

Annual Report

July 2015

2014

**Introduction**

The Office of Research Integrity (ORI) 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 2014 to -July 2015 year..

**Institutional Review Board Overview**

The IRB scheduled meetings from 3:00pm to 5:00pm on the 2nd and 4th Wednesdays of each month. Special meetings were held to conduct Full Board reviews as needed. The specific dates of the IRB meetings for the 2014-2015 academic year can be seen in the chart below. The IRB members represent a variety of departments on the UNCG campus. As noted below, several members rolled off the committee the past year and were replaced by new members.

**IRB Meeting Dates**

|  |
| --- |
| **IRB Membership (2014-2015)** |
| **Represents** | **Name** | **Category** | **Term** |
|  |  |  |  |
| ORI | Melissa Beck | Non-Scientist | 6/30/15 |
| NUR | Dr. Heidi Krowchuk |  Scientist | 6/30/14 |
|  ITS | Ms. Gloria Thornton | Non-Scientist | 6/30/16 |
|  KIN | Dr. Laurie Wideman  | Scientist | 6/30/16  |
| PSY | Dr. Kari Eddington  | Scientist | 6/30/17 |
| ECO | Dr. Jeremy Bray | Non-Scientist  | 6/30/16 |
| KIN | Dr. Randy Schmitz | Scientist | 6/30/16  |
| External | Mr. Steve Hayes | Scientist  | 6/30/18 |
| Prison Rep | Dr. Jennifer Adams |  |  |

 Ex-Officio Mr. Tim Slone

August 13, 2014

August 27, 2014

September 10, 2014

September 24, 2014

October 8, 2014

October 22, 2014

November 12, 2014

December 10, 2014

January 14, 2015

January 28, 2015

February 11,2015

February 25, 2015

March 11, 2015

March 25, 2015

April 8, 2015

April 23, 2015

May 13, 2015

 May 27, 2015

\*Some meetings may have been cancelled if there were no submissions to review

**IRB Applications and Submissions**

Between June 2014- and July 2015, the IRB conducted reviews of 1,292 submissions, which was an increase of 60 additional submissions compared to the previous year.

As seen below in Figure 1 the large majority of the total submissions received fell under the expedited and exempt review categories, which is consistent with previous years. Full Board Reviews decreased slightly from 17 submissions the previous year to 14 submissions this year.

While we are focusing on the first four categories below, it is also significant to note the number of closures, renewals, and modifications as well. In the 2013-2014 academic year, 407 modifications were reviewed. The number of modifications submitted in the 2014-2015 academic year increased to an even 500. The number of renewals reviewed remained exactly the same at 298 between the 2013-2014 and 2014-2015 academic years. Although the ORI has been educating faculty and students regarding when it is acceptable to close out a study, rather than faculty and students allowing their studies to expire, the number of closure reports submitted and reviewed decreased this academic year. We will continue to educate the campus regarding study closures.

**Figure 1:**

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| **Total Submissions by Outcome** |
| **Category** | **Count** | **Percentage** |
| Full Board Review |  14 |  1.14% |
| Expedited (initial submissions) |  124 |  10% |
| Exempt (initial submissions) |  218 |  18% |
| NHSR |  91 |  7.4% |
| Closures |  47 |  3.8% |
| Modifications |  500 |  41% |
| Renewals |  298 |  24% |
| **Total** |  **1292** | **100%** |

**Initial Submissions**

There were 435 initial applications submitted to the ORI during the 2014-2015 academic year. Of all the initial submissions, 79% were approved in the expedited or exempt categories. This is consistent with previous years.

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| **Initial Submission by Outcome****FY 2012-2103** |
|  | **Category** |  | **Count** | **Percentage** |
| Full Board Review | 2 |  0.5% |
| Expedited |  | 124 |  29% |
| Exempt |  | 218 |  50% |
| NHSR |  |  | 91 |  21% |
|  |  |  |
|  |  | **Total** | **435** | **100%** |

**Figure 2:**

**Submissions Counts by UNCG Department**

The 1,292 submissions were broken down by the affiliated department of the Principal Investigator. There are many departments across the campus that submit initial, renewal, modification, or determination applications each year, however, only the top 10 departments are reported below. As in previous years, the Psychology department (PSY) and the Department of Kinesiology came in first and second for the total number of submissions. There were also several departments from the School of Education that were included in the top ten.

**Figure 3:**

**Top 10 Departments by Submission Counts in Fiscal Year 2015**

|  |  |
| --- | --- |
| **Department** | **Total number of submissions** |
| Psychology | 193 |
| Kinesiology, Dept of | 130 |
| Council and Ed Development | 92 |
| Teacher Ed/Higher Ed | 92 |
| Ed Leadership and Cultural Foundation | 81 |
| Human Develop and Family Studies | 79 |
| Specialized Education Services | 71 |
| Public Health Education | 57 |
| Nutrition | 56 |
| SERVE | 36 |
| Comm Science and Discord | 36 |

**Total Submissions by Approval Time**

The total of 1,292 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. There are many factors to consider when determining the time it takes to approve a study such as: 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 with stipulations, and how quickly those stipulations are responded to.

Once the IRB receives and processes a submission, the IRB issues an initial response, which is most often a letter with stipulations attached for the PI to address. In the IRB initial 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. Another factor to consider is how accurately the stipulations are responded to by the PI. If not responded to accurately, additional stipulations may need to be issued.

As seen below, 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 the meeting schedule and 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.

 As noted below, the turnaround time for expedited reviews is much less than full board studies. As predicated last year, the turnaround time has decreased now that faculty and students have become better acquainted with the system and now that all submissions are online. When comparing the numbers below to the numbers from last year, it is noted that the turnaround time has decreased for each category. For example, the initial IRB response to initial expedited reviews remained the same at 3 days, however, the final approval decreased from 19 days to 17 days. For full board studies the initial IRB response time dropped from four days to one day and the final approval for initial full board reviews decreased from 52 days to 32 days.

**Figure 4 – Expedited Review Turnaround Time**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Initial Expedited** | **Initial Full board** | **Modification Expedited** | **Renewal Expedited** | **Renewal Full Board** |
| **Initial IRB Response** | 3 |  1 | 2 |  1 |  13 |
| **Final Approval** |  17 |  32 |  5 |  2 |  14 |

**Unanticipated Problems and Non-Compliance**

There were no adverse events, neither serious nor non-serious, reported for the 2014-2015 fiscal year. There were thirteen unanticipated problems reported and one unintentional deviation reported. These matters were reported to the ORI which provided appropriate follow-up and action to each incident and in all cases, all were not reportable to sponsors. All were handled avoiding any risks to participants and most were reported out of diligence to the participants and research team. In each case, the research team provided the appropriate information and resolution/corrective action plan.

There were *no* reported incidents of non-compliance.

 **Data Safety Monitoring**

Twenty-one studies were selected for the DSM audit in 2014-2015. Audits resulted in one or a combination of the following three outcomes: no problems, minor issues, or significant issues. There were a few instances where a study was selected, but it was determined after selection that the study was closed to enrollment and in data analysis only. There were also a few studies where, after being selected, the investigator informed the ORI reviewer that the study was closed to enrollment and in data analysis or some studies had been closed out as enrollment and data analysis were complete. In each instance, these studies were replaced by other randomly selected studies.

The charts below show the comparison between the 2012-2013 audits and this year:

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| --- |
| **DSM 2014-2015** |
| **DSM Status** | **Number** | **Percentage** |
| No Problems | 3 | **14%** |
| Minor Issues | 18 | **86%** |
| Substantive Issues | 0 | **0%** |
| Significant Deficiencies | 0 | **0%** |
| **Total**  | 20 | **100%** |

**Figure 5:**

**Figure 6:**

**Data Safety Monitoring (continued)**

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.

**Institutional Animal Care and Use Committee (IACUC)**

Between July 1st, 2014 and June 30th, 2015, there have been several changes within the IACUC program following an evaluation of the program by an outside consultant. It may be important to note the changes as a way of looking toward the future of the program, and as a way of evaluating the effects of these changes. The IACUC program at UNCG has slowly declined in the number of animal use protocols over the past five years. Over the Spring 2015 semester, one of the two existing animal facilities was shuttered permanently and will be allocated to campus space needs.

There were staff changes in the animal facility and currently there is a full-time manager who is qualified to provide animal use training and post-approval monitoring as well as husbandry and management of one part-time husbandry animal technician.

The census for animal care and use protocols is below. This does not include amendments and annual reviews:

|  |  |
| --- | --- |
| IACUC active research protocols |  4  |
| IACUC active field/teaching protocols |  6  |
| IACUC approved protocols (not currently being worked on) | 2 |
| Animal Facility protocols | 2 |
| New protocols approved between 7/14-6/15 | 3 |

The IACUC program will continue to be assessed over the coming year in terms of growth or campus use. Currently there are three departments accessing the animal facility: Nutrition, Biology and Kinesiology. Field protocols are from the Biology department.

**IACUC Members**

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| **IACUC Membership (2014-2015)** |
| **Represents** | **Name** | **Category** | **Term Expires** |
| NUTR | Dr. Deborah Kipp, Chair | Scientist | 6/30/16 |
| KIN | Joseph Starnes | Scientist | 6/30/16 |
| NUTR | Dr. Michael McIntosh |  Scientist | 6/30/16 |
|  SOE | Dr. Randall Penfield  | Non-Scientist | 6/30/17 |
|  BIO | Matina Kalcounis-Ruppell | Scientist  | 6/30/17 |
| External | Dr. Jason Streck | Community | 6/30/15 |
| Ex-officio |

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| --- | --- |
| Timothy Slone |  |

 | UNCG |  |
| Veterinarian | Dr. Alyssa McIntyre | Veterinarian |  |

**Institutional Biosafety Committee (IBC)**

Currently, there are 26 IBC protocols on file since 2002 registered at UNCG. Meetings are held every other month, and inspections of labs are handled by a member of the UNCG campus safety office on a rolling basis and as new protocols are approved. Lab safety training is also provided by this office and the individual departments. The ORI Director receives and distributes all new applications. In fall 2015, there will be a new Chair for the IBC, and some members added and replaced. It is expected that with some of the changes, there will be more of an effort to synthesize the program and collaborate with the expectations of receiving more applications, as well as a stronger partnership with JSNN.

**IBC Members**

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| --- |
| **IBC Membership (2014-2015)** |
| **Represents** | **Name** | **Category** | **Term** |
| JSNN | Dr. Dr. Ethan Taylor, Chair | Scientist | 6/30/15 |
| BIO | Dr. Yashmati Patel | Scientist | 6/30/16 |
| NUTR | Dr. Ron Morrison |  Scientist | 6/30/16 |
|  External | Bryan Hill  | Community | 6/30/15 |
|  External | Christopher Watkins | Community | 6/30/16 |
| Ex-officio | Aisha Holloman | JSNN |  |
| Ex-officio |

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| Timothy Slone |  |

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**IRBIS Online System and Responsible Conduct of Research Curriculum**

In fall 2015, the ORI will launch the IRB component of AIR, which is an online system to monitor conflict of interest as it relates to research. Once this system is in place, IRB staff will be able to monitor conflict of interest in research, as applicable, for each initial and renewal submission submitted for review. When an investigator submits a study, they will be sent an email requesting that they complete a short conflict of interest questionnaire. Depending on their response, the study will continue with no conflict, or will require further review.

**Responsible Conduct of Research (RCR) Training**

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

Since January 1, 2015 until August 4, 2015, fifty-four NIH or NSF proposals have been submitted at UNCG. Since March 2015, the Office of Research Integrity has sent an email to each PI that submitted an NIH or NSF proposal to make them aware of the Responsible Conduct of Research training options offered by our office.

In the upcoming year, the Office of Research Integrity plans to re-design the Slippery Slope Series for the upcoming year. Rather than focus the training on one specific topic,, this three hour course will be offered once each spring and fall semester. All relevant RCR modules will be offered. The course will offer a variety of speakers and engage the audience with case studies and videos. The pilot for this course will be first offered to the Kinesiology department in October 2015. For the pilot, all interested DGS will be invited to attend. After the pilot session, we will make the program available to all faculty, staff and students. The proposed course content is below:

* Questionable Research Practices / Research Misconduct
* Management of Conflict of Interest
* Mentor / Mentee Relationship
* Responsible Authorship and Publication
* Peer Review
* Data Ownership/Management
* Lab Safety (when applicable to the department)
* Industry Collaboration

While the current plan is to offer the full course once each spring and Fall semester, the course can also be customized to meet the needs of specific departments.

The ORI will also continue to offer RCR training via CITI as well as an in-person Human Subject’s Research training session once each semester.

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. 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. More

“Slippery Slope sessions may be arranged in 2016 since they were very popular and allow for a range of topics.

 In March, the Director of the ORI, the IRB Chair and Assistant Director of the ORI 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. We also plan to offer a customized version of the course in which departments can choose particular modules in the session that are applicable to the type of research they conduct.

The ORI office has also been reviewing the reports of grant submissions monthly and have been sending informational emails to all PI’s whose studies are required for RCR training certification.

Epigeum is also offered by ORI as a RCR training course. Epigeum is an online, interactive course that covers all the RCR topics required by NIH and NSF. Researchers and their research team can use the Slippery Slope in-person sessions and Epigeum together to meet the training requirements required by NIH and NSF. Epigeum can also be used in undergraduate, graduate, and doctoral programs in fulfillment of a course or just in addition to providing students with knowledge in the area of Responsible Conduct of Research. Participants may self-enroll and class materials can be uploaded by the instructor of the course.