



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163

July 19, 2019

Re: Animal Welfare Assurance  
A4550-01 [OLAW Case A]

Dr. Yu Geng  
President  
ProSci, Inc.  
12170 Flint Place  
Poway, California 92064

Dear Dr. Geng,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 15, 2019 letter responding to my June 5, 2019 request for information regarding an allegation of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at ProSci, Inc. According to the information provided, OLAW understands the following:

- 1) An Occupational Health and Safety Program is in place and covers all company personnel including the animal care staff. Annual safety training is provided, personal protective equipment is provided, a health insurance program is in place, and hazards such as zoonoses, allergies, bites/scratches are evaluated. A copy of the risk assessment work evaluation questionnaire for staff working with animals was provided.
- 2) The rabbits are housed in outdoor facilities which are not temperature controlled in the same manner as indoor ones would be. Temperature mitigation occurs through roof sprinklers and misting. The USDA Animal Care inspectors have found the cooling system acceptable.
- 3) Pest control is in place and consists of storing feed in a vermin-proof building, storing open bags of feed in covered metal containers, and using automatic insecticide sprayers. The USDA Animal Care inspectors have found the pest management acceptable.

Based on its assessment of this explanation and on the review of the supporting documents, OLAW concurs that the allegations could not be substantiated and that ProSci, Inc. is compliant with the provisions of the PHS Policy and the USDA regulatory requirements. We hereby close this investigation and will inform the complainant of OLAW's determination. Thank you for your prompt and thorough attention to this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair  
Robert Gibbens, D.V.M., USDA-APHIS-AC



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Facsimile: (301) 402-7065

July 19, 2019

Dr. Neil S. Lipman  
Executive Director  
Memorial Sloan Kettering Cancer Center  
1275 York Avenue, Box #270  
New York, NY 10065-6007

Via e-mail: [lipmann@mskcc.org](mailto:lipmann@mskcc.org)

Dear Dr. Lipman,

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation into your allegations regarding noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at ProSci, Inc. OLAW has determined the following:

- 1) An Occupational Health and Safety Program is in place and covers all company personnel including the animal care staff. Annual safety training is provided, personal protective equipment is provided, a health insurance program is in place, and hazards such as zoonoses, allergies, bites/scratches are evaluated. A copy of the company's risk assessment work evaluation questionnaire for staff working with animals was evaluated by OLAW and found to be comparable to other institutions' forms.
- 2) The rabbits are housed in outdoor facilities which are not temperature controlled in the same manner as indoor ones would be. Temperature mitigation occurs through roof sprinklers and misting. The USDA Animal Care inspectors have found the cooling system acceptable.
- 3) Pest control is in place and consists of storing feed in a vermin-proof building, storing open bags of feed in covered metal containers, and using automatic insecticide sprayers. The USDA Animal Care inspectors have found the pest management acceptable.

OLAW finds the animal care and use program at ProSci, Inc. to be compliant with the provisions of the PHS Policy and the USDA regulatory requirements and sees no cause to take any further actions. Thank you for contacting this Office with your concerns.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare



July 15, 2019

Re: Animal Welfare Assurance A4550-01 [OLAW Case A]

Axel Wolff, MS, DVM  
Deputy Director  
Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892-6910

Dear Dr. Wolff,

Thank you for your notification of the allegation of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Upon IACUC review, the following responses are provided regarding each statement:

1. ProSci does not have an Occupational Health & Safety Program (OSHP) for employees working with animals.
  - a. A full OHSP review and update was requested by the ProSci IACUC during its August 2018 meeting. Pursuant to this review, a new OHSP was drafted and approved by the IACUC in March 2019. The OHSP is coordinated by the Safety Officer and covers all company personnel, including members of the animal care staff. Annual refresher courses are provided to all company personnel.
  - b. Zoonosis, allergies, bites/scratches, noise, use of machinery, and general prevention measures are just a few examples of the hazards that are included in the OHSP.
  - c. Annual safety training is provided for employees and includes proper hygiene practices. All animal and personnel areas have sinks for washing hands. No eating or drinking is allowed in the animal areas; there are designated break areas. Personal protective equipment is available to all animal care employees.
  - d. ProSci has a health insurance program and highly recommends that animal facility employees get annual physical from their primary care physician and discuss their working conditions and any concerns they may have. ProSci's Human Resources is currently in the process of setting up a new vendor for medical evaluations. A copy of the medical evaluation forms is attached for reference.
2. ProSci does not have a temperature control system for rabbit barns.
  - a. This statement is not true as all of the rabbit barns do have temperature mitigation systems in place. Recognize that these are outdoor facilities as defined by USDA animal welfare regulations, and hence these are not temperature controlled facilities as expected and required with indoor facilities. The systems in place at ProSci are based upon a "swamp cooler" effect as is common for Southern California. This is accomplished through roof sprinklers for initial cooling and supplemented by an interior misting system when additional cooling is needed. The barns had roof sprinklers installed prior to housing rabbits and a new interior misting system was installed in 2016

# ProSci



**ProSci Incorporated**  
12170 Flint Place  
Poway, CA 92064



**Toll Free:** +1 (888) 513 9525  
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**Info@prosci-inc.com**  
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in all three rabbit barns. Multiple USDA Animal Care inspectors have examined these systems over the course of many inspections during a variety of weather conditions and they meet the Animal Welfare Act regulatory requirements.

3. ProSci does not have a vermin control system in place.
  - a. This statement is not true as pest control measures are included in the Program of Veterinary Care and in other husbandry Standard Operating Procedures. It is understandable how this could be overlooked as vermin control is not a formal standalone document. USDA Animal Care inspectors have examined these systems and they meet the AWA regulatory requirements.
  - b. Past rodent infestation in the large animal feed storage shed led to the replacement of this structure in August 2017 with a vermin-proof building. Per policy, all open bags of feed are stored in covered metal containers within this feed building. The rabbit barns and large animal pens are equipped with automatic insecticide sprayers. Per policy, all opened containers of feed are stored in vermin proof containers.

I trust that the responses above adequately address the concerns. Should you have questions or require additional details, do not hesitate to ask.

Sincerely,

(b) (6)

Yu Geng, MD  
CEO  
ProSci Incorporated

Enclosure:

Medical Evaluation Forms

cc: Robert Gibbens, D.V.M., USDA-APHIS-AC  
IACUC Chair



Please complete this form, along with forms B & C (Medical History Questionnaire)

**Return this form to Human Resources**  
**(Copy to Occupational Health if Form B applies)**

**ProSci Occupational Health**  
**Risk Assessment Work Evaluation Questionnaire for**  
**Employee/Affiliate (Participant) with Animal Exposure**

**Purpose:** This form is provided to Principal Investigators (P.I.) or supervisors for the purpose of identifying specific work exposures and potential health hazards in the work environment.

This form is used in conjunction with the **Form B Medical History Questionnaire** for participants with Animal Contact to determine what health and safety services or recommendations are appropriate for the individual to work safely with research animals.

**Instructions:** The P.I. or supervisor must complete the A form for each individual under their supervision. Both the PI and employee/participant must sign the completed Form A. The completed **Form A** should be given to the participant to return to Human Resources. The participant submits a copy of **Form A** and the completed **Forms B & C** to Human Resources in a sealed envelope.

**SECTION A: Employee or affiliate (participant) information.**

Participant Name: \_\_\_\_\_ Job Title: \_\_\_\_\_  
Email Address: \_\_\_\_\_ Work Telephone: \_\_\_\_\_

**NOTE for non-ProSci participants:** Submit the completed Form A and attach your home institution medical clearance for research animal contact. Send to ProSci Human Resources. If a medical clearance form is attached, you do not need to complete Form B. If medical clearance documentation is not attached, you must complete the B form (medical history).

Participant Status (check all that apply):

☐ ProSci Paid ☐ Non-Research Staff (specify below)  
☐ Customer \_\_\_\_\_

☐ Other (specify): \_\_\_\_\_

**SECTION B: Principal Investigator/Supervisor information.**

P.I./Supervisor Name: \_\_\_\_\_ Job Title: \_\_\_\_\_  
E-mail Address: \_\_\_\_\_ Telephone: \_\_\_\_\_

**SECTION C: Must be completed by P.I. / supervisor of employee or affiliate.**

Is animal husbandry an essential part of the participants duties? Yes ☐ No ☐

Will the participant's animal work involve potential contact with:	YES	NO
Human blood, tissues or cells? Please list specific type:		
Infectious agents, BSL-2, or BSL-3 agents? Please list:		
Chemicals (including waste anesthetic gas)? Please list:		





Please complete this form, along with forms B and C (Medical History Questionnaire)

**Return this form to Human Resources  
(Copy to Occupational Health)**

**Species Contact:** Identify all levels of exposure for each species or tissue for the participant named above and check the appropriate column[s]. Check "0" if no direct or indirect contact.

- Level 0** - No animal contact (Form B, Medical History Questionnaire, optional).  
**Level 1** - No direct contact, but enters area where research animals are used (Form B optional).  
**Level 2** - Does not conduct procedures on live animals but handles "unfixed" animal tissues and fluids (Form B required).  
**Level 3** - Handles, restrains, performs procedures or administers substances to live animals; works in area where live animals are used (Form B required).  
**Level 4** - Performs invasive procedures such as surgery, necropsy, and/or cage changing (Form B required.)

**LEVEL OF EXPOSURE**

Species	0	1	2	3	4	
Mice	[ ]	[ ]	[ ]	[ ]	[ ]	
Chicken	[ ]	[ ]	[ ]	[ ]	[ ]	
Rabbit	[ ]	[ ]	[ ]	[ ]	[ ]	
Goat	[ ]	[ ]	[ ]	[ ]	[ ]	
Llama	[ ]	[ ]	[ ]	[ ]	[ ]	
Other	[ ]	[ ]	[ ]	[ ]	[ ]	List: _____

**SECTION D: Supervisor certification**

By signature, I certify that the information provided is accurate to the best of my knowledge.

\_\_\_\_\_  
P.I./SUPERVISOR SIGNATURE

\_\_\_\_\_  
DATE

By signature, I certify that I received a copy of the animal hazards information form (attached) and I acknowledge and agree with all of the above.

\_\_\_\_\_  
EMPLOYEE/PARTICIPANT SIGNATURE

\_\_\_\_\_  
DATE

# B

Please complete this form, along with forms A & C (Risk Assessment Work Evaluation Questionnaire)

Mail or give all forms to – Human Resources

To protect your privacy, please put all forms in a sealed envelope.

## ProSci Occupational Health

### Medical History Questionnaire for Personnel with Animal Exposure

**Purpose:** Personnel working with research animals or entering the ProSci Animal Facility are required to complete this questionnaire to identify applicable health and safety recommendations. Your answers are confidential. Employees with indirect animal contact may elect to complete the questionnaire. The purpose of the following questions is to determine if you have any special health needs to work safely with animals. A common health risk includes allergies or respiratory sensitivities which may be caused or aggravated by work around animals. Chronic health conditions, pregnancy, or immune system deficiencies may increase risk of infection from animals (zoonotic disease) or infectious agents used in animals. Chemical exposure from treated animals may also present additional risks during pregnancy or for certain respiratory or chronic health disorders. Based on your answers, medical recommendations will be provided to reduce risk of undesirable health effects and may include wearing additional personal protective equipment or modifying work procedures. In some cases, further medical evaluation may be indicated by the Occupational Health and Safety Physician. **If your personal health status changes (e.g., allergies, pregnancy, chronic disease, immune suppression), it is your responsibility to notify Occupational Health and complete a new Form A and Form B for their review.**

**Instructions:** Please complete this form and sign below. You must also complete **Form A**. Please bring all forms to Occupational Health. Receipt of both forms is required to get medical clearance to work with or around animals.

Name (Please Print):	Date of Birth :
Gender: <input type="checkbox"/> male <input type="checkbox"/> female	SSN – Last 4 numbers only:

- List animals you will be working with: \_\_\_\_\_
- Date of last Tetanus vaccine booster: \_\_\_\_\_
- If you will be working with human blood/tissues/cells/cell lines in animals, have you received a Hepatitis B vaccination series?  
Yes ☐ No ☐ No use in animals ☐ If yes: a) List dates and attach vaccination record: \_\_\_\_\_  
b) If post-vaccination titer was done, list date: \_\_\_\_\_ Titer result (attach record): \_\_\_\_\_ Not done ☐
- Do you have any of the following medical conditions?

Allergy and Respiratory System Health History	
Yes	No
<input type="checkbox"/>	<input type="checkbox"/>
Asthma or other chronic respiratory disease	
<input type="checkbox"/>	<input type="checkbox"/>
Skin conditions such as eczema, psoriasis, dermatitis	
<input type="checkbox"/>	<input type="checkbox"/>
Allergic skin reactions such as hives, rash, itching. If yes, explain: _____	
<input type="checkbox"/>	<input type="checkbox"/>
Known or suspected animal allergies. <b>Circle any animal-related reaction(s):</b> runny/stuffy nose, itching eyes, sneezing, coughing, wheezing, chest tightness, shortness of breath, hives, skin rash, throat swelling.	
If yes, list animal(s): _____	
<input type="checkbox"/>	<input type="checkbox"/>
Known or suspected allergies to chemicals, latex, food, or environment.	
If yes, please list: _____	
<input type="checkbox"/>	<input type="checkbox"/>
Are you currently using respiratory protection or mask?	
<input type="checkbox"/>	<input type="checkbox"/>
If yes, have you been fit-tested? List type of respirator/mask you are using: _____	
Immune/Metabolic System Health History	
Yes	No
<input type="checkbox"/>	<input type="checkbox"/>
Chronic health conditions such as diabetes	
<input type="checkbox"/>	<input type="checkbox"/>
Kidney or liver disease	
<input type="checkbox"/>	<input type="checkbox"/>
Valvular heart disease	
<input type="checkbox"/>	<input type="checkbox"/>
History of spleen problems or absence of spleen	
<input type="checkbox"/>	<input type="checkbox"/>
Pregnant or planning to become pregnant	
<input type="checkbox"/>	<input type="checkbox"/>
Immune system deficiencies or other limitations to your ability to fight off disease or infection (for example: cancer, lupus, organ transplant, HIV infection, chronic infections) If yes, please list: _____	
<input type="checkbox"/>	<input type="checkbox"/>
Current medication or treatment that may suppress your immune system (for example: high-dose steroids, prednisone, cancer therapy, radiation therapy) If yes, please list: _____	

I assert that the information provided above is correct and accurate to the best of my knowledge:

EMPLOYEE/PARTICIPANT SIGNATURE	DATE
OHS use only	
REVIEWING CLINICIAN SIGNATURE	DATE

Please complete this form, along with forms A and B (Risk Assessment Work Evaluation Questionnaire)



**Mail or give all forms to – Occupational Health**  
**To protect your privacy, please put all forms in a sealed envelope.**

**Occupational Health Clearance**  
*(Participant complete top half)*

Employee Name: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Department: \_\_\_\_\_

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**This section is to be completed by the Occupational Health Office only**

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Further evaluation by Provider required: ☐ YES ☐ NO

Additional Personal Protective Equipment (PPE's) needed (beyond lab coats and gloves):

☐ YES ☐ NO

Recommended additional PPE's:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Other Comments:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

Occupational Health Staff – Please upload a completed copy of this form to the shared network folder.



**Wolff, Axel (NIH/OD) [E]**

---

**From:** Ward, Joan (NIH/OD) [E]  
**Sent:** Tuesday, July 16, 2019 6:27 AM  
**To:** Wolff, Axel (NIH/OD) [E]  
**Subject:** FW: OLAW Case A4550-A  
**Attachments:** OLAW 20190715.pdf; ProSci OHS Forms ABC.pdf

---

**From:** Yu Geng <ygeng@prosci-inc.com>  
**Sent:** Monday, July 15, 2019 4:18 PM  
**To:** Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>  
**Cc:** (b) (6) Gibbens, Robert - APHIS (Robert.M.Gibbens@aphis.usda.gov)  
<Robert.M.Gibbens@aphis.usda.gov>  
**Subject:** Re: OLAW Case A4550-A

Dear Joan and Axel,

Attached please find the response to your email on June 6th, 2019. Should you have any questions, feel free to contact us.

Sincerely,

Yu Geng

On Jun 5, 2019, at 11:17 AM, Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov> wrote:

Dear Dr. Geng,

Attached please find Dr. Axel Wolff's initial response to OLAW Case A4550-A.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,  
Joan

*Joan Ward  
Program Specialist  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Dr., Suite 2500  
Bethesda, MD 20892  
301-496-7163  
[wardjoa@od.nih.gov](mailto:wardjoa@od.nih.gov)*

Yu Geng, M.D.  
CEO  
ProSci, Inc.  
12170 Flint Place  
Poway, CA 92064

TEL: (b) (6)  
FAX: [REDACTED]  
[www.prosci-inc.com](http://www.prosci-inc.com)



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June 5, 2019

Re: Animal Welfare Assurance  
A4550-01 [OLAW Case A]

Dr. Yu Geng  
President  
ProSci, Inc.  
12170 Flint Place  
Poway, California 92064

Dear Dr. Geng,

The Office of Laboratory Animal Welfare (OLAW) has received an allegation of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at ProSci, Inc. The complaint was made by a client who purchased monoclonal antibodies from rabbits and states the following:

- 1) ProSci, Inc. does not have an occupational health and safety program in place for employees working with animals. Please elaborate on the description of the risk-based occupational health and safety program described in the Animal Welfare Assurance.
- 2) ProSci, Inc. does not have a temperature control system in place for rabbits housed in a pole barn structure.
- 3) ProSci, Inc. does not have a vermin control system in place.

Please have the Institutional Animal Care and Use Committee assess whether these statements are true, and if so, provide a reasonable and specific plan and schedule for correction of these serious deviations from the provisions of the *Guide for the Care and Use of Laboratory Animals*. Please provide a response by **July 15, 2019**. Feel free to contact me should you have any questions.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair  
Robert Gibbens, D.V.M., USDA-APHIS-AC



## Initial Report of Noncompliance

By: Pat Brown

Date: 5/24/18

Time: 11:30

Name of Person reporting: Neil Lipman from Memorial Sloan Kettering

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Pro Sci Poughkeepsie, NY

Assurance number: A4550

Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

monitored at study. Concern of no occ health, open barn w/ no temp control, no vermin control but no animal welfare concerns

Species involved: Rabbits

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

OLAW Notify USDA, investigate, inform MSK

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_