

ROSE-HULMAN INSTITUTE OF TECHNOLOGY

ASSURANCE OF COMPLIANCE

WITH

PUBLIC HEALTH SERVICE

POLICY ON HUMANE CARE AND

USE OF LABORATORY ANIMALS

Rose-Hulman Institute of Technology, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

"Institution" includes the following branches and major components: Rose-Hulman Institute of Technology, 5500 Wabash Avenue, Terre Haute, Indiana. There are no other institutions, branches, or components, to be covered by the Assurance.

II. INSTITUTIONAL POLICY

A. This institution will comply with all applicable provisions of the Animal Welfare Act and other federal statutes and regulations relating to animals.

B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this assurance as well as all other applicable laws and regulations pertaining to animal care and use.

D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this policy are shown in Appendix 1.

At present, the institution's program for animal care and use is administered through the Office of the Dean and Vice President for Academic Affairs, the Institutional Official (IO), at RHIT. The Dean recommends to the Rose-Hulman Institute of Technology President, Dr. Samuel F. Hulbert, individual members of the faculty, staff, administration and community to serve as members of the Institutional Animal Care and Use Committee (IACUC). The President makes the final decision on committee membership and makes all appointments. The committee functions and facilitates decisions with recommendation and guidance from the laboratory animal care veterinarian. The veterinarian has a direct and open line of communication with the IO as well. Committee decisions and recommendations are also passed directly to the Dean (IO) for ultimate implementation.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are:

Qualifications:

Dr. James J. Holscher	B.S.	1976	Purdue University
	D.V.M.	1980	Purdue University

In 1983 Dr. Holscher established and continues to practice in a general veterinary clinic. He was the attending veterinarian at the Pfizer Animal Research Facility from 1997 to 2002, an IACUC member of Pfizer Animal Research from 1991 to 2003, and is currently the attending veterinarian at Rose-Hulman Institute of Technology.

Dr. Holscher's service will correspond to the duties outlined in the Guide and include advising the IACUC and Facility Manager on the interpretation of OLAW policies, overseeing the health of animals in the facility, technical supervision of the animal care staff, advising the scientific staff in surgical procedures and participation in animal care

training as needed. He also provides all clinical and diagnostic pathology service and health care for all laboratory animals at RHIT.

If Dr. Holscher is unavailable, he typically has another veterinarian on call, or there are over 20 veterinarians and animal hospitals in the community for us to call on.

Authority:

Dr. Holscher is a voting member of the IACUC and his line of authority goes directly to the Dean and Vice President for Academic Affairs (IO).

He will inspect the laboratory facilities on a regular basis as he deems necessary and participates in the semi-annual IACUC inspections. He may also conduct unscheduled inspections at any time to check that the guidelines are being followed.

Percentage of Time:

Dr. Holscher estimates that this contract utilizes 5% of his time.

C. This institution has established an Institution Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached in Appendix 2 is a list of the names, degrees, position titles, specialties and institution affiliations of the IACUC chairperson and members.

D. The IACUC will:

1. Review, at least once every six months, the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC meets monthly during the academic year, with the October and April meetings designated for semi-annual reviews.

- a. The semiannual program review is conducted at regular semiannual meetings using the semiannual review checklist provided on the OLAW website.
- b. Each member receives or has a copy of the *Guide for the Care and Use of Laboratory Animals*, the previous semiannual program and facilities inspection report, and IACUC's policies and procedures.
- c. Before the date of the semiannual meetings each facility or area is completely inspected by no less than two IACUC members and the results discussed at the convened meeting.
- d. All members are invited to attend and participate in the semi-annual facilities inspection and program evaluation. All findings and reports will be made available to all members for their review.

2. Inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the *Guide* as a basis for evaluation. Typically the veterinarian and the chair of the committee with one other committee member will conduct the semi-annual facilities inspection just prior to the semi-annual program evaluation meeting using the facilities review checklist provided on the OLAW website. Other committee members are invited to join the inspection party if they so desire. Deficiencies or departures from conditions specified by the *Guide* are identified as minor or significant. Included in the facilities inspections are inspections of animal care records. Reports of deficiencies in the facility are forwarded to the Animal Facilities Manager who devises a plan for correction. Both major and minor deficiencies are reported to the IO together with a plan of corrective action. The Animal Facilities Manager will be responsible for seeing that the work is completed and that the committee is informed of its completion. The committee will then inspect the laboratory to assure that the changes have been made.

Note: The most recent report to the IO that includes the “Semiannual Program Review and Facilities Inspection” checklists and review report table is attached as Appendix 4.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Vice President for Academic Affairs and Dean of Faculty. The IACUC chairperson will prepare a written, semi-annual report on the program and facilities following the semiannual meeting that will be signed by a majority of the IACUC committee members and will include any minority opinions expressed by any member. The report will also include the Animal Facilities Manager's plan for corrective actions if applicable.

4. Review concerns involving the care and use of animals at the institution. Signs are posted in all animal areas that direct individuals to report any concern regarding animal welfare to the IO, IACUC chairperson and/or Animal Facilities Manager (by name and telephone number). Should such a concern be brought to the attention of the IACUC directly or through the other aforementioned parties, the chairperson of the IACUC would meet with the concerned individual to determine if the concern can be resolved without filing a formal complaint. If this does not result in a solution satisfactory to both, the concerned party will be asked to present his/her concern either in writing or in person to the IACUC committee at a meeting that will be scheduled within eight days. At this level the concern is considered to be informal and the name of the concerned person will not be published. If the concern is not resolved by a meeting with the IACUC, the concerned person will be advised to file a formal letter of protest with the *Dean and Vice President for Academic Affairs* (IO) and advised that his/her name will be held confidential to the maximum extent possible. At the same time the IACUC will prepare a report of the committee action to the IO and to OLAW. This report will outline the PHS or USDA regulations that are applicable to the concern and make a recommendation for a

resolution of the problem.

In evaluating the complaint, the IACUC will consider whether the complaint is justified. The committee action might vary from dismissal of the complaint to a minor or major adjustment to the investigation in question, or withdrawal of IACUC approval of the protocol. In the latter case a notification to the funding agency, IO, and OLAW would follow. Minority opinions and the results of the vote would also be included in all reports to the IO, OLAW, and the USDA as appropriate.

5. Make written recommendations to the Vice President for Academic Affairs and Dean of Faculty regarding any aspect of the institution's animal program, facilities, or personnel training. The IACUC recommendations to the IO are approved by a majority vote of the committee. The chairperson then prepares a letter that is reviewed and approved by a majority vote of the committee and then sent to the IO.

6. Review and approve, require modifications in (to secure approval) or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C.

Protocols are submitted to the IACUC chairperson in the prescribed IACUC format by the investigator. Each protocol is prepared with the help of and signed by the veterinarian. The investigator is required to obtain approval of the Veterinarian, EHS Coordinator, Animal Care Facility Manager, and his/her Department Head prior to submitting the protocol to the IACUC chairperson. The IACUC chairperson assigns a protocol number to the protocol, files this protocol in the IACUC files, and sends a copy to each member of the committee. (The "full-committee review" method is used.) At the next regularly scheduled meeting of the IACUC the protocol is reviewed. The IACUC will review the protocol in complete conformance with specifications set forth in section IV.C of the Guide.

The committee will have full authority to approve, withhold approval, or require modification(s) before final approval on all projects involving animal subjects. This protocol review process will be applicable to all animal studies and proposals whether they are externally funded or not, or the result of faculty consultancies.

Notification of approval, request for modifications or denial will be sent by letter or email as described in paragraphs 7 and 8 below.

7. Review and approve, require modification in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. At this time any proposed changes to a protocol are submitted by the investigator to the IACUC chairperson. The full committee will receive a copy of the proposed change(s) and will discuss these at a regularly scheduled meeting. An affirmative vote by a majority of the committee is required for approval of the change.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. Notification of approval or denial will be in writing by letter or email to the author of the protocol by the IACUC chairperson. In the event of a denial, the letter or email will contain a form listing the reason for denial and requirements for approval. This letter or email would inform the author of his/her right to protest the action of the IACUC either in writing or in person. The Institutional Official will be notified, in writing, either via meeting minutes or letter, of all IACUC decisions to approve or deny approval of a proposed activity, that is, of all IACUC decisions to approve, require modifications (to secure approval), or withhold approval of proposed activities. If the author chooses to contest the decision of the IACUC, the protest would be handled in the same way as a concern for animal welfare outlined in paragraph 4 above.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS policy at IV.C.1-4 at least once every three years.

At the present time the IACUC approves protocols for one year. Prior to the expiration date of the protocol and if the protocol is to remain active, the investigator submits a status form that requests an administrative extension. A protocol may be administratively extended twice for a total project period of up to three (3) years. After two administrative extensions, a full IACUC review is required.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. If it comes to the attention of the IACUC, by whatever means, that research or educational use of animals is not being carried out according to the law, the procedure used by the committee to investigate the violation of the approved protocol would be the same as outlined in paragraph 4 above. The IACUC is authorized to suspend any activity involving animals as set forth in section IV.C.6 and consistent with that described in sections IV.C.7 and 8.

E. The individual authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of laboratory animals is: the Dean and Vice President for Academic Affairs, the Institutional Official.

F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is:

This Institution adheres to the regulations and guidelines of all government agencies having jurisdiction over environmental health and safety (EHS) in the workplace of faculty, staff and students. It employs a staff that oversees both State and Federal OSHA safety requirements. The EHS staff oversees training and work with bio-hazardous agents. It also oversees the **risk assessment** associated with hazardous biologic, chemical, and physical agents, as well as the handling of animals.

A yearly review of health status of the animal care staff is carried out at meetings of the IACUC. With specific regard to the health of animal health care personnel, all are required to maintain current tetanus immunization and those that would work with potentially rabies-infected animals would be required to have prophylactic vaccinations. This is a subject of periodic review commensurate with the semi-annual meetings.

Faculty, staff and students are instructed to report any incident, animal bites or scratches to their supervisor immediately. The faculty, staff or student will be treated at an approved medical facility. The site coordinator for the department must file a "RHIT Incident Report" with the office of EHS. Records of injuries, as well as illnesses and allergies (as part of zoonosis surveillance), will be kept on file for all animal care personnel.

Since all scientists have doctorate degrees in their respective disciplines and extensive research experience in their fields, they are each responsible for specific hazards peculiar to their own research and for maintaining a safe research program with the assistance of the office of EHS. This includes possible exposure to zoonotic organisms. Where there is a known potential for exposure to zoonotic organisms, the precautions to prevent transmission must be addressed in the protocol submitted to the IACUC and the office of EHS. In addition the subject of zoonosis is treated as a part of the ongoing training program for those engaged in animal research.

All personnel involved with the use of animals are to be advised as to precautions, including the use of gloves and masks to avoid unnecessary exposure to potential allergens. Any person sustaining injury or becoming ill will receive medical attention and any personnel showing allergic reaction will be removed from contact with the animals. Those receiving medical support and clearance will be allowed to continue working with the subject animal.

No primate research is carried out at this institution.

G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in Appendix 3.

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is provided by the Office of Environmental Health and Safety in cooperation with the IACUC. On-line training sessions are available at any time and records are kept for all sessions. Specific attention is made on (1) limiting or minimizing the number of animals to be used (reduction), (2) limiting or minimizing pain and distress (refinement), and (3) replacing animals with less sentient species or inanimate alternatives (replacement). Appropriate species specific

information packets, training and procedures are made available to investigators and laboratory personnel by the appropriate educational faculty department. In addition, a variety of video tapes on handling techniques, the use of the USDA animal welfare information center and IACUC functions are available for review. Any new laboratories or researchers planning new animal research techniques, survival surgeries, etc., are monitored for proficiency by the veterinarian and specific training is provided.

Also, provisions are being made for lab instructors, technicians, students and student scientists to attend training sessions at Indiana State University in Terre Haute, IN that includes attention to the requirements specifically addressed in Federal Code 9 CFR, Part 2, Subpart C, Section 2.32(c).

The IACUC maintains a file of current literature received from OLAW as well as records of training sessions on campus and off.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2, as Category 2, all of this institution's programs and facilities, including satellite facilities, for activities involving animals have been evaluated by the IACUC and will be re-evaluated by the IACUC at least once every six months in accord with IV.B.1 and 2 of the PHS Policy, and reports prepared in accord with IV.B.3 of the PHS Policy (*Public Health Services Policy on Humane Care and Use of Laboratory Animals*).

All IACUC semi-annual reports will include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations will be submitted by letter to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) for review and inspection upon request.

The latest report to the Institutional Official is attached.

V. RECORD KEEPING REQUIREMENTS

A. This institution will maintain for at least three years:

1. A copy of this assurance and any modifications thereto, as approved by PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.

3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semi-annual IACUC reports and recommendations (including minority views) as forwarded to the Vice President for Academic Affairs and Dean of Faculty (IO).
5. Records of accrediting body determinations.

B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized PHS representatives or other related agencies at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. At least once every 12 months, the IACUC, through the Institution Official, will report in writing to OLAW:

1. Any change in the status of the institution (*e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked*), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institution Official.

B. The IACUC will provide, with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.
2. Any serious deviations from the provisions of the Guide.
3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A. and VI.B above shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institution Official

Name: Dr. Arthur B. Western

Title: Vice President for Academic Affairs and Dean of Faculty

Address: 5500 Wabash Avenue, Terre Haute, Indiana 47803

Phone: (812) 877-8337

Fax: (812) 877-1035

Signature: 

Date: 02/20/04

B. PHS Approving Official

Name: Dr. Axel Wolff-Senior Assurance Officer
Division of Assurances-OLAW

Title: National Institutes of Health
RKL1, Suite 360-MSB 7982

Address: 6705 Rockledge Drive
Bethesda, MD 20892-7982

Phone: (301) 594-2061

Fax: (301) 402-7065

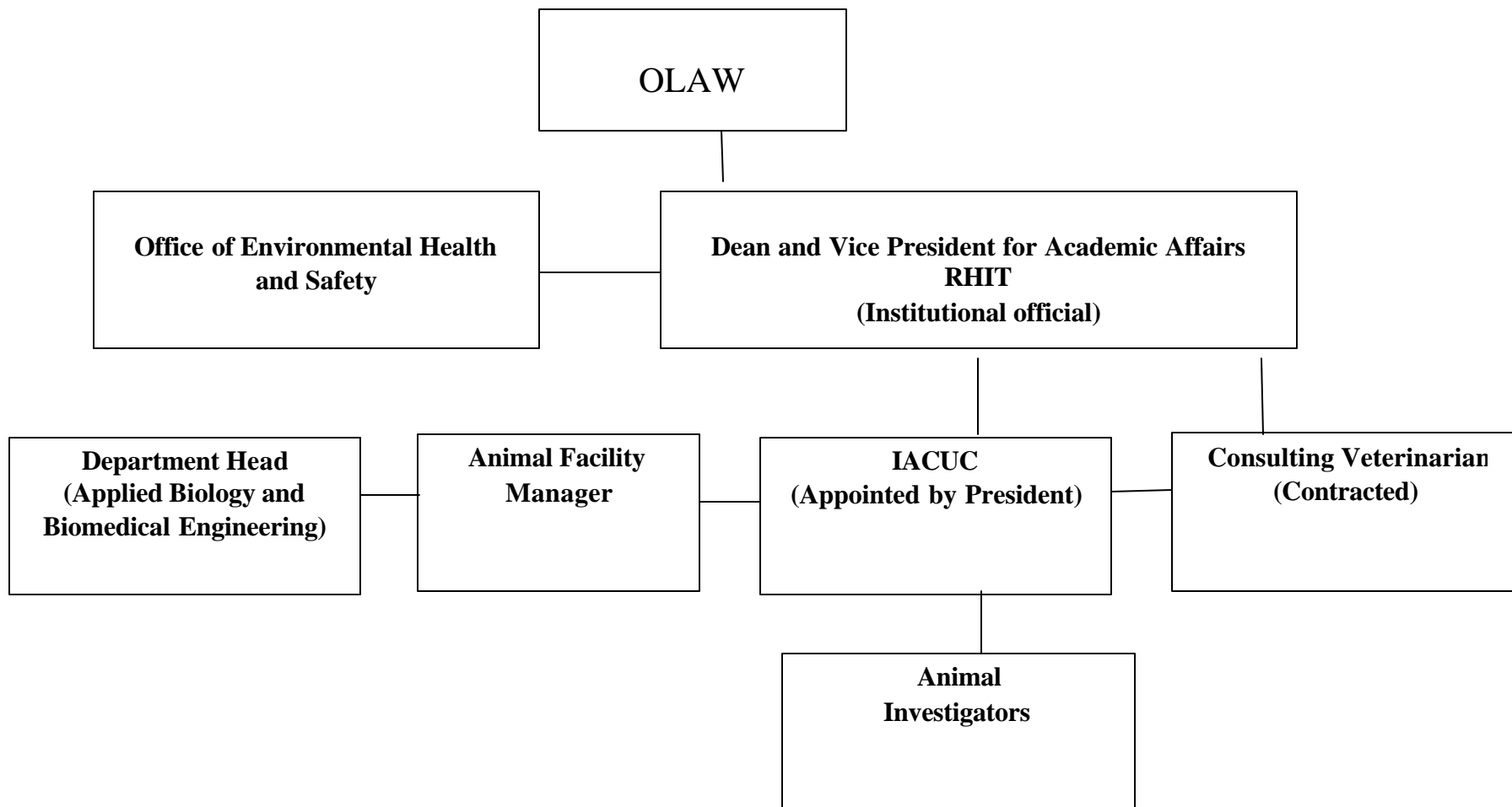
Signature: 

Date: 2/25/04

C. Effective Date of Assurance: 2/25/04

D. Expiration Date of Assurance: 1/31/09

Appendix 1
Lines of Authority and Responsibility for Administering Animal Research



Appendix 2

MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Date: February 14, 2004

NAME OF INSTITUTION: Rose-Hulman Institute of Technology

ASSURANCE NUMBER:

Chairperson Name, Title, and Degree/Credentials		Business Address, Phone, Fax, and Email of Chairperson	
Name: Dr. Ronald Artigue		Address: 5500 Wabash Avenue, Terre Haute, Indiana 47803	
Professor – Chemical Engineering			
Degree/credentials: MS, BS Bioengineering; D. Eng. in Chemical Engineering	Phone: 812-877-8369	Fax: 812-877-8992	ronald.artigue@rose-hulman.edu
Name of Member	Degree	Position Title	PHS Policy Membership
Dr. James J. Holscher	DVM	Veterinarian	Veterinarian
Dr. Jameel Ahmed	Ph. D.	Assistant Professor	Scientist
Bill Allen	M.S.	Secondary Education	Non-Affiliate
Dr. Diane Evans	Ph. D.	Assistant Professor	Scientist
Michael Howard	B.S.	EHS Coordinator	Non-Scientist
Sarah Liechty	M.S.	Secondary Education	Non-Affiliate
Dr. Penney Miller	Ph. D.	Assistant Professor	Scientist
Dr. Anneliese Watt	Ph.D.	Assistant Professor of English	Non-Scientist
Terri Gosnell (non-voting)	B.S.	Administrative Assistant	Secretary

Appendix 3

FACILITY AND SPECIES INVENTORY

Date: February 14, 2004

NAME OF INSTITUTION: Rose-Hulman Institute of Technology
 ASSURANCE NUMBER:

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed in Unit (use complete common names)	Approx. Average Daily Inventory
Olin Hall			
O107	1,200 sq. ft.	Frogs	10
		Zebrafish	20
O109B	200 sq. ft.	Rats	4

*Institutions may identify animal areas in any manner, e.g., initials, ID number, etc. However, the name and location must be provided to OLAW upon request.

Appendix 4

IACUC Report to the RHIT Institutional Official