Worcester Polytechnic Institute, 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 Worcester Polytechnic Institute:

- Bioengineering Institute (BEI)
- Department of Biomedical Engineering
- Department of Biology and Biotechnology
- Department of Chemical Engineering
- Department of Chemistry and Biochemistry
- Department of Electrical and Computer Engineering
- Department of Mechanical Engineering

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:

President
Edward A. Parrish, Jr.

Provost and Vice President for Academic Affairs
John F. Carney, Ill

Associate Provost and Vice President for Research
William W. Durgin

Institutional Animal Care and Use Committee
Chair: Ross D. Shonat

Veterinarian
Richard F. Rodger, DVM

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

Dr. Richard F. Rodger, D.V.M. is a graduate of Holy Cross College, Worcester, MA (B.A., 1969) and the National University of Mexico, Mexico (DVM, cum laude, 1978). He has over 25 years experience or pertinent training in the use and care of laboratory animals.

Dr. Rodger is the consulting veterinarian, an adjunct professor, and implements PHS policy through site visits, telephone and email communications, the IACUC, and the Institutional Official. He advises faculty investigators, IACUC members, and other personnel on issues related to animal care and use.
Percentage of time contributed: 5% of annual time is spent at WPI (10% of each week during the Spring semester (January – May)), two IACUC meetings per year, and email and telephone conversations as needed.

In order to provide for adequate veterinary care of research animals in the event that Dr. Rodger is unavailable, provisions have been made for back-up coverage by Dr. William S. Webster, DVM, PhD through the Department of Animal Medicine at the University of Massachusetts Medical School, which is located 3 miles away.

C. This institution has established an Institutional 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 is a list of the chairperson and members of the IACUC and their names, degrees, position titles, specialties and institutional affiliations.

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 procedures for conducting semiannual program evaluations are:
   a) Review semiannually the University's Program for Laboratory Animal Care and Use at a convened meeting.
   b) Utilize the "Sample Semiannual Program and Facility Review," the Guide, the Policy, and as applicable, 9 CFR Chapter I, subchapter A, as a basis for evaluation during a convened meeting.
   c) Categorize any program deficiencies as minor or significant and develop a plan and schedule for correction for any deficiencies.

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. The IACUC procedures for conducting semiannual facility inspections are:
   a) Inspect every six months all of the University's animal facilities, including satellite facilities, using the Guide, the Policy, and as applicable, 9 CFR Chapter I, subchapter A, as a basis for evaluation, with at least two IACUC members inspecting all facilities.
   b) Document inspection findings in a report to each facility director or protocol director with a schedule for correction if any deficiencies are found.
   c) Require a response from the facility director or protocol director to the inspection report with a description of how the deficiency has been corrected.
   d) Review and discuss a compilation of the facility inspection reports at a convened meeting of the IACUC.
3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to William W. Durgin, Associate Provost and Vice President for Research. The IACUC process for developing reports and submitting them to the Institutional Official is:

   a) Prepare reports of the IACUC evaluations, addressing the requirements outlined in the "Sample Format for the Semiannual Report to the Institutional Official," and as applicable, 9 CFR Chapter I, subchapter A.

   b) Describe the nature and extent of the institution's adherence to the Guide, PHS Policy, as applicable, 9 CFR Chapter I, subchapter A, and describe any newly approved exceptions or departures to existing standards and state the reason for each departure.

   c) Distinguish significant deficiencies from minor deficiencies and assign reasonable and specific plans and schedule for correcting each deficiency.

   d) List the dates when program evaluation and facilities inspections were conducted and provide any minority views or a statement that there were no minority views.

   e) Have the program evaluations signed by an IACUC quorum, and submit reports to the Institutional Official.

4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are:

   a) Post the names, telephone numbers, and email addresses for reporting concerns anonymously in multiple locations, including the main animal use facilities and on the Institution’s IACUC website. A copy of this posting, titled “Statement Concerning Animal Use in this Facility” is attached.

   b) Provide to each student operating under a teaching protocol a “Statement to Students Concerning Animal Use”, which outlines the responsibilities and rights of the course or project instructor, the IACUC, and the student. Included are detailed instructions for reporting concerns regarding vertebrate animal use. A copy of this statement is attached.

   c) Post a method for reporting concerns anonymously within the protocol application. A copy of the relevant page of the full animal use protocol application is attached.

   d) Review all concerns with safeguards to protect the individual's identity, and if warranted, appoint a subcommittee to perform an IACUC investigation.

   e) Review any subcommittee findings at a convened meeting and take appropriate action, if warranted, up to and including suspension of a protocol and notification of the Institutional Official, OLAW and the USDA.

5. Make written recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are:
a) The IACUC Chair and/or the Veterinarian will monitor the animal program and facilities on a day-to-day basis. Any minor issues regarding the facilities, training, or the animal care program will be addressed directly by the Chair and/or Veterinarian. A summary of such actions will be provided to the remaining members of the IACUC.

b) The Chair will communicate any major issue identified by a member of the Committee or animal user to the full IACUC for review. If warranted, a Committee meeting will then be scheduled to discuss the issue. Any recommendations developed by the IACUC will be forwarded to the Institutional Official in writing.

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. The IACUC procedures for protocol review are:

a) Review and Approval

(1) Receive both a signed hardcopy and electronic version of the protocol in the IACUC office. Have staff review the protocol for completeness and provide applicable information on animal care to comply with federal regulations and University policies/practices to protocol directors.

(2) All IACUC members then receive an electronic copy of the protocol and all are designated reviewers (procedure based on an article by Alex Wolff in Lab Animal Magazine (Volume 31) entitled “Correct Conduct of Full-Committee and Designated-Member Protocol Reviews”).

(3) Each designated reviewer reviews the protocol and indicates approval, requests modifications, or requests a full committee review. Electronic communication is permissible.

(4) Each designated reviewer receives the comments of every other designated reviewer throughout the review process and examines each modification and subsequent protocol revision. Electronic communication is used to facilitate this process.

(5) For the protocol to be ultimately approved, each designated reviewer must approve the protocol, as this procedure does not operate on a majority-rule basis. Abstention is not permissible.

(6) In cases where unanimous approval can not be obtained, the protocols must undergo a full committee review at a convened meeting of a quorum of the IACUC. Protocol approval then requires a majority vote of the quorum present.

b) Modifications and Withholding of Approval

(1) Inform the protocol director via email (or in writing if necessary) of any reviewer required modifications, comments, questions, or concerns about the protocol and require clarification, modification, or elimination of concerns from the protocol director.

(2) Circulate the protocol director’s responses (either written or electronic) to the reviewers.
(3) Repeat the process until all reviewers are in agreement or wish to have the protocol presented and discussed at a convened IACUC meeting.

(4) Consider the list of full-review protocols at the next IACUC meeting, vote to approve protocols, approve protocols with additional conditions, or disapprove protocols.

c) Handling of a Typical Animal Protocol

(1) Provide input and assistance to the protocol director in developing the protocol. Web-based resources and instructions are available to the protocol director.

(2) Receive the protocol (both signed hardcopy and electronic) in the IACUC office and perform preliminary review through staff.

(3) Route the protocol to reviewers using electronic means (principally email).

(4) Synthesize all reviewers’ questions to send to the protocol director and require a reply within a specified time. An email response is acceptable.

(5) Distribute the protocol directors’ responses to all reviewers.

(6) Maintain lines of communication (both verbal and electronic) until protocol is ultimately approved or disapproved.

d) Policies on Meeting Attendance and Voting on Research Projects

(1) Require a quorum to conduct its business.

(2) Require members to decline participation in the review and/or vote if this would result in a potential conflict of interest situation.

(3) Considers and approves only those protocols that have been assigned full committee review after first undergoing the designated review process outlined in (a) above. Protocol approval requires a majority vote of the quorum present.

e) Designated Reviewer Process

(1) All protocols undergo a designated review process first. See Section D.6.a for details.

7. Review and approve, require modifications 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. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are:

a) Receive both a signed hardcopy and electronic version of the protocol amendment form in the IACUC office.

b) Conduct the protocol amendment review in a manner identical to that done for a new protocol. See section D.6.a for details.

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. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are:

a) Notify protocol directors, in writing, of the IACUC's decision regarding their protocols. Protocol directors will be reminded that the Committee will review their protocols on an annual basis.

b) Provide verification of laboratory animal approval to sponsoring agencies, as required.

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. The IACUC procedures for conducting continuing review are:

a) Require the protocol director to complete a renewal application for the protocol on an annual basis. Review the renewal application with the initial protocol submission to ensure that it conforms to the Guide, PHS Policy, and as applicable, 9CFR Chapter I, subchapter A. Perform the IACUC review as outlined above in Section D.6.

b) Require the protocol director to submit a completely new protocol every three years. Perform the IACUC review as outlined above in Section D.6.a.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are:

a) Suspend any protocol or activity involving animals after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

b) Review the reasons for suspension with the Institutional Official and take appropriate corrective action.

c) Submit a full report to the Institutional Official, and for PHS supported research to OLAW, USDA and relevant Federal entities, as required.

11. The institution's procedures for off site activities involving research animals are:

a) Require that laboratory animal research or research training protocols conducted by institutional protocol directors at an off site facility provide: a letter of approval from the host IACUC; proof of a currently approved PHS Assurance; and (if applicable) USDA registration number.

b) Require that certification of training be provided for all employees and students of the institution working on a protocol approved by another IACUC.
E. The individual(s) authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is/are Ross D. Shonat (Chair) and Yitzhak Mendelson (IACUC member and acting authority for protocols submitted by the Chair).

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

1. The Laboratory Animal Occupational Health Program (LAOHP) is administered through Environmental & Occupational Safety (E&OS) in close cooperation with the IACUC. The LAOHP provides information and safeguards for personnel working with laboratory animals and hazardous agents.

2. Institutional policies and procedures relating to personal hygiene, handling of medical and hazardous waste materials, hazard communication, and pathogen exposure are contained in the following attachments:
   a) WPI Chemical Hygiene Plan: Includes personal hygiene and protection.
   b) Exposure Control Plan for Occupational Exposure to Bloodborne Pathogens.
   c) Protecting Yourself From Bloodborne Pathogens.
   d) Written Hazardous Communication Program.
   e) WPI Medical Waste Disposal Guidelines.
   f) Hazardous Waste Management Plan.

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 the attached table.

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is:

1. General
   a) Training in all topics in 9CFR, Part 2, Subpart c, section 2.32(c) is provided either as part of video tape training tutorials described below or is available in the form of individualized training sessions given on an as-needed basis as indicated during the protocol review process.
   b) This institution provides faculty/staff/student access to AGRICOLA and the online resources available through AWIC/NAL.

2. Video tape training tutorials (the ACLAM Lab Animal Medicine and Science Series II programs developed in conjunction with the University of Washington's Health Sciences Center for Educational Resources) are provided to individuals (protocol directors, research staff, animal care staff, students, etc.) who are directly involved with hands-on animal care and use at this institution. Certification of training (and the issue of an IACUC certification number) is conferred only after viewing the relevant tutorials. The following video tape training tutorials are used:
a) Laboratory Animals: Laws, Regulations, and Guidelines. Required for all personnel.
b) Laboratory Animals: Alternatives to Traditional use. Required for all personnel.
c) Rats and Mice: Introduction and Use in Research, Part I. Required for all protocol directors, research staff, and students.
d) Rats and Mice: Introduction and Use in Research, Part II. Required for all protocol directors, research staff, and students.
e) Rats and Mice: Care and Management. Required for all animal care staff.
f) Rats and Mice: Biology. Required for all animal care staff.
g) Rats and Mice: Viral Diseases. Required for all animal care staff.
h) Rats and Mice: Parasitic Diseases. Required for all animal care staff.
i) Rats and Mice: Bacterial and Mycotic Diseases. Required for all animal care staff.

3. Other Training Methods
   a) Individual Training. All personnel involved in the care of animals and the maintenance of the animal core facility will be instructed by the IACUC Chair, the IACUC Veterinarian, or the Animal Facility Manager as to the proper procedures.
   b) The electronic version of the animal use protocol form (the form used for review by IACUC) contains numerous suggestions and resource links needed to comply with all aspects of the Guide.
   c) All personnel who will become involved in handling the animals and maintaining the animal care facility will also be trained by the Environmental and Occupational Safety Officer.

4. Evaluation of Protocol Personnel Training. All protocols submitted to the IACUC for review must describe experience/training personnel have had or will have with this specific animal model(s). The IACUC then performs an assessment of the personnel's ability to work humanely with animals. The IACUC may assign specific training to personnel as a condition of their approval.

5. Additional Training Resources
   a) The IACUC maintains a web site with resource information on protocol preparation and training.
   b) The Environmental & Occupational Safety Office maintains a web site with resource information on the Laboratory Animal Occupational Health Program.

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 reevaluated 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.

All IACUC semiannual 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 to William W. Durgin, Associate Provost and Vice President for Research. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request. The most recent semiannual report of the IACUC 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 semiannual IACUC reports and recommendations (including minority views) as forwarded to William W. Durgin, Associate Provost and Vice President for Research.
   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 OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. At least once every 12 months, the IACUC, through the Institutional 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 William W. Durgin, Associate Provost and Vice President for Research.

B. The IACUC, through the Institutional Official, will provide the OLAW promptly 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 Institutional Official

Name: William W. Durgin
Title: Associate Provost and Vice President for Research
Address: Worcester Polytechnic Institute
100 Institute Road
Worcester, MA 01609
Phone: (508) 831-5065
Fax: (508) 831-5774
Signature:
Date:

B. PHS Approving Official

Name:
Title:
Address:
Phone:
Fax:
Signature:
Date:

C. Effective Date of Assurance:
D. Expiration Date of Assurance:
MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE  Date: January 1, 2004

NAME OF INSTITUTION: Worcester Polytechnic Institute
ASSURANCE NUMBER: A3277-01

<table>
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<tr>
<th>Chairperson Name, Title, and Degree/Credentials</th>
<th>Business Address, Phone, Fax, and Email of Chairperson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Ross D. Shonat</td>
<td>Address: Department of Biomedical Engineering</td>
</tr>
<tr>
<td></td>
<td>Worcester Polytechnic Institute</td>
</tr>
<tr>
<td></td>
<td>100 Institute Road, Worcester, MA 01609</td>
</tr>
<tr>
<td>Title: Assistant Professor of Biomedical Engineering</td>
<td>Phone: 508-831-6086</td>
</tr>
<tr>
<td></td>
<td>Fax: 508-831-5541</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:shonat@wpi.edu">shonat@wpi.edu</a></td>
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<tr>
<th>Name of Member/Code*</th>
<th>Degree/Credentials</th>
<th>Position Title</th>
<th>PHS Policy Membership Requirements**</th>
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<tbody>
<tr>
<td>Rebecca R. Hill</td>
<td>BS – Biomedical Engineering</td>
<td>Philips Medical Systems – Biomedical Engineer</td>
<td>Nonaffiliated Member</td>
</tr>
<tr>
<td>Yitzhak Mendelson</td>
<td>PhD – Biomedical Engineer</td>
<td>Associate Professor – WPI</td>
<td>Scientist</td>
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<tr>
<td>Richard F. Rodger</td>
<td>DVM</td>
<td>Veterinarian – Private Practice</td>
<td>Veterinarian</td>
</tr>
<tr>
<td>Samuel L. Politz</td>
<td>PhD – Biology and Biotechnology</td>
<td>Associate Professor – WPI</td>
<td>Scientist</td>
</tr>
<tr>
<td>Thomas A. Shannon</td>
<td>PhD – Religion and Ethics</td>
<td>Professor – WPI</td>
<td>Nonscientist</td>
</tr>
</tbody>
</table>

*Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

**PHS Policy Membership Requirements:
- Veterinarian - a veterinarian with direct or delegated program responsibility.
- Scientist - a practicing scientist experienced in research involving animals.
- Nonscientist - a member whose primary concerns are in a non-scientific areas (e.g. ethicist, lawyer, member of the clergy).
- Non-affiliated member - a member who is not affiliated with the institution in any way other than as a member of the IACUC, and who is not a member of the immediate family of a person who is affiliated. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting attending veterinarian may not be considered non-affiliated.

NOTE: Nonvoting members must be so identified
# FACILITY AND SPECIES INVENTORY

**NAME OF INSTITUTION:** Worcester Polytechnic Institute  
**ASSURANCE NUMBER:** A3277-01  
**Date:** January 1, 2004

<table>
<thead>
<tr>
<th>Laboratory, Unit, or Building*</th>
<th>Gross Square Feet (including service areas)</th>
<th>Species Housed in Unit (use complete common names)</th>
<th>Approx. Average Daily Inventory</th>
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*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.*