NORTHERN ARIZONA UNIVERSITY

Internal Audit Department

Institutional Review Board

November 2015
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Northern Arizona University
Institutional Review Board
Audit Report
November 30, 2015

Summary

Our audit of NAU's Institutional Review Board is in the Annual Audit Plan for FY 2016, as approved by the Audit Committee of the Arizona Board of Regents. This audit links to Northern Arizona University's goals of nationally recognized research excellence and having efficient, effective, and accountable practices.

Background: The Code of Federal Regulations (CFR) Title 45 §46 requires that NAU maintain an Institutional Review Board (IRB). The purpose of IRB review is to ensure that appropriate steps are taken to protect the rights and welfare of humans participating as research subjects.This includes protecting the identity of subjects and data that may result in a loss of participants' anonymity. Additional safeguards are required for vulnerable populations such as children, pregnant women, and prisoners. The IRB is required to be registered with Health and Human Services (HHS) every three years. Every five years NAU renews its commitment to comply with the federal regulations for the protection of human subjects by signing and submitting a Federalwide Assurance (FWA) to HHS.

The Code of Federal Regulations requires research proposals to be categorized based on research methodology and risk. The three categories requiring IRB review are termed "exempt", "expedited", and "full-board." To be categorized as exempt or expedited the research must involve only minimal risk to subject(s). When the proposed research cannot be categorized as exempt or expedited, the research proposal must be reviewed by the IRB full committee. The Board consists of eleven members, including the Assistant Vice President for Regulatory Compliance, who also serves as the IRB Institutional Official, and the IRB Coordinator. The Institutional Official, IRB Coordinator, and any authorized reviewers are responsible for determining the research risk(s) to the subject(s) and for categorizing the research. Research projects can range from undergraduate students performing interviews for a class project to complex biomedical research. During FY 2015, 590 research proposals, amendments, continuing reviews, and other actions were submitted to NAU's IRB office for review. Only eleven required full board review.

The IRB office currently consists of the Assistant Vice President for Regulatory Compliance and one full-time IRB Coordinator. Since the audit started, a 10-hour per week student worker and a temporary half-time administrative assistant were added. The latter is being trained.

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Audit Objectives: The primary objective of the audit is to determine whether the Institutional Review Board reviews and approves human subject protocols on research projects in accordance with federal requirement and NAU rules and regulations.

Scope: The scope of our audit included a review of current policies and procedures currently in effect and research protocols submitted to the IRB office from July 2014 through September 15, 2015.

Methodology: The following procedures were performed to accomplish the audit objectives:

- reviewed the Code of Federal Regulations relating to human research and compared to NAU's formal policies. Identified any discrepancies by preparing a gap analysis;
- enrolled in the on-line training course developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The course must be taken by all NAU researchers if human subjects are involved in their research;
- obtained access to the electronic web-based software, IRBNet, to identify all research documentation submitted to the IRB;
- selected the first 500 records, representing research submitted beginning July 2014 through September 15, 2015 as a population from which to extract samples and gather statistics. For each of the 500 records, identified the date submitted and the date approved;
- selected a sample of 20 research projects from the first 500 records in IRBNet for detailed review;
- using HHS decision charts, analyzed the research protocols to confirm that the research was properly classified and reviewed. Reviewed attached documentation such as applications, questionnaires, consent forms and approval letters for adequacy and completeness;
- surveyed NAU's ABOR-assigned peer institutions regarding their IRB procedures and staffing, and
- met with the IRB Coordinator to gather preliminary information and subsequently discussed concerns and possible recommendations.

The audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*.

Conclusion: NAU has been slow to adopt the procedures and practices necessary to build the infrastructure necessary to support increased research expenditures. The IRB office does not provide adequate support to NAU researchers who plan to use human subjects as part of their research protocols, primarily due to understaffing. Insufficient staffing resources within the IRB office has resulted in lengthy delays to approve research protocols. As a result, NAU may be on course to miss opportunities for increasing grant expenditures and may place the university at risk for unapproved research on human subjects.

Management is supportive of our recommendations and has actively begun working to implement their identified action items.

The control standards we considered during this audit and the status of the related control environment are provided in the following table.

General Control Standard (The bulleted items are internal control objectives that apply to the general control standards, and will differ for each audit.)	Control Environment	Recommen-dation No.	Page No.
Reliability and Integrity of Financial and Operational Information	Not Applicable		
Safeguarding of Assets	Not Applicable		
Authorization Procedures	Not Applicable		
Effectiveness and Efficiency of Operations			
• The IRB office is effectively and efficiently communicating Federal regulations and the process to submit research proposals to the IRB office for prompt review.	Opportunity for Improvement	2	8
• The IRB office effectively processes research submitted to its office.	Reasonable to Strong Controls in Place		
• The IRB office is able to efficiently process research submitted to it.	Opportunity for Significant Improvement	1	5

General Control Standard (The bulleted items are internal control objectives that apply to the general control standards, and will differ for each audit.)	Control Environment	Recommen-dation No.	Page No.
• The IRB office communicates and resolves issues effectively.	Reasonable to Strong Controls in Place		
Compliance with Laws and Regulations			
• NAU's policies and procedures support federal regulations related to human research.	Reasonable to Strong Controls in Place		
• A system is in place to help ensure compliance with federal regulations.	Reasonable to Strong Controls in Place		
• The IRB meets federal guidelines.	Opportunity for Improvement	3	11

We appreciate the assistance of the IRB Coordinator, who responded to questionnaires and interviews and who provided access to web-based training and software.

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Audit Results, Recommendations and Responses

1. Staffing of the Institutional Review Board office is inadequate.

Condition: Research projects submitted to the IRB office continue to increase in complexity and volume. However, the IRB office has been unable to timely process all research submitted for review. Of approximately 600 IRB records submitted for review during FY 2015, 56 projects were pending review as of September 15, 2015. Researchers complain of the time required for review and approval of research protocols. The IRB has not established or communicated standard processing times for review of application protocols. Data from the 2015 Association for the Accreditation of Human Research Protection Program (AAHRP) report compared to NAU's data for FY 2015 indicates that IRB's turn-around time exceeds the national average.

NAU's Processing Times Compared to the Accreditation of Human Research Protection Program

Type of Research	AAHRP's Average No. of Days	NAU's Average No. of Days	Difference
Exempt	21 days	26 days	5 days
Expedited	29 days	50 days	21 days
Full Board	43 days	92 days	49 days

Thirty-nine research proposals submitted during FY 2015 did not involve human subjects and were not required to be reviewed by the IRB office. The IRB office noted that research protocols often are incomplete or without sufficient detail to determine the type of IRB review required.

IRB staffing levels are inadequate for timely review of the research protocols submitted. All research submitted to the IRB office is initially reviewed by the IRB Coordinator or the Assistant Vice President for Regulatory Compliance. The Assistant VP balances his time reviewing research proposals with overseeing animal research, radioactive material, import/export controls, chemical safety, air quality, waste water, hazardous chemical

waste, employee safety, and conflict of interests relating to research. Reviewing research proposals represents an inefficient use of an Assistant Vice President's time, knowledge, and skills.

The IRB Coordinator is unable to timely process research proposals efficiently due to related job duties. In addition to reviewing research proposals, the IRB Coordinator:

- provides training to principal investigators on Federal regulations and University policies;
- provides guidance to principal investigators and staff on submission of application materials and review requirements;
- prepares training materials and standard operating procedures for use by researchers when submitting research proposals for review;
- serves as internal support desk for CITI and IRBNet software applications;
- trains and supervises IRB office student worker;
- analyzes research protocols and records submitted with IRB applications to ensure compliance with federal regulations and University policies;
- notifies and questions principal investigators of any deficiencies or ambiguities in their applications or documentation;
- notifies researchers when their application has been approved or disapproved;
- ensures that IRB reviews are sufficiently and clearly documented and entered to IRBNet;
- keeps abreast of federal regulation changes and policy changes;
- identifies potential IRB Committee members; and
- schedules IRB Committee meetings and prepares meeting agendas and documents.

In the event IRB Coordinator or Assistant Vice President is absent, there is no one available to advance the review process.

IRB committee members do not have all the specialized background and knowledge required to review complex technical proposals.

Criteria: As part of the terms of the Federal wide Assurance, HHS requires that "*The Institution will ensure that each IRB upon which it relies for review of research to which the FWA applies has meeting space and sufficient staff to support the IRB's review and recordkeeping duties.*"

Cause: The IRB office is inadequately staffed.

Effect: Lack of staffing inhibits efficiency. Research involving human subjects is not being timely reviewed and approved.

Inadequacy of this component of the research infrastructure undermines NAU's efforts to substantially increase research expenditures.

Lack of staffing increases the difficulties NAU will face should turnover of IRB staff occur; also, lack of staffing detracts from the IRB's office's ability to streamline its review processes and meet regulatory requirements.

Recommendation: Staffing of the IRB office should be increased to a level that enables the responsibilities of the office to be met. The IRB office should obtain statistics regarding the staffing levels and job responsibilities of IRB offices of NAU's peer institutions and increase staffing accordingly.

The IRB office should develop and communicate standard processing times for reviewing IRB applications.

Response: We agree that staffing for the growing demands on NAU's Human Research Subjects Protection Program (HRSPP) needs to be increased. We have in the past month taken a number of steps to rectify this situation.

In early September we asked Interim Associate VPR, Jerry Fife, recently retired from Vanderbilt University, to provide an independent review of the NAU Office of Regulatory Compliance, including the HRSPP. He provided the report directly to President Cheng and subsequently shared the report with me. In this report, he stated that the HRSPP needed an additional senior person and lower level admin support person (full or part time). I have taken this recommendation back to President Cheng and she has agreed to support a new HRSPP Director, seeking to hire a Director with at least 7 years of university IRB experience and someone who is familiar with the Flexibility Coalition (an approach to HRSPP management that balances regulatory compliance with the need to provide timely service to the University faculty). In fact, the primary informal consultant for our HRSPP is Mariette Marsh, from UA, and she is involved in the Flexibility Coalition movement.

In addition, to ease the current workload pressure this Fall, my office has requested that Heidi Wayment, Chair of the IRB Committee, assist with exempt and expedited cases within Social and Behavioral Sciences, and she has agreed to do this. In addition, my

office is providing a professional stipend for two members of the IRB Board to assist with clearing the remaining exempt and expedited cases. The HRSPP is also planning to train lead faculty in key departments and colleges (also IRB Committee members) to do initial reviews of IRB applications and sign off on exempt applications. These decisions will be sampled to ensure that the training provided to these lead reviewers is resulting in appropriate decisions. These processes will greatly streamline the workload on the HRSPP senior staff, who will have more time to document standard procedures and policies. The training will continue and expand when the new Director is hired, and we will use Mariette Marsh for additional training of lead departmental faculty.

In addition, the OVPR has provided .5 FTE of an administration Assistant to handle initial and final clerical work, including routine e-mailing, scheduling, phone answering, and approval paperwork.

The position announcement for the Director has been sent to HR and we expect to open the search within a week.

If necessary, we will continue all of the support mechanisms described above through the Spring of 2016, until the HRSPP office is stable and operating efficiently. We will also ask Mariette Marsh, from UA, to provide additional assistance as appropriate as we transition the office into a much more responsive unit.

2. The operations of the IRB office should be made more efficient.

Condition: IRB office operations are inefficient. The office:

- lacks standard operating procedures;
- does not have efficient processes; and
- sometimes has difficulty locating important documents. The IRB Coordinator was unable to locate the original copy of NAU's Registration of its IRB with the HHS.

Criteria: HHS regulations at 45 CFR 46.103(b) require that institutions have written IRB procedures. The Office for Human Research Protections provides guidance on the topics that should be addressed in the IRB's written operating procedures. The IRB office should include additional subjects to ensure consistency in entering data into IRBNet and provide guidance on often asked questions.

The IRB should continually evaluate methods to streamline its review processes while ensuring compliance to federal regulations.

The IRB office should be able to locate important documents.

Cause: Staff turnover and the lack of staffing resources has kept IRB officials focused on reviewing research protocols; as a result, it has been unable to organize its office and streamline procedures or evaluate alternative processes.

Effect: Standard operating procedures and office organization will help to streamline and make consistent the operations of the IRB office. In addition, written operating procedures would help with training research personnel and provide guidance in the event of staff turnover.

Recommendation: The IRB office should streamline its review processes and operations. The IRB office should:

a. Develop standard operating procedures and should ensure that IRB policies relating to research involving human subjects are current.

b. Evaluate its system of reviewing research protocols. Some options to consider include:
   - employing administrative staff to perform a preliminary review on IRB applications for completeness and determination of review type before a thorough review is performed by IRB officials;
   - requesting IRB members and IRB Chair to provide assistance with expedited reviews based on their areas of expertise;
   - training “authorized IRB specialists” in colleges and departments to perform departmental level reviews before submitting research proposals to the IRB;
   - working with the IRB to identify ways to streamline full-board reviews and gain any specialized knowledge required to review complex technical proposals. Five of NAU’s peer institutions are using two IRB Committees. Generally, one committee reviews biomedical research while the other is dedicated to social and behavioral research. Another option to consider is outsourcing complex and technical research protocols to other IRBs.
   - continuing to provide outreach to Principal Investigators (PIs);
   - providing training to PIs at a University-wide level on how to properly document research proposals and submit research applications;
   - providing on-line guidebooks and standard operating procedures for reference; and
   - developing IRB screening forms to discourage nonscientific research from being submitted.

c. Improve document storage procedures.

Response: We concur with these recommendations. I have responded to a number of these points in the first response above. I will respond to additional items listed under recommendations (b) and (c) that have not already been addressed:

1. We will institute a process by which we reduce significantly the number of calendar days from application to Full Board approval. The 2013 national mean for full board approval is 43 days. We currently operate at double this national median number. Our goal is to be at or near the 2013 national mean for Full Board reviews that begin by June 30th, 2016 (goal of 50 calendar days). (This date assumes a fairly rapid search for a Director, with the hire starting by March 1, 2016. Otherwise, the movement to the national mean time for full board approvals will be expected within five months of the hiring of the new IRB Director.)

2. At the moment, we believe that the number of Full Board reviews at NAU remains at the level for one IRB, and we will consult on this with both the new Director and with Mariette Marsh (from UA). It may be true that four peer universities have more than one Board; however, two of these institutions have medical schools and seven have more than double the amount of research expenditures that we have. National Statistics for numbers of IRB applications and Full Board applications suggest that, at our current level of research expenditures, we should have one IRB at this time (although this may change as we grow our research programs at NAU).

3. With the increasing resources and capacity in the coming 4-5 months, we will implement more robust outreach to Principal Investigators (PIs). We will provide training to PIs on how to properly document research proposals and submit research applications, provide on-line guidebooks and standard operating procedures for reference, and develop IRB screening forms to discourage nonscientific research from being submitted. We will have these processes and documents completed and available by September 1st, 2016 (assuming a successful search for an IRB Director).

4. With the new HRSPP Director and the administrative support, the HRSPP will improve IRB storage procedures by June 30, 2016.

3. IRB membership should include someone not affiliated with NAU.

Condition: IRB membership does not include at least one member not affiliated with the University.

Criteria: Federal regulations require that the IRB is required to have at least one member who is not affiliated with the University (45 CFR §46.107). Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

Cause: The IRB is seeking to find a nonaffiliated member who can assist in reviewing biomedical research protocols. The Committee is having difficulty finding a volunteer who can be present during meeting times.

Effect: The IRB is not in compliance with federal regulations.

Recommendation: The IRB should continue to focus on finding a nonaffiliated member, preferably an individual with experience in biomedical research.

Response: We will appoint an appropriate non-NAU member to the IRB by January 31, 2016.

Distribution:

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This report is intended for the information and use of the Arizona Board of Regents, NAU administration, the Arizona Office of the Auditor General, and federal awarding agencies and sub-recipients.