Rabbits at Barrow

David Michael Faguy

Tue 2/25/2020 9:29 AM

To [redacted]

Cc:Kimberley Cohen <Kimberley.Cohen@nau.edu>;

Importance: High

Hi [redacted]
The USDA is requesting information on the 5 rabbits we transferred to Barrow. We need to know the date of any surgeries on these rabbits and when these rabbits were shipped.
Your annual and final reports do not detail any transfers.
Please call my cell at [redacted] as soon as you can.

Thanks
David

David M. Faguy, Ph.D.
Assistant Vice-President for Research Compliance
Northern Arizona University

525 S. Beaver Street 4th Floor
Flagstaff, AZ
86011-4062

RE: Rabbit surgery at Barrow Neurological Institute

David Michael Faguy

Tue 2/25/2020 9:50 AM

To [redacted]

Cc [redacted] Tad Theimer <Tad.Theimer@nau.edu>; Kimberley Cohen <Kimberley.Cohen@nau.edu>;

Hello [redacted]
I was wondering if you had completed your investigation and could provide NAU with a final report.
I'm including our attending vet and IACUC chair on this.
Thanks for your help,
David

From: [redacted]>
Sent: Thursday, May 30, 2019 12:55 PM
To: David Michael Faguy <David.Faguy@nau.edu>
Cc: [redacted]
Subject: RE: Rabbit surgery at Barrow Neurological Institute

Dr. Faguy

I've included our IACUC Chair, [redacted] on this message. We are following up on the complaint. If there is any additional information you need from us, please do not hesitate to reach out to us. We will also inform you of the results of our investigation,

Sincerely,
[redacted]

[redacted]
Animal Care Program
Dignity Health
St. Joseph's Hospital and Medical Center
350 W. Thomas Rd.
Phoenix, Arizona 85013
[redacted]
F (602) 798-9914

"Kindness is difficult to give away because it keeps coming back." - Marcel Proust

---

From: [redacted]
Sent: Thursday, May 30, 2019 12:11 PM
To: David Michael Faguy
Cc: [redacted]
Subject: Re: Rabbit surgery at Barrow Neurological Institute

Dignityhealth.org made the following annotations

STOP, THINK, READ. This is an external email. Exercise extra caution responding to it, opening attachments and following links.

For the surgeries at BNI, the Co-PIs provided the aneurysm treatment device and delivered the device. The aneurysm model was surgically created and the delivery catheters were placed by the surgical team at BNI, all of whom are listed under the approved BNI animal protocol and followed the procedures also listed in the protocol.

The number "10" does not match the number of animals treated under the BAF grant. There were 8 animals used under this grant, all of which were performed between March and April 2019.

BNI's contact is [redacted] (cc'd here).

[redacted]

On May 30, 2019, at 9:05 AM, David Michael Faguy <David.Faguy@nau.edu> wrote:

Dear [redacted]
NAU has received an anonymous complaint concerning animal welfare during the course of collaborative research between BNI and NAU. I believe you are co-PIs on this research project.
The complaint alleges protocol violations and the unexpected death of 10 animals.
I would greatly appreciate any information you can provide on this research project and any information on this specific alleged incident.
Can you confirm that the project in question is A19-0094 (according to NAU's Sponsored Projects Office numbering); funded by the Brain Aneurysm Foundation? I believe the work in question was funded at BNI by NAU, as a result BNI and NAU share oversight.
Also, could you provide the name and contact information for the IACUC coordinator and/or Attending Veterinarian at Barrow?
I am copying our IACUC coordinator and chair on this correspondence.
Thanks for your help as we work to resolve this allegation.
David

David M. Faguy, Ph.D.
Assistant Vice-President for Research Compliance
Institutional Official for Animal Care and Use
Northern Arizona University

[redacted]

Mechanical Engineering (ME)
PI-Bioengineering Devices Lab (BDL)
College of Engineering, Informatics, and Applied Sciences (CEIAS)
Northern Arizona University (NAU)
Flagstaff, AZ 86011

[redacted]

Re: Rabbits at Barrow

[redacted]

Tue 2/25/2020 11:29 AM

To: David Michael Faguy <David.Faguy@nau.edu>;

Cc: Kimberley Cohen <Kimberley.Cohen@nau.edu>;

Importance: High

1 attachments (3 MB)

MTA-BNI-NAU-Fully Exec-061418.pdf;

Here's the executed animal transfer agreement with rabbit # details and transfer date. They were rabbit numbers 2002, 2003, 2005, 2008, 2009. They were originally received to NAU on 3/14/18. The elastase surgery to form aneurysms were done at NAU on 4/5/18 (2002, 2003, 2005, 2008) and 4/11/18 (2009). We decided not to treat them at NAU, so we executed the MTA (attached). I transported the rabbits to BNI on 7/10/18.

Call me if you need further info [redacted]).

[redacted]

On Feb 25, 2020, at 9:29 AM, David Michael Faguy <David.Faguy@nau.edu> wrote:

Hi [redacted]
The USDA is requesting information on the 5 rabbits we transferred to Barrow. We need to know the date of any surgeries on these rabbits and when these rabbits were shipped.
Your annual and final reports do not detail any transfers.
Please call my cell at [redacted] as soon as you can.

Thanks
David

David M. Faguy, Ph.D.
Assistant Vice-President for Research Compliance
Northern Arizona University

525 S. Beaver Street 4th Floor
Flagstaff, AZ
86011-4062

[redacted]
Mechanical Engineering (ME)
PI-Bioengineering Devices Lab (BDL)
Bioengineering Program
College of Engineering, Informatics, and Applied Sciences (CEIAS)
Northern Arizona University (NAU)

Flagstaff, AZ 86011
[redacted]
[redacted]

NORTHERN ARIZONA UNIVERSITY

Standard Material Transfer Agreement
Agreement No. M2018-0078

The Provider and Recipient identified below hereby agree to be bound by the terms set forth in the attached Exhibit A, and Exhibit B if applicable, to govern the transfer of the Original Material described herein.

■ If checked, this Agreement is also subject to additional terms and conditions set forth on the attached Exhibit B. In the event of a conflict between any specific terms or conditions in Exhibit A and Exhibit B, Exhibit B shall govern.

Provider (the organization providing the Original Material)	**Recipient** (the organization receiving the Original Material)
Name: The Arizona Board of Regents, for and on behalf of Northern Arizona University Address: 1395 South Knoles Drive Flagstaff, AZ 86011-4087	Name: Dignity Health d/b/a St. Joseph's Hospital and Medical Center Address: 350 West Thomas Road Phoenix, AZ 85013

Provider Scientist	**Recipient Scientist**
Name: [redacted] Title: Associate Professor of Practice Mechanical Engineering	Name: [redacted] Title: Director Neurosurgery Research

Original Material (description of the material being transferred)	**Shipping Address**
New Zealand White Rabbits (5 total, approx. 5kg each)	Name: [redacted] Address: St. Joseph's Hospital and Medical Center 350 W. Thomas Rd. Phoenix, AZ 85013

Provider Authorized Signatory	**Recipient Authorized Signatory**
[redacted]	[redacted]
Signature	
[redacted]	[redacted]
Print Name	Print Name
Vice President for Research	Executive Director
Title	Title
6/14/18	6-12-18
Date	Date

Exhibit A
Standard Terms

I. DEFINITIONS:

1. **Provider:** Organization providing the Original Material. The name and address of this party is specified on page 1 of this Agreement.

2. **Provider Scientist:** The name and address of this party is specified on page 1 of this Agreement.

3. **Recipient:** Organization receiving the Original Material. The name and address of this party is specified on page 1 of this Agreement.

4. **Recipient Scientist:** The name and address of this party is specified on page 1 of this Agreement.

5. **Original Material:** The description of the Material being transferred is specified on page 1 of this Agreement.

6. **Material:** Original Material, Progeny, and Unmodified Derivatives. The Material shall not include: (a) Modifications, or (b) other substances created by the Recipient through the use of the Material which are not Modifications, Progeny, or Unmodified Derivatives.

7. **Progeny:** Unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism.

8. **Unmodified Derivatives:** Substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Material. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Original Material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.

9. **Modifications:** Substances created by the Recipient which contain/incorporate the Material.

10. **Commercial Purposes:** The sale, lease, license, or other transfer of the Material or Modifications to a for-profit organization. Commercial Purposes shall also include uses of the Material or Modifications by any organization, including Recipient, to perform contract research, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Material or Modifications to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the Material or Modifications for Commercial Purposes per se, unless any of the above conditions of this definition are met.

11. **Nonprofit Organization(s):** A university or other institution of higher education or a not-for-profit organization officially recognized or qualified under the laws of the country in which it is organized or located, or any nonprofit scientific or educational organization qualified under a federal, state or local jurisdiction's nonprofit organization statute. As used herein, the term also includes national, state or local government agencies.

II. TERMS AND CONDITIONS OF THIS AGREEMENT:

1. The Provider retains ownership of the Material, including any Material contained or incorporated in Modifications.

2. The Recipient retains ownership of: (a) Modifications (except that, the Provider retains ownership rights to the Material included therein), and (b) those substances created through the use of the Material or Modifications, but which are not Progeny, Unmodified Derivatives or Modifications (i.e., do not contain the Original Material, Progeny, Unmodified Derivatives). If either 2 (a) or 2 (b)

results from the collaborative efforts of the Provider and the Recipient, joint ownership may be negotiated.

3. The Recipient and the Recipient Scientist agree that the Material:

   (a) is to be used solely for teaching and academic research purposes;

   (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Provider;

   (c) is to be used only at the Recipient organization and only in the Recipient Scientist laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision; and

   (d) will not be transferred to anyone else within the Recipient organization without the prior written consent of the Provider.

4. The Recipient and the Recipient Scientist agree to refer to the Provider any request for the Material from anyone other than those persons working under the Recipient Scientist's direct supervision. To the extent supplies are available, the Provider or the Provider Scientist agrees to make the Material available, under an agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at Nonprofit Organization(s)) who wish to replicate the Recipient Scientist's research; provided that such other scientists reimburse the Provider for any costs relating to the preparation and distribution of the Material.

5. (a) The Recipient and/or the Recipient Scientist shall have the right, without restriction, to distribute substances created by the Recipient through the use of the Original Material only if those substances are not Progeny, Unmodified Derivatives, or Modifications.

   (b) Under an agreement at least as protective of the Provider's rights as this Agreement, the Recipient may distribute Modifications to Nonprofit Organization(s) for research and teaching purposes only.

   (c) Without written consent from the Provider, the Recipient and/or the Recipient Scientist may NOT provide Modifications for Commercial Purposes. It is recognized by the Recipient that such Commercial Purposes may require a commercial license from the Provider and the Provider has no obligation to grant a commercial license to its ownership interest in the Material incorporated in the Modifications. Nothing in this paragraph, however, shall prevent the Recipient from granting commercial licenses under the Recipient's intellectual property rights claiming such Modifications, or methods of their manufacture or their use.

6. The Recipient acknowledges that the Material is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, including any altered forms of the Material made by the Provider. In particular, no express or implied licenses or other rights are provided to use the Material, Modifications, or any related patents of the Provider for Commercial Purposes.

7. If the Recipient desires to use or license the Material or Modifications for Commercial Purposes, the Recipient agrees, in advance of such use, to negotiate in good faith with the Provider to establish the terms of a commercial license. It is understood by the Recipient that the Provider shall have no obligation to grant such a license to the Recipient, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the Material to any third party(ies), subject to any pre-existing rights held by others.

8. The Recipient is free to file patent application(s) claiming inventions made by the Recipient through the use of the Material but agrees to notify the Provider upon filing a United States Provisional, Non-Provisional, or PCT patent application claiming Modifications or method(s) of manufacture or use(s) of the Material.

9. Any Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Material by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.

11. This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the Material or the Modifications. The Recipient Scientist agrees to provide appropriate acknowledgement of the source of the Material in all publications.

12. The Recipient agrees to use the Material in compliance with all applicable statutes and governmental regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

13. This Agreement will terminate on the earliest of the following dates: (a) on completion of the Recipient's current research with the Material, or (b) on thirty (30) days written notice by either party to the other, or (c) on the date specified in Exhibit B, provided that:

    (i) if termination should occur under 13(a) or (c) above, the Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications;

    and

    (ii) in the event the Provider terminates this Agreement under 13(b) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the Provider will defer the effective date of termination for a period of up to one year, upon request from the Recipient, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications.

14. Paragraphs 6, 9, and 10 shall survive termination.

Exhibit B
Optional Terms

If checked, the following terms apply to this Agreement:

☐ This Agreement shall terminate on . Upon termination, the Recipient will either destroy any remaining Material or return it to the Provider, as directed by the Provider.

☐ A transmittal fee of shall be paid by Recipient to Provider, for preparation and distribution costs.

■ The Recipient intends to use the Material for purposes including but not limited to those described below:

Rabbits in which carotid aneurysms have been surgically created by [redacted] and are scheduled for endovascular obliteration using techniques developed at the BNI Neurosurgery Research Laboratory under [redacted] of the BNI Neurosurgery Dept. [redacted] veterinarian chief of BNI-SJMHC is aware of the study. This study is part of long-standing collaborations in development of endovascular biomaterials and procedures between Northern Arizona University and BNI for years. This project results will be submitted as basis for upcoming grants and is already in formation as articles for publications.

☐ To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about the Material that is stamped "Confidential" ("Confidential Information"). Any oral disclosures from Provider to Recipient shall be identified as being Confidential Information by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Confidential Information does not include information that:

a. has been published or is otherwise publicly available at the time of disclosure to the Recipient;

b. was in the possession of or was readily available to the Recipient without being subject to a confidentiality obligation from another source prior to the disclosure;

c. has become publicly known, by publication or otherwise, not due to any unauthorized act of the Recipient;

d. Recipient can demonstrate it developed independently, or acquired without reference to or reliance upon Confidential Information; or

e. is required to be disclosed by law, regulation, or court order.

■ Additional binding terms: NIH Animal Transfer Terms

- Recipient agrees to use the animal(s) solely in connection with biomedical or behavioral research.
- Relevant documents concerning the medical history, health status, and research uses of the animal(s), including prior surgical procedures and any infectious disease (human or zoonotic) to which the animal(s) may have been exposed, are attached to this agreement.
- For domestic recipients, recipient agrees that it will comply with the Animal Welfare Act and its implementing regulations, as applicable. Recipient agrees that it will adhere to all applicable national standards for humane care and use of the animal(s), and assures the Provider that it has appropriate animal care and use policies in place. The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" and the "Guide for Care and Use of Laboratory Animals" are examples of acceptable standards for humane care and use of research animals.
- Recipient agrees that it will adhere to appropriate biosafety practices and use the animals in a

safe and responsible manner. The National Institutes of Health/Centers for Disease Control publication "Biosafety in Microbiological and Biomedical Laboratories" is an example of acceptable standards for biosafety practices. Recipient agrees that it will comply with applicable import/export regulations.

- In accepting the animal(s), recipient accepts full ownership, custody, and control of the animal(s), except that to the extent the Government has any patent, invention or any other intellectual property rights in the animal(s), the Government retains these rights. Additionally, to the extent that any party other than the Government has any patent, invention or other intellectual property rights in the animal(s), these rights are not transferred to the recipient.
- Provider is transferring the animal(s) as a service to the research community. The animal(s) is transferred to the Recipient with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Unless prohibited by law from doing so, Recipient agrees to hold the United States Government harmless and to indemnify the Government from all liabilities, demands, damages, expenses and losses arising out of Recipient's care, use, or treatment of the animal(s).
- Recipient agrees not to claim, infer, or imply Governmental endorsement of the Recipient, the research project, the institution or personnel conducting the research, or any resulting product(s).
- The undersigned Provider and Recipient expressly certify and affirm that they are authorized to sign this agreement on behalf of their respective institutions, and that the statements made herein are truthful and accurate.

Transfer of New Zealand white rabbits
5 rabbits (ear tag #s: 2002, 2003, 2005, 2008, 2009)

Transferred by:

[redacted] _ 7/10/18

Northern Arizona University

Becker

Rabbit [redacted]

Post Surgical Monitoring

Northern Arizona University- Biological Sciences Annex

VETERINARY RECORD- SMALL ANIMAL

Animal ID/	Species	PI	Cage #	Treatment/Route	Comments	Initials
2002 4/6	Rabbit	[redacted]		SQ 0.9 saline 200cc	not drinking much admin saline SQ SQ Bupe < 0.05 mg/kg 0810 " " 1810	[redacted]
2003 4/6	↓	↓		SQ 0.9% saline 200cc -	not drinking much, mild dehydration Buprenorphine < 0.05 mg/kg 0800 0.05 mg/kg 1500	
2008 4/6					Eating/drinking normally Bupe < " " 0830 " " 1530	
2005 4/7					eating/drinking okay mild decrease activity SQ Bupe < 0800 1500	
2009 4/12					normal eating drinking Buprenorphine < 0815 1700	

Animal ID/	Species	PI	Cage #	Treatment/Route	Comments	Initials
~~02~~	Rabbit	[redacted]				[redacted]
02 4/7	↓	↓			surgical incision dry intact, eating/drinking normal SQ Bupe 0900, 1700	
03 4/7					" " eating/drinking mild depression Bupe 0910, 1710	
08 4/~~8~~7					" "	
2005 4/~~8~~					incision D/I mild decrease energy, eating/drinking ok SQ Bupe 0830, 1710	
2009 4/13 ~~4/12~~					incision D/I eating/drinking normal SQ Bupe 0830, 1740	

Animal ID/	Species	PI	Cage #	Treatment/Route	Comments	Initials
02 4/8	Rabbit	[redacted]			surgical incision dry/intact no tx. no more monitor	[redacted]
03 4/8	↓	↓			dry/intact normal behavior - no more monitor	
08 4/8					dry/intact release from monitor	
05 4/9					incision dry intact no monitor	
09 4/14	↓	↓			incision dry intact no monitor	

Northern Arizona University- Biological Sciences Annex
SMALL ANIMAL ANESTHESIA RECORD

Animal ID/PI	Date	Species	Time of Induction	Time of Recovery	Anesthesia Agent/Dose	Route	Toe Pinch Absent- every 15 minutes					Comments	Initials
2002	4/5/18	Rabbit	0930	1030	Ketamine Xylazine ACE	IM	☐ 45	☑ 60	☐ 15	☑ 30	☐	Anesthesia Sx. awake at 1040	BAR at 1800 PM check BAR 11:00 Bupe SNV
Weight 4.3 kg					1.5 ml		☐	☐	☐	☐	☐	normal recovery	
2003	4/5/18	" "	1100	1215	Ketamine Xyl/ACE		☑ 15	☑ 30	☑ 45	☑ 00	☑ 15	BAR @ 1300 PM ✓ SNV ok	
Weight 4.4 kg					1.5 ml		☐	☐	☐	☐	☐		
2008	4/5/18		1415	1310	Ketamine Xylazine/Ace		☑ 30	☑ 45	☑ 00	☐ 15	☐	BAR at 1500	
Weight 4.1 kg					1.5 ml		☐	☐	☐	☐	☐		

Post-Surgical Monitoring

Animal ID/PI	Date	Time	Incision site: Dry and intact	Incision site: Other (describe)	Posture: Hunched	Posture: Normal posture	Activity: Normal activity	Activity: De-creased activity	Activity: Inactive	Comments	Initials
2002	4/6	0740	☑		☐	☑	☐	☑	☐	Admin 30cc SG 0.9 NaCl IL not observed to be drinking	
	4/7	915	☑		☐	☑	☐	☑	☐	"	
2003	4/6/18	0740	☒		☑ mild	☐	☐	☑	☐	Post Sx. recovery normal slight decrease in activity	
	4/7	915	☑		☐	☐	☑	☐	☐	Eating / drinking ok	
2008	4/6	0740	☒		☐	☑	☐	☑	☐		
	4/7	915	☒		☐	☑	☑	☐	☐		

Analgesics

Animal ID/PI	Date	Time	Analgesic	Dose (mg), route	Initials
2002	4/5	1030	Buprenorphine	.05 mg/kg IM	SNV
	4/6		Buprenorphine	" "	SNV
2003	4.5	1235	"	" "	
	4/6		"	BPC 0.05 mg/kg	SNV
2008	4.5	1500	"		
	4/6		Buprenorphine	.05 mg/kg	

Suture, staple, wound clip removal

Animal ID	Date
None removed - internal sutures	

4/5 Bupe #2002 PM

Northern Arizona University- Biological Sciences Annex
SMALL ANIMAL ANESTHESIA RECORD

Anesthetic Mix 10 ml 100 mg/ml ketamine
1.4 ml 100 mg/ml xylazine
2.0 ml 20 mg/ml Dexmedetomidine

0.3 → 0.5 ml/kg

Animal ID/PI	Date	Species	Time of Induction	Time of Recovery	Anesthesia Agent/Dose	Route	Toe Pinch Absent- every 15 minutes					Comments	Initials
2005	4.6 2018	[redacted] rabbit	0915	1030	Ketamine Xylazine Acepro 1.5 ml	IM	☐ 30	☐ 45	☐ 00	☐ 15	☐	Base 11 AM ✓ 1900 SBV calm,	[redacted]
Weight 4.6 kg							☐	☐	☐	☐	☐		
							☐	☐	☐	☐	☐		
2009	4/11	[redacted] rabbit	1000	1115	ketamine Xylazine/Ace 1.5ml	IM	☒ 15	☒ 30	☒ 45	☒ 00	☒ 15	Waking up @ 1130 PM check 1900 normal	
weight 4.4kg							☐	☐	☐	☐	☐		
							☐	☐	☐	☐	☐		

2018

Post-Surgical Monitoring

Animal ID/PI	Date	Time	Incision site: Dry and intact	Incision site: Other (describe)	Posture: Hunched	Posture: Normal posture	Activity: Normal activity	Activity: De-creased activity	Activity: Inactive	Comments	Initials
2005 [redacted]	4/7	0750	☑	OK	☐	☑	☐	☐	☐	mild decrease in activity observed to be eating/drinking. PM ✓ normal 7pm	[redacted]
	4/8	0810	☑	OK	☐	☑	☐	☐	☐	normal eating/drinking	
			☐		☐	☐	☐	☐	☐		
2009 [redacted]	2018 4.12	0900	☐	minor some scraping	☐	☑	☐	☑	☐	mild decrease, not at front of cage as usual PM ✓ normal	
	4.13		☐		☐	☑	☑	☐	☐	normal eating + drinking	
			☐		☐	☐	☐	☐	☐		

Analgesics

Animal ID/PI	Date	Time	Analgesic	Dose (mg), route	Initials
2005			incision infiltrated w/ marcaine topical & skin ID		[redacted]
2009			Marcaine topical at incision		

Suture, staple, wound clip removal

Animal ID	Date

* Bupivacaine at accessite use in future

RE: Rabbit surgery at Barrow Neurological Institute

[redacted]

Tue 2/25/2020 12:35 PM

To: David Michael Faguy <David.Faguy@nau.edu>;

Cc: Tad Theimer <Tad.Theimer@nau.edu>; Kimberley Cohen <Kimberley.Cohen@nau.edu>;

1 attachments (278 KB)

543 Rabbit Investigation Report 8.5.19 Redacted.pdf;

Hello Dr. Faguy

I've attached a redacted copy of our investigation report that went to our IO, since you guys fall under the sunshine laws. If you have any questions regarding our findings, please do not hesitate to call me.

Sincerely,

[redacted]
Animal Care Program
Dignity Health
St. Joseph's Hospital and Medical Center
350 W. Thomas Rd.
Phoenix, Arizona 85013
[redacted]
F (602) 798-9914

"Kindness is difficult to give away because it keeps coming back." - Marcel Proust

---

From: David Michael Faguy [mailto:David.Faguy@nau.edu]
Sent: Tuesday, February 25, 2020 9:51 AM
To: [redacted]
Cc: [redacted]; Tad Theimer; Kimberley Cohen
Subject: RE: Rabbit surgery at Barrow Neurological Institute

Dignityhealth.org made the following annotations

STOP, THINK, READ. This is an external email. Exercise extra caution responding to it, opening attachments and following links.

Hello [redacted]
I was wondering if you had completed your investigation and could provide NAU with a final report.
I'm including our attending vet and IACUC chair on this.
Thanks for your help,
David

From: [redacted]
Sent: Thursday, May 30, 2019 12:55 PM
To: David Michael Faguy <David.Faguy@nau.edu>
Cc: [redacted]
Subject: RE: Rabbit surgery at Barrow Neurological Institute

Dr. Faguy

I've included our IACUC Chair, Dr. Tom Hamm on this message. We are following up on the complaint. If there is any additional information you need from us, please do not hesitate to reach out to us. We will also inform you of the results of our investigation,

Sincerely,

[redacted]

Animal Care Program
Dignity Health
St. Joseph's Hospital and Medical Center
350 W. Thomas Rd.
Phoenix, Arizona 85013
P (602) 406-4003
F (602) 798-9914

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From: [redacted]
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STOP, THINK, READ. This is an external email. Exercise extra caution responding to it, opening attachments and following links.

For the surgeries at BNI, the Co-PIs provided the aneurysm treatment device and delivered the device. The aneurysm model was surgically created and the delivery catheters were placed by the surgical team at BNI, all of whom are listed under the approved BNI animal protocol and followed the procedures also listed in the protocol.

The number "10" does not match the number of animals treated under the BAF grant. There were 8 animals used under this grant, all of which were performed between March and April 2019.

BNI's contact is [redacted]

[redacted]

On May 30, 2019, at 9:05 AM, David Michael Faguy <David.Faguy@nau.edu> wrote:

Dear [redacted],
NAU has received an anonymous complaint concerning animal welfare during the course of collaborative research between BNI and NAU. I believe you are co-PIs on this research project.
The complaint alleges protocol violations and the unexpected death of 10 animals
I would greatly appreciate any information you can provide on this research project and any information on this specific alleged incident.
Can you confirm that the project in question is A19-0094 (according to NAU's Sponsored Projects Office numbering); funded by the Brain Aneurysm Foundation? I believe the work in question was funded at BNI by NAU, as a result BNI and NAU share oversight.
Also, could you provide the name and contact information for the IACUC coordinator and/or Attending Veterinarian at Barrow?
I am copying our IACUC coordinator and chair on this correspondence
Thanks for your help as we work to resolve this allegation.
David

David M Faguy, Ph D
Assistant Vice-President for Research Compliance
Institutional Official for Animal Care and Use
Northern Arizona University

[redacted]
Mechanical Engineering (ME)
PI-Bioengineering Devices Lab (BDL)
College of Engineering, Informatics, and Applied Sciences (CEIAS)
Northern Arizona University (NAU)
Flagstaff, AZ 86011
[redacted]

BARROW
Neurological Institute

Dignity Health.
St. Joseph's Hospital and Medical Center

August 5, 2019

Ph.D.
Chairman, Department of Neurobiology
Interim Chief Scientific Officer, Barrow Neurological Institute
Institutional Official, St. Joseph's Hospital and Medical Center

Dear Dr. ,

The Institutional Animal Care and Use Committee at St. Joseph's Hospital and Medical Center (IACUC) met on July 10, 2019 to conduct an investigation prompted by an anonymous complaint forwarded to the IACUCs from the University of Arizona and Northern Arizona University. The complaint stated several concerns regarding a failed research project using rabbits that had been conducted in the Department of Neurosurgery Research (NSR) at Barrow Neurological Institute of St. Joseph's Hospital and Medical Center. This study was conducted in collaboration with a laboratory at Northern Arizona University. The items of the complaint are as follows.

1. The project did not closely follow protocol, in particular "some animals did not receive medication as stated in protocol or Heparin...."

2. The person conducting the surgery was not a surgeon ... "and was rough and negligent with rabbits..."

3. Statements of concern that some rabbits where in pain were ignored.

4. All rabbits in the study died when the study should have been successful based on the success of studies at Mayo Clinic.

This report will summarize the resources used in the investigation, a brief description of the project, an evaluation of each item of the complaint, problems identified in the investigation, and actions and recommendations of the IACUC in consequence of this investigation. This report has been reviewed by all members of the IACUC, each of whom has indicated his or her approval.

Resources used in the investigation

Information was gathered from the following resources: interviews with participants in the study and Animal Care personnel; review of medical records; and review of emails between NSR, the Attending and Clinical Veterinarians, and the Veterinary Technician in Animal Care. Some published papers on rabbit aneurysm models were also reviewed.

Interviews were conducted in June, 2019, starting the week of June 3 and concluding on June 27. The interviews were conducted by the Attending Veterinarian, and me. All members of the NSR lab who participated throughout the project were interviewed, including the Director of NSR, Dr. We also interviewed Dr. , director of the participating lab at NAU, and a graduate student working with Dr. Also interviewed were the Clinical Veterinarian of the Animal

Care Program, Dr. , and the veterinary technician involved in postoperative care of the rabbits used in this study. Interviews were conducted with the promise of confidentiality to promote frank responses.

Dr. and I reviewed medical records for all rabbits used in study, and I reviewed email related to the project.

Information gathered from the interviews, medical records and emails were summarized and presented to members of the IACUC at the meeting on July 10 for discussion and deliberation. Notes from the interviews, medical records and emails were available to IACUC members.

Summary of the Project

The goal of the project was to optimize a new medical device for the treatment of aneurysms. The medical device utilizes a biocompatible liquid embolic polymer. This device was tested in a rabbit model of aneurysms. This study required two surgical procedures. The first procedure was to create the aneurysm by injecting elastase near the base of a common carotid artery while blood flow through the vessel was occluded by inflation of a balloon. Following a recovery period of 21 days or more during which the aneurysm was expected to form, a second surgical procedure was performed to treat the aneurysm with the device. In this second procedure, a guide catheter was inserted into the femoral artery and guided to the site of the aneurysm. A pair of smaller catheters were inserted through the guide catheter, one to inject the polymer, and a second balloon catheter to block blood flow until the polymer set.

Thirteen rabbits were used in this project. The first procedure (aneurysm formation) was performed at NAU in the first five rabbits. These were transported to Phoenix for the second procedure (treatment) in NSR. Both procedures were performed in NSR in the remaining eight rabbits.

One rabbit in the second group was euthanized by order of the Clinical Veterinarian following the first procedure; all other rabbits had good recoveries. Seven of the twelve rabbits used in the second procedure were euthanized during the procedure; two of the twelve suffered cardiac arrest near the end of procedure 2; three of the twelve recovered sufficiently from procedure 2 for return to animal housing in the Vivarium but died within a day or two following the procedure.

Evaluation of Items in Complaint

1. *The project did not closely follow protocol, in particular "some animals did not receive medication as stated in protocol or Heparin...."*

Medical records, including records made during procedures and records for postoperative care made by NSR and Animal Care, were reviewed for consistency of procedures and compliance with protocol. Interviews confirmed that observations and events were recorded at the time they occurred, indicating the reliability of the records. Anesthetic agents, analgesics and antibiotics were administered consistently in both the first and second procedures in accordance with the IACUC-approved protocol.

Several anti-coagulants were administered to the rabbits, heparin during the procedures, and aspirin and Plavix following the procedure. These medications were administered consistently to all rabbits following the second procedure and in all but two rabbits following the first procedure. In these two rabbits, the administration of heparin was not recorded during the first procedure. One of these rabbits

was subsequently used in the second procedure, the other did not recover well from the first procedure and was euthanized by direction of the Clinical Veterinarian. Both rabbits were given aspirin and Plavix postoperatively.

It is possible that the apparent failure to administer heparin to the one rabbit contributed to its difficult recovery, although the observations and directions for treatment of the Clinical Veterinarian indicate several factors contributed to the difficult recovery. Aside from this one case, there was no evidence that failure to follow protocol contributed to the failures in this project, and in nearly all cases procedures were followed and drugs administered as planned.

The use of anticoagulants was indicated by the vascular procedures performed in this study, and email records demonstrate coordination and agreement between NSR and the Veterinarians and Veterinary Technician regarding their use and administration. However, these drugs were not included in the protocol reviewed and approved by the IACUC. Although their use was necessary, appropriate and justified for purpose of the study and veterinary care, their use should have received IACUC review and approval.

2. *The person conducting the surgery was not a surgeon ... "and was rough and negligent with rabbits..."*

Nearly all surgical procedures in NSR were performed by the department's Clinical Coordinator. (A BNI faculty neurosurgeon performed polymer injections in three cases). Although he does not have formal surgical training as a physician or veterinarian, he has more than thirty years' experience in surgical procedures under the direction of BNI neurosurgeons. Moreover, he has extensive experience working with rabbits and with experimental vascular procedures including various animal models of vascular malformations such as aneurysms. The IACUC had reviewed and approved his participation in this study.

Interviews with most persons involved with the study included questions regarding the performance of surgery. No problems were noted except by one individual who stated that it seemed that mistakes were made but could not identify them.

The IACUC did not find support for this concern.

3. *Statements of concern that some rabbits where in pain were ignored.*

Interviewees stated that concerns about rabbits during recovery from surgical procedures had been expressed in some cases. These statements were typically met with a statement that the recovery was typical for rabbits following such procedures. Such statements were made by the NSR Clinical Coordinator as authoritative with the apparent expectation that his judgment would be sufficient to address the concern. Based on the conducted interviews, this was not always the case.

IACUC members were concerned that rabbits in this project may not have received adequate assessment of and treatment for pain based on this item in the complaint. This possibility was investigated by review of medical records and interviews with the Clinical Veterinarian and Veterinary Technician. Records of anesthesia, analgesia and vital signs during procedures were consistent with maintenance of adequate surgical anesthesia throughout. Consistent administration of a slow-release formulation of an analgesic would also be consistent with effective pain management.

However, postoperative care records kept by NSR were unsatisfactory in many cases. In some, only the times of arrival in the recovery room and departure for the Animal Care facility were recorded. Such records did not document observations or supportive care. The IACUC found the failure to adequately record postoperative care to be unsatisfactory and a serious concern.

The Clinical Veterinarian and the Veterinary Technician stated in interviews that their observations of rabbits following procedures did not suffer unacceptable levels of pain and that pain management was satisfactory. Their judgment in these interviews is supported by the records of IACUC-approved analgesia administration and records of postoperative care maintained by Animal Care. However, also based on their statements, medical records and prescribed treatments, and the failed recovery of four rabbits postoperatively, some rabbits suffered significant physiological distress.

Interviews of NSR staff members included questions regarding signs of pain in rabbits and their knowledge of the protocol, prompted by the first and third items in the complaint. The duties of these staff members were varied, but generally required less knowledge, and their work was directed by Dr. and the NSR Clinical Coordinator. Their knowledge of signs of pain in rabbits was rudimentary. The primary responsibility for pain assessment was assumed by Dr. and the Clinical Coordinator in NSR, and by the Clinical Veterinarian and Veterinary Technician in Animal Care. However, this limited knowledge, coupled with evident physiological distress in the cases of four rabbits that failed to recover from surgical procedures, likely contributed to concerns regarding postoperative pain.

Other concerns about the preparation of the NSR staff arose from the interviews and the medical records. Staff members were provided access to the protocol on relatively short notice (one or two days before, reportedly), such that time required for preparation left little time for thorough familiarization with the protocol and procedures. Furthermore, the inadequate postoperative records of NSR, maintained in large part by these NSR staff members, suggests that elements of training, for postoperative care and/or record keeping, in addition to pain assessment in rabbits, was insufficient or ineffective.

4. *All rabbits in the study died when the study should have been successful based on the success of studies at Mayo Clinic.*

The rabbit model for aneurysms has been employed at other institutions, including Mayo Clinic, Rochester, which has published several publications with this model. The prominence of this work, and the benefit of using a model that may be widely adapted for this work, was a factor in its use in this study, particularly for Dr. . Survival in animals for the first procedure to create the aneurysm in NSR was comparable to published studies.

The project conducted in NSR differed in one significant aspect from the published studies. Application of the polymer device required the use of two 2 Fr catheters, a balloon catheter for vessel occlusion and a catheter for injecting the polymer. These catheters were guided to the aneurysm site using a 6 Fr (2 mm diameter) guide catheter. The number of catheters and the size of the guide catheter are larger than used in other studies. The use of two small catheters and a larger-than-usual guide catheter are required for application of the polymer device under investigation in this study, but the relatively small vessels in the rabbit arterial system was a challenge for applying this particular device. At the least, some participants stated that the time required to insert and position the catheters satisfactorily before polymer injection was prolonged, possibly complicating the recovery process and survival. The

investigators were particularly concerned regarding the size of the rabbit arterial system compared to that of the required catheters. With the failure of the study the investigators have abandoned the rabbit model and will test the device in larger animal models.

Seven of the rabbits were euthanized in the operating room. The reasons stated for euthanasia were given as failure to form an aneurysm of suitable form for testing or physiological distress (while under anesthesia). These reasons were stated during interview but were not included in the medical records. The IACUC found this omission to be another deficit in the record keeping by NSR.

The medical records also indicated the intention to conduct necropsies in some cases, but records did not include results of the autopsies and Animal Care was not involved. Based on the interviews, the NSR Clinical Coordinator collected portions of the arterial trees and provided them to Dr. for examination. These samples were examined for evidence of device failure and some histological samples were collected. These examinations were not conducted to determine cause of death, aside from possible contribution of device failure, which were not observed. The failure to conduct necropsies by an independent party (i.e., not directly involved in the study) in the four cases of unexpected death is considered by the IACUC to be a deficit in this project. The absence of a clear IACUC-approved policy and guidelines on necropsies following unexpected deaths is considered to be a contributing factor to this deficit.

The failure of this project is very likely attributable to the greater level of difficulty posed by application of the experimental device to an animal the size of the rabbit, rather than malpractice by NSR, although definitive conclusion cannot be made in the absence of satisfactory necropsies to determine cause of death in the four unexpected deaths. Survival following the first procedure was comparable to published studies from other institutions. The use of larger animal models for testing the device is indicated. While failure of the project probably can be attributed to the problems with the animal model chosen, deficiencies were noted in the failure to record reason for euthanasia, failure to conduct suitable necropsies following unexpected deaths, and lack of suitable IACUC-approved policy and guidelines on necropsies following unexpected deaths.

Identified Problems; Responding Actions and Recommendations

The IACUC found that the concerns expressed in the complaint were largely unfounded. However, the investigation identified several items of concern for the IACUC.

1. *The use of anti-coagulant drugs did not receive IACUC review and approval.*

All investigators will be reminded that use of drugs and medications in animal use studies require IACUC review and approval before use. As part of this reminder, investigators will be encouraged to consult with the Clinical Veterinarian regarding the use of veterinary drugs during protocol development. While all veterinary drug use in each protocol is reviewed by a veterinarian as part of protocol review, this provision will facilitate timely review and approval and protocol completeness. Veterinarians consulted on drug use for approved protocols will confirm inclusion of drug in approved protocol and will direct investigator to submit a protocol amendment if drug has not been approved previously.

2. *Failure to properly maintain records of postoperative care by NSR from the end of surgery until the return to the Vivarium.*

Requirements for postoperative care and record maintenance have been updated in the Animal Care Program's Policy on Surgical Standards and Guidelines. Following review by the IACUC, the final IACUC-approved version will be distributed to all investigators. Also, the Policy on Surgical Standards and Guidelines will be made available to all laboratory staff members engaged in survival surgery with lab animals, e.g., in My Journey. All personnel involved in the conduct of survival surgery will be required to review this policy before protocol approval.

Labs that maintain procedure records off-line for contemporaneous recording of events, procedures and observations during surgery and postoperative recovery before transfer to the Vivarium will be required to submit scanned copies of the records to the Clinical Veterinarian in addition to the Surgical and Postoperative Record that is entered online subsequent to surgery. These records will be subject to review by the Clinical Veterinarian. Procedure records as well as Surgical and Postoperative records must be accessible to the IACUC for review during facility inspections and program reviews.

3. *Ineffective training for staff in pain assessment, postoperative care, postoperative care records, study procedures and protocol.*

Following required training on Surgical Standards and Guidelines, as described in the previous section, and currently required species-specific CITI training, staff members of labs that conduct projects requiring survival surgery will meet with the Clinical Veterinarian (or Attending Veterinarian) for review and counseling regarding pain assessment, postoperative care and record keeping. Each new employee and volunteer in labs conducting survival surgery is to receive this counseling. This meeting will also be held for lab members before work with a new species is started.

Each employee and volunteer working in a lab that conducts research with lab animals should be encouraged to express concerns. Ideally such concerns can be addressed by the Investigator or senior staff within the lab. If concerns are not satisfied, however, each individual should have the opportunity to consult with the veterinary staff regarding his or her concerns. This consultation should be conducted expeditiously but in a manner that does not disrupt work in the laboratory. However, if a consultation regarding the health or welfare of an animal cannot be conducted without causing an interruption in lab work, the consultation will take precedent in order to ensure the health and welfare of the animal(s). The Clinical or Attending Veterinarian will advise employees and volunteers of their access to such consultation during the counseling described in the previous paragraph.

Protocols should be submitted not only in sufficient time for IACUC review and approval but also with sufficient time so that staff members have sufficient time to familiarize themselves with the protocol and procedures to be used in the protocol.

The IACUC recommends that you arrange a meeting with Drs., and to discuss the implementation of these measures for studies conducted by Neurosurgery Research.

4. *Failure to document reason for euthanasia in records.*

Surgical record keeping must conform to the Policy on Surgical Standards and Guidelines discussed above. Accordingly, procedure and surgical records should document reasons for euthanasia and other

significant events and decisions made during the course of surgery and recovery as outlined in this policy. Investigators and their staffs will be trained as noted previously, and adherence to these record-keeping standards will be reviewed by the Clinical and Attending Veterinarians and by the IACUC during facility inspections.

5. *Lack of IACUC-approved policy and guidelines for conducting necropsies following unexpected deaths.*

A policy will be developed by the Attending and Clinical Veterinarian on necropsy following unexpected deaths. This policy will be reviewed, modified if necessary, and approved by the IACUC before implementation. The policy will be distributed to investigators and made available to staff members of labs conducting research with lab animals, e.g., in My Journey. All Investigators and staff with protocols requiring survival surgery will be required to review this policy before protocol approval.

Sincerely,

[redacted]

, Ph.D.
Professor, Department of Neurobiology
Chair, Institutional Animal Care and Use Committee

RE: Rabbit Investigation

David Michael Faguy

Wed 2/26/2020 7:39 AM

To [redacted]

Cc:Kimberley Cohen <Kimberley.Cohen@nau.edu>;

Hi [redacted]
I was mistaken. NAU did perform the first surgery and then transported the 5 rabbits to Barrow. The rabbits underwent surgery to create the aneurysm model on 4/5/18 and 4/11/18. In late June, NAU did not have the surgical expertise for the second surgery available so the animals were transferred by an NAU employee to Barrow on 7/10/18.
I'm sorry for the confusion. Please let me know if we can provide any more information.
David

From: David Michael Faguy
Sent: Tuesday, February 25, 2020 9:25 AM
To: [redacted]
Cc: Kimberley Cohen <Kimberley.Cohen@nau.edu>
Subject: RE: Rabbit Investigation

Hi [redacted]
I'm sorry for the delay. Our IACUC chair and coordinator were out of town until today. I still haven't talked with the PI.
We did have 5 rabbits here until July 9, 2018.
We will get you more information by the end of today, or at the latest tomorrow.
I'm also copying our new Attending Vet – Kimberley Cohen, she started last week.
Thanks
David

From: [redacted]>
Sent: Tuesday, February 25, 2020 8:07 AM
To: David Michael Faguy <David.Faguy@nau.edu>
Subject: Rabbit Investigation

David,

Were you able to find the information regarding the rabbits that were sent to Dignity Health? In the report it is stating that NAU sent 5 rabbits after doing the 1st procedure of the study (aneurysm formation). I am wondering why the rabbits were transported after having this procedure. Why wasn't the entire study just done at Dignity Health?

I need to know the date of when this procedure was done and when these rabbits were shipped.

[redacted]

[redacted]
USDA, APHIS, Animal Care

Arizona
[redacted]

Re: Rabbits at Barrow

[redacted]

Wed 2/26/2020 2:42 PM

To: David Michael Faguy <David.Faguy@nau.edu>;

For the rabbit study, Barrow and NAU studies are separate. The past grant for the rabbit study is to an outside entity that sub awards to NAU and Barrow separately. NAU does not subcontract to Barrow. Once the animals and their paperwork from NAU were transferred to Barrow, all NAU involvement on those studies ended.

[redacted]

On Feb 26, 2020, at 8:43 AM, David Michael Faguy <David.Faguy@nau.edu> wrote:

Hi [redacted]
Thanks for that information. Hopefully that is what the USDA needs.
Could you clarify the relationship between Barrow and NAU? The type of relationship can determine whether NAU has any oversight responsibility for animal work done at Barrow.
Specifically, have we paid any money to Barrow? If so, how was this done? A subcontract?
Thanks for any help with this,
David

From: [redacted]
Sent: Tuesday, February 25, 2020 11:30 AM
To: David Michael Faguy <David.Faguy@nau.edu>
Cc: Kimberley Cohen <Kimberley.Cohen@nau.edu>
Subject: Re: Rabbits at Barrow
Importance: High

Here's the executed animal transfer agreement with rabbit # details and transfer date. They were rabbit numbers 2002, 2003, 2005, 2008, 2009. They were originally received to NAU on 3/14/18. The elastase surgery to form aneurysms were done at NAU on 4/5/18 (2002, 2003, 2005, 2008) and 4/11/18 (2009). We decided not to treat them at NAU, so we executed the MTA (attached). I transported the rabbits to BNI on 7/10/18.

Call me if you need further info ([redacted]).

[redacted]

On Feb 25, 2020, at 9:29 AM, David Michael Faguy <David.Faguy@nau.edu> wrote:

Hi [redacted]
The USDA is requesting information on the 5 rabbits we transferred to Barrow. We need to know the date of any surgeries on these rabbits and when these rabbits were shipped.
Your annual and final reports do not detail any transfers.
Please call my cell at [redacted] as soon as you can.

Thanks
David

David M. Faguy, Ph.D.
Assistant Vice-President for Research Compliance
Northern Arizona University

525 S. Beaver Street 4th Floor
Flagstaff, AZ
86011-4062

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