such as de-identification of study data and awaiting publication of an article. If study data has been de-identified or if the investigator is awaiting publication and has no further need to continue analyazing or re-analyzing the data, a closure form may be submitted to terminate the project. The IRB Standard Operating Procedures have been updated to reflect this change. The closure form can be submitted electronically via the IRBIS online system or, until further notice, via the paper closure form.

***Minor Issues***

Several of the minor issues in this year’s audit were related to participants signing a consent form without an IRB stamp. As noted in the report, 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. At the DSM meetings where this was discovered, the reviewer discussed the importance of the IRB stamp with each investigator. The investigators were made aware that the IRB stamp is not only to ensure the use of the most recently approved and/or valid consent form, but also to inform participants that the consent form was reviewed and approved by the UNCG IRB.

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. 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.

***Substantive Issues***

Although there was not an increase in substantive issues this year, each study had more than one issue. The issues were unintentional; however, the ORI took each issue seriously and required the investigators to submit action plans. The issues did not present an increased risk to participants and each investigator involved responded appropriately to the issues. The ORI will continue to remain available to educate both the campus and individual researchers by making efforts to reach out to departments via presentations about the Office of Research Integrity policies and procedures and federal regulations as it pertains to the research in their department.