AUDIT OF RESEARCH AGREEMENT
(BRAIN SAFE PROJECT)

THE UNIVERSITY OF NEW MEXICO

Report 2015-08
September 2, 2016

Audit and Compliance Committee Members
Jack L. Fortner, Chair
Thomas Clifford, Vice Chair
Ryan Berryman

Audit Staff
Manu Patel, UNM Internal Audit Director
Chien-chih Yeh, Audit Manager
Victor Griego, Internal Auditor III
CONTENTS

EXECUTIVE SUMMARY ................................................................. 1

BRAIN SAFE PROJECT ......................................................... 1
LEASE AGREEMENT ............................................................... 3
CONCLUSION ................................................................. 3

INTRODUCTION ............................................................................ 6

BACKGROUND ................................................................. 6
PURPOSE AND OBJECTIVES ................................................... 7
SCOPE AND PROCEDURES PERFORMED ................................. 7

OBSERVATIONS, RECOMMENDATIONS AND RESPONSES ........... 8

BRAIN SAFE PROJECT ......................................................... 8
LEASE AGREEMENT ............................................................... 16

APPROVALS .............................................................................. 18

ABBREVIATIONS

Brain Safe..............Brain Safe Project
FY ......................Fiscal Year
HRRC....................Human Research Review Committee
HSC ......................Health Sciences Center
Internal Audit ........University of New Mexico Internal Audit Department
IRB ......................Institutional Review Board
MEG ..................Magnetoencephalogram
MRI ....................Magnetic Resonance Imaging
MRN ....................The Mind Research Network
OHRP .................Office for Human Research Protection
UAPP ..................University Administrative Policies and Procedures
University ..........The University of New Mexico
UNM ....................The University of New Mexico
UNMHSC ..............The University of New Mexico Health Sciences Center
EXECUTIVE SUMMARY

As a management request project, Internal Audit conducted a limited scope audit of the professional services research agreement for the Brain Safe project and lease agreement with the Mind Research Network.

BRAIN SAFE PROJECT

Research Agreement
The Mind Research Network and UNM entered into the a Research Agreement with MRN to jointly pay for a Brain Research project (Brain Safe), which would cost UNM approximately $500,000 per year over a three year period for a total cost of $1,500,000.

Due to a potential issue of serious non-compliance with federal regulations and UNM policies and procedures, the Brain Safe project was suspended indefinitely on September 25, 2014, as it posed a serious risk of adversely affecting the rights and welfare of the subjects. UNM filed a notice with the Office of Human Research Protection (OHRP), Department of Health and Human Services.

Purchase of Professional Services
Although an approved purchase order had not been issued, UNM received an invoice for $810,000 from MRN dated April 20, 2015 for professional services related to the Brain Safe project.

Deliverables
MRN billed $500,000 to UNM for 200 scans for year one from September 21, 2013 through June 1, 2014. MRN also billed UNM for 124 scans from June 2, 2014 through August 17, 2014. The Agreement does not indicate that UNM will be charged on a per scan basis, nor does it
The Research Agreement states, "The University will pay $500,000 per year in relation to this project as outlined in the Repayment Plan terms. This is based on $5,000 per Athlete per year of which $2,500 will be paid by UNM and $2,500 by MRN."

Of 246 participants and 326 scans provided on a list by MRN, Internal Audit was able to verify deliverables, by athletic program, of 97 athletes for a total of 100 scans.

The Brain Safe project was not submitted to HRRC for review and approval.

indicate a time period when project year begins and ends.

Internal Audit received a detailed listing of athletes and scans from UNM athletic physicians. Internal Audit reviewed scans and reports prepared by MRN Radiologists and also noted the following for scans which UNM was billed:

- Reasoning for repeat scans could not be determined for participants that had multiple scans in the same year. A written protocol for repeat scans was not provided to Internal Audit.
- UNM was billed for three scans which did not have any data.
- Four participants were scanned in April 2014 for year one and then again in June 2014 (within 2 months) for year two.
- Two scans were taken for the same participant within a few minutes with the same results.

**Human Research**

UNM Faculty Handbook E90: Human Beings as Subjects in Research requires that any research conducted on human subjects must obtain prior approval from a Human Research Review Committee (HRRC). This policy is in place to ensure UNM is in compliance with federal regulation 45 CFR 46: Human Subjects Research Governing the Protection of Human Subjects in Research.

A UNM Health Sciences Center (HSC) investigative committee submitted a written report on September 15, 2014 unanimously
A written notice was issued on September 25, 2014 to suspend the project immediately, and UNM filed a notice with the Office of Human Research Protection (OHRP), Department of Health and Human Services.

Rental income collected by UNM HSC for fiscal years 2013 through 2015 was $131,788, $118,817, and $118,978, respectively.

concluding that the activities conducted during the Brain Safe project were “human research” related and recommended the project be submitted to the appropriate Institutional Review Board (IRB) for final determination.

On March 10, 2015, a HRRC sub-committee presented their findings and recommendations to the fully convened HRRC. The HRRC confirmed that the Brain Safe project was research involving human subjects as defined by the federal regulations at 45 CFR 46 and the project was conducted without HRRC review and approval.

45 CFR part 46 has criteria for the protection confidential data during research on human subjects.

LEASE AGREEMENT

The Mind Research Network leases space in a building owned by UNM at 1101 Yale NE. On March 5, 2013, a Settlement Agreement and Release was entered between the UNM Board of Regents and the Mind Research Network. The purpose of the Agreement is to incorporate all terms of a written agreement dated November 16, 2012, and fully settle court actions and claims arising from prior agreements.

CONCLUSION

Established internal controls were not followed for the Research Agreement (Brain Safe Project). Internal Audit noted findings of non-compliance with UNM policies and procedures when contracting for professional services with the Mind Research Network. The following is a summary of recommendations.

- Goods and services should only be purchased with funding in place,
established budgets, and approved purchase orders. The UNM President should work with the Executive Vice President for Administration, Provost/Executive Vice President for Academic Affairs, and HSC Chancellor to identify funding for UNM's cost related to the Brain Safe project. A budget should then be established in a separate Banner index and an official approved purchase order should be issued for this Brain Safe Agreement.

- Professional services agreements entered by UNM should provide a clear understanding between UNM and its vendor. Agreements should clearly state deliverables to be received by UNM. Agreements should also clearly state the terms of the compensation if based on time-periods, price per unit, and/or both. The University may consider paying approximately $242,500 on the September 30, 2015 per the payment terms indicated in “Exhibit A’ of the agreement.

- The President should submit a written termination notice to MRN for the research agreement dated October 29, 2013.

- The UNM President should work with the UNM Institutional Official (Chancellor for Health Sciences) and Provost/Executive Vice President for Academic Affairs to require MRN to securely transfer all data collected and results generated from the Brain
Safe project to the University. MRN should be required to provide certification and assurance to the University that all data collected and results generated from the Brain Safe project have been securely deleted and are unrecoverable from their system(s), including personal and portable devices.

- Administration should review current policies, processes, and management controls to reduce the risk of non-compliance with federal regulation CFR 45 part 46: Human Subjects Research Governing the Protection of Human Subjects in Research and UNM Faculty Handbook E90: Human Beings as Subjects in Research.
INTRODUCTION

BACKGROUND

Mind Research Network

The Mind Research Network (MRN) is an independent non-profit organization dedicated to advancing the diagnosis and treatment of mental illness and brain injury. Headquartered in Albuquerque, New Mexico, MRN consists of an interdisciplinary association of scientists located at universities, national laboratories and research centers around the world and is focused on imaging technology and its emergence as an integral element of neuroscience investigation.

Founded in 1998, the MRN’s initial plan called for the building of state-of-the-art magnetic resonance imaging (MRI) and magneto-encephalogram neuroimaging (MEG) systems to be applied to studies of mental illness. In 2011, MRN partnered with Lovelace Respiratory Research Institute in Albuquerque. The MRN has a lease agreement to occupy space in a building owned by UNM.

Brain Safe Project

The Mind Research Network partnered with the University of New Mexico (UNM) to conduct the “Brain Safe” project, a sports-related concussion assessment project designed to study and reduce the impact of brain injury on NCAA athletes. The project was intended to address the growing concerns about sports-related concussions by performing thorough cognitive and behavioral assessments and brain imaging sequences of UNM athletes prior to the start of the season. Under this project, more than 200 UNM athletes were to receive an MRI scan of brain structure, chemistry, connectivity and function at the beginning of each season as part of the athlete’s physical examination. The athletes would then be rescanned every year, or after any on-field head injuries.

The project started in the fall of 2013 with initial brain scans of student-athletes playing football, women's and men's soccer, women’s and men’s basketball, and women's volleyball. The MRN and UNM entered into a Research Agreement on October 29, 2013 to jointly pay for the project, which would cost $500,000 per year to UNM over a three-year period. The project was suspended in September 2014 due to activities conducted being related to human research bypassing the Institutional Review Board review and approval process.

Lease Agreement

The Mind Research Network leases space in a building owned by UNM at 1101 Yale NE. The MRN and UNM initially entered into a lease agreement on July 1, 2006 for a portion of the building containing 77,511 square feet (“Old Construction Lease”). A separate lease also with an effective date of July 1, 2006 was entered for other portions of the building (“New Construction Lease”).
INTRODUCTION

Lease”). On March 5, 2013, a Settlement Agreement and Release (“Settlement Agreement”) was entered into between the UNM Board of Regents and the Mind Research Network. The purpose of the Agreement was to incorporate all the terms of prior agreements and fully settling court actions and claims arising from prior lease activity. This represents the current lease agreement between UNM and MRN.

PURPOSE AND OBJECTIVES

UNM received an invoice dated April 20, 2015 from the Mind Research Network (MRN) for $810,000 for professional service performed during the Brain Safe project. Funding and deliverables for the billed professional services were uncertain, resulting in a management request for an audit over the research agreement with MRN and activity conducted during the Brain Safe Project. The objectives of this audit were to:

- Obtain an understanding of “Research Agreements” entered with Mind Research Network for the Brain Safe project.
- Determine if applicable UNM policies and procedures were followed for the signed agreement with the Mind Research Network.
- Determine if UNM received deliverables specified by the signed agreement.
- Determine a status of lease agreement with the Mind Research Network (MRN).
- Determine compliance with lease terms.

SCOPE AND PROCEDURES PERFORMED

Our audit focused on “research agreements” dated October 29, 2013. Audit procedures for the Brain Safe project were from the inception of the project through the date of this report. Compliance test work for the lease agreement was for FY 2014 and a trend analysis of rent income over a three-year period for FYs 2013-2015. Procedures performed are as follows:

Research Agreement for Brain Safe Project:
- Review and document history of the “Brain Safe” project and activities conducted for the duration of the project.
- Review signed research agreement issued by the University Purchasing Division for this project.
- Interview personnel and review documentation to determine if applicable UNM policies and procedures were followed.
- Perform test work to verify deliverables.

Lease Agreement with Mind Research Network:
- Review terms of current lease agreement with the Mind Research Network (MRN).
- Test for compliance with lease terms.
- Document historical lease and rental payment summary for FYs 2013-2015.
OBSERVATIONS, RECOMMENDATIONS AND RESPONSES

BRAIN SAFE PROJECT

Research Agreement

The Mind Research Network and UNM entered into a Research Agreement to jointly pay for a Brain Research project (Brain Safe), which would cost UNM $500,000 per year over a three year period for a total cost of $1,500,000. The Agreement at Exhibit 1 was executed on October 29, 2013, prior to UNM identifying funds for the “Brain Safe” project. Therefore, the University did not establish a budget for this project in the Banner accounting system and an official purchase order was not issued for professional services for this Agreement.

Purchase of Professional Services

UNM has procurement policies and procedures in place pertaining to contracts for goods and services exceeding certain thresholds. The Regents Policy Manual – Section 7.4: Purchasing (adopted on September 12, 1996) stated, “Contracts between $250,000 and $500,000 will be submitted to the Regents’ Finance and Facilities Committee for information.” The policy further stated, “The Regents shall authorize the execution of contracts for the purchase of goods and services in excess of $500,000 per year.” This policy was amended on 4/18/2014 to increase the threshold to $1,000,000. Although the research agreement was submitted to the Regents’ Finance and Facilities Committee on 10/4/2013 and authorized by the Board of Regents on 10/8/2013, funding was not in place for the project and clarification for funding source was not provided to the UNM Board of Regents.

The Mind Research Network also began scanning athletes for the Brain Safe project prior to the signed research agreement and approved purchase order. UNM Purchasing and Accounts Payable policies and procedures states, “A Purchase Order is the basic procurement contract issued to all off campus sources for goods and/or services. This document is a legal contract binding the University and the vendor. A Purchase Order provides details about the goods and/or services the University wishes to purchase including a description, price per unit, quantity being purchased and delivery date.” The policy further states, “Goods and/or services should NOT be rendered or solicited until a Purchase Order is approved and disseminated by the Purchasing department.”

Although an approved purchase order had not been issued, UNM received an invoice for $810,000 from MRN dated April 20, 2015 for professional services related to the Brain Safe project. See invoice at Exhibit 2.
Recommendation 1:

Internal Controls should be strengthened to ensure Purchasing and Accounts Payable policies and procedures are always followed for the purchase of goods or services. Goods and services should only be purchased with funding in place, established budgets, and approved purchase orders. The UNM President should work with the Executive Vice President for Administration, Provost/Executive Vice President for Academic Affairs, and HSC Chancellor to identify funding for UNM’s cost related to the Brain Safe project. A budget should then be established in a separate Banner index and an official approved purchase order should be issued for this Brain Safe Agreement.

Response from the UNM President:

<table>
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<tr>
<th>Action Items</th>
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<tbody>
<tr>
<td><strong>Targeted Completion Date:</strong> December 31, 2015</td>
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<tr>
<td><strong>Assigned to:</strong> Executive Vice President for Administration</td>
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<tr>
<td><strong>Corrective Action Planned:</strong> The Executive Vice President for Administration and Provost identified funding for UNM’s cost associated with the Brain Safe project. A DPI (#I1080573) was approved in Banner and payment processed through an approved DP-EZ (#DZ0695945) on December 22, 2015.</td>
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**Repayment Plan**

Recitals D of the signed Research Agreement indicates that “MRN has agreed to provide the services described in Exhibit A and cover the $500,000 annual costs associated with the services in exchange for the promise that the University agrees to repay MRN according to the repayment schedule in Exhibit A. The University agrees that repayment of the total cost of this agreement to MRN is not dependent on any outside funding.” The Repayment Plan noted in the Agreement further states, “MRN has agreed to provide the services described above and cover the $500,000 annual costs associated with the services in exchange for the promise that the University agrees to pay MRN back according to this repayment schedule. Any changes to the repayment schedule or alternative repayment agreements must be in writing signed by both parties.” Although the Brain Safe project was effective on August 5, 2013 and suspended on September 25, 2014, MRN billed UNM $310,000 for year two of the project. The amount calculated for year two is based on 124 scans. The Research Agreement does not indicate that MRN will bill UNM based on a number of scans.
Exhibit A of the Agreement provides the following payment terms for the University to MRN:

<table>
<thead>
<tr>
<th>Date</th>
<th>Amount</th>
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<tbody>
<tr>
<td>September 30, 2015</td>
<td>$250,000</td>
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<tr>
<td>December 31, 2015</td>
<td>$250,000</td>
</tr>
<tr>
<td>March 31, 2016</td>
<td>$250,000</td>
</tr>
<tr>
<td>June 30, 2016</td>
<td>$250,000</td>
</tr>
<tr>
<td>September 30, 2016</td>
<td>$250,000</td>
</tr>
<tr>
<td>December 31, 2016</td>
<td>$250,000</td>
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</table>

In the invoice submitted by MRN dated 4/20/15, net 30 payment terms is not consistent with the first scheduled quarterly payment specified in the Agreement. Although the invoice requires full payment of $810,000 by May 20, 2015, the signed Agreement indicates quarterly payments of $250,000 beginning on September 30, 2015.

**Deliverables**

The Research Agreement states, “Baseline behavioral, blood, and brain measures will be collected annually from 200 athletes. Any athletes who have a sports-related concussion during the season will receive additional behavioral, blood, and brain MRI data collection.” The Agreement does not indicate a time period when the project year begins and ends. Although the Agreement has an effective date of August 5, 2013, the scans billed for year one were from September 21, 2013 through June 1, 2014, and from June 2, 2014 through August 17, 2014 for year 2. The normal annual period would be based on a 12 month time frame for each annual time period, unless otherwise stated in the Agreement. MRN billed UNM $500,000 for year one based on 200 scans and $310,000 for year two based on 124 scans, as indicated on the invoice dated April 20, 2015. The Agreement does not indicate that UNM will be charged on a per scan basis. However, the Agreement states, “The University will pay $500,000 per year in relation to this project as outlined in the Repayment Plan terms. This is based on $5,000 per Athlete per year of which $2,500 will be paid by UNM and $2,500 by MRN.”

Internal Audit received a listing from MRN which included 246 participant identification numbers with a total of 326 scans. Internal Audit received a detailed listing of athletes and scans from UNM athletic physicians to whom was assigned to receive deliverables. Of the participants and scans on the MRN listing, Internal Audit was able to verify deliverables, by athletic program, of 97 athletes for a total of 100 scans (including 3 repeat scans). Internal Audit reviewed scans and reports prepared by MRN Radiologists and also noted the following for scans which UNM was billed:

- Reasoning for repeat scans could not be determined for participants that had multiple scans in the same year. A written protocol for repeat scans was not provided to Internal Audit.
- UNM was billed for three scans which did not have any data.
- Four participants were scanned in April 2014 for year one and then again in June 2014 (within 2 months) for year two.
- Two scans were taken for the same participant within a few minutes with the same results.

**Recommendation 2:**

Professional services agreements entered by UNM should provide a clear understanding between UNM and its vendor. Agreements should clearly state deliverables and billings to be received by UNM. Agreements should also clearly state the terms of the compensation if based on time-periods, price per unit, and/or both. This will reduce the risk of confusion when invoices are received. The University may consider paying approximately $242,500, based on verification of 97 athletes, on September 30, 2015, per the payment terms indicated in “Exhibit A of the agreement.

**Response from the Executive Vice President for Administration:**

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<td><strong>Targeted Completion Date:</strong> December 31, 2015</td>
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<tr>
<td><strong>Assigned to:</strong> Executive Vice President for Administration</td>
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<tr>
<td><strong>Corrective Action Planned:</strong> UNM entered into a settlement agreement on December 22, 2015 regarding the payment for services in the research agreements.</td>
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**Termination of Agreement**

Internal Audit noted that Section 2.2 of the Research Agreement states, “This agreement may be terminated by either of the parties hereto upon written notice delivered to the other party at least thirty (30) days prior to intended date of termination.” Although the Brain Safe project has been suspended indefinitely by the University’s Institutional Official, an official termination notice has not been submitted by UNM.

**Recommendation 3:**

The UNM President should submit a written termination notice to MRN for the research agreement dated October 29, 2013.
Response from the UNM President:

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<tr>
<td><strong>Targeted Completion Date:</strong> 12/31/2015</td>
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<tr>
<td><strong>Assigned to:</strong> Executive Vice President for Administration</td>
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<tr>
<td><strong>Corrective Action Planned:</strong> A settlement agreement regarding payment for services was entered into on December 22, 2015, and the Institutional Official has suspended the project indefinitely. These actions are sufficient in addressing the intent of this recommendation.</td>
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**Human Research**

UNM has policies and procedures in place pertaining to research on human subjects to ensure compliance with Federal Regulations related to research activity. UNM Faculty Handbook E90: Human Beings as Subjects in Research requires that any research conducted on human subjects must obtain approval from a Human Research Review Committee (HRRC) prior to conducting research on human subjects. This policy is in place to ensure UNM is in compliance with federal regulation 45 CFR 46: Human Subjects Research Governing the Protection of Human Subjects in Research. The Brain Safe project was not submitted to an HRRC for review and approval.

Internal Audit performed procedures to determine if activities conducted during the Brain Safe project were research related and would require HRRC approval. Internal Audit noted the following:

The Code of Federal Regulations at 45 CFR part 46.102(d) defines research as: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” UNM Faculty Handbook E90: Human Beings as Subjects in Research, Section 1a states:

“The dean of each school or college, or the chief administrative officer of each UNM division or agency involved in research of this type (human research), is directly responsible that a Human Research Review Committee exist to evaluate proposals which may come from her/his faculty or professional staff.

In carrying out this responsibility, the administrative officer may establish a Human Research Review Committee to serve his/her particular school, college or agency. Or, if deemed desirable and feasible, she/he may cooperate with another dean or administrative officer in setting up a joint committee to serve more than one group. (In any case, any proposed research involving human beings as subjects would have to be reviewed in advance by some Human Research Review Committee.)” Section 4 of the policy further states, “The investigator shall be...
responsible for obtaining approval from a Human Research Review Committee prior to conducting any research involving human subjects.”

The Board of Regents have designated an Institutional Official with respect to all human research conducted at or through the University. The Institutional Official’s obligations are to ensure that all activities that fall under the definitions of “human research” are conducted in accordance with the federal laws and regulations (45 CFR part 46), University policies (UNM Faculty Handbook E90), and ethical standards.

On August, 26, 2014, the Institutional Official formed an investigative committee (ad hoc committee) to determine any liability or risk assumed by the University arising out of/or related to the activities of the Brain Safe project. The ad hoc committee submitted its written report to the Institutional Official on September 15, 2014 and unanimously concluded that the activities conducted were “human research” related and recommended the project be submitted to the appropriate Institutional Review Board (IRB) for final determination. During the investigation, a UNM Physician stated in an interview, “Although of interest to the treating physician, baseline fMRI and post-concussion fMRI were clinically irrelevant for “return-to-play” decisions and to the best of his knowledge were being conducted for research purposes.”

Due to the potential issue of serious non-compliance with federal regulations 45 CFR part 46, the Institutional Official submitted a written notice to suspend the project immediately, as it posed a serious risk of adversely affecting the rights and welfare of the subjects. The Institutional Official filed a notice with the Office of Human Research Protection (OHRP), Department of Health and Human Services. Based on the findings of the ad hoc committee, the UNM Health Sciences Center Office of Research requested further investigation by an IRB since the project had bypassed the IRB process. An HRRC sub-committee was formed to conduct further investigation of the Brain Safe project to determine whether they were research related.

On March 10, 2015, the HRRC sub-committee presented their findings and recommendations to the fully convened HRRC. Based on the information submitted by the sub-committee, the HRRC confirmed that:

- The Brain Safe project was research involving human subjects as defined by the federal regulations at 45 CFR 46 and the project was conducted without HRRC review and approval
- Conduct of the Brain Safe project, without HRRC review and approval, presents serious non-compliance under the federal regulations and faculty handbook E90: Human Beings as Subjects in Research
- The non-compliance will be filed with the Office of Human Research Protection (OHRP) as required by 45 CFR 46.103 (b)(5)
- All research activity related to Brain Safe project should be suspended

45 CFR part 46 has criteria to ensure the protection of confidential data during research on human subjects. 46.111 (7): Criteria for IRB Approval states, “when applicable, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”
Recommendation 4:

The UNM President should work with the UNM Institutional Official (Chancellor for Health Sciences) and Provost/Executive Vice President for Academic Affairs to require MRN to securely transfer all data collected and results generated from the Brain Safe project to the University. MRN should be required to provide certification and assurance to the University that all data collected and results generated from the Brain Safe project have been securely deleted and are unrecoverable from their system(s), including personal and portable devices.

Response from the Chancellor for Health Sciences:

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<tr>
<td><strong>Targeted Completion Date:</strong> 12/31/2015</td>
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<td><strong>Assigned to:</strong> Chancellor for Health Sciences</td>
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<td><strong>Corrective Action Planned:</strong> On March 10, 2015, the HSC IRB determined that the conduct of the Brain Safe Project without IRB review and approval by MRN researcher Kent Kiehl, PhD, represented serious noncompliance with the federal regulations and UNM HSC Faculty Handbook Policy E90. The IRB determination of serious noncompliance was filed with OHRP on March 23, 2015. As a result of its investigation into the conduct of the Brain Safe Project, the IRB, in ensuring the protection of human subjects, required that The Mind Research Network (MRN) forfeit custody of any and all Brain Safe data to UNMHSC. MRN complied with the directive on July 27, 2015. Prior to taking this action, the IRB consulted with an outside firm whose expertise lies in human subjects research compliance. On July 6, 2015, they issued their report acknowledging the actions taken by the IRB, and confirmed that the corrective action suggested by the IRB, including the transfer of data custody from MRN to UNMHSC, was appropriate.</td>
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Recommendation 5:

Administration should review current policies, processes, and management controls to reduce the risk of non-compliance with federal regulation CFR 45 part 46: Human Subjects Research Governing the Protection of Human Subjects in Research and UNM Faculty Handbook E90: Human Beings as Subjects in Research.
**Response from the Chancellor for Health Sciences:**

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<td><strong>Targeted Completion Date:</strong> 12/31/2015</td>
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<td><strong>Assigned to:</strong> Chancellor for Health Sciences</td>
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**Corrective Action Planned:** As a result of the Brain Safe Project investigation and subsequent notice of serious noncompliance on behalf of the MRN researcher, the IRB conducted a thorough review of all IRB processes and procedures. The in-depth investigations conducted by the HSC Human Research Protections Office (HRPO), an ad-hoc investigative committee, and external IRB consultants each noted that HSC IRB current policies, processes, and management controls are adequate and appropriate to reduce the risk of non-compliance with federal regulation 45 C.F.R. part 46: Human Subjects Research Governing the Protection of Human Subjects in Research and UNM Faculty Handbook E90: Human Beings as Subjects in Research.

The shortcomings in the UNM process were not due to inadequate processes within the IRB, but rather the research agreement being executed despite clear direction by the HSC Vice Chancellor of Research indicating not to proceed with the agreement until clarification as to the status of the clinical trial and the need for IRB approval was determined.

On September 13, 2013, Dr. Larson notified Michael Dougher, Ph.D., UNM Vice President of Research, via email that it appeared the proposed Research Agreement did not conform to a previous legal settlement between MRN and UNM since there was noted concern regarding "clinical diagnostic scans," and the need for HSC Faculty to serve as PI for clinical trials. It was suggested that UNM legal should review the proposed Research Agreement prior to its execution. It is imperative that HSC faculty serve as PI on clinical trials since clinical faculty have the necessary expertise and it ensures patients are not referred to outside clinical care system.

On October 8, 2013, Dr. Larson notified Bruce Cherrin and Michael Dougher via email that if HSC Faculty were involved with the Brain Safe Project that the proposed Research Agreement would have to be amended. The Research Agreement should not have been accepted and signed since it was noted that HSC Faculty were involved in the Project, and it was determined that the Project was a clinical trial.

The Research Agreement was executed on October 28, 2013 without IRB approval or consistency with the legal settlement between UNM and MRN.

The HSC and the HRRC have a well-established Human Research Protections Program, being one of the first universities to achieve the prestigious accreditation status by AAHRPP. We have also contracted with external consultants on several occasions to have in-depth evaluation of our processes and procedures. We have been deemed by AAHRPP and external consultants as
having an exemplary program for the protections of human research participants.
Bruce Cherrin the UNM Purchasing Officer shall be contacted regarding controls that may be in place in purchasing to prevent this occurrence.

LEASE AGREEMENT

The Mind Research Network leases space in a building owned by UNM at 1101 Yale NE. On March 5, 2013 a Settlement Agreement and Release was entered between the UNM Board of Regents and the Mind Research Network. The purpose of the Agreement is to incorporate all terms of a written agreement dated November 16, 2012, and fully settle court actions and claims arising from prior agreements. Rent for the lease space occupied by MRN is paid to UNM HSC.

The terms of the current lease agreement requires MRN to pay rent of $16.50 per square foot for 2,801 square feet through June 30, 2016. After that, MRN’s space allocation will be recalculated and UNM will receive rent of $20.82 per square foot of lease space occupied. UNM HSC receives rental income for three categories, which include Old Lease Agreement – New Provisions ($3,851 monthly), New Construction Lease Renewal ($1,686), and New Construction Lease Maintenance ($3,695). Rental income collected by UNM HSC for FYs 2013-2015 was $131,788, $118,817, and $118,978. Internal Audit performed test work to ensure rent collected from MRN is in compliance with the terms of the settlement agreement and release signed on March 5, 2013, and rental payments are received in a timely manner. No exceptions were noted. The following graph presents rental income for FY’s 2013-2015.

UNM HSC Rental Income from MRN
FYs 2013-2015

Source: Banner Accounting System
MRN is responsible for its pro-rata share of leasehold operating costs, maintenance charges, and other costs associated with the building. MRN’s pro-rata share was calculated at 44% for FY 2014.

The signed lease agreement provides provisions regarding MRI and MEG scans. Beginning July 1, 2013 UNM HSC began paying MRN for MRI and MEG scans at a rate of $720 per scan. On July 1st of each year thereafter until June 30, 2016, the price per scan may be increased by 3%. During FY 2015, UNM HSC’s cost per MRI and MEG scan was $742 per scan.
APPROVALS

Manu Patel, CPA
Director, Internal Audit Department

Approved for Publication

Chair, Audit Committee