FAU
BOARD OF TRUSTEES
Florida Atlantic University

Item: AF: I-1a

AUDIT AND FINANCE COMMITTEE

Thursday, February 16, 2012

SUBJECT: REVIEW OF AUDITS: REPORT NO. FAU 11/12-1, ANIMAL & HUMAN SUBJECTS RESEARCH COMPLIANCE AUDIT, 1/1-12/31/10.

PROPOSED COMMITTEE ACTION

Information Only.

BACKGROUND INFORMATION

Primary objectives of this audit were to determine whether:

- University oversight of research involving *human* subjects complies with federal requirements and established policies and procedures which govern its Institutional Review Board (IRB); and,
- University oversight of *animal* subjects research complies with federal requirements and established policies and procedures which govern its Institutional Animal Care and Use Committee (IACUC).Primary objectives of the audit were to determine whether:

There were no reportable findings or recommendations as a result of this audit.

IMPLEMENTATION PLAN/DATE

Not Applicable.

FISCAL IMPLICATIONS

Not Applicable.

Supporting Documentation: Audit Report FAU 10/11-5

Presented by: Mr. Morley Barnett, Inspector General **Phone:** 561-297-3682

Report No. FAU 11/12-1
December 9, 2011

Office of Inspector General

Animal & Human Subjects Research Compliance Audit
1/1 – 12/31/10

SCOPE AND OBJECTIVES

In accordance with the University's Internal Audit Plan for fiscal year 2011-12, we have conducted an audit of the University's policies, procedures and practices related to management and oversight of animal and human subjects research compliance at Florida Atlantic University for the period January 1 through December 2010. The primary objectives of this audit were to determine whether:

- University oversight of research involving *human* subjects complies with federal requirements and established policies and procedures which govern its Institutional Review Board (IRB); and,

- University oversight of *animal* subjects research complies with federal requirements and established policies and procedures which govern its Institutional Animal Care and Use Committee (IACUC).

We obtained an understanding of the internal control environment pertaining to animal and human subjects research compliance by interviewing key research compliance personnel, and reviewing applicable laws, rules, regulations, policies, and procedures pertaining to the administration of the IRB and IACUC functions for research protocols. Testwork to achieve the audit objectives primarily consisted of a detail examination of IRB and IACUC oversight documentation for judgmentally-selected protocols classified as new, continuing, amended, terminated, and serious adverse events/unanticipated problems. Our examination also included performing a walk-through of the University's animal facilities and examination of relevant records to ascertain whether select animals were purchased after approval of the protocol and acquired lawfully from authorized vendors in accordance with protocol terms.

Populations, sample sizes, and selection methods were determined based on our evaluation of internal controls, our assessment of audit risk, the availability of pertinent University records, and other factors including auditor judgment.

We conducted our audit in accordance with the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

BACKGROUND

The Division of Research administers key research-related assurance and compliance programs required by federal and state agencies for research conducted at the University. Research Integrity, a unit within the Division of Research, administers the Human Research Protection Program (HRPP) and the animal care and use program through two vital committees - the IRB and the IACUC. The primary focus of both committees is the research protocol which is meant to detail a study's objectives, research methods and restrictions, including informed consent by human participants and humane treatment of animals. Florida Atlantic University's IRB and IACUC committees are comprised of 14 and 12 members respectively, including non-University-affiliated members who have been formally designated to review and monitor research involving human and animal subjects. Both boards meet on a monthly basis to review and approve protocols under their respective purviews.

The IRB's function is to determine and certify that human subjects research protocols conform to the HRPP which is governed by several guiding principles and laws set forth by federal agencies such as the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), US Department of Veteran Affairs, and the US Department of Defense. Human research typically involves studies with clinical or behavioral measurement objectives, all of which may place participants at more risk than they would otherwise encounter in daily life and which require their consent to participate. The IRB has ultimate responsibility for determining whether the risks to participants have been minimized in light of the anticipated benefits, and is responsible for performing continuing reviews of all protocols annually. Based on an evaluation of the unique risks posed by clinical trials research, the University, in September 2009, contracted with Western IRB for compliance oversight for all industry-sponsored or investigator-initiated clinical trials.

The University's IACUC was established in accordance with the US Department of Agriculture (USDA) Animal Welfare Act and Regulations and the Guide for the Care and Use of Laboratory Animals (*Office of Laboratory Animal Welfare – OLAW*), and is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals in Testing, Research and Training. Separate from Research Integrity, the Office of Veterinary Services is administered by the University's Attending Veterinarian and is charged with the veterinary care and husbandry of the animals used in research. Determination of the type of IACUC review is based upon the expected level of animal pain or discomfort and types of procedures. Protocols involving USDA-covered species are reviewed annually while those involving non-USDA covered species are reviewed every three years, per agency regulatory requirements. In addition to reviewing specific research projects, the IACUC carries out federally-mandated functions such as reviewing and reporting on the overall animal care program, as well as inspecting and evaluating all animal facilities, lab space and study areas at least once every six months.

Research Integrity personnel estimate that the IRB and IACUC managed/facilitated 282 new and continuing human and 21 new animal protocols respectively during 2010. In addition, there were approximately 120 human and 96 animal protocol amendments respectively, including seven unanticipated (human subjects) problem reports and one animal protocol suspended by the applicable committee during our audit period.

Prior Audit Recommendations

Our examination generally includes a follow-up on findings and recommendations of prior internal audits, where the subjects of such findings are applicable to the scope of the current audit.

Within the past three fiscal years, there have not been any internal audits of animal and human subjects research compliance. Accordingly, a follow-up on prior audit recommendations is not applicable.

CONCLUSION

Based on our observations, limited examination of judgmentally-selected research protocols reviewed and approved by the IRB and IACUC, and interviews with key research compliance personnel, we believe the University's IRB and IACUC are adhering to federal requirements and established University policies and procedures. There were no reportable findings or recommendations as a result of this audit.

We wish to thank Research Integrity personnel for their cooperation and assistance which contributed to the successful completion of this audit.

Morley Barnett, CPA, CFE
Inspector General

Audit Performed by: Ben Robbins, CPA