

FOR PUBLIC RELEASE



Shipp, Allan (OD)

From: Shipp, Allan (OD)
Sent: Friday, August 10, 2001 3:57 PM
To: 'Collis, Phil'
Subject: RE: cdc contact

You should have gotten a letter by fax today (for which the original will also come in the mail). If you didn't receive it, please let me know, and I'll follow up.

Thank you.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

-----Original Message-----

From: Collis, Phil [mailto:pcollis@ehs.ufl.edu]
Sent: Tuesday, August 07, 2001 4:09 PM
To: Shipp, Allan (OD)
Cc: Richmond, Jonathan Y. (CDC); Properzio, Dr. William;
'gulig@ufl.edu'; 'rvomacka@rgp.ufl.edu'
Subject: cdc contact

good afternoon allan.

dr. fleming at the cdc had dr. jonathan richmond,
director of the office of health and safety at cdc
contact me regarding the transgenic pig incident
at uf. we proceeded to have a couple of discussions
regarding the particulars, after which dr. richmond
suggested that this was not a cdc issue. dr.
richmond may be contacted at 404-639-2453.

this will conclude uf's efforts to notify
potentially concerned federal agencies.
we have now officially confirmed that
none of the suggested contacts required
notification of the incident.

please confirm that uf may now close
the file on this incident.

sincerely,

philip s. collis, ph.d
secretary, ibc
associate director, ehs
university of florida
352-392-7399

Shipp, Allan (OD)

From: Shipp, Allan (OD)
Sent: Friday, July 27, 2001 9:45 AM
To: 'Collis, Phil'
Cc: 'gulig@ufl.edu'; Properzio, Dr. William; 'rvomacka@rgp.ufl.edu'; Patterson, Amy (OD); Lanman, Robert (OD); Shih, Tom (OD)
Subject: RE: uf transgenic pig - various

Thank you for following through with our request. Your cooperation is appreciated.

-----Original Message-----

From: Collis, Phil [mailto:pcollis@ehs.ufl.edu]
Sent: Friday, July 27, 2001 9:35 AM
To: Shipp, Allan (OD)
Cc: 'gulig@ufl.edu'; Properzio, Dr. William; 'rvomacka@rgp.ufl.edu'
Subject: RE: uf transgenic pig - various

good morning dr. shipp.

i have contacted both the fda and the cdc as directed.

at the fda i spoke with john matheson, office of surveillance and compliance at the fda/cvm. he indicated that his office was the correct one to notify. he did not think an official report was necessary and the verbal report was sufficient. he indicated that he might call you, but if he has not his telephone number is 301-827-6649.

at the cdc i spoke with the deputy director, dr. david fleming. he was not sure whether the cdc had a group compiling data of this type, but he was going to check. i have not yet heard back from him. as requested, i will report the result of that conversation when it occurs.

best wishes,
phil collis
university of florida
352-392-7399

-----Original Message-----

From: Shipp, Allan (OD) [mailto:ShippA@OD.NIH.GOV]
Sent: Monday, July 23, 2001 11:19 AM
To: 'Collis, Phil'
Cc: Patterson, Amy (OD); Lanman, Robert (OD); Shih, Tom (OD); Rosenthal, Eugene (OD); Carr, Sarah (OD)
Subject: RE: uf transgenic pig - various

Dear Dr. Collis:

Thank you for providing the contact information in follow up to our last phone conversation. In that conversation you noted that your USDA contact had told you that notification of the FDA was unnecessary. You also stated that, in your assessment, it was unnecessary to contact CDC because the viral vector used in the pig experiments was replication incompetent and thus not infectious or capable of causing disease. Finally, you said that your interpretation of my email of June 27 was that we were leaving you the discretion to determine federal reporting requirements in whatever manner seemed reasonable to you.

With regard to the last point, the email actually said, "Since we did not know all the specifics surrounding the incident, we trusted that you would

investigate whatever requirements might exist and act accordingly." We suggested that CDC, FDA, and USDA might have an interest and said that "those agencies are best poised to inform you about what they might need to know."

This was meant to convey that you should contact those agencies directly, determine what federal reporting requirements might exist, and act accordingly.

We do not believe that USDA can speak on behalf of FDA. Also, the CDC is best poised to tell you if they have an interest in a situation where humans consumed an animal containing a viral vector, as well as substances used to euthanize it.

Please contact those agencies directly and report to us the outcomes of those conversations. Many thanks for your cooperation.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152

-----Original Message-----

From: Collis, Phil [mailto:pcollis@ehs.ufl.edu]

Sent: Monday, July 23, 2001 9:58 AM

To: Shipp, Allan (OD)

Cc: 'gulig@ufl.edu'; Properzio, Dr. William; 'rvomacka@rgp.ufl.edu'; 'john.h.payne@usda.gov'; 'thomas_belcuore@doh.state.fl.us'

Subject: uf transgenic pig - various

good morning dr. shipp.

here is the information you requested this morning to supplement my july 9, 2001 letter.

- 1) the report referred to was the final police report. it was communicated seperately to oba and the health department.
- 2) the director of the local office of the state health department is mr. thomas belcuore. he can be contacted at 352-334-7901.
- 3) we contacted dr. jonh payne, usda, aphis. dr. payne is the director of biotechnology and scientific services. he may be reached at 301-734-8786.
- 4) the cdc was not contacted since there was nothing infectious or disease causing involved in the project.

please call me if you have additional questions.

sincerely,
philip s. collis



UNIVERSITY OF
FLORIDA

Administrative Affairs
Division of Environmental Health and Safety
Biological Safety Office

Allen → Amy Patterson
→ Bob Lamm
→ Sarah Carr

PO Box 112190, Building 1079
Gainesville, FL 32611-2190
(352) 392-1591 Suncom: 622-1591
Fax: (352) 392-3647
<http://www.ehs.ufl.edu/bio>

July 9, 2001

Allan Shipp
Office of Biotechnology Activities
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Dr. Shipp,

Thank you for your June 27, 2001 email clarifying the Office of Biotechnology's April 26, 2001 letter.

The University of Florida has completed its investigation and we have provided copies of the final report to both the State of Florida Department of Public Health and your office.

The State Health Department stated that no additional information or federal assistance was necessary. In addition, the USDA indicated that neither they nor the FDA would require notification.

As a result, UF has concluded its actions with regard to the incident. Thank you again for your assistance.

Sincerely,

Philip S. Collis, Ph.D.
Secretary
UF IBC

cc: Dr. Phillips
Dr. Gulig
Dr. Properzio
Dr. Patterson



UNIVERSITY OF FLORIDA

Administrative Affairs
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Biological Safety Office

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March 13, 2001

Amy P. Patterson, M.D.
Director, OBA
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Dr. Patterson,

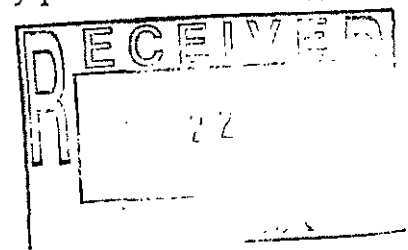
I am writing in reply to your letter of February 20, 2001. As a result of our transgenic pig incident, the University of Florida was asked to review our procedures for the disposal of animal carcasses to determine whether they needed modification.

The point of breakdown was the terminal step; between storage of the carcass and incineration. A group of employees delivered the carcasses to the holding cooler immediately adjacent to the incinerator. The incinerator operator returned during non-work hours and stole some of the carcasses but logged that they had been incinerated. This type of criminal activity is difficult to foresee.

Nonetheless, UF will implement two additional requirements that should preclude even this type of occurrence.

1. Large animal carcasses will be spray painted with a bright paint like day-glo orange immediately following their euthanasia.
2. A member of the research group will be required to observe the final disposition of all animals and log the activity accordingly.

Taken together, we feel these new requirements will prevent any possible recurrence.

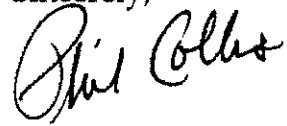


Dr. Patterson - Page 2

Additionally, since our initial report, UF has received information that some of the stolen meat may have been consumed. The UF Police Department is conducting a follow-up investigation. I discussed this with Dr. Shih on March 12, 2001. UF will provide that information as it becomes available should OBA require it.

Please call if you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Phil Collis".

Philip S. Collis, Ph.D.
Secretary
IBC

cc: Dr. Phillips
Dr. Gulig
Dr. Tomson
Dr. Lewin



UNIVERSITY OF FLORIDA

Administrative Affairs
Division of Environmental Health and Safety

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PO Box 112190
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www.ehs.ufl.edu

February 12, 2001

Dr. Thomas Shih
Office of Biotechnology Activities
National Institutes of Health

VIA: Facsimile

Dear Dr. Shih,

As we discussed earlier today, I am writing to report an incident that occurred at the University of Florida concerning transgenic pigs. The incident occurred on 1/12/01.

A university researcher was conducting a project studying ribozyme therapy for retinitis pigmentosa. The model system being used was transgenic pigs containing a mutant rhodopsin gene, which causes blindness. The purpose of the project was to try to correct this by introducing a ribozyme to clip the mutant rhodopsin m-RNA.

Treatment consisted of inoculating the pig's eyes with recombinant Adeno Associated Virus (AAV) containing either a GFP marker or a ribozyme for the mutant rhodopsin gene. 10^9 (iu) AAV were injected in 75 ul. This project was registered with and approved by the UFIBC.

After 22 months of analysis, the pigs were euthanized and the eyes harvested.

The pigs were euthanized by a veterinarian who used a ketamine/xylozine cocktail i.m. to sedate the animals and an intra cardiac injection of pentobarbital for euthanizing.

Following removal of the eyes, the carcasses were then loaded on a truck for transport to the University's large animal incinerator. Following delivery to the storage room, three of the six pigs were stolen by a UF employee. Two were given to a private citizen who had them butchered and one was sold to another individual.

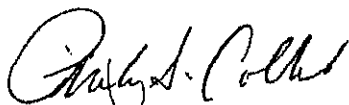
Dr. Thomas Shih
Office of Biotechnology Activities
Page 2

This was discovered when the butcher contacted UF about the pigs. The incident was immediately reported to the UF Police Department who conducted an investigation. The criminal was arrested and interrogated. Police investigators recovered all of the butchered meat and the other pig. The materials were returned to the UF incinerator and disposed of as originally planned. There is no evidence that any of the meat was ingested or not recovered. .

The incident was reported previously to the OLA by Dr. Farol Tomson, director of Animal Resources.

I can provide additional details and information as necessary.

Sincerely,



Philip S. Collis, Ph.D.
Secretary
University of Florida IBC

cc: Dr. Phillips
Dr. Tomson



UNIVERSITY OF
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Administrative Affairs
Division of Environmental Health and Safety

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→ Fax: (352) 392-3647

FAX

Date: 2/12/01

2 pages to follow...

TO:

DR. THOMAS SHIH
OBA

FROM:



UNIVERSITY OF
FLORIDA

Philip S. Collis, Ph.D.
Associate Director

FAX #: 301-496-9839

PHONE #: _____

Environmental Health and Safety
PO Box 112190
Gainesville, FL 32611-2190

Tel: (352) 392-1591
Fax: (352) 392-3647
pcollis@ehs.ufl.edu

☐ Urgent ☐ For Your Review ☐ Please Reply ASAP ☐ Please comment

Remarks:

Tom,
as discussed.
Phil Collis

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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive
MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/oprr/oprr.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive, MSC 7982
Bethesda, Maryland 20852
Telephone: (301) 496-7163 ext 7
Facsimile: (301) 402-7065

July 24, 2001

Re: Animal Welfare Assurance
#A3377-01

Winfred M. Phillips, PhD
Vice President for Research
University of Florida
223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500

Dear Dr. Phillips:

Thank you for your July 19, 2001 letter regarding the disposition of the carcasses of six genetically engineered swine at the University of Florida-Gainesville (UF-G).

Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) understands that the Florida State Department of Health, the U. S. Department of Agriculture, and the Food and Drug Administration were notified of this matter. We also understand that the Centers for Disease Control and Prevention was not notified because the viral vector used in the pigs was not considered to be infectious or transmissible.

With the completion of these actions, coupled with previously described plans designed to prevent a recurrence, this Office considers the matter closed. Your efforts and those of other UF-G staff in resolving the issues involved in this incident are appreciated.

Sincerely,

Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Miava Binkley, USDA
Dr. Amy Patterson, OBA, NIH



UNIVERSITY OF FLORIDA

Research and Graduate Programs
Winfred M. Phillips
Vice President for Research and
Dean of the Graduate School

223 Grinter Hall
P.O. Box 115500
Gainesville, Florida 32611-5500
(352) 392-1582/9271
Fax: (352) 846-0491

VIA US MAIL AND FACSIMILE

July 19, 2001

Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive
MSC 7982
Bethesda, Maryland 20892-7982

Dear Dr. Potkay:

This letter is being sent in response to your letter of June 18, 2001, regarding the final disposition of the carcasses of six genetically engineered swine at the University of Florida-Gainesville. Dr. Phil Collis received the enclosed e-mail from Allan Shipp at OBA. This e-mail has been the only response from OBA regarding Dr. Collis' letter of June 4, 2001 which included the final police report. Dr. Collis has also forwarded an e-mail to me (enclosed) indicating that all appropriate notifications have occurred.

Please let me know if we can provide additional information at any time.

Sincerely,

Winfred M. Phillips, D.Sc.
Vice President for Research

ENCLOSURES

cc: Dr. Farol Tomson, Interim Director, Animal Care Services
Dr. Pushpa Kalra, Chairperson, ACUC-01
Mr. Robert B. Vomacka, Acting Asst. Director for IACUC
Dr. Phil Collis, EH&S

-----Original Message-----

From: Shipp, Allan (OD) [mailto:ShippA@OD.NIH.GOV]
Sent: Wednesday, June 27, 2001 5:29 PM
To: 'pcollis@ehs.ufl.edu'
Cc: Patterson, Amy (OD); Lanman, Robert (OD)
Subject: Reporting to State and Federal Public Health Officials

Dear Dr. Collis:

Thank you for your call today in which you referenced our April 26, 2001 letter that stated that OBA trusted that the University of Florida would "notify state and federal public health officials to ensure that all appropriate measures were taken" in response to reports that genetic pigs stolen from the University had been consumed. Our understanding at the time was that the pigs were not only genetically altered using a viral vector, but also contained significant amounts of substances that had been used to euthanize them. Consequently, it was unclear to us what risks might be faced by those who consumed the meat, as well as those with whom consumers might come in contact, and thus such notification seemed a prudent measure.

You asked specifically which authorities at the federal level should be notified. I think implicit in our statement were the words "as appropriate." Since we did not know all the specifics surrounding the incident, we trusted that you would investigate whatever requirements might exist and act accordingly. Given that a virus, possible toxins, a food product, and a meat substance were involved, we considered that a report to the CDC, the FDA, or the USDA might be appropriate, depending on the facts. Of course, those agencies are best poised to inform you about what they might need to know about this incident, if anything. It is also advisable to approach your state public health authorities, with whom you seem to have established working relationships, and seek their advice about whom, if anyone, to contact at the federal level.

I hope this helps. Please contact us again if you have additional questions.

Allan Shipp
NIH Office of Biotechnology Activities
301-435-215

Robert Vomacka
From: Collis, Phil [pcollis@ehs.ufl.edu]
Sent: Friday, June 29, 2001 11:38 AM
To: 'wphil@ufl.edu'
Cc: Properzio, Dr. William; 'rvomacka@rgp.ufl.edu'
Subject: FW: Reporting to State and Federal Public Health Officials

good morning win.

we finally received a reply from the oba regarding the transgenic pig notifications. as you can see it is a generic advisement. we have contacted the usda and they indicate that this is not something under their purview nor is it under the supervision of the fda. since nothing infectious or transmissible was involved the cdc does not need to be notified. we also recontacted the state health office and they do not feel the need to solicit any federal assistance.

this should close the file on this incident. do you have any additional concerns or suggestions as we wrap this up? does olaw still need something from us?

i'll wait for your input before responding to oba. i intend to thank them and indicate that uf has attended to all the necessary notifications.

regards, phil collis.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Rockledge I, Suite 1051
6705 Rockledge Drive, MSC 7982
Bethesda, Maryland 20852
Telephone: (301) 496-7163 ext 7
Facsimile: (301) 402-7065

June 18, 2001

Re: Animal Welfare Assurance

#A3377-01

Winfred M. Phillips, PhD
Vice President for Research
University of Florida
223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500

Dear Dr. Phillips:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of a copy of Dr. Philip S. Collis' June 4, 2001 letter to Dr. Amy P. Patterson, Office of Biotechnology Activities (OBA) enclosing a copy of the final police report regarding the disposition of the carcasses of six genetically engineered swine at the University of Florida-Gainesville.

Please provide a copy of any final action by OBA and any other agency that brings this matter to closure. If final actions are not available by July 27, please notify OLAW of their anticipated release date.

Thank you for your attention to these matters.

Sincerely,

Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Miava Binkley, USDA
Dr. Amy Patterson, OBA, NIH



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive, MSC 7982
Bethesda, Maryland 20852
Telephone: (301) 496-7163 ext 7
Facsimile: (301) 402-7065

May 3, 2001

Re: Animal Welfare Assurance
#A3377-01

Winfred M. Phillips, PhD
Vice President for Research
University of Florida
223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500

Dear Dr. Phillips:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 27, 2001 letter responding to concerns regarding the disposition of the carcasses of six genetically engineered swine at the University of Florida-Gainesville (UF-G). This Office has the following comments regarding the UF-G responses to its March 19 letter.

- 1) carcass disposal described in the allegations: This Office understands that any future reports of incidents by the UF-G will include a full explanation of the circumstances in accordance with PHS Policy expectations (IV.F.3.) and the UF-G Animal Welfare Assurance.
- 2) plan and schedule to prevent recurrence: Based on the description provided, OLAW understands that it is UF-G policy that dead research animals be incinerated unless another disposal method (e.g., dissection, tissue and/or organ removal, skeleton preparation) is approved by the Director of Animal Care Services (ACS) and the Animal Care and Use Committee (ACUC). We also understand that, in addition to re-training employees and notifying animal users by memorandum of the importance to adhere to established policy, ACS supervisors will conduct spot checks, and a member of the research team will be required to witness and document the euthanasia and—unless another disposal method has been sanctioned—placement of food and fiber animals in the incinerator.
- 3) describe UF-G current institutional policy on disposition/consumption of food-producing animals: Based on the clarifications provided, we understand that, in the Health Sciences Center (HSC), the final disposition of food-producing animals is identical to that applied to non food-producing animals used in biomedical research, testing and teaching. We further understand that the disposal of food-producing

animals used in agricultural research and teaching may involve public sales, sales to slaughter houses, or slaughter at the UF-G's abattoir, all of which activities are under USDA's oversight. Unless informed to the contrary, OLAW assumes that if carcasses of food-producing animals used in agricultural research and teaching are to be disposed of by incineration, the procedures described for biomedical research animals will be applied. This Office also acknowledges that the disposition of certain wildlife species is done in accordance with State or Federal fish and wildlife/game regulations.

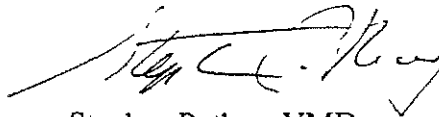
4) the outcome of the UF-G investigation of allegations that carcasses of other euthanized swine were diverted for human consumption in past years: OLAW understands that the university, based on the outcome of its investigation, has determined that the carcasses of no other euthanized swine have been diverted to human consumption over the past several years, including pigs from a project of Dr. Labota, Veterans Affairs Medical Center—Gainesville.

Regarding the *UF-G Guidelines for Animal Euthanasia*, this Office recognizes that its concerns were considered and that appropriate modifications were made in the *Guidelines*.

According to correspondence to Dr. Phillip Collis (Enclosure), it appears that some of the stolen meat may have been consumed, and the UF-G has been asked to conduct a prompt and thorough follow-up investigation of that issue. While appropriate procedures appear to be in place to prevent the diversion of carcasses of research animals to the human food supply, we cannot consider bringing this matter to closure until we have evaluated any new evidence that may be discovered in the course of the requested follow-up investigation. Consequently, please provide a copy of the UF-G's findings to this Office. If a copy of the report of findings is not available to us by May 31, 2001, please notify OLAW, by June 1, 2001 of the anticipated release date.

Thank you for your attention to these matters.

Sincerely,



Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Miava Binkley, USDA
Dr. Elwood Headley, VA
Dr. Michael Fallon, VA
Dr. Amy Patterson, OBA, NIH



UNIVERSITY OF FLORIDA

Research and Graduate Programs
Office of the Vice President for Research
Office of the Dean of the Graduate School

223 Grinter Hall
P.O. Box 115500
Gainesville, Florida 32611-5500
(352) 392-1582
Fax: (352) 392-9605

VIA US MAIL AND FAXSIMILE

April 27, 2001

Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive
MSC 7982
Bethesda, Maryland 20892-7982

Dear Dr. Potkay:

This letter is being sent in response to your letter of March 19, 2001, requesting clarification on the incident involving pigs that occurred at the University of Florida on January 12, 2001.

Additional information related to your specific concerns follows:

1. **Allegations about Carcass Disposal:** In accordance with PHS Policy expectations and our Assurance, future reports of any incident should include as much information about the circumstances as possible.
2. **Other Disposal Methods Applicable to Such Dead Research Animals:** Animal Care Services (ACS) will frequently receive requests for dissection or for tissue/organ removal or for skeletal preparation of carcasses. Disposal methods for these procedures are frequently not considered during the initial review of protocols. When these requests are received, the Director of ACS and the Animal Care and Use Committees (ACUCs) will ensure that appropriate documentation and approval of disposal methods is obtained.

Tracking Animals from Euthanasia to Incineration: Several actions were taken in relation to this procedure as follows:

Stephen Potkay, VMD
 April 27, 2001
 Page 2

- (a) All employees of ACS have been retrained in disposal of animal carcasses, which includes attaching appropriate tags to each carcass or bag of carcasses. Also, incineration logs now include the tags from the animals or from the bag of animals.
- (b) A formal memorandum (enclosed) was sent to all animal users at the University to reinforce the importance of and to remind users about existing rules.
- (c) ACS supervisors will ensure that proper procedures are being followed by periodically examining the disposal logs.
- (d) Whenever food and fiber animals will be euthanized, a member of the research team is now required to witness and document the euthanasia. These carcasses will be spray-painted a bright orange by the research team. When these animals are incinerated, a member of the research team will witness and document the disposal up to the point that the entire carcass is placed in the incinerator.

3. **Disposition of Food-Producing Animals:** The method of final disposition for all animals used in research and teaching programs at the University of Florida is described in the Animal Use Approval Form that is reviewed and approved by the ACUCs. The information provided to OLAW and the policy described in the document "Moribund or Dead Animals" refers to both biomedical research and any other projects served by the animal facilities of the Health Science Center (HSC) or facilities that are managed by ACS at the University. Separate procedures are used for the disposal of agricultural animals that are used strictly in agricultural research and teaching. These involve public sales, sales to slaughter houses, and slaughter at their own abattoir. These activities occur in compliance with USDA regulations and under USDA oversight.

The final disposition of wildlife is governed by various state or federal Fish and Game regulations and is described and explained in the Animal Use Approval Forms that are reviewed and approved by the appropriate ACUC. Whenever wildlife animal species are brought to the HSC, the logging system described above is applied.

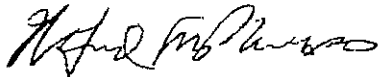
4. **Outcome of the UF-G investigation of the Allegations that Euthanized Swine were Diverted for Human Consumption in Past Years:** There have been no other cases of euthanized animals being diverted for human consumption. This was a single event. There is no evidence that would support speculation that Dr. Lobato's swine carcasses were diverted. Dr. Lobato opens the chest and removes the heart and lungs when the animals are euthanized. These pigs are then double wrapped and returned for incineration.

Stephen Potkay, VMD
April 27, 2001
Page 3

5. **Regarding the requested changes in "Guidelines for Animal Euthanasia" and "Moribund or Dead Animals" Documents:** All have been incorporated and the revised documents are enclosed.

The University of Florida remains committed to animal welfare and regulatory compliance. We will continue to be diligent in our efforts to provide quality animal care and to provide all oversight agencies with all necessary information for assurance and assessment. Please let me know if we can provide additional information at any time.

Sincerely,



Winfred M. Phillips, D.Sc.
Vice President for Research

ENCLOSURES

cc: Dr. Farol Tomson, Interim Director, Animal Care Services
Dr. Pushpa Kalra, Chairperson, IACUC-01
Mr. Robert B. Vomacka, Acting Asst. Director for IACUC



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[[Mad Cow Disease](#)] [[Foot & Mouth](#)]

February 28, 2001

MEMORANDUM

TO: All Biomedical Animal Research Faculty

FROM: Farol N. Tomson, DVM

SUBJ: Carcass Disposal

When animals are euthanized (either by you or your technician), these carcasses become "Biohazardous Waste." The disposal of the carcasses follows your instructions on the Animal Use Approval Form. Ultimately, carcasses are placed into various cold rooms or refrigerators/freezers for disposal. When using the walk-in cold rooms in Animal Care, there are logs available that must be completed that identify the animal, the faculty member and the date placed in the cooler. Available tags must be placed on the carcass (or the plastic bag) that direct us to either incinerate, save or necropsy the carcass.

When we incinerate, the tag is removed and taped into the incinerator log; and the cold room log is updated. This provides the documented trail from when an animal is euthanized until when the carcass is incinerated.

Carcasses are not to be removed for any reason without the approval of the Director and the IACUC. There may be very legitimate reasons for gaining access to these carcasses and the Director and the IACUC can make this decision.

Live animals leaving your research programs that are not in compliance with your own Animal Use Approval Form will call for further investigations. Anyone distributing or taking live animals from the premises without proper documentation will be charged with theft as well as the responsible faculty member facing compliance issues with the IACUC and possibly your funding agency.

Please help me with assuring compliance to these animal disposal procedures. None of the above items are new. They are all part of our existing operating procedures and policies. Please see me if you have any questions.

cc: IACUC office

Last updated on: 04/26/2001

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GUIDELINES FOR ANIMAL EUTHANASIA

SOP 4 - Last updated and approved on 4/26/01

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<u>Responsibilities of Researcher</u>	<u>Rodent Tumor Euthanasia</u>	<u>Rodent Ascites Euthanasia</u>	<u>Carcass Disposal</u>
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1. While it is recognized that many of the animals used for science, teaching and service purposes must be euthanized, the manner of euthanasia has sometimes drawn extreme criticism. The University of Florida's Institutional Animal Care & Use Committee (IACUC) has adopted the following guidelines to ensure that animals do not experience pain or distress prior to and during euthanasia.
2. The ideal euthanasia method involves sedation prior to death. Once the animal is sedated/anesthetized, any number of methods can be used to euthanize, i.e. cervical dislocation, decapitation, various chemicals and physical agents. To assure euthanasia, sufficient attention must be given to assure the cessation of heart beats; or the lungs should be collapsed (thoracotomy).
3. The various agents that sedate or anesthetize animals prior to euthanizing include: tranquilizers, barbiturates, carbon dioxide, inhalant anesthetics (methoxyflurane, halothane).
4. Ether and chloroform are NOT acceptable methods for sedation, anesthesia or euthanizing, unless that method is part of the research objective and have the approval of the Environmental Health and Safety Office.
5. If animals cannot be sedated prior to euthanasia, cervical dislocation and decapitation are acceptable methods to use only on poultry, other small birds, mice, rats weighing less than 200 g. and rabbits weighing less than 1 kg, other small amphibians, fish and reptiles. Cervical dislocation in research settings is limited to those situations in which the IACUC has approved a scientific justification provided by the investigator and can ensure that the personnel given the responsibility for performing the technique are properly trained and consistently apply them humanely and effectively. Decapitating machines must be kept clean and sharp.
6. Controversy exists and will continue to exist over the amount of pain/distress felt by a conscious animal that is decapitated. This technique can be used only when scientifically justified and approved by the IACUC. Those responsible for performing this technique must be properly trained.
7. The use of captive bolts, guns and electrocution to euthanize animals requires a special obligation on the scientist. Although these methods can be humane, things may happen to make them inhumane. You must explain why other methods cannot be used and you must indicate the amount of skill or training the person has who will be euthanizing the animals.

8. These guidelines have been written in general terms to allow maximum variability for euthanasia methods. The principle of painless death **MUST** be followed. If your method has a potential of allowing any pain/distress, or if you have any questions about these guidelines, please contact us for assistance.

9. After the euthanasia of biomedical research animals, the carcasses are considered biohazardous wastes and are treated as such. The euthanasia of food & fiber animals for human consumption follow the appropriate federal and state guidelines governing these procedures.

"2000 Report of AVMA Panel on Euthanasia", *JAVMA*, 218(5):669-696, 2001. This is a pdf file. Clicking of the right mouse button will give you the option of reading it or downloading it. Clicking on the left button will activate the Adobe program and open the file.

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Moribund Or Dead Animals

Moribund animals:

are those that are exhibiting signs of severe illness or incapacitation, unconscious or otherwise obviously near death.

1. When moribund animals are discovered by Animal Care Service personnel during normal working hours, our Clinical Veterinarian and Veterinary Technicians are to be notified immediately. The Clinical Veterinarian or the Veterinary Technician will notify the principal investigator, provide appropriate treatment, or euthanize the animal, whichever is appropriate.
2. When moribund animals are discovered after normal working hours or on weekends or holidays, the on call veterinarian and the principal investigator are to be notified immediately via home phone or beeper.
3. The animal's condition, persons notified, and date and time should always be noted on the clinical record sheet or cage card.

Dead Animals:

1. All animal carcasses and any organic material intended for necropsy or disposal should be handled with gloves and should be properly packaged and identified.
2. Note the animal's death on the clinical record or cage card, including date and time of discovery.
3. Remove the animal from its cage, place it in a plastic bag of appropriate size, tie the bag securely, and place either a SAVE, NECROPSY or INCINERATE tag on the bag. The "SAVE" tag will be used in most cases. When the save tag is used the carcass will be saved for 48 hours (not counting weekends and holidays) after which it will be incinerated. The "NECROPSY" tag will be used when the investigator, Clinical Veterinarian or the Pathologist wish to have a necropsy of the animal, recover instruments, or collect tissues. The "INCINERATE" tag will signify that the animal may be incinerated immediately or at the next scheduled incineration. In all cases, the tag must be filled out completely, providing animal number, investigator, encumbrance number, project number, etc.
4. The investigator or their staff should be notified immediately of the animal's death. If unable to contact the investigator or their staff, indicate on the death notice number of attempts made with time of day and turn death notice in to the business office who will then make additional attempts to notify the investigator of the animal's death. If successful in contacting the investigator, note name of person notified, time of day and turn death notice in to the business office. During weekends and holidays, notify the veterinary technician who will in turn notify the investigator by whatever means possible or, if unable to contact the investigator, will leave written notification at the business office for notification at the earliest available time.
5. Immediately place the animal in the necropsy cooler on the "save" rack. The necropsy cooler should not exceed 10° C (45° F). Do not freeze any animal that is to undergo a necropsy.
6. Unless prior arrangements for disposal have been made, all carcasses will be held for 72 hours (3

days), not counting weekends and holidays, or until the responsible investigator or veterinarian releases the carcass for disposal.

7. No animal will be discarded until death is certain. If there is any question, report the animal to the veterinary staff immediately.

8. Animals infected with pathogenic organisms and who die in the "Infectious Disease Isolation Area" must be bagged and specifically identified with appropriate labels and specific instructions provided to the personnel responsible for their disposal and stored in the refrigerator located in room CB 104. The animals will be removed and disposed of according to specific protocols written by the responsible investigator and approved by Campus Environmental Health and Safety staff.

9. Animals containing radioactive substances that are found dead must be bagged and specifically identified with appropriate labels and specific instructions provided to the personnel responsible for their disposal and stored in the cold room. Animals containing radioactive isotopes must be handled as specified by Campus Environmental Health and Safety staff. A protocol for handling these carcasses will be provided by the responsible investigator.

10. Euthanized animals are not to be removed or otherwise distributed to anyone without the specific approval of the Director and approval of the IACUC. There may be instances where animal tissue(s) may be obtained in the pursuit of a project or a class. All carcasses are to be incinerated.

Last updated on: 04/26/2001

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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive
MSC 7982
Bethesda, Maryland 20892-7982
Home Page <http://grants.nih.gov/grants/oprr/oprr.htm>

FOR EXPRESS MAIL

Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive, MSC 7982
Bethesda, Maryland 20852
Telephone (301) 496-7163 ext 7
Facsimile (301) 402-7065

March 19, 2001

Re: Animal Welfare Assurance
#A3377-01

Winfred M. Phillips, PhD
Vice President for Research
University of Florida
223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500

Dear Dr. Phillips:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 28, 2001 letter responding to concerns regarding the disposition of the carcasses of six genetically engineered swine at the University of Florida-Gainesville (UF-G).

This Office has the following observations, comments, and requests for clarification regarding the UF-G responses to requests contained in its February 6 letter.

1) carcass disposal described in the allegations

Based on the information provided, this Office recognizes that the carcasses of three of six genetically engineered swine, euthanized at the UF-G on January 12, 2001 and scheduled for incineration, were stolen by two employees. We further understand that two of the carcasses, given to a private citizen, were taken to a butcher who reported the matter to the UF-G on January 13, and that a third was sold to another citizen. OLAW recognizes that the UF-G Police Department, notified of this incident on January 17, investigated, determined the whereabouts, and assisted in the recovery of the meat which was then incinerated. This Office received notification from the UF-G, on January 22, of the attempted improper disposal of pig carcasses and acknowledges that the Office of Biotechnology Activities was notified of the matter by the UF-G on February 12, 2001. We also understand that when the pigs outgrew their originally approved housing, they were moved to a facility that was able to accommodate them and that this change was approved by two UF-G Animal Care and Use Committees.

This Office understands that the situation described in OLAW's February 6, 2001 letter, based on the allegations it received, was the same as that reported to this Office by the UF-G on January 22. To ensure that all pertinent information is available to OLAW on which to base an assessment of proposed corrective actions and plans to prevent recurrence, **this Office requests that future reports of any incident include a full explanation of the circumstances in accordance with PHS Policy expectations (IV.F.3.) and the UF-G Animal Welfare Assurance.**

2) plan and schedule to prevent recurrence

OLAW understands that the UF-G has modified its policies dealing with dead research animals, mandating that they be incinerated unless another disposal method is approved by the Director of Animal Care Services and the ACUC. **Please indicate what other disposal methods may be applicable to such dead research animals.** We concur that the reported incident was a purposeful violation of institutional policies and procedures which is being handled locally as a criminal matter. This Office also acknowledges that persons who intend to perform criminal acts may not be dissuaded from doing so by guidelines, policies, procedures, or regulations. In this regard, and based on information provided in the February 26, 2001 memorandum, we recognize that a mechanism to track animals between the time they are killed to the time that they are incinerated was in place at the time of the incident. **Please comment on the use of this mechanism to establish oversight of the future disposition of animal carcasses—by documented spot checks or periodic reviews, for example, or provide an alternative method for oversight.**

3) describe UF-G current institutional policy on disposition/consumption of food-producing animals

The information provided regarding food-producing animals appears to apply to those animals used in biomedical research, testing and teaching—which also happen to be traditional food-producing species (e.g., livestock, poultry, rabbits, and certain wildlife species). It is not clear whether the described institutional policy also applies to traditional food-producing animals (e.g., livestock, poultry, rabbits, and certain wildlife species) used in agricultural or wildlife research. OLAW is unable to determine, based on the information provided, whether UF-G institutional policy applies to animals used in biomedical research or agricultural research or both and fears that faculty and other employees may not understand the applicability of the policies either. Consequently, we strongly recommend that policy be clarified, and that any exceptions to the policy be clearly defined. See also a related concern under euthanasia guidelines, item 9, and *Carcass Disposal* (below).

4) the outcome of the UF-G investigation of allegations that carcasses of other euthanized swine were diverted for human consumption in past years

The UF-G did not respond to this request. **We re-request that, using the mechanisms described above or any other method deemed appropriate, the allegation that carcasses of other euthanized swine may have been diverted to human consumption over the past several years,**

including pigs from a project of Dr. Labota, Veterans Affairs Medical Center—Gainesville, in 2000 be investigated and OLAW notified of the outcome.

Regarding the *UF-G Guidelines for Animal Euthanasia*, this Office has the following observations and requests for re-evaluation:

item 2. To avoid possible misinterpretation of the phrase "the lungs should be collapsed," we suggest that a specific example(s), or modifier(s), be provided (eg., "by thoracotomy").

item 3. Decompression is not a sedative nor an anesthetic agent and its use for euthanasia is unacceptable. Please revise the *Guidelines* accordingly.

items 5. and 6. may be misleading as written.

Cervical dislocation in research settings is limited to those situations in which the ACUC has approved a scientific justification provided by the investigator and can ensure that the personnel given the responsibility for performing the technique are properly trained and consistently apply them humanely and effectively. Please note that the procedure is recommended for use only on poultry, other small birds, mice, rats weighing *less* than 200 g and rabbits weighing *less* than 1 kg. by technically competent individuals and that the animals must be sedated or anesthetized if the operator has not demonstrated technical competency. Guinea pigs are not specifically included among the animals for which the procedure is recommended in the 2000 Report of the AVMA Panel on Euthanasia (Panel).

The Panel goes further in its recommendations regarding decapitation, stating that this method is conditionally acceptable and should be used when required by experimental design and approved by the ACUC which must also ensure that persons who perform the procedure have been properly trained to do so. The Panel lists rodents and small rabbits as well as amphibians, fishes, and reptiles under this conditionally acceptable technique.

We also note that the approvals for these procedures must be on a case-by-case (project-by-project) basis and that blanket approvals may not be issued by institutions. Please clarify the *Guidelines* to ensure that they reflect the recommendations of the 2000 Report of the AVMA Panel on Euthanasia.

item 9. This item states that laboratory animal carcasses are treated as biohazardous waste and labeled with save, necropsy, or incinerate tags as described in the document *Moribund or Dead Animals*. If the laboratory animals happen to be domestic livestock, however, it appears that they could be sent to a (commercial?) slaughterhouse, though the conditions under which this is permitted are not stated. Alternatively, with the approval of the Attending Veterinarian and the ACUC, it seems that they may be killed somewhere else from which place their meat may enter the human food chain. Please clarify the guidance offered in item 9; OLAW's concerns here are similar to these stated in 3), above.

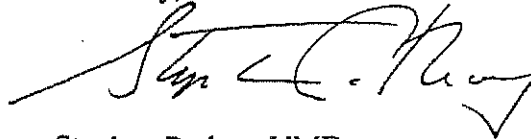
Regarding the document, *Moribund or Dead Animals*, and based on unfortunate situations involving errors in disposing of infected and radioactive carcasses that have occurred at other institutions, we

strongly recommend that dead animals known to contain infectious agents (item 8) and those harboring radioactive substances (item 9) be specifically identified with appropriate labels, and specific instructions provided to the personnel responsible for their disposal. We note that this document states that euthanized animals are not to be removed or otherwise distributed without the specific approval of the Director and approval of the ACUC.

Regarding the memorandum, *Carcass Disposal*, OLAW notes the statement that carcasses are not to be removed [from coolers] for any reason without the approval of the Director or the ACUC. This Office assumes that this does not prevent the removal of dead animals for disposal in accordance with the ACUC-approved animal study protocol, and as described in the document, *Moribund or Dead Animals*. We note, however, that removal for any purpose other than that originally approved by the ACUC must first be re-reviewed and approved by the ACUC. **The memorandum, *Carcass Disposal*, should be revised to reflect the requirement for ACUC review and approval of proposed changes in carcass disposition.**

A response to these concerns by **April 27, 2001** is requested. Thank you for your attention to these matters.

Sincerely,



Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Miava Binkley, USDA
Dr. Elwood Headley, VA
Dr. Michael Fallon, VA
— Dr. Amy Patterson, OBA, NIH



UNIVERSITY OF FLORIDA

Research and Graduate Programs
Office of the Vice President for Research
Office of the Dean of the Graduate School

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February 28, 2001

Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive
MSC 7982
Bethesda, Maryland 20892-7982

Dear Dr. Potkay:

This letter is being sent in response to your letter of February 6, 2001, and the anonymous allegations that were enclosed. The incident described in your letter and the incident that I originally reported to OLAW on January 22, 2001, are the same.

This incident occurred on January 12, 2001. Euthanized animals scheduled for incineration were removed from the University and sold. When this situation was brought to the attention of Dr. Farol Tomson, Interim Director of Animal Care Services, he investigated but could not verify whether or not the incident actually occurred. The employees involved denied the allegations. When enough evidence was received to support these allegations, Dr. Tomson personally notified the University Police Department (UPD) of the theft of these animal carcasses, at which time this became a criminal investigation. I have enclosed a copy of the police report for this incident.

Contrary to the anonymous letter, the University notified UPD of the stolen carcasses and reported this incident to OLAW. Also, our Environmental Health and Safety Office reported this incident to NIH (encl). Further, the Gainesville Sun reported that pigs were stolen from the University and that criminal action was pending (encl). It is my understanding that all of the pork resulting from this incident has now been recovered and incinerated. As a direct result of this investigation the University has accepted the resignation of one employee and has initiated termination proceedings against another.

The original animal use request for this protocol designated the 34th street facility for housing. It was expected that this study would end before these animals

Dr. Stephen Potkay
February 28, 2007
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attained a weight of 100 lbs. When the study end point was delayed the animals became too large for this facility a move to the IFAS swine unit was approved by both the IACUC 01 and the IACUC 02. I have enclosed a copy of report submitted to the IACUCs during December. This report documented the change in housing arrangements for these animals and was approved by the IACUC. While this housing arrangement was unusual there was no violation of the approved protocol.

The University is very concerned about this incident and has made every effort to properly report it. It is important to note that the incident was a criminal act and was not due to lapses in University policies or procedures. Nevertheless, as a result of this incident, the Standard Operating Procedures for Animal Care Services have been reviewed. University guidelines for euthanasia that were in effect at the time of this incident clearly indicate that carcasses of research animals are biohazardous waste and are to be treated as such (encl). To clarify this, we have modified our policy on dead research animals to mandate that they be incinerated. Exceptions will only be allowed with the written approvals of the Director of Animal Care Services and the IACUC. A memorandum about these policies is being sent to all staff in Animal Care Services (encl).

The University of Florida remains committed to animal welfare and regulatory compliance. We will continue to be diligent in our efforts to provide quality animal care and to provide all oversight agencies with all necessary information for assurance and assessment. Please let me know if we can provide additional information at any time.

Sincerely,



Winfred M. Phillips, D.Sc.
Vice President for Research

ENCLOSURES

cc: Dr. Farol Tomson
Mr. Robert B. Vomacka

Wednesday, January 31, 2001

Around the Region: UF worker charged with selling 6 research hogs...

POLICE BEAT

UF worker charged with selling 6 research hogs

A University of Florida employee was charged Monday with stealing six dead hogs, which were used in eye research and if consumed could have been harmful to humans.

Kenneth R. Atkins of Alachua, a senior laboratory technician at UF, is charged with one count of misdemeanor theft and another second-degree felony count of dealing in stolen property.

The hogs, used in various research projects at UF, were euthanized before Jan. 12 and were supposed to be burned at incinerators off campus, said Farol Tomson, interim director of animal resources at UF. Before incineration, the carcasses still contained a concoction of barbiturates that rendered the animals unconscious before killing them. If eaten in large quantities, the chemicals could cause dizziness or significantly lower a person's blood pressure.

"There were several drugs in the animals," Farol said. "The employee thought that he could make a quick buck by getting the pig meat into the food chain."

Atkins sold a few of the hogs and gave the others away. He has since been placed on administrative leave, Farol said.

-- A.P. Thompson

We have two IACUC-01 biomedical projects that are using domestic livestock where these animals are being housed in agricultural settings. We have two IACUC-02 biomedical projects using domestic livestock where these animals are being housed in agricultural settings.

PIGS

8695 William Hauswirth – "Gene Therapy for Autosomal Dominant Retinitis Pigmentosa" using 72 transgenic pigs over a period of three years. This is a category C study involving an injection of a gene 'package' into the eye and then evaluating the eyes over time to see if the injected genes take effect.

This project was first thought to be finished before the pigs got to be over 100 pounds. The pigs have reached 200 pounds and are still growing. The pigs have outgrown their dog runs and have been moved to open fields in the Swine unit managed by IFAS personnel. The animals are doing fine.

The ICUC-02 monitors this unit and will assume the responsibility of this project while the animals are housed at the Swine unit. Dr. Harvey Ramirez is the DVM of record and will cooperate with the RAMS veterinarians of the Veterinary Teaching Hospital in the event veterinary help is requested.

CHICKENS

8678 Susan Semple-Roland – "Rescue of the rd Phenotype Using Somatic Gene Therapy" using 50 chickens over the next five years. These are breeding chickens where fertile eggs and chicken embryos are the items of interest. These rd phenotype of the specific chickens results in blindness, so some of the breeding chickens are blind. Blind chickens get along fine in known environments.

It was difficult to set up chicken breeding environments in dog cages – which is what they used to do. Arrangements have been made years ago to allow this NIH funded project to house their chickens in a section of the Poultry Center here on campus. The Poultry Center is an IFAS managed facility. The IACUC-02 monitors this unit and will assume the responsibility of this project while the animals are housed at the Poultry Unit. Dr. Harvey Ramirez is the DVM of record and will cooperate with Dr. Gary Butcher of the Poultry Health Management service of the Veterinary Teaching Hospital in the event veterinary help is requested.

PIGS

A274 William Buhi – "Antisense Oligonucleotide Inhibition of POSP Expression" using 100 pig (crossbred gilts) in a USDA/NIH funded study. The animals are bred and reproductive fluids are taken at various times, including necropsy. Surgical procedures to remove reproductive tissues are performed in the Animal Science surgical theater. These animals are large pigs and are best housed in their agricultural settings with IFAS.

The IACUC-02 has reviewed and approved this project. The IACUC-02 monitors this unit and will assume the responsibility of this project while the animals are housed at the Swine unit. Dr. Harvey Ramirez is the DVM of record and will cooperate with the RAMS veterinarians of the Veterinary Teaching Hospital in the event veterinary help is requested.

HORSES

A457 Al Merrit - "Effect of Acupuncture of Visceral Pain in an Equine Model" using 5 horses in an NIH funded project. The horses are kept in the paddocks and pastures under the management of the VMTH Equine Research Program.

The IACUC-02 has reviewed and approved this project. The IACUC-02 monitors this unit and will assume the responsibility of this project while the animals are housed at the Swine unit. Dr. Harvey Ramirez is the DVM of record and will cooperate with Dr. Michelle LeBlanc of the Veterinary Teaching Hospital in the event veterinary help is requested.

12/11/00 for IACUC and DVM records.

fnf



GUIDELINES FOR ANIMAL EUTHANASIA

SOP 4 - Last updated and approved on 1/22/01

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Responsibilities of Researcher	Rodent Tumor Euthanasia	Rodent Ascites Euthanasia	Carcass Disposal
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1. While it is recognized that many of the animals used for science, teaching and service purposes must be euthanized, the manner of euthanasia has sometimes drawn extreme criticism. The University of Florida's Institutional Animal Care & Use Committee (IACUC) has adopted the following guidelines to ensure that animals do not experience pain or distress prior to and during euthanasia.
2. The ideal euthanasia method involves sedation prior to death. Once the animal is sedated/anesthetized, any number of methods can be used to euthanize, i.e. cervical dislocation, decapitation, various chemicals and physical agents. To assure euthanasia, sufficient attention must be given to assure the cessation of heart beats; or the lungs should be collapsed.
3. The various agents that sedate or anesthetize animals prior to euthanizing include: tranquilizers, barbiturates, carbon dioxide, decompression, inhalant anesthetics (methoxyflurane, halothane).
4. Ether and chloroform are NOT acceptable methods for sedation, anesthesia or euthanizing, unless that method is part of the research objective and have the approval of the Environmental Health and Safety Office.
5. If animals cannot be sedated prior to euthanasia, cervical dislocation and decapitation are acceptable methods to use on small rodents only and must be performed by trained technicians. Decapitating machines must be kept clean and sharp. Guinea pigs, rats over 200g, and rabbits over 1kg must be sedated prior to decapitation or cervical dislocation unless otherwise exempted by the IACUC.
6. Controversy exists and will continue to exist over the amount of pain/distress felt by a conscious animal that is decapitated. This technique can be used only when scientifically justified and approved by the IACUC. Those responsible for performing this technique must be properly trained.
7. The use of captive bolts, guns and electrocution to euthanize animals requires a special obligation on the scientist. Although these methods can be humane, things may happen to make them inhumane. You must explain why other methods cannot be used and you must indicate the

amount of skill or training the person has who will be euthanizing the animals.

8. These guidelines have been written in general terms to allow maximum variability for euthanasia methods. The principle of painless death **MUST** be followed. If your method has a potential of allowing any pain/distress, or if you have any questions about these guidelines, please contact us for assistance.

9. After euthanasia, laboratory animal carcasses become biohazardous wastes and are treated as such. Domestic livestock, if euthanized in an abattoir or with the approval of the Attending Veterinarian and the IACUC may enter the food chain. The Attending Veterinarian and faculty member involved are responsible for maintaining accurate records of such disposals.

"1993 Report of AVMA Panel on Euthanasia", *JAVMA*, 202(2):229-249, 1993.

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are those that are exhibiting signs of severe illness or incapacitation, unconscious or otherwise obviously near death.

1. When moribund animals are discovered by Animal Care Service personnel during normal working hours, our Clinical Veterinarian and Veterinary Technicians are to be notified immediately. The Clinical Veterinarian or the Veterinary Technician will notify the principal investigator, provide appropriate treatment, or euthanize the animal, whichever is appropriate.
2. When moribund animals are discovered after normal working hours or on weekends or holidays, the on call veterinarian and the principal investigator are to be notified immediately via home phone or beeper.
3. The animal's condition, persons notified, and date and time should always be noted on the clinical record sheet or cage card.

Dead Animals:

1. All animal carcasses and any organic material intended for necropsy or disposal should be handled with gloves and should be properly packaged and identified.
2. Note the animal's death on the clinical record or cage card, including date and time of discovery.
3. Remove the animal from its cage, place it in a plastic bag of appropriate size, tie the bag securely, and place either a SAVE, NECROPSY or INCINERATE tag on the bag. The "SAVE" tag will be used in most cases. When the save tag is used the carcass will be saved for 48 hours (not counting weekends and holidays) after which it will be incinerated. The "NECROPSY" tag will be used when the investigator, Clinical Veterinarian or the Pathologist wish to have a necropsy of the animal, recover instruments, or collect tissues. The "INCINERATE" tag will signify that the animal may be incinerated immediately or at the next scheduled incineration. In all cases, the tag must be filled out completely, providing animal number, investigator, encumbrance number, project number, etc.
4. The investigator or their staff should be notified immediately of the animal's death. If unable to contact the investigator or their staff, indicate on the death notice number of attempts made with time of day and turn death notice in to the business office who will then make additional attempts to notify the investigator of the animal's death. If successful in contacting the investigator, note name of person notified, time of day and turn death notice in to the business office. During weekends and holidays, notify the veterinary technician who will in turn notify the investigator by whatever means possible or, if unable to contact the investigator, will leave written notification at the business office for notification at the earliest available time.

5. Immediately place the animal in the necropsy cooler on the "save" rack. The necropsy cooler should not exceed 10o C (45o F). Do not freeze any animal that is to undergo a necropsy.
6. Unless prior arrangements for disposal have been made, all carcasses will be held for 72 hours (3 days), not counting weekends and holidays, or until the responsible investigator or veterinarian releases the carcass for disposal.
7. No animal will be discarded until death is certain. If there is any question, report the animal to the veterinary staff immediately.
8. Animals who have been infected with pathogenic organisms and die in the "Infectious Disease Isolation Area" must be bagged and labeled as described above and stored in the refrigerator located in room CB 104. The animals will be removed and disposed of according to specific protocols written by the responsible investigator and approved by Campus Environmental Health and Safety staff.
9. Animals containing radioactive isotopes must be handled as specified by Campus Environmental Health and Safety staff. A protocol for handling these carcasses will be provided by the responsible investigator.
10. Euthanized animals are not to be removed or otherwise distributed to anyone without the specific approval of the Director and approval of the IACUC. There may be instances where animal tissue(s) may be obtained in the pursuit of a project or a class. All carcasses are to be incinerated.



UNIVERSITY OF FLORIDA

Animal Care Services
Room CB 159
Communicore Building

P.O. Box 100006
Gainesville, Florida 32610-0006
(352) 392-2978
Fax (352) 392-3766

February 26, 2001

MEMORANDUM

TO: All Animal Care Employees

FROM: Farol N. Tomson, DVM

SUBJ: Carcass Disposal

When animals are euthanized (either by our staff or by the researcher), these carcasses are identified as "Biohazardous Waste." The carcasses are placed into cold rooms either by our staff or by research staff. There are logs available that must be completed that identify the animal, the faculty member and the date placed in the cooler. Tags are placed on the carcass either to incinerate, save or to necropsy.

When the animals or plastic bags are incinerated, the tag is removed and taped into the incinerator log. So, there is a documented trail from when an animal is euthanized until when the carcass is incinerated.

These carcasses are not to be removed for any reason without the approval of the Director or the IACUC. There may be very legitimate reasons for gaining access to these carcasses, but the Director or the IACUC makes this decision.

The disposition of live animals after a project is completed also follows the procedures already described and approved by the IACUC. Any live animal leaving our premises and destined to become a pet must have adoption papers signed, sealed and available. No live animal is to go home and be used as food. No live animal is to go home as a 'gift' from the research faculty. Any and all such gifts must be reported to the Director immediately so that the appropriate documentation can be completed. Anyone taking live animals from the premises without such documentation will be charged with theft as well as the responsible faculty member facing some compliance problems with the IACUC and his funding agency. There are very legitimate ways for faculty to release their animals for human consumption, and this is to be explained within their IACUC Animal Use Approval Form.

None of the above items are new. They are all part of our operating procedures and policies. Please see me if you have any questions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive
MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/oprr/oprr.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge I, Suite 1051
6705 Rockledge Drive, MSC 7982
Bethesda, Maryland 20852
Telephone: (301) 496-7163 ext 7
Facsimile: (301) 402-7065

February 6, 2001

Re: Animal Welfare Assurance
#A3377-01

Winfred M. Phillips, PhD
Vice President for Research
University of Florida
223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500

Dear Dr. Phillips:

Thank you for your January 22, 2001 letter reporting an instance noncompliance with University of Florida-Gainesville (UF-G) policies and procedures regarding carcass disposal. We understand that neither the animals nor the studies involved were Public Health Service-supported.

Subsequent to receipt of your letter, this Office received detailed, anonymous allegations (Enclosure 1) that the carcasses of genetically engineered swine, euthanized at the UF-G on January 12, 2001 and scheduled for incineration, had been stolen and processed at a commercial plant and their meat sold for human consumption. The allegations included concerns that the euthanasia agent and other drugs may have been present in the meat, that the carcasses may not have been gutted for a long interval between death and presentation for processing, and that all of the meat may not have been recovered. It was also alleged that the carcasses of other euthanized swine may have been similarly diverted to human consumption over the past several years, including pigs from a project of Dr. Labota, Veterans Affairs Medical Center—Gainesville, in 2000.

OLAW is concerned that, if the alleged disposition of swine reportedly killed on January 12, 2001 is the same situation as that described in your January 22, 2001 letter, the corrective actions described may not be sufficient to assure this Office that animal contaminated carcasses from PHS-supported projects could not be so disposed of in the same manner. If the UF-G determines that the alleged inappropriate or illegal disposition of the swine occurred, please request your Animal Care and Use Committee to provide a plan and schedule to prevent animals designated for euthanasia and incineration from being diverted for human consumption. Exceptions, such as healthy, normal animals whose carcasses do not contain drug residues or foreign genes, including those which are by-products of feed

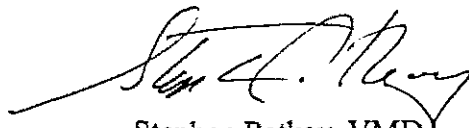
trials, unmanipulated experimental control animals, surplus production, etc. should be clearly defined.

Please notify OLAW as to whether or not the carcass disposal described in the allegations involved the same pigs as those you reported to this Office, and if so, provide a 1) plan and schedule to prevent recurrence and 2) a copy of the UF-G current institutional policy on disposition/consumption of food-producing animals. Also notify OLAW regarding the outcome of its investigation of allegations that carcasses of other euthanized swine were diverted for human consumption in past years.

Should the allegation that meat from genetically engineered pigs was sold for human consumption be verified and considered an adverse event under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (Enclosure 2), please notify the National Institutes of Health's Office of Biotechnology Activities.

A response to these concerns by **March 2, 2001** is requested. Thank you for your attention to these matters.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Potkay", is written over a horizontal line.

Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

Enclosures (2)

cc: Dr. Miava Binkley, USDA
Dr. Elwood Headley, VA
Dr. Michael Fallon, VA
Dr. Amy Patterson, OBA, NIH

rec'd 1/29

Genetically altered pigs from the University of Florida entered the human food chain following euthanasia. Although they were biomedical research pigs, they were housed at the IFAS Swine Unit, a site not registered with the USDA and in violation of the UF Institutional Animal Care and Use Committee (IACUC) approved protocol. On Friday, 1/12/2001, the investigator, Dr. Hauswirth, euthanized six pigs and removed the eyes for his research project. The animals were supposed to be transported to the Barn at Progress Park for incineration, but at least four were diverted to a meat processing plant at High Springs. Portions of these pigs were sold to various individuals in the High Springs and Alachua area. Some was also buried apparently in an attempt to avoid detection. Rumor has it that theft of pigs has happened previously (as long ago as last summer?) with animals belonging to Dr. Labota of the Veterans Administration Hospital. However, the animals belonging to Dr. Labota were not genetically engineered. As in the Hauswirth case, the animals also were euthanized and were supposed to be incinerated. In any case, other chemicals, drugs, or treatments administered to the animals are not known.

Meat from these animals is unsafe for consumption. First, it is derived from genetically engineered animals. Strict federal guidelines administered by the National Institutes of Health, Office of Recombinant DNA Activity (ORDA) govern how genetically engineered animals can be used and improper accounting for these animals is a violation of federal regulations and is reportable to NIH/ORDA. Second, the animals received an unknown amount of various dangerous drugs during surgery and euthanasia. These drugs could have an effect on individuals who eat this meat, especially if the meat is somewhat undercooked. Finally, the pigs were not processed for several hours, thus allowing bacteria that normally live in the gut to contaminate the meat. Therefore, eating of pork from these animals could lead to serious food poisoning.

Despite notification that Dr. Hauswirth's pigs could have been diverted to a meat processing plant, only a cursory investigation was conducted by Dr. Farol Tomson, the interim Director of Animal Care Services. He, in fact, notified the investigator that he had fully investigated the incident and the rumors were not true. Later, it was proven that the pigs were diverted to the processing plant and eventually UF Environmental Health & Safety were notified. Dr. Phil Collis of EH&S notified the University Police who investigated the allegation. One employee of Animal Care Services (Mr. Kenny Atkinson) has been arrested and another (Mr. Not public information) was sent home on administrative leave due to their probable involvement in this incident. However, UF apparently has not notified the Public Health Department or other authorities. This is exceedingly dangerous, as it is by no means certain that all of the meat from these animals has been recovered. It appears that Drs. Farol Tomson, and Winfred Phillips, Vice President for Research, and other University of Florida officials may have conspired to cover up this incident.

This following information or Sunshine Document Requests can be used to verify this story.

Emails between Dr. Tomson and Dr. Hauswirth - will demonstrate that Tomson assured Dr. Hauswirth that the pigs were present in the animal morgue. Indicates that he did not investigate adequately or notify Police in a timely fashion.

Emails and correspondence between Tomson, Winfred Phillips, Phil Collis, and the University

Police.

The University Police Report

Call to the Public Health Department to verify that they haven't been notified.

Mr. Not public information the manager of the IFAS Swine Unit.

Checking to find out the meat processing plant in High Springs and talking to the individual that called Not public information wanting to purchase more pigs.

Arrest records for Mr. Atkinson.

Interviews with Mr. Not public information and other Animal Care Service employees who have had to gather as much meat from the stolen pigs as possible and dispose of it.

IACUC approval for Dr. Hauswirth

Guidelines for Research Involving Recombinant DNA Molecules available at

www.NIH.gov/od/orda. Section IV-C-c-3. Office of Recombinant DNA Activities and Section IV-D Compliance with NIH Guidelines.

Enclosure 2



NATIONAL INSTITUTES OF HEALTH
Office of Extramural Research



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Text Only

NIH Guidelines for Research Involving Recombinant DNA Molecules

TO: All Institutions Conducting Human Gene Transfer Research

FROM: Amy P. Patterson, M.D., Director, Office of Recombinant DNA Activities

SUBJECT: Requirements for Reporting Serious Adverse Events: Request for Institutional Review

The NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) require the immediate reporting of serious adverse events associated with human gene transfer clinical research. The purpose of this memorandum is to request that you conduct a review to ensure that your institution is in compliance with these requirements.

The NIH Guidelines apply to all NIH-funded projects involving recombinant DNA techniques as well as to all non-NIH funded research involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving such techniques. The requirements for reporting serious adverse events in human gene transfer research are found at Appendix M-VII-C in the NIH Guidelines. Appendix M-VII-C states:

Investigators who have received approval from FDA to initiate a human gene transfer protocol must report any serious adverse event immediately to the local Institutional Review Board, Institutional Biosafety Committee, Office for Protection from Research Risks (if applicable), NIH/ORDA, and FDA, followed by the submission of a written report filed with each group. Reports submitted to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health/MSB 7010, 6000 Executive boulevard, Suite 302, Bethesda, Maryland 20892-7010, 301-496-9838.

As stated in Section I-D of the NIH Guidelines, noncompliance may result in: (i) suspension, limitation, or termination of NIH funds for recombinant DNA research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the institution.

Please review all ongoing gene transfer clinical trials being conducted at your institution for compliance with the reporting requirements as specified in Appendix M-VII-C. Note that all serious adverse events should be reported regardless of whether or not they are thought to be related to the gene transfer intervention. If, in the course of this review, you find that serious adverse events have not been reported as required, please submit the requisite reports to the NIH Office of Recombinant DNA Activities (ORDA). The Serious Adverse Event Reporting Form found on the NIH/ORDA web site (<http://www.nih.gov/od/orda/>) should be used for this purpose and for reporting any future serious adverse events. The NIH Guidelines (Section IV-B) require that your institution have policies and procedures to ensure compliance with the NIH Guidelines. As part of this review, please send to ORDA a description of your specific policies and procedures which relate to the serious adverse event reporting requirements in the NIH Guidelines.

NIH recently published a Federal Register notice outlining proposed changes to the NIH Guidelines regarding the reporting and public disclosure of serious adverse events. A copy of the notice can be found on the NIH/ORDA web site (<http://www.nih.gov/od/orda/>). The proposed changes add a definition of serious adverse event; stipulate the time-frame in which serious adverse events are to be reported; mandate that serious adverse event reports not contain any trade secret or commercial or financial information that is privileged or confidential; emphasize that all information in the adverse event report is to be considered public; and, in order to protect patient confidentiality, direct that serious adverse event reports be stripped of individually identifiable patient information. At its upcoming meeting on December 8-10, 1999, the NIH Recombinant DNA Advisory Committee will consider public comments and make

recommendations regarding the proposed changes.

Please submit all information requested in this memorandum to Director, NIH Office of Recombinant DNA Activities, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892, by December 13, 1999. If you have any questions about this memorandum, please contact Dr. Eugene Rosenthal at 301-496-9838. Thank you for attention to this important matter.

cc:

Principal Investigators

Institutional Biosafety Committees

Members, Recombinant DNA Advisory Committee

Office for Protection from Research Risks

Dr. Harold Varmus, NIH

Dr. Ruth Kirschstein, NIH

Dr. Lana Skirboll, NIH

Dr. Kathryn Zoon, FDA

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The Office of Recombinant DNA Activities (ORDA) has been changed to the Office of Biotechnology Activities (OBA).

The page you are requesting at

<http://www.nih.gov/od/orda/> has changed to

<http://www.nih.gov/od/oba/>

Please update your bookmarks!

Page Updated : 11/19/99



UNIVERSITY OF FLORIDA

Research and Graduate Programs
Winfred M. Phillips
Vice President for Research and
Dean of the Graduate School

223 Grinter Hall
P.O. Box 115500
Gainesville, Florida 32611-5500
(352) 392-1582/9271
Fax: (352) 846-0491

January 22, 2001

Dr. Stephen Potkay, VMD
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 1050
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982

Dear Dr. Potkay:

This is to inform you of a recent incident at the University of Florida concerning Animal Care Services employees who tried to improperly dispose of pig carcasses. The actions were reported to Dr. Farol Tomson. The University of Florida Police Department contacted the persons involved and the carcasses were disposed of properly.

This project was not funded by the PHS.

All employees have been instructed on the necessity and requirement to properly dispose of carcasses. Unless approved otherwise by the IACUC, all carcasses are incinerated.

The employees have been disciplined. There have been no changes in our existing policies and procedures regarding carcass disposal.

If you have any questions or concerns regarding this matter, please contact me.

Sincerely,

WMP/kaw

cc: Farol Tomson, DVM

Rec'd 1/25/01